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FACULTY OF MEDICINE

HUMAN DEVELOPMENT AND HEALTH

Self-management of Falling in Parkinson's Disease: Building Upon Experiences of People with Parkinson's, their Caregivers and Healthcare Professionals to Develop and Conduct a Feasibility Study of a New Intervention.

by

Charlotte Louise Owen

ORCID ID 0000-0003-4883-4322

Thesis for the Degree of Doctor of Medicine

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ABSTRACT

FACULTY OF MEDICINE

HUMAN DEVELOPMENT AND HEALTH

Doctor of Medicine

Self-management of Falling in Parkinson's Disease: Building upon Experiences of People with Parkinson's, their Caregivers and Healthcare Professionals to Develop and Conduct a Feasibility Study of a New Intervention.

By **Charlotte Louise Owen**

Falls are common in people with Parkinson's disease (PwP) and a recognised research priority. Falling is associated with physical and psychological morbidity for PwP and their informal caregivers. This thesis reports a mixed-methods programme of research to develop and conduct a feasibility study of a falls-based self-management intervention for PwP and their caregivers.

A systematic review of falls-based self-management interventions was undertaken. Six studies were identified, and their self-management components and outcomes mapped. The review could not draw clear conclusions about the effect of these interventions or beneficial components that they should contain.

A mixed-methods study of falls experiences was conducted. 61 PwP and 56 caregivers completed questionnaires and 20 PwP and 18 caregivers were interviewed. Falls experiences and self-management were variable but unmet falls-related needs were consistently described, in particular, identifying reasons for falls and communicating with healthcare professionals (HCPs).

A qualitative study exploring HCPs' experiences of falls in PwP was undertaken (n=12). HCPs discussed how current healthcare provision left dyads' needs unmet, and how challenging dyads' misperceptions of falling, and engaging them with falls-management, may enhance dyads-HCPs communication.

A falls-based self-management intervention was developed, drawing on existing literature and insights from the aforementioned PwP, caregiver and HCPs studies. The intervention consisted of a paper-based guide alongside brief telephone support. PwP, caregivers and HCPs (n=13) participated in usability testing, leading to intervention modifications.

The acceptability and feasibility of the intervention was assessed in a mixed-methods study. 74 PwP and 58 caregivers completed pre and post intervention questionnaires. A subsample were interviewed (n=15 PwP, n=11 caregivers). Some described reduced falls concerns, increased focus on falls management and enhanced falls-related problem-solving. Ways to improve acceptability and engagement were identified. Further research should assess the efficacy of the intervention for falls and psychological outcomes in PwP and caregivers.

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Academic Thesis: Declaration of Authorship

I, Charlotte Owen declare that this thesis and the work presented in it are my own and has been generated by me as the result of my own original research.

“Self-management of falling in Parkinson’s disease: building upon experiences of people with Parkinson’s, their caregivers and healthcare professionals to develop and conduct a feasibility study of a new intervention.”

I confirm that:

1. This work was done wholly or mainly while in candidature for a research degree at this University;
2. Where any part of this thesis has previously been submitted for a degree or any other qualification at this University or any other institution, this has been clearly stated;
3. Where I have consulted the published work of others, this is always clearly attributed;
4. Where I have quoted from the work of others, the source is always given. With the exception of such quotations, this thesis is entirely my own work;
5. I have acknowledged all main sources of help;
6. Where the thesis is based on work done by myself jointly with others, I have made clear exactly what was done by others and what I have contributed myself;
7. Parts of this work have been published as:

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Owen C, Dennison L, Gaulton C, Boswell A, Ibrahim K, Kirby S, Roberts HC. What are the Needs and Preferences of People with Parkinson’s and their Informal Caregivers for the Effective Self-Management of Falling? A Mixed Methods Study. *Age and Ageing*. 2019 February; 48 suppl 1:i36

Owen C, Dennison L, Kirby S, Roberts HC. What are the Needs and Preferences of People with Parkinson’s and their Informal Caregivers for the Effective Self-Management of Falling, as Perceived by Healthcare Professionals? A Qualitative Study. *Age and Ageing*. 2019 February; 48 suppl 1: i36

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Signed:

Date: 30th March 2021

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List of Abbreviations

ACE-R	Addenbrooke's Cognitive Assessment
AD	Alzheimer's dementia
ADL	Activities of daily living
AMED	Allied and Complementary medicine database
CARE	Congratulate, Ask, Reassure Encourage
CDSM Programme	Chronic Disease Self Management Programme
CI	Cognitive impairment
CINAHL	Cumulative Index to Nursing and Allied Health Literature
DHSC	Department of Health and Social Care
FES-I	Falls Efficacy Scale International short version
GDS	Geriatric Depression Scale
HCPs	Healthcare Professionals
HR-QOL	Health Related Quality of Life
JBI	Joanna Briggs Institute
LBD	Lewy Body dementia
LTC	Long term conditions
MeSH	Medical Subject Heading
MMSE	Mini Mental State Examination
MoCA	Montreal Cognitive Examination
MRC	Medical Research Council
MST	Movement Strategy Training
N	Number
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
PAM	Patient Activity Measure
PBA	Person Based Approach
PETS	Problematic Experiences of Therapy Scale
PD	Parkinson's disease
PDD	Parkinson's disease dementia
PDNS	Parkinson's disease nurse specialist
PDQ-39	Parkinson's Disease Questionnaire 39
PDQ-8	Parkinson's Disease Questionnaire 8
PDQ-8-SI	Parkinson's Disease Questionnaire 8 Single Item
PPI	Patient and Public Involvement
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-analyses
PRISMS	Practical Reviews in Self-management Support
PRST	Progressive Resistance and Strength Training
PwP	Person/ People with Parkinson's disease
QOL	Quality of Life
RCT	Randomised Controlled Trial
SALT	Speech and language therapy
SCT	Social Cognitive Theory
SD	Standard Deviation
SDT	Self Determination Theory

List of Abbreviations

SEE	Self-Efficacy for Exercise Scale
SF-12	12-item Short Form Survey
SF-6D	Short-Form Six-Dimension
SPSS	Statistical Package for the Social Sciences
UPDRS	Unified Parkinson's Disease Rating Scale
WHO	World Health Organisation
ZBI	Zarit Burden Interview short version

1 Background to the Project: Parkinson's Disease and the Significance of Falls

This thesis describes the development and evaluation of a falls-based self-management intervention for community dwelling people with Parkinson's and their caregivers. In this chapter, the background context to the project is described.

1.1 Parkinson's Disease

Parkinsonism is clinically defined by a triad of rigidity, bradykinesia and tremor; with Parkinson's Disease (PD) the most common cause (1). A diagnosis of PD can be made through following the UK Parkinson's Disease Society brain bank criteria (2). The pathology of PD is neurodegenerative, typified by the presence of Lewy Bodies within dopaminergic neurons in the substantia nigra and extranigral pathways at post mortem (3). Lewy bodies are abnormal cytoplasmic proteinaceous aggregates, predominantly composed of α -synuclein, which lead to cell death (4).

PD is commonly diagnosed when an individual is in their early to mid 60s or older (1). PD is more common amongst men, and the prevalence increases with age; a recent systematic review found that 2,953 per 100,000 people aged 80 and over residing in Europe, North America and Australia were affected (5).

The Hoehn and Yahr Scale is a widely utilised clinical rating scale which grades PD, by motor impairment, on a scale of one to five. Stage one disease reflects unilateral involvement with minimal or no functional disability, stage three reflects falls, and those with stage five disease are confined to a bed or wheelchair unless aided. PD is a progressive neurological condition; patients typically progress through each these stages over the course of the disease (6).

1.2 Non-motor Symptoms

PD has many associated non-motor symptoms, which may present before diagnosis, and often progress over time. The list of symptoms is broad, and they are often poorly acknowledged and treated; they include neuropsychiatric symptoms such as depression, anxiety, hallucinations and cognitive impairment; sleep disorders; and autonomic dysfunction causing postural hypotension and gastrointestinal problems such as gastric stasis and constipation (7). The regional burden and

distribution of Lewy bodies within the brain determines the development of these non-motor symptoms (4).

1.3 Dementia and Cognitive Impairment

Parkinson's Disease Dementia (PDD) is characterised by a cognitive decline arising as a direct pathological consequence of PD, with deficits in memory and at least one domain of language, visuospatial or executive function (8).

Lewy body dementia (LBD) and PDD are both characterised by the presence of Lewy bodies. LBD and PDD reflect a continuum of disorders, they are not distinct clinical entities (4). In LBD, Lewy bodies are predominantly limbic and neocortical; in PD they are characteristically within the substantia nigra and extranigral pathways (3,9). Involvement of Lewy bodies within the limbic and higher cortical structures in PD is associated with the development of PDD (10). At diagnosis, the motor symptoms are often bilateral in LBD and predominantly unilateral in PD (4). For a diagnosis of LBD to be made over PDD, patients must develop cognitive impairment within one year of onset of motor symptoms, with cognitive impairment occurring later in PDD (4).

After excluding reversible causes, a diagnosis of dementia is made through a combination of patient and collateral history, physical examination and cognitive assessment. Cognitive assessment often takes place in the form of a mini mental state examination (MMSE), Montreal Cognitive Test (MoCA) or Addenbrooke's Cognitive Assessment (ACE-R). The MMSE is scored out of 30, with a score of less than 24 being the most commonly used threshold for a diagnosis of dementia (11). The MoCA is a better assessor of executive function than the MMSE; it is also scored out of 30, with scores of more than 26 indicating normal cognitive function (12).

The prevalence of dementia in PD varies between 10 to 80%, rising with increasing patient age and disease duration (13). In one cohort of patients followed up at 15 years after diagnosis, dementia was present in 48% and cognitive impairment in a further 36% (14). In those who were still alive at 20 years, the prevalence of dementia had risen to 83% (13). However, many previous studies exploring the experiences of PwP have excluded those with cognitive impairment (15–21). Given the prevalence of cognitive impairment/ dementia it is imperative that these PwP are included in research to enhance the external validity of the findings presented (22).

1.4 Falls in PD

A prospective study found two thirds of PwP fall in one year compared to one third of the general older population (23). In PD, falls are often multifactorial and arise due to a complex interaction between motor disability, axial rigidity, dyskinesias, stooped posture, loss of appropriate postural reflexes, cognitive impairment and urinary incontinence (7,24,25). However, whilst the multitude of reasons for falls in PwP has been extensively reported in the literature, few studies have sought to identify the understanding of the aetiology of falls from the perspective of PwP or the caregiver (7,24–26). Research in older people without Parkinson’s disease has identified that older people without PD may attribute falls to personal error to maintain their identity as a non-faller (27).

The best predictor for falling in PD is a history of previous falls, with recurrent falls more likely to occur in those with moderate cognitive impairment (28). Case notes and patient recall often underestimate the frequency of falling, irrespective of the presence of cognitive impairment (28). Falling is likely to increase as the disease progresses, with one study showing that 87% of patients had fallen at 20 years from diagnosis (13,28).

Falls often cause PwP to lose confidence and to develop a fear of falling and of hurting themselves (29,30). It is also true of the reverse: a fear of falling in itself, without a prior history of falls, significantly increases the future risk of falling (31). This interplay can produce a spiral of events, whereby the individual becomes more sedentary, leading to a decline in physical function, which further increases their falls risk (24,31). Those who feel less confident in being able to get up from the floor following a fall are more sedentary compared to their self-assured peers (24). A sedentary lifestyle carries risks; regular physical exercise is associated with improvements in quality of life (QOL), mobility and physical function; and with reductions in cognitive decline, cardiovascular disease, osteoporosis, constipation, insomnia, progression of disease and caregiver burden (32,33).

Fear of falling has been reported in 37-57% of PwP. It is more common amongst those with walking difficulties, postural hypotension, motor fluctuations and fatigue (30,34,35). The Falls-Efficacy Scale- International (FES-I) is recognised as the most appropriate tool to measure fear of falling amongst PwP (34). The FES-I does not measure falls self-efficacy, as the name suggests, but measures concerns of falls across five separate domains: (i) communication, (ii) mobility, (iii) self-care, (iv) domestic life and (v) community, social and civic life (36). Self-efficacy theorises that an individual’s self-reflective thought affects their capability to manage difficulties; heightened belief in their ability to perform a task or to manage a situation is associated with an

improved outcome (37). Self-efficacy can be generalised or specific to an activity. Following this theory, through improving falls related self-efficacy, patients would have greater confidence and capability to manage falls.

1.5 Usual Practice for PD Treatment, Management and Falls

Where PD is suspected, patients should be referred untreated to a specialist with expertise in the condition (38). As recommended by the National Institute for Health and Care Excellence (NICE), the management of PD takes a multidisciplinary approach, involving PD nurse specialists (PDNS), physiotherapists, occupational therapists and speech and language therapists (SALT) (38).

Patients should be reviewed by a PD specialist at least annually. Locally, the usual practice is for contact to be made with the local Parkinson's Disease Nurse Specialist (PDNS) soon after the initial diagnosis, with the first meeting covering general information about PD, and patients receiving an information pack produced by Parkinson's UK, a UK based PD support and research charity. Patients are offered early referral to physiotherapists and occupational therapists for health promotional advice and have access to SALT and dietetic support.

PD has no cure; like all chronic diseases, treatment involves the management of symptoms to improve function and health related quality of life (39,40). There is no universal definition of QOL, but there is a consensual agreement that it is a self-perceived sense of well-being, which has many components including health, with the direct effects of a disease on one's quality of life defined as health related quality of life (HR-QOL) (39).

NICE recommend that those at risk of falling should be advised of the physical and psychological benefits of reducing falls and offered oral and written information (41). All of those over 65 years who fall should undergo a multifactorial risk assessment, guided by the individual patient, which may include assessment of fear of falling and the person's perceived functional ability (41).

Patients should receive information on how to manage after a fall, including where they can seek further advice and assistance (41). However, PwP and caregivers have previously reported a need for more support and improved co-ordination of healthcare (42–44).

Parkinson's UK provides many valuable resources for PwP, their families and informal caregivers. At the time of conducting the studies within this thesis, the documents published by Parkinson's UK aimed to support PwP who fall were '*Falls and Parkinson's*' and '*Keeping Moving: Exercise and Parkinson's*', both of which can be downloaded from their website. '*Keeping moving and Parkinson's*' is very lengthy with 51 pages; it contains information about different physical

exercises to work on posture and balance, but does not contain any information directly related to falls (45). The information leaflet 'Falls and Parkinson's' has seven pages of uninterrupted text and explains risk factors for falling in PD, how to reduce these risks, and advises which professionals and organisations can offer further information and support (46). There are five quotes from PwP embedded into this leaflet, however only two of these explore how PwP have overcome their difficulties, which may be helpful for others in similar situations. No studies evaluating this booklet have been published.

Parkinson's UK also provides local support groups that give patients an opportunity to meet other PwP, with sessions often involving a guest speaker which is sometimes a healthcare professional.

1.6 The Role of Informal Caregivers and the Impact of Falls

The majority of PwP live in their own homes and are cared for by family members. These individuals are typically over the age of 65 years, and are frequently referred to as 'informal caregivers' (43). Informal caregivers provide a vital role in providing physical, emotional and social support, which may be a complement, or a substitution to, 'formal' care (28,43). In chronic diseases, such as PD, it is the PwP and their informal caregiver that manage the day to day aspects of disease, with healthcare professionals (HCPs) serving as a source of additional assistance (40). PD may affect the HR-QOL of the PwP and the caregiver, and one can negatively impact on the other (39,47).

The Department of Health and Social Care (DHSC) recommends that informal caregivers should have access to appropriate support and services that recognise their needs in their role as a carer and in their own right (48). However, caregivers of PwP have reported that they feel that professionals are often 'ignorant' of their needs as a caregiver (49). Caregiving is associated with an increase in mental and physical health problems. In one cohort, 71% of caregivers reported that caring had affected their mental and emotional health, with another study concluding that nearly half of caregivers had elevated markers of depression (47,49). Amongst older individuals, caregiving is an independent risk factor for mortality (47,50).

The DHSC also recommends that informal caregivers should receive training and support in moving and handling skills (48). However, they often receive no formal training or have a one-off session with a physiotherapist, at a time which they report is not relevant (42,43). Caregivers have reported that they perceive that they should simply 'manage' when their relative has fallen, and may physically injure themselves whilst helping their relative off the floor (42,51). In one

study, not limited to PwP, following an individual's first fall, caregiver burden increased and 24% of caregivers altered their usual routine, mainly through reluctance to leave their relative on their own (52). However, few qualitative studies exploring the views and experiences of PwP and caregivers have included both PwP and caregiver perspectives (17,19,53). Given the significant role that caregivers play in the management of falls, and the substantial negative impact that falling has on both PwP and caregivers' physical and mental wellbeing, it is vital that both viewpoints are explored to allow for suitable interventions to be developed to support them (24,31–33,42,47).

The prevalence of caregiver stress increases with PD duration and with symptoms of PD, to include confusion and falls (39,47). The prevalence of depression amongst caregivers looking after those with all forms of dementia, not restricted to PDD, has been reported at 24%, with higher levels of caregiver stress amongst carers for those with LBD and PDD (54). When caregiver stress is not effectively managed, this often results in those with PD needing to move to a nursing home, which has considerable personal and financial consequences (55). Nursing home costs vary by geographical location. In the local area to where the studies forming this thesis were conducted (Hampshire, UK), a place in a nursing home averages more than £1000/week (56). Relocating to a nursing home is therefore an expensive move for either the PwP, social services or the National Health Service (NHS); with the decision of who pays dependant on the results of financial and continuing health healthcare assessments (56–58).

1.7 Falls and PD Research

Despite optimal medical management, many motor and non-motor symptoms remain troublesome for PwP. These include freezing of gait and postural instability, which both contribute to falls risk (59). Given the high prevalence of falls in PwP and the associated healthcare costs, there has been interest surrounding the implementation of programmes for PwP who fall. Areas researched include physiotherapy, occupational therapy and education programmes (59).

1.7.1 Physiotherapy and Occupational Therapy

The most extensively researched domain has been physiotherapy. This may take the form of aerobic exercise, as well as training to improve strength, balance and gait (59). Systematic reviews of physiotherapy interventions for falls conducted in 2011 and 2012 reported

inconclusive results of their effect on fall rate and proportion of fallers in PwP (60–62). However, this may relate to the nature of studies included in the reviews; there was heterogeneity of the interventions studied and outcomes measured, and the majority were of low-moderate methodological quality (60–62). A later review conducted by Shen et al. in 2016, reported a reduction in fall rate, but outcomes from the individual studies included in the review were mixed and the effect size was small (61). In Shen et al., studies where the intervention was conducted within a healthcare setting were associated with better outcomes than those located within the community or at home (61). However, studies conducted away from home may exclude individuals with more advanced PD or with cognitive impairment, who may find travel more difficult. Additionally, rehabilitative interventions may be less effective in individuals with more advanced PD, among whom falling is more common (63,64). The review of physiotherapy interventions published in 2012 also reported a lack of benefit of physiotherapy on fear of falling and QOL (60).

The effectiveness of occupational therapy was assessed through a review incorporating both randomised and quasi-experimental studies published between 1997- 2008 (65). Eight studies were identified, there was considerable variation in their methodology, intervention studied and outcomes. The review found benefits of occupational therapy in improving motor function and QOL for the duration of the intervention. Whilst motor function is related to risk of falls, no falls-related outcomes were measured in the studies included in the review (66). Additionally, the improvement in QOL was based upon the results of three small studies (65). Few studies measured long-term effects of the interventions. Subsequent to this review two large multicentre randomised controlled trials (RCTs) have assessed the effect of an intervention containing occupational therapy (67,68). The first of these studies compared 10 weeks of occupational therapy to normal care (68). This study reported improvements in PwP's self-perceived performance of daily activities at three months, which persisted to six months. However, no significant improvements were seen in caregiver outcomes or in HR-QOL, coping, mood or fatigue in PwP (68). The second RCT (PD REHAB) studied the effect of occupational therapy and physiotherapy compared to no therapy (67). Participants received four visits of a median duration of 58 minutes each, over a period of eight weeks. This multicentre RCT recruited 782 PwP and reported no improvements in activities of daily living (ADL) or HR-QOL in PwP at three months. Whilst the authors of PD REHAB commented that their findings may relate to the low intensity of the intervention, the duration of therapy received by participants exceeded what would likely be feasible within usual practice. In addition, the majority of PwP included in these two RCTs had

mild-moderate PD, the very group who have been proposed to obtain the best outcomes from rehabilitative interventions (63,67,68).

Tai- Chi, a balance-based exercise originating from Chinese traditional medicine combining deep-breath relaxation with slow and rhythmic movement, may also benefit PwP who fall. Systematic reviews published in 2014 and 2019 of Tai Chi interventions for PwP have shown improvements in mobility, balance and fall rate in PwP (69,70).

1.7.2 Education Programmes and Information Distribution

Previous educational programmes for PwP have had falls information embedded within them as opposed to being solely focused on falls.

One study had a programme of lectures designed and delivered to trained caregivers looking after PwP in a residential home. The lectures contained information about PD, with some details about falls embedded within the programme. Improvements were seen in HR-QOL, as measured by Parkinson's Disease Questionnaire 39 (PDQ-39), and in scores on the Geriatric Depression Scale (GDS) in PwP (55). Falls outcomes were not measured.

Another programme designed for PwP, consisting of five weekly sessions, each comprised of one hour of education about the physical and psychological symptoms of PD, followed by one hour of dance, aimed to help PwP to manage daily activities and mobility patterns (71). Improvements were reported in the 'psychological dysfunction' component of the Sickness Impact Profile, a measure of QOL and level of dysfunction from illness, and in PwP's 'mobility pattern'. However, benefits did not translate to improvements in PwP's ability to perform activities of daily living (ADL) and falls outcomes were not measured (71). A meta-analysis of educational programmes to support those living with long term conditions (LTCs), reported that interventions are more efficacious when they are multifaceted or include social learning (group based) or behavioural modification techniques compared to those that contain didactic approaches alone (72).

Therefore, this may suggest that educational programmes to support PwP's independence with their ADL should be targeted toward the ADL directly, or stray away from traditional didactic educational approaches for improvements to be observed.

An individualised multidisciplinary rehabilitation and educational programme containing some falls related information, was reported to be successful in enhancing the health and well-being of PwP and their caregivers (73). Falls outcomes were not measured. However, like many of the educational based programmes for PwP, this was labour intensive and the researchers found that

with 'heavy case loads' of therapy staff and specially appointed research and programme coordinators required for successful completion of the project, this was a programme which would be unlikely to meet cost-benefit analyses for roll-out on a large scale.

The Psychosocial Patient Education Programme in Parkinson's disease (PEPP) was developed by a European consortium, with an aim to 'empower people with PD and their caregivers to deal with challenges related to their disease through improving their knowledge and skills'. The programme, which was based upon cognitive behavioural therapy techniques, has been reported to lead to improvements in disease specific psychosocial scores. None of the studies assessing the effectiveness of PEPP have measured falls-related outcomes. However, trials have not involved populations that are representative of the overall population of PwP; they have excluded those with cognitive impairment or have had a significant majority of cognitively intact individuals (74–76).

The PROPATH programme was a pharmaceutically- sponsored patient education and health promotion programme available in the USA. It consisted of an educational pamphlet and a videotape and was designed for PwP with an aim to improve perceived general health and psychological well-being. A randomised study found those enrolled on the programme had significant improvement in 'patient perception of general health and psychological well-being' measured through non-validated scales, which were created by the researchers for use in the study (77). However, it is therefore difficult to assess the acceptability and relevance of this programme as limited domains of HR-QOL were tested, those with advanced disease were excluded, and no data on the prevalence of cognitive impairment or cost analyses were presented.

Although these group and lecture based educational programmes have been reported to lead to benefits in HR-QOL and in scores on the GDS, there is little data on whether they have helped with physical outcomes, and no data on whether they have helped with fall rates, fear of falling or other falls-related outcomes (71,73–75,77,78). Additionally, no cost analyses have been performed. Given the limited resources within healthcare provision and the amount of professionals' time required to provide these interventions, it is unlikely that these interventions could be reproduced on a large scale to be made available to all PwP. In addition, many studies either excluded participants with more advanced PD, or predominantly included those with Hoehn and Yahr stages one to three (71,74,77). PwP with less debilitating disease have reported greater perceived satisfaction of information provision than PwP with more advanced disease, which may go some way to explain the benefits reported in these studies (78). Many studies

excluded those with cognitive impairment (71,73–75,77,78). Given the progressive nature of PD, the prevalence of cognitive impairment in PD, and the association of these clinical features with enhanced fall risk, it is vital that studies have inclusive selection criteria to improve their external validity.

1.8 Self-management of Long-term Conditions

1.8.1 Self- management: Why it is Important

Self-management can be broadly defined as increased responsibility or confidence of an individual in managing their condition (79). The Corbin and Strauss framework identifies that for an individual to self-manage a LTC they require medical, behavioural and emotional techniques across five domains (79):

1. Problem solving.
2. Decision making; for which an individual requires the appropriate information.
3. Resource utilisation, which requires teaching people how to access and use these resources, rather than simply informing them of their presence.
4. Formation of a patient- healthcare provider partnership.
5. Taking action through learning how to change behaviour.

Promotion and provision of supported self-care of those with LTCs has been identified as a key development strategy by the DHSC (80). People with LTCs have consistently reported that they want to be provided with access to information about their condition, be involved in decision-making processes and to be supported in their confidence to manage their conditions themselves (81). Improved self-care amongst people with LTCs leads to improvements in patient, ethical and financial parameters. Involvement of patients in decisions about their care promotes autonomy; one of the four pillars of medical ethics. The DHSC Compendium of Information for LTCs highlights the financial implications of LTCs on the NHS, and the potential of improved self-care to address this (80).

1.8.2 Health Literacy and Empowerment

For a self-management programme to be effective it must address the beliefs and concerns of the individual. It must provide relevant knowledge about the illness and its available treatment, and recognise an individual's health literacy (72,82–85). The World Health Organisation (WHO)

defines health literacy as ‘the personal characteristics and social resources needed for individuals and communities to access, understand, appraise and use information and services to make decisions about health’ (86). Some researchers have defined health literacy as an ‘asset’, which can be developed through education and communication (87). Low health literacy has been linked to a reduced knowledge of health services and global measures of health (88).

Rowlands et al. reported the interaction between ‘functional health literacy’ and the ‘health information environment’ and explained that information could be obtained from the health service, friends, family, libraries and the media (89). When too much information is presented, or when it is irrelevant or poorly presented, it can lead to ‘Information overload’. This can result in dis-engagement, anxiety or a feeling of being overwhelmed (90).

Whilst health literacy defines the skills and abilities of an individual, empowerment describes the participation of an individual in health related decisions (91). Improved health outcomes have been found in those who have both high health literacy, and who are also empowered (92). Individuals with high health literacy and low levels of empowerment may be dependent upon HCPs for support and have low levels of satisfaction. Individuals with low health literacy who are empowered may make inappropriate decisions (91). Acknowledgement of an individuals’ health literacy and the provision of tailored information has been associated with improved healthcare outcomes (87).

A qualitative study was conducted to explore the facilitators and barriers to empowerment of older adults during an acute hospital admission (84). Interviews were conducted in the UK, Ireland and USA with 26 patients over 65 years, 32 caregivers, and 33 HCPs in urban university hospitals from 2012 to 2014. Providing information that was patient-centred, relevant, and targeted toward patient-directed outcomes was a facilitator to patient empowerment. However, information alone was often insufficient; effective professional-patient communication, and involvement of patients in decision-making processes was required for patients to feel empowered (84).

1.8.3 Behavioural Change Theory and Self-management

Interventions

Behavioural change theories describe and anticipate what factors drive behaviour change, and consequently help predict and explain the likely effect that an intervention will have on an individual’s behaviour. Educational programmes for individuals with LTCs are more likely to be

efficacious when they contain social learning (group based) and behavioural modification techniques (72). The theories that underpin the self-management intervention developed as part of this thesis (described in phase three, chapter six, page 155) were Social Cognitive Theory (SCT) and Self-Determination Theory (SDT); these are described below.

1.8.3.1 Social Cognitive Theory

Social Cognitive theory (SCT) describes how human motivation and behaviour are regulated by forethought (93). A central concept of SCT is self-efficacy, which relates to an individual's personal belief in their ability to perform an action (37). Heightened belief in an individual's ability to perform a task or to manage a situation (i.e. 'self-efficacy') is associated with an improved outcome (37). Other constructs of SCT include perceptions of the outcome, perceived facilitators and impediments, and potential goals (93).

The majority of self-management programmes are based upon the concept of self-efficacy, which can be improved through (79):

1. 'Performance mastery'. When an individual obtains early experience of success, through grading of tasks, this leads to enhanced self-belief. Performance mastery can be aided through the production and completion of an action plan.
2. 'Modelling'. Learning through vicarious experience, through either watching or hearing about others' success stories to provide a model for how an individual can manage their own difficulties.
3. 'Re-interpretation of symptoms'. By helping an individual to understand that there are alternative explanation/s of their symptoms, it allows them to explore alternative self-management behaviours. To aid this, symptoms should be described to individuals as having a multitude of aetiologies.
4. 'Social persuasion'. Encouragement from family, friends and peers can help to strengthen views that an individual can succeed.

Greater self-efficacy for managing PD associated symptoms has been identified as an independent predictor of better self-management of PD (94).

1.8.3.2 Self-determination Theory

Self-management interventions for other LTCs have often been underpinned by Self-Determination Theory (SDT) (22). SDT is a metatheory of behavioural change composed of

several sub-theories of human motivation. It incorporates basic needs theory, organismic integration theory and personality constructs (93). SDT predicts that for a particular behaviour to be initiated and maintained, an individual's three basic psychological needs must be satisfied, and the behaviour should be associated with intrinsic motivation to change (95). The three basic psychological needs are autonomy, competence and relatedness (95). Autonomy is satisfied when an individual's decisions or actions are self-directed. Competence is satisfied when an individual has confidence in performing an action and can control the outcome. Relatedness is satisfied through interaction with or caring for others (93,95). Fulfilment of the three basic needs leads to improved mental health (96).

Intrinsic motivators are where the change in behaviour itself is valued by the individual (93). Extrinsic motivators are where the behaviour leads to a separate outcome that is valued by the individual. Organismic integration theory describes how extrinsic motivators to behavioural change are internalised by an individual (93).

Extrinsic motivators to behaviour change can be 'extrinsic regulators', 'introjected regulators' or 'identified regulators'. 'Extrinsic regulators' promote behavioural change through reward or recognition; they relate to how an individual is perceived by others (93). 'Introjected regulators' promote behavioural change through guilt or enhanced self-worth. 'Identified motivators' are outcomes from a behaviour that are personally valued by an individual, for example keeping active to reduce fear of falling. When an intervention targets 'identified motivators', the change is more likely to be perceived as autonomous. When an individual perceives that a change is autonomous, the change is more likely to be maintained (93,95).

A systematic review and meta-analysis of health behavioural interventions found support or respect for autonomy, and identification of intrinsic motivators to change, were associated with improved mental and physical health (97).

1.8.4 Self-management Programmes in other Long-term

Conditions

Self-management programmes aim to provide individuals with the skills to manage their chronic condition (83). Whilst programmes do contain educational components, they also aim to build upon an individual's self-efficacy, problem-solving and confidence in managing their condition (83). Self-management programmes targeted toward a specific behaviour, as opposed to generalised advice and support, are more likely to lead to success (98). This is supported by SCT;

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to change an individual's perception of their ability to perform a task (their self-efficacy), the intervention should be task-specific (79).

Self-management educational programmes reported within the literature have often been modelled on the 'Chronic Disease Self-Management Program' (CDSM). The programme, based upon SCT, was designed at Stanford University in 1996. It is community based, peer-led, and consists of seven condition-specific sessions, each lasting two and a half hours. The sessions are delivered to groups of 10-15 people, and family members have the option to attend. It was first developed for those with the LTCs of arthritis, stroke, heart disease or lung disease. The sessions include information about nutrition and medicines, and the management of fatigue, sleep and cognitive symptoms (99). A study conducted across 22 sites in North America from 2010-2012 found the programme led to improved mental well-being, communication with doctors and hospitalisation (100).

A self-management programme for people with multiple sclerosis modelled on the CDSM programme, led to improvements in generalised self-efficacy and physical status. Benefits were maintained at 12 months (101). However, in a study of a six-week self-management education programme for adults with various LTCs, improvements in anxiety and depression scales were often short lived. Scores on these scales deteriorated in a third of participants after the programme had ended (102). This may suggest that participants require ongoing support from an intervention for improvements to persist. The importance of ongoing support was also highlighted by Wilson et al., who conducted a qualitative analysis of the Expert Patient Programme, a UK adaptation of the CDSM programme. This group-based self-management intervention was delivered to participants with a range of long term physical and mental health conditions, not including PwP. Many participants were positive of the socially cohesive nature of the intervention, and some reported feeling isolated at programme end (85).

Ducharme described the development of an interactive one-to-one psycho-educational intervention programme for caregivers of recently diagnosed people with Alzheimer's Dementia (AD), a progressive neurodegenerative condition. Through semi-structured interviews, caregivers identified that they would like information about AD and potential sources of support. They were keen to find a sense of 'meaning' within their new role, and wanted to learn about how to adapt, through developing new skills and building upon their communication skills. Caregivers also wanted to learn about how to plan for future needs given the progressive nature of AD. The programme was underpinned by behavioural change and coping theory, with content mapped to caregiver's needs. The program was only evaluated by two caregivers through semi-structured

interviews, but they were positive about the ability of the programme to increase their knowledge and found signposting useful. They found that the programme allowed them to reframe stressors and they were more open to seeking support from family members (103).

Systematic reviews of self-management programmes to support people with LTCs other than PD have reported improvement in physical and psychological outcomes (104–107). Self-management programmes in chronic obstructive pulmonary disease (COPD) have led to improvements in health-related quality of life, number of hospital admissions and shortness of breath (104). In diabetes, computer-based self-management interventions can improve blood sugar control (105). Community-based self-management programmes post-stroke have led to improvements in QOL and self-efficacy (106). Lay-led self-management programmes for people with LTCs, not including PwP, have led to improvements in self-efficacy and self-rated health (107). However, these reviews have all described considerable heterogeneity in the content and delivery of the self-management interventions studied within the articles included in their respective analyses, which has led to difficulty in identifying the key effective ingredients contributing to change (104–107).

1.9 Self-management and Parkinson's disease

PD is a progressive condition with no cure. Treatments are focused on symptom control, which are often inadequately addressed with pharmacological and physiotherapy interventions (7,108–110). It has been proposed that self-management interventions might help PwP and their caregivers to identify and address problems relating to how Parkinson's affects them (111).

PwP have previously reported a preference for autonomous decision making, and cited the importance of understanding patterns in their condition and of interventions that might enhance their well-being (112,113). Improvements in overall satisfaction have been observed in association with increased involvement of PwP in decisions about their care (114). Several studies have evaluated self-management programmes for PwP; the main ones will be discussed here. None of these studies focus on interventions that are specific to falls.

Parkinson's UK has designed and implemented two group-based programmes: the 'Self-Management Programme' and the 'First Steps' programme. Both programmes are led by trained volunteers; the content is guided by each group of participants and neither are dictated to contain any falls-specific information. The 'Self-Management Programme' was implemented in 2013 and is led by volunteers with first-hand experience of PD. It aims to help PwP and their caregivers to

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self-identify and address problems relating to how Parkinson's affects them (111). It has not been formally evaluated. The 'First Steps' programme is led by volunteer PwP, is targeted toward newly diagnosed PwP and those close to them (115). It aims to support participants to address any fears and misperceptions through story-telling (116). It consists of an initial session that provides information about PD and potential sources of support, and a follow up session six to eight weeks later to review their progress; participants also receive an exercise session from a physiotherapist. Through semi-structured interviews participants have described improvements in their mindset and confidence, and increased physical activity, linked to their participation in the programme (116).

A self-management programme for PwP and their informal caregivers, modelled on the CDSM, has been assessed in a feasibility study. The programme contained no components specific to falls. The programme was delivered to 13 PwP and seven informal caregivers by two psychologists who were certified as 'master trainers' by the CDSM programme team at Stanford University. 'Master Trainers' received training in how to deliver the programme through a standardised course held at Stanford University. Participants in the study found the programme acceptable, with only one dropping out for reasons not directly related to the programme. Improvements were seen in HR- QOL, general self-efficacy and fatigue at six weeks. Although improvements on these measures did not reach statistical significance, this feasibility study was not adequately powered. Through open-ended questionnaire responses, participants raised that they felt that the content needed to be more flexible, with greater attention paid to the physical and emotional impact of disease progression. Unfortunately, the study was not inclusive of the PD population; it excluded those with cognitive impairment, high scores on the Geriatric Depression Scale and those with Hoehn and Yahr scores of one, four or five. Caregivers with a diagnosis of dementia, depression or more than one chronic medical problem were also excluded. Having the programme delivered by 'master trainers' also reduces the programme's reproducibility and the likelihood of favourable cost- effectiveness analysis (37).

In the UK, Hertfordshire Neurological Services have organised condition-specific self-management group programmes, including a group for PwP, since 2002. The programme contains a variety of information about PD; topics include general information about the condition, exercise examples, tips for enhancing mobility and medication management. There is no falls-related information and caregivers are in a parallel group as the designers felt that they 'tended to change the agenda'. Participants enjoyed mutual support in a group comprised of people who were in a similar situation; the most helpful component of the course was listening to the experiences of others. However, a group-based intervention may be less suitable for those who are newly

diagnosed; participants with less advanced PD found it difficult to attend a group with individuals who had been diagnosed longer and had deteriorated (117).

Canivet assessed the effect of a 12-month programme consisting of group-based and one-to-one sessions. The study was conducted in France in 2016. There were three group sessions, each lasting one hour, covering stress management, physical activity, communication and social support. The programme contained no falls-related components. In addition, there were quarterly one-to-one education sessions, each lasting 90 minutes. During one-to-one sessions participants received personalised information, coaching for self-monitoring techniques and developed action plans to implement changes within their day to day life. The programme was not associated with an improvement of QOL as measured by PDQ-39 (118).

Three pilot studies have identified that PwP and their caregivers may benefit from signposting to appropriate health and social care services, and support in communicating with HCPs (119–121). Holloway et al. conducted a pilot study of a user-led care pathway in PwP in Hull, UK (119). 22 PwP were asked to complete information sheets before and after meeting HCPs and were provided with an information pack containing signposting to health and social care services. Nearly all participants were positive about completing symptom information sheets prior to contact with HCPs and reported that these helped them to feel more prepared for the consultation. The pack was also well received by PwP and their caregivers, and most found signposting useful. However, few contacted the services suggested (119). McShane et al. conducted a pilot study of ‘information prescriptions’ in the North East of England between 2010 and 2012. ‘Information Prescriptions’ aim to provide individualised signposting, which may allow people with LTCs to feel more in control of their condition and to improve patient- professional communication (120). Participants had a diagnosis of COPD, inflammatory bowel disease or PD. PwP requested information about a wide range of topics; the most common requests were for general information about PD, and information about medication. The majority of users were positive about the service, and felt that information was delivered at an appropriate time and was relevant to their needs (120).

Signposting and the provision of individualised information was further emphasised in the study of the intervention *‘Living well with Parkinson’s’*. The programme was developed in Christchurch, New Zealand, and aimed to enable effective self-management in living with PD. It consisted of six weekly seminars, each organised and delivered by a physiotherapist specialising in PD and lasting one and a half hours. The seminars covered knowledge about PD, medication, exercise, updates on current research, nutrition and psychological elements of PD. There was no specific falls

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related information. A subset of participants, eight PwP and three caregivers, were interviewed. Providing information about the different services and resources available led some participants to feel more empowered to cope with PD. However, participants reported that they would have liked to learn more about potential strategies for adapting their daily activities in association with PD (121).

EduPark, a group-based programme designed by a consortium of professionals from seven European Countries, based upon cognitive behavioural therapy for PwP and their caregivers, consists of eight 90 minute sessions delivered on a weekly basis (122). It aims to support PwP and their caregivers to manage the behavioural and emotional consequences of PD, and to develop coping mechanisms for stressful social situations and acceptance of the diagnosis (122). The programme does not provide any information on falls. EduPark has been assessed in several pilot studies (122,123). Two studies, conducted in the UK in 2006, and in Finland in 2008, reported the intervention led to improvement in participants' mood, and participants found the programme useful. However, QOL outcomes from these pilot studies were conflicting (122,123). In one study, where no improvement in QOL was observed, authors reflected that QOL outcome measures may be less appropriate than measures to assess self-efficacy or coping strategies, which would more accurately correlate with the aims of the programme (123).

In 2017, an integrative review conducted by Kessler and Liddy of self-management support programmes for PwP found most interventions had been designed specifically for PwP (124). 18 interventions were identified, which displayed considerable heterogeneity. Interventions varied in terms of delivery, content and outcomes measured. Seven of 13 self-management interventions were delivered alongside a rehabilitation intervention. Content of the interventions was often poorly reported, and most studies did not evaluate the self-management programme. The authors concluded that there was insufficient evidence to support the effectiveness of self-management programmes in PD. However, Kessler and Liddy utilised a non-exhaustive searching strategy. The reviewers stipulated that study authors needed to explicitly use the term self-management (124). Given the heterogeneity of interventions that may support self-management, this may have resulted in eligible articles not being identified (104–107,124). Also, following self-efficacy theory, self-management programmes in other LTCs have been more effective when targeted toward a specific behaviour as opposed to providing generic advice and support (79,98).

1.10 Key Points and Gaps that this Thesis Will Address

Falls are common in PwP and are associated with physical and psychological morbidity for PwP and their caregivers (23,29,30,32,33,42,51,52). Cognitive impairment and dementia are also common, and recurrent falls more likely to occur in those with moderate cognitive impairment (13,28). However, many previous studies exploring the experiences of falls in PwP have excluded those with cognitive impairment or dementia (14–21,25,53). Perspectives of PwP and caregivers of their understanding of the aetiology of falls, and their experiences of them, have rarely been explored within the same study (17,19,53). This thesis reports a study that identifies the needs and preferences of both PwP and caregivers for the effective self-management of falls. PwP with Cognitive impairment/ dementia and caregivers of PwP have been included in the studies reported within this thesis to provide a more accurate depiction of the range of problems encountered by PwP and caregivers.

HCPs perspectives of the problem are described; to include their own experiences of helping to prevent and manage falls in PwP as well as their interpretations of PwP and caregiver experiences. Through providing a different perspective of the problem, HCPs were able to supplement the findings presented from PwP and their caregivers, to include interpretation of the experiences of the population of PwP and caregivers who might not normally present themselves to be included within research.

The majority of interventions to support PwP who fall have centred on physiotherapy, occupational therapy or education (59). Outcomes from studies of these interventions have been mixed, and rehabilitative interventions may be less effective in those with more advanced PD, where falling is more common (60–64). Going forwards, self-management has been suggested as a potential strategy to support PwP and their caregivers to identify and address problems related to PD (111). Self-management can be broadly defined as increased responsibility or confidence of an individual in managing their long-term condition (79). Self-management interventions in other LTCs have led to improvements in physical and psychological outcomes (104–107). Following SCT, improving in the perception that PwP and caregivers have of their ability to manage falls (their falls related self-efficacy) might lead to enhanced falls-related outcomes (79).

The evidence for the effectiveness of falls-based self-management programmes for PwP and caregivers is currently unclear (124). A review published in 2017, which utilised a non-exhaustive searching strategy, and included interventions that aimed to support the self-management of any aspect of PD, concluded that there was currently insufficient evidence to support the

Chapter One: Background to the Project

effectiveness of self-management programmes for PwP (124). However, following SCT, a behavioural intervention is more likely to be successful if it targets a specific behaviour (79). Therefore, prior to the planned development of a falls-based self-management intervention, I conducted a systematic review to identify and assess the efficacy of self-management interventions that targeted the management of falls in PwP. I combined information from my studies with PwP and caregivers and HCPs, alongside information from my systematic review and the background literature to develop a falls-based self-management intervention for PwP and their caregivers. This intervention aimed to target all PwP who fall, to include those with cognitive impairment/ dementia and those with more advanced PD, who often benefit less from existing interventions (60–64). Caregivers were also targeted as they play a key role in the day to day management of falls, which can have a detrimental impact on their own physical and psychological well-being (28,39,40,43,47).

The quality of the reporting of the content and delivery of self-management interventions has been identified as a barrier to understanding the key ingredients contributing to change (104–107). Therefore, a chapter describing how the intervention was developed has been included in this thesis. Finally, the intervention was evaluated in a mixed methods feasibility study.

1.11 Aims and Objectives

In this thesis, a falls-based self-management intervention for PwP and their caregivers was developed and evaluated in a mixed-methods feasibility study through the following consecutive stages:

- A systematic review of falls-based self-management interventions for PwP to identify current interventions and their effectiveness.
- A mixed-methods study to establish the experiences, needs and preferences of people with Parkinson's (PwP) who fall, and their caregivers, and their views on suitable future self-management materials. Given the important role that caregivers play, and the prevalence of cognitive impairment/ dementia in PwP, these individuals were included.
- A qualitative study to explore HCPs experiences of falls. This included their own experiences of helping to prevent and manage falls in this population as well as their interpretations of experiences of PwP and caregivers. HCPs were able to supplement the findings presented from PwP and their caregivers through providing a different perspective of the difficulties encountered.
- The development of a falls-based self-management intervention for PwP and their caregivers utilising information from (i) the background literature, (ii) my systematic review of falls-based self-management interventions for PwP, and the information gathered from PwP, caregivers and HCPs during the earlier studies reported in this thesis. The prototype of the intervention underwent usability testing with subsequent modification to increase its acceptability.
- A mixed-methods feasibility study of the self-management intervention. PwP with cognitive impairment/ dementia and caregivers were included. Participants used the intervention over 12 weeks. Feedback was provided through questionnaire and semi-structured interviews with a purposive sample. Before and after analyses were performed on quantitative scales to assess the likely impact of the intervention, whilst acknowledging that the study was not powered to draw conclusions. Results from the analyses were incorporated using a triangulation protocol.

2 A Systematic Review of Falls- based Self-management Interventions for People with Parkinson’s Disease

This chapter reports the methods and results of my systematic review of falls-based self-management interventions for PwP. This review was conducted to identify and assess the efficacy of existing interventions, to support the development of the intervention developed as part of this thesis.

2.1 Methods

This review was conducted according to the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) guidelines (125). The protocol for this review was registered on PROSPERO, CRD42017052585 (Appendix A1). The systematic review was presented as a poster at the British Geriatrics Society in November 2019 and was published in full in 2019 (126).

2.1.1 Searching Strategy and Identification of Articles

2.1.1.1 Design of Systematic Search Strategy

A sensitive and inclusive search strategy was developed in MEDLINE in collaboration with a medical librarian. Medical Subject headings (MeSH) with corresponding free text terms and Boolean operators were used to identify: (1) studies about PD, (2) studies about self-management (Appendix A2). To ascertain the appropriate MeSH terms to identify studies about self-management, search strategies utilised within other systematic reviews of self-management interventions and the Corbin and Strauss Framework for chronic disease self-management were reviewed (79,104,106,127,128). The search was limited to studies published from 1986 onwards, when the concept of self-management emerged in the literature, as has been adopted in previous systematic reviews of self-management interventions (107). Animal studies were excluded. The search was adapted for use in EMBASE, CINAHL, AMED, PSYCHInfo and Science Citation Index Expanded (Web of Science).

The search strategy contained no falls-related terms because in many of the studies referenced within the background section of this thesis (page 30) the term ‘falling’ was often only used within

the full text. The interventions to support self-management in LTCs display heterogeneity, therefore use of the term 'self-management' by the authors was not required (104–107).

2.1.1.2 Additional Searches

Additional searches were made in clinical trials registers. Scoping searches were performed in Delphis and the grey literature was searched at opengrey.eu. Reference lists of relevant retrieved articles and relevant journals were screened to locate potential additional studies.

2.1.1.3 Identification of Relevant Articles

Inclusion and Exclusion Criteria

Articles included where they reported interventions that aimed to improve the self-management of falls in PwP. A broad definition of self-management was used; studies were included where they aimed to increase the responsibility or confidence of PwP managing falls. No prior assumptions about the types of interventions that might affect self-management were made. This review aimed to assess the effect of interventions that go beyond usual physiotherapy and occupational therapy; where the intervention used these techniques alone the study was excluded.

Multi-modal interventions were included where one component aimed to support the self-management of falls in PwP.

Studies were included regardless of design. Whilst randomised controlled trials often have the best study design to assess the effectiveness of an intervention, qualitative methods can help to understand the concepts, behaviours and perceptions that people have of an intervention (129,130).

No restrictions on language were applied.

Screening of Articles

I downloaded studies into the bibliographic software programme EndNote. After de-duplication, titles were screened by myself and were excluded when clearly irrelevant. I and co-author Kinda Ibrahim (KI) independently screened all article abstracts for eligibility. Full texts of all potentially relevant articles were reviewed for relevance, discrepancies were resolved through discussion. Searches were re-run prior to analysis in June 2018. Figure 2-1 depicts the search results and the inclusion/ exclusion process.

2.1.2 Data Analysis and Assessment of Study Quality

2.1.2.1 Data Extraction

I extracted data from the selected articles into a predefined database, with all content confirmed by KI. Authors of all included articles were contacted to provide clarification or for additional information. Where theses and conference abstracts were identified, authors were asked if their data had been published in a peer reviewed journal.

2.1.2.2 Identification of the Self-management Components of the Interventions

Self-management programmes are often complex interventions (131). Complex interventions have multiple interacting components, and there is often heterogeneity of intervention delivery (132). Reviews of self-management interventions in other LTCs have often concluded that there is inadequate detail in the reporting of the content and delivery of interventions to allow clear conclusions to be drawn about what works and why (93,131,133). The Practical Reviews in Self-management Support (PRISMS) taxonomy, details the 14 active components that a self-management programme might contain, and has successfully been used in reviews of self-management interventions to support patients with heart failure, COPD, cancer, diabetes and asthma (131,134). The PRISMS taxonomy was used to characterise the components of the self-management interventions studied within the articles included within this review (Table 2-2).

2.1.2.3 Quality Appraisal

I and KI independently appraised each included article using The Joanna Briggs Institute (JBI) Critical Appraisal Checklist (135). The JBI has produced critical appraisal checklists for different study designs and was therefore felt to be the most appropriate method for this systematic review, as articles were included regardless of study design. However, all articles included were RCTs, and therefore The JBI RCT Critical Appraisal Checklist was used for each of the articles (135). To provide a comprehensive review of the literature, all articles were included irrespective of the outcome of the quality assessment.

2.1.2.4 Data Analysis

Given the heterogeneity of the articles identified for review, the analysis took the form of a narrative synthesis, using words and descriptive statistics to provide a summary of the literature.

2.2 Results

2.2.1 Study Selection and Quality Appraisal

Of the 11693 titles identified, 48 articles were screened and four met the eligibility criteria for inclusion. This comprised 3 scientific papers and one thesis. The thesis had not been published as a scientific paper but contained enough data to allow for conclusions to be drawn about the intervention studied and was therefore included in the review. A further two scientific papers were identified through reference screening. No additional articles were identified from the grey literature or clinical trials registers. Therefore, in total, six articles were included in the review (Figure 2-1).

A conference abstract was identified that described the development of a falls guide for PwP, which was designed to be delivered alongside physiotherapy (136). The author was contacted. The study had not been published as a full text article, and there were no details of the participants or of how the intervention was implemented or evaluated. Consequently, it was excluded from the review as there was insufficient data to allow conclusions to be drawn.

The quality of the included studies was assessed using the JBI Quality Appraisal Checklist for Randomised controlled trials (Table 2-1). Articles scored between 7-9 out of 13 possible quality criteria.

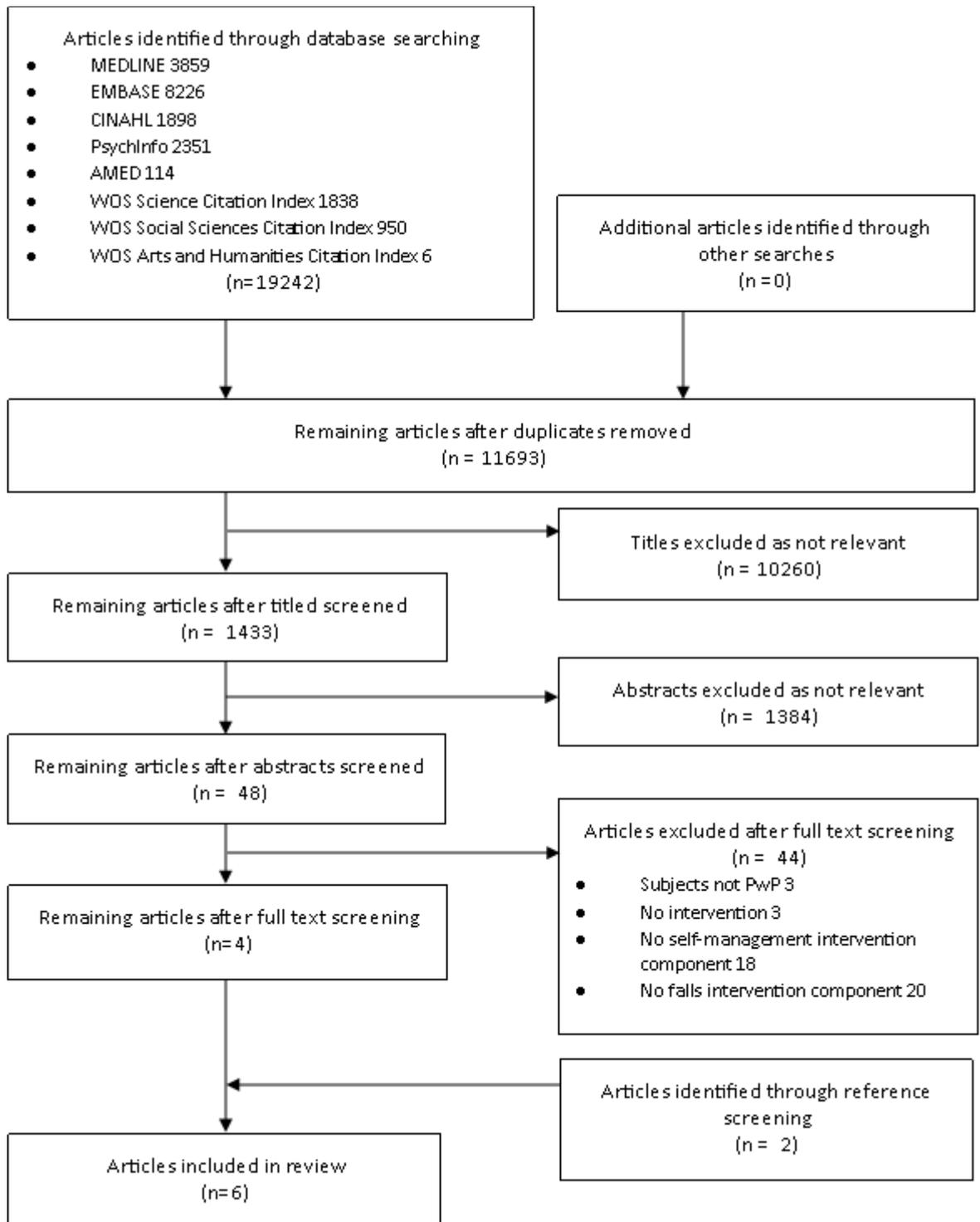


Figure 2-1 Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) Diagram Detailing the Search Process.

Abbreviations: PRISMA= Preferred Reporting Items for Systematic Reviews and Meta-analyses

Table 2-1: Quality Appraisal of Included Studies

Question	Peteet (137)	White (138)	Tickle-Degnen (139)	Canning (140)	Morris et al. 2015 (141)	Morris et al. 2017 (142)
Was true randomization used for assignment of participants to treatment groups?	0	1	1	0	1	0
Was allocation to treatment groups concealed?	0	0	0	1	0	0
Were treatment groups similar at the baseline?	1	1	1	1	1	1
Were participants blind to treatment assignment?	1	0	0	0	0	0
Were those delivering treatment blind to treatment assignment?	0	0	0	0	0	0
Were outcomes assessors blind to treatment assignment?	1	1	1	1	1	1
Were treatment groups treated identically other than the intervention of interest?	1	1	1	1	1	1
Was follow up complete and if not, were differences between groups in terms of their follow up adequately described and analysed?	1	0	1	1	1	1
Were participants analysed in the groups to which they were randomized?	0	0	1	1	1	1
Were outcomes measured in the same way for treatment groups?	1	1	1	1	1	1
Were outcomes measured in a reliable way?	1	1	1	0	0	0
Was appropriate statistical analysis used?	0	0	0	1	0	0
Was the trial design appropriate, and any deviations from the standard RCT design (individual randomization, parallel groups) accounted for in the conduct and analysis of the trial?	1	1	1	1	1	1
Total	8	7	9	9	8	7

Quality Appraisal performed using the JBI Critical Appraisal Checklist for RCTs

2.2.2 Description of the Included Studies

2.2.2.1 Study Design

Six articles were identified consisting of five research papers and one thesis, all reported RCTs. Characteristics of the included studies are shown in Appendix A3. Two of the articles, White et al. and Tickle-Degnen et al., studied the same intervention on the same participants but reported different outcome measures (138,139). Therefore, six articles reporting five interventions were included in this review.

No articles studied the effect of a falls self-management intervention in isolation. All evaluated an intervention comprised of a self-management component in conjunction with a physiotherapy

component. Canning et al. assessed the effect of an intervention comprised of physiotherapy and self-management, and compared this to self-management alone (140). The other five articles assessed the effect of an intervention comprised of physiotherapy and self-management and compared it to a control which did not contain either physiotherapy or self-management (138–142).

2.2.2.2 Setting and Participant Characteristics

Studies were conducted between 2003 and 2016; three in Australia and three in the USA. There were 718 participants in total (range in each study was 27 to 231); all were PwP. Mean age of participants was from 58 to 71.4 years. All studies had predominantly male participants. Mean time from PD diagnosis was recorded in four of five data sets; it ranged from 6.7 to 8.75 years (137,139–141). In five of six articles, the majority of PwP had a Hoehn and Yahr stage of less than three and two excluded those with a Hoehn and Yahr stage of four (137,139,141,142). Hoehn and Yahr Stage three reflects falls (6). All studies assessed participants' cognition with the mini mental state examination (MMSE) prior to enrolment and excluded those with cognitive impairment. Four data sets reported mean baseline MMSE scores, which varied between 28.2 and 29.3 out of 30. In the three data sets that reported fall rate at baseline, 55 to 78% of participants had fallen within the last year (140–142).

2.2.2.3 Intervention Delivery

Self-management components to the interventions were delivered through either group discussion or falls booklets. Each of the interventions based upon group discussion targeted self-management of a range of PD related difficulties, and one of the difficulties targeted was falls (137–139). In the three articles that studied an intervention whose self-management component was through the provision of a falls booklet, falls were the key target of the intervention (140–142).

Group Discussion

Three articles, which evaluated two different interventions, described group discussion of self-management facilitated by a physiotherapist, which was delivered alongside physiotherapy (137–139). Peteet assessed the effect of a physical exercise and self-management education programme compared to exercise alone. Sessions were delivered weekly by a physiotherapist over six weeks. Education sessions were individualised to participants. Only the fourth week focused on falls, where a physiotherapist led a 20-25-minute discussion on falls; topics included falls prevention, safety and strategies to minimise falls. The development and completion of

exercise-related action plans was encouraged. Tickle-Degnen et al. and White et al. assessed the effect of six weekly self-management rehabilitation sessions, compared to social group sessions that contained no self-management or falls-based content (138,139). Sessions were delivered by a physiotherapist and were comprised of one hour of physiotherapy and speech therapy followed by a 30 minute group discussion (138,139). Topics relevant to falls that were discussed included 'preventing falls', 'strategies to improve walking', 'relaxation, stress management' and 'benefits of exercise'.

Falls Booklets

Three articles, Canning et al., Morris et al. 2015 and Morris et al. 2017, had a self-management component to the intervention based upon the same falls booklet (140–143). The booklet, titled '*Don't fall for it. Falls can be prevented!*', is 32 pages long, contains no PD-specific information and is aimed toward all older people at risk of falls (140–143). In Canning et al., the booklet was distributed to participants in the intervention and control arms of the study and no verbal falls education was delivered; only the physiotherapy component differed between the two participant groups (140). In Morris et al. 2015 and Morris et al. 2017, participants in the intervention arm of the study received falls education based upon the content of the booklet during weekly physiotherapy sessions, and received a copy take away (141,142). In Morris et al. 2015 the intervention was delivered over eight weeks and it was unclear whether the education was individualised to participants; in Morris et al. 2017 the intervention was delivered over six weeks and it was individualised to participants (141,142). In both Morris et al. 2015 and Morris et al. 2017, participants in the control groups attended weekly non-falls education sessions, and in Morris et al. 2017 participants in the control group also received a non-self-management-based falls information sheet to take home (142).

2.2.2.4 Self-management Components of the Interventions

The self-management component of each of the interventions was assessed using the PRISMS taxonomy (Table 2-2). Within all articles, the description of the self-management components was very brief; mean word count was 60 words (138–142). Additional information was obtained from three authors (137,141,142). Through references provided within the articles, I was able to directly review the falls booklet '*Don't fall for it. Falls can be prevented!*', utilised within Canning et al., Morris et al. 2015 and Morris et al. 2017 (140–143).

Table 2-2 PRISMS Self-Management Components of the Interventions

PRISMS taxonomy component	Peteet (137)	Tickle Degnen et al. (139)	White et al. (138)	Canning et al. (140)	Morris et al. 2015 (141)	Morris et al. 2017 (142)
A1. Information about the condition and/or its management	✓	-	-	✓	✓	✓
A2. Information about available resources	-	-	-	✓	✓	✓
A3. Provision of/ agreement on specific clinical action plans and/or rescue medication	-	-	-	-	-	-
A4. Regular clinical Review	✓	-	-	-	-	-
A5. Monitoring of condition with feedback	✓	-	-	-	-	-
A6. Practical support with adherence (medication or behavioural)	-	-	-	-	-	-
A7. Provision of equipment	-	-	-	-	-	-
A8. Provision of easy access to advice or support when needed	-	-	-	-	-	-
A9. Training/ rehearsal to communicate with health care professionals	-	-	-	✓	✓	✓
A10. Training/ rehearsal for everyday activities	-	✓	✓	✓	✓	✓
A11. Training/ rehearsal for practical self-management. Includes skill acquisition	-	-	-	✓	✓	✓
A12. Training/ rehearsal for psychological strategies Includes action planning and goal setting	✓	✓	✓	✓	✓	✓
A13. Social support	✓	✓	✓	-	-	-
A14. Lifestyle advice and support Includes advice about exercise and a healthy diet	-	✓	✓	✓	✓	✓

Information About the Condition and/or it's Management

To effectively self-manage their LTC, patients require appropriate knowledge about the condition and/or its management. Four out of the six articles utilised this component. However, there were differences in the amount, topics, and presentation of information provided. Peteet provided participants within both the intervention and control arms of the study with written information about PD; however, only participants in the intervention arm received falls information (137). In the intervention studied by both Tickle-Degnen et al. and White et al., it is not clear if participants received any PD or falls information (138,139).

The booklet *'Don't fall for it. Falls can be prevented!'* utilised within three articles (Canning et al., Morris et al. 2015 and Morris et al. 2017) contains a wide breadth of falls-related topics (143). It includes information about the potential causes of falls and suggests strategies to manage them. However, it is targeted toward all older people at risk of falls and contains no PD-specific information (140–143). Morris et al. 2015 and Morris et al. 2017 also delivered verbal falls education based upon the contents of the booklet.

Training/ Rehearsal for Everyday Activities

Self-management interventions commonly encourage the learning and practicing of behaviours and skills that are relevant for an individual's everyday activities. All articles studied an intervention that delivered this component through physiotherapy strategies. Physiotherapy approaches included education of cueing strategies, support and advice about transfers, and movement strategy training, which includes training for common functional tasks (137–142). Five articles delivered this component through self-management strategies. However, whilst the group discussions delivered by Tickle-Degnen et al. and White et al. contained information about the performance of day to day activities, it was unclear whether this was specific to falls (138,139). The booklet utilised within three articles encourages users to plan ahead, risk assess potential situations, and to ask for help from others if they consider a task to be high risk (143).

Training/ Rehearsal for Psychological Strategies

Often, self-management interventions encourage patients to develop psychological management strategies such as problem-solving, re-framing of symptoms, and goal setting. All articles included this component. Interventions that included a self-management component based upon group discussion (Peteet, Tickle-Degnen et al. and White et al.) encouraged participants to problem solve and to develop realistic action plans in collaboration with a physiotherapist (137–139). However, no details were provided surrounding their implementation and it is unclear whether action plans were related to falls. The booklet utilised by three articles (Canning, Morris et al.

2015 and Morris et al. 2017) contains a page to develop action plan. However, the interventions that contained a self-management intervention based upon this booklet did not describe providing participants with training about how these should be completed (140–143).

Lifestyle advice and Support

Self-management interventions often contain information about health and lifestyle. This component was provided within five of six of the articles. In the group discussions within the intervention studied by Tickle-Degnen et al. and White et al., participants discussed the ‘Benefits of exercise’ (138,139). The booklet utilised within three articles promotes a healthy lifestyle; it promotes physical activity and provides dietary advice (140–143). However, it was often unclear whether this information was falls related.

Social Support

All three articles that contained an intervention with a self-management component delivered through group discussion (Peteet, White et al. and Tickle-Degnen et al.) provided social support (137–139). However, it was unclear whether this was falls related. Peteet asked users to identify a ‘buddy’ for support; but this appeared to be for the promotion of exercise and not for the management of falls (137). The articles that contained a self-management intervention based upon the falls booklet contained no social support (140–142).

Other Self-management Components

Self-management interventions may contain regular clinical review and monitoring with feedback. Whilst this was provided within the intervention studied by Peteet, this was for exercise and not for falls (137).

In addition to the elements detailed above, the falls booklet utilised within three articles (Canning, Morris et al. 2015 and Morris et al. 2017) supports falls self-management through containing (i) information about available resources, (ii) training to communicate with HCPs, and (iii) training/ rehearsal for practical self-management by describing strategies to reduce the risk of falls within the home (140–143).

Further components that a self-management intervention might contain, but were not included within any of the interventions studied were (i) development of individualised action plans in conjunction with a HCP, (ii) practical support with adherence (medication or behavioural), (iii) equipment provision, and (iv) provision of easy access to advice or support when required.

2.2.3 Outcome Measures

The primary outcome measure was fall frequency in three articles: Canning, Morris et al. 2015 and Morris et al. 2017 (140–142). QOL was the primary outcome measure in the article by Tickle-Degnen et al. (115). Physical activity related outcomes were the primary outcome measures in the articles by White et al. and Peteet et al. (137,138).

All the included articles assessed the effect of the intervention as a whole (Appendix A4). None studied the separate effects of the self-management and physiotherapy components. No articles assessed adherence to the self-management component or skill acquisition. No studies included or assessed the effects of the intervention on caregivers.

2.2.3.1 Falls Outcomes

All three articles where the self-management component was based upon the booklet *'Don't fall for it. Falls can be Prevented!'* reported falls outcomes. In Morris et al. 2015 participants fell less when they received combined physiotherapy and self-management versus no physiotherapy or self-management (141). However, no reduction in falls was observed in either Canning et al. or Morris et al. 2017. Sub analysis in Canning et al, found a 69% reduction in falls in participants with less advanced PD who received physiotherapy and self-management compared to those who received self-management in isolation (140).

Fear of falling was only assessed by Canning et al. Fear of falling was evaluated using the FES-I (140,144). At six months, participants who received physiotherapy and self-management had significant improvement in FES-I score compared to participants who received self-management in isolation (140).

Articles where the self-management intervention was group discussion did not report falls outcomes.

2.2.3.2 Quality of Life

Four articles assessed QOL. A variety of different validated scoring measures were used. In the intervention studied by Tickle-Degnen et al., significant improvement in QOL, as measured by Parkinson's Disease Questionnaire 39 (PDQ-39), was observed at programme end (six weeks) in individuals who received combined physiotherapy and self-management versus those who received no physiotherapy or self-management; improvement persisted at 6 month follow up (139).

Inconsistent QOL outcomes were observed in the three studies whose self-management component was based upon the fall booklet. Canning et al. reported that in participants who received physiotherapy and self-management compared to self-management alone there was significant improvement in QOL as measured by Short-Form Six-Dimension (SF-6D), but no improvement in either the mental and physical sub scores of the 12-item Short Form Survey (SF-12) or PDQ-39 (140). Morris et al. 2015 reported a significant improvement in QOL scores at 12 months in one of the intervention arms (physiotherapy via progressive resistance strength training (PRST)) alongside self-management) as measured by PDQ-39 but no change was observed in EuroQol 5 Dimensions Visual Analogue scale (EQ-5D VAS); in the other intervention arm (physiotherapy via movement strategy training (MST) plus self-management) no improvements were seen in either PDQ-39 or EQ-5D VAS (141). Morris et al. 2017 recorded no change in QOL in those who received the combined physiotherapy and self-management versus those who received no physiotherapy or self-management (142).

2.2.3.3 Other Outcome Measures

Physical activity outcomes were reported by four articles (137,139–141). Peteet, White et al. and Morris et al. 2015 reported no difference in physical outcome measures in association with each of the respective physiotherapy and self-management interventions studied (137,139,141). Canning et al. reported mixed outcomes on physical activity measures; improvements were reported in the sit to stand and short physical performance battery in participants who received physiotherapy and self-management compared to self-management alone, but no improvement was seen in the other measures reported, which included exercise hours/ week (140).

Unified Parkinson's disease rating scale (UPDRS) was measured in two articles, Morris et al. 2015 and Morris et al. 2017; no improvements were reported (141,142).

No articles reported adverse outcomes related to the self-management component of the intervention. Canning et al. reported that two participants fell whilst exercising at home, which related to the physiotherapy component of the intervention (140).

2.3 Discussion

This review was the first systematic review of self-management interventions for PwP who fall (126). It builds upon the findings of a previous review of self-management interventions in PwP where the approach used was not exhaustive and the review was not specific to falls-based interventions (124). This is not a well-researched area; few relevant articles were identified despite a thorough and systematic search. Of the six articles identified, two studied the same

intervention on the same population but measured different outcomes, and three of the articles were based upon the same falls booklet. Self-management was often not the main focus of the intervention. All articles studied the effect of a self-management intervention, comprised of either group discussion or a falls booklet, in combination with physiotherapy. Description of the interventions was limited, and there was extensive variation in the outcomes measured.

2.3.1 Methodological Comments

Studies did not include a population that was representative of the range of PwP who fall. In only one study were the majority of participants of Hoehn and Yahr Stage three, which reflects falls (6). No studies listed falling as an inclusion criterion, and only three studies recorded fall rates at baseline. PwP with cognitive impairment were excluded from all studies, yet this subgroup are at increased risk of falls and their adverse physical and psychological connotations (28). Caregivers play a key role in falls management, yet no studies included them (28,43). The inclusion of caregivers may facilitate the inclusion of PwP with cognitive impairment and might improve caregiver outcomes; future research programmes should look to explore this.

Interventions included a wide range of self-management strategies. However, the description of these was often inadequate, as has been reported by authors of reviews of self-management programmes for other LTCs (93). Self-management was often not the main focus of the interventions studied, and it could be difficult to ascertain whether the self-management components were specific to falls. Whilst people who fall may be more likely to benefit from multifaceted interventions, without a clear detailed description this can hinder identification of the key ingredients contributing to change (145). Interventions should be well described to allow identification and subsequent replication of their successful components (146–148).

To effectively self-manage a LTC, individuals require the ability to effectively problem-solve, make decisions and set goals (79). None of the interventions within the articles in this review encouraged and taught participants all three of these skills. Individuals also require information specific to their needs; but only the intervention studied by Morris et al. 2017 provided participants with individualised information (79,142). Falling is heterogenous in PwP; the provision of generic information to a heterogeneous population can lead to information overload and disengagement (90,140–143). Future falls self-management programmes for PwP should seek to individualise information to participants' personal requirements to increase user engagement and subsequent behavioural change (107,149).

2.3.2 Impact of Self-management Programmes on Falls and Other Clinical Outcomes

All articles assessed the effect self-management in combination with physiotherapy. Therefore, it was not possible to draw definite conclusions about the contribution of falls self-management.

Articles where the self-management component provided information about PD and its management showed inconsistent outcomes as measured by QOL, UPDRS and fall rate. However, only Morris et al., 2017 provided individualised falls information which has previously been associated with greater success (79,107,142). Future research programmes of self-management interventions should look to individualise the information provided to participants.

Falls outcomes were measured in three articles, none recorded a reduction in the number of people who fell, and only one recorded a reduced fall rate (140,141,150). Given that the evidence of physiotherapy interventions to reduce falls remains unclear, the effect of self-management on falls is also uncertain. Fear of falling was only measured by Canning et al. 2015, however with both the intervention and control groups receiving the self-management component, the effect of self-management on fear of falling has not been explored (140).

Most articles measured QOL; however, only Tickle-Degnen et al., where the self-management component to the intervention contained group discussion and educated participants to problem-solve and develop action plans, reported an improvement (139). Future research should look to explore the acceptability of group-based self-management interventions in PwP. They may be less acceptable to those with reduced mobility, where travel may be difficult, and programme-end can lead participants to feel isolated (85,98).

Self-management outcomes were not measured in any articles. Self-management outcomes considered important to those with LTCs include independence and applicable knowledge (151). No articles assessed engagement with the self-management with the interventions. Studies of future self-management programmes should include process evaluation to explore acceptability, adherence and engagement of participants; this would be supported by the use of mixed methods (152).

2.4 Conclusion

Few self-management interventions for PwP who fall have been evaluated and reported in the literature. Reporting of the content of the interventions is poor, and the components of an effective intervention are unclear. It was not possible to draw conclusions about the effect of

Chapter Two: Systematic Review

falls-based self-management interventions for PwP or the key components that they should contain.

Within the articles included in this review, it was unclear whether interventions were targeted toward PwP who had experienced falls, and those with cognitive impairment/ dementia, who are at heightened risk of falls and their adverse consequences, were excluded. Information was rarely individualised to participants. Future studies of falls-based self-management interventions may benefit from targeting those who are most vulnerable, to include PwP with a history of falls or fear of falls, PwP with cognitive impairment/ dementia, and caregivers of PwP.

Self-management programmes have been successful in supporting people with other LTCs. The evidence of rehabilitative interventions to support falling in PwP is inconclusive. Therefore, effective falls self-management programmes for PwP should be developed, implemented and evaluated to assess their potential efficacy. Studies reporting these programmes should clearly describe the intervention components, and the methods used, to allow for key ingredients to be identified and subsequently replicated.

3 Methodology

This mixed methods programme of research consisted of four consecutive phases and took place in the South of England from December 2016 to January 2019 (Figure 3-1): (1) a mixed methods study with PwP and caregivers to establish their needs and preferences for the effective self-management of falls, (2) a qualitative study with HCPs to establish their perspective of PwP and caregivers' needs and preferences for the effective self-management of falls, (3) development of the intervention, usability testing and modification of the intervention, and (4) mixed methods feasibility study of the intervention.

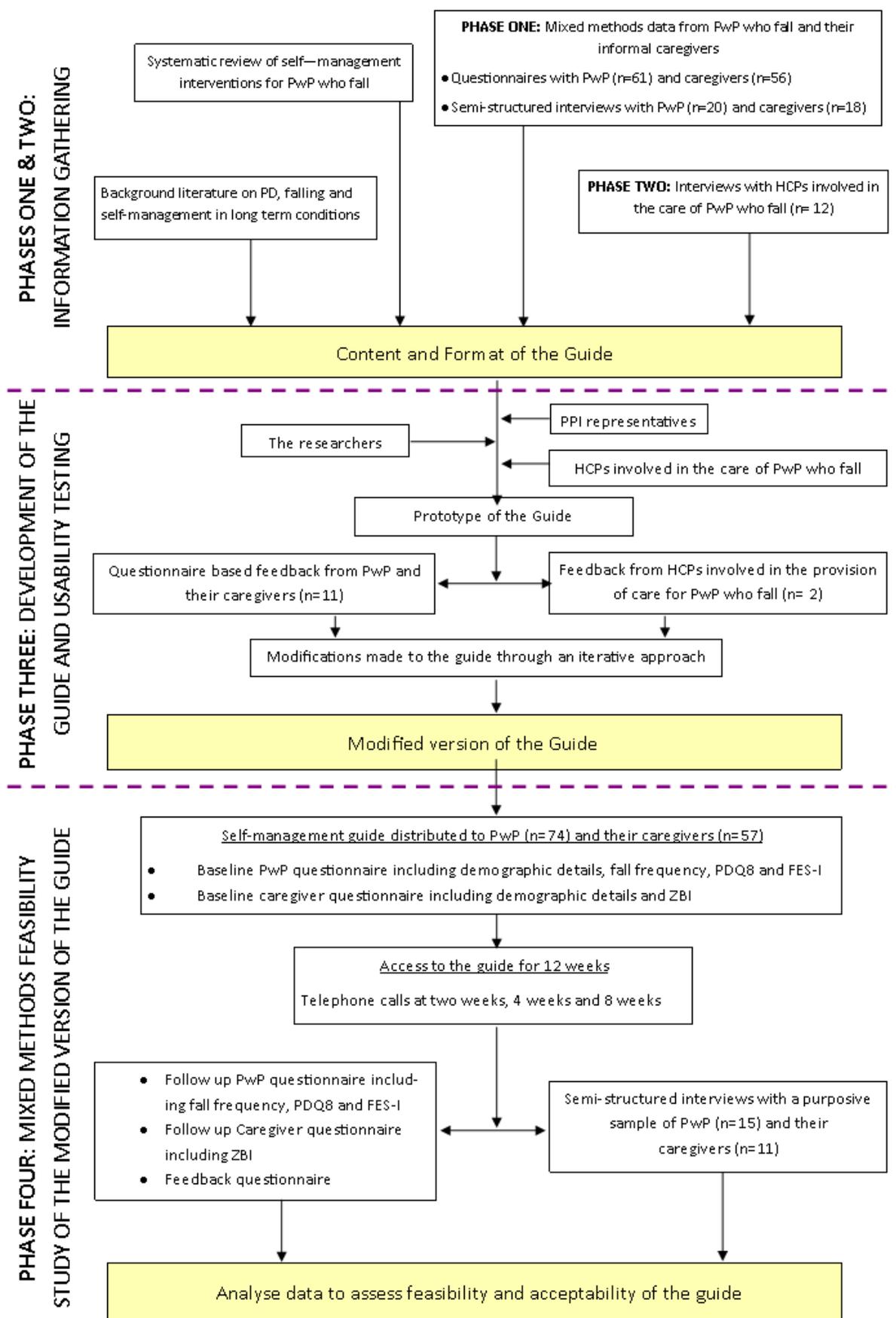


Figure 3-1 Outline of Programme of Research

Abbreviations: FES-I= short form Falls-efficacy scale international; HCPs= Healthcare professionals; PPI= patient and public representatives; PDQ-8= Parkinson’s disease questionnaire 8; ZBI= Zarit Burden Interview (short version).

3.1 Theoretical Constructs Underpinning Development of the Self-management Intervention

The self-management intervention developed was a “complex intervention” as outcomes can be influenced by the intervention, individual characteristics of the participants, and by interactions between PwP and their caregivers (132).

3.1.1 MRC Guidance for the Development and Evaluation of Complex Interventions

The Medical Research Council (MRC) framework for the development and evaluation of complex interventions outlines key stages in the process: (i) development, (ii) piloting and feasibility, (iii) implementation and (iv) evaluation (Figure 3-2) (146,152). It proposes that the development-evaluation- implementation process should not be linear, and that findings should be reported at each stage (146). Newer iterations of the guidance have outlined the importance of process evaluation, which can help to identify what works and why, to include the identification of contextual factors contributing to the outcome and the quality of implementation achieved (132,152).

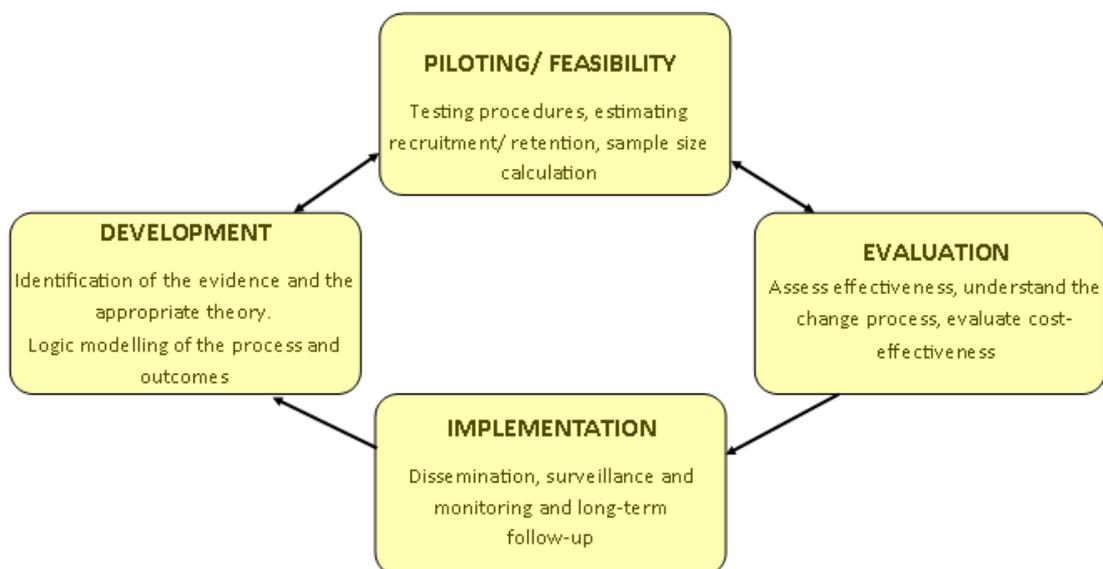


Figure 3-2 MRC Process for the Development and Evaluation of Complex Interventions: Key Stages

Adapted from Craig et al. 2006 (146).

This thesis focuses on the (i) development, and (ii) piloting and feasibility stages of an intervention that aims to support the self-management of falls in PwP and their caregivers. Following MRC

guidance, the intervention was developed through incorporation of the latest evidence and appropriate theory (132,152). I conducted usability testing of the intervention (phase three, chapter six, page 155) before evaluating the feasibility of delivering the intervention (phase four, chapter seven, page 179).

3.1.2 The Person Based Approach

Complementary to the MRC guidance, the ‘person-based approach’ (PBA) for the development and evaluation of health behavioural interventions was used (22,153). The PBA places emphasis on the viewpoints and experiences of service users through the incorporation of in-depth qualitative research during the (i) planning, (ii) design and (iii) development and evaluation of an intervention. It seeks to understand the psychosocial contexts of users to increase the acceptability, use and effectiveness of the intervention, and has been used successfully during the development self-management interventions for other LTCs (22,153–158).

3.1.2.1 Intervention Planning

Following the PBA, I conducted in-depth new qualitative research of user’s current experiences to allow identification of the likely barriers and facilitators to the intervention (159). I conducted two studies (i) a mixed methods study with PwP and caregivers (phase one, chapter four, page 71) and (ii) a qualitative study with HCPs to identify their perspective of the problem (phase Two, chapter five, page 121).

The PBA outlines that qualitative experiences of existing interventions should be considered (159). However, my systematic review (chapter two, page 47) identified few existing falls self-management interventions for PwP, and none of the studies utilised qualitative methodology (126).

3.1.2.2 Intervention Design

Following the PBA, I triangulated the data from the background literature, systematic review of falls-based self-management interventions, and the results from phases one and two to describe the issues, needs and challenges experienced by PwP who fall and their caregivers (phase, three, chapter Six, page 155) (159). This information was used to create the ‘key intervention objectives’: the issues that the intervention would seek to address. ‘Key Features of the Intervention’ were then designed to meet each of these objectives. Together the ‘Key Intervention Objectives and the ‘Key Features of the Intervention’ formed the guiding principles of the intervention. Guiding principles help during intervention design as they provide a coherent

description of the issues, needs and challenges within the population, and outline how the intervention will address them (22,153–157).

3.1.2.3 Development and Evaluation

Following the PBA, qualitative methods should be used to elicit and observe user's views of the prototype of the intervention prior to performing detailed longitudinal mixed methods analyses (159). This should include analysis of how each component is interpreted, and how and when the intervention is likely to be used. Iterative modification of the intervention in response to the results of this analysis helps to enhance the intervention's acceptability, and the engagement of users with it (154,155,158,159). Papers reporting the development of other self-management interventions underpinned by the PBA have used interviews, focus groups or think aloud studies at this stage (154–158). Think aloud methodology is often useful as it allows a detailed real-time assessment of user's interpretation of the intervention, providing a deeper understanding of whether the desired meaning has been achieved (154,158,159).

However, in this thesis, due to time constraints, it was not possible to obtain detailed qualitative feedback at this stage. Instead, feedback of the prototype of the intervention was obtained through completion of a questionnaire (phase three, chapter six, page 155). The questionnaire contained Likert-type questions followed by open-ended responses. I felt that it would be more beneficial, within the time allocated, to conduct a thorough mixed methods feasibility study of the intervention (phase four, chapter seven, page 179), to provide comprehensive information of the longitudinal experiences of PwP and caregivers using the intervention.

3.1.3 Epistemology and Overview of Research Methods

3.1.3.1 Epistemology

In philosophy, ontology describes the nature of reality. Epistemology is the study of knowledge or reality. There are many schools of thought within philosophy, with three mainstream approaches being (i) positivism, (ii) critical realism and (iii) constructivism; each adopts different epistemological assumptions (160). A positivist assumes that reality is independent from human interpretation; only what can be objectively measured is considered real and valid (160,161). A positivist uses quantitative methods; objective and precise measurements are recorded in a controlled environment to produce findings that are generalisable to the wider population (152,162–164). A constructivist assumes that all knowledge is socially and culturally interpreted, one cannot prove what is true and what is not true. A constructivist uses qualitative methods; an

Chapter Three: Methodology

interpretative approach is used to provide a rich, multifaceted and contextualised understanding (160,161,164).

Lying between the extremes of positivism and constructivism is critical realism. Critical realism adopts the positivist ontology assuming that concepts do exist, and a constructivist epistemology assuming that our knowledge of concepts is defined by historical and cultural context. A critical realist explores how causation occurs, acknowledging the strengths and limitations of both quantitative and qualitative research, and seeks to understand what it is about the context which changes the outcome (160,165).

Pragmatism embraces the middle ground between positivist and constructivist epistemologies. The framework of pragmatism holds that all research involves human interpretation, and that all research aims to achieve a better and richer experience whether information is obtained through quantitative objective measurement or through qualitative contextualised interpretation (161). Researchers adopting the framework of pragmatism select the most appropriate methodology guided by their research question, they are not bound by one epistemology and can use quantitative and qualitative to enhance their understanding (161,165,166). Critical realism and pragmatism are often perceived to be compatible, as critical realism adopts a pragmatic approach to research methods (165).

3.1.3.2 Overview of Research Methods Employed

In this thesis, I report two studies which informed the development of the intervention: the mixed methods study with PwP and caregivers (phase one, chapter four) and the qualitative study with caregivers (phase two, chapter five). In these two studies I sought to identify patterns and commonalities within the data relevant to the context in which they were presented, consistent with a critical realist approach. The mixed methods feasibility study (phase four) is also consistent with a critical realist approach as data from quantitative and qualitative methods was integrated through a triangulation protocol to facilitate a greater understanding of participants' perceptions, whilst acknowledging the strengths and limitations of quantitative and qualitative research (165,167,168).

The framework of pragmatism was adopted throughout the studies forming this thesis; the most appropriate methodology was selected to answer each of the research questions and to obtain a greater understanding of the problem (161). Phases one, three and four utilised 'mixed methods'; the complementary use of quantitative and qualitative methods is common in implementation research (163,164). Phase two used qualitative methodology.

Quantitative methods were used in the mixed methods study with PwP and caregivers (phase one, chapter four, page 71) to describe the population studied, identify the frequency of falls, and to elicit fear of falling and caregiver burden through completion of standardised scales. In the feasibility study of the intervention (chapter seven, phase four, page 179), quantitative methods were used to identify (i) fall frequency, and (ii) fear of falling, health related quality of life (HR-QOL), caregiver burden and falls self-efficacy through completion of standardised scales. No quantitative measures were utilised in the qualitative study with HCPs (phase two, chapter five, page 121), as quantitative measures would not have supported the aims of the study.

Quantitative and qualitative methods can be used to provide different perspectives of a problem (164). Mixed methods are useful to assess the effect of complex interventions, where it is important to consider process evaluation measures, to include the quality and quality of what was implemented. Qualitative methods can be used to explore the experiences and opinions of participants to provide a contextualised understanding of quantitative findings, with insight into how or why a phenomenon arises (152,162–164). Qualitative components can also be the most relevant when conducting process evaluation, through assessment of outcomes that may be difficult to measure on standardised quantitative scales (129,130,152).

The specific methods used for each of the phases of this programme of research precede the findings in each of their respective chapters.

3.2 Ethical Considerations

Phase one was approved by the University of Southampton Faculty of Medicine Ethics Committee ERGO reference 29763 (Appendix B1). Phase two was approved by the University of Southampton Faculty of Medicine Ethics Committee, ERGO reference 25988 (Appendix B2).

Phase Three was conducted as a quality improvement project and did not require approval from an ethics committee. Phase Four was approved by the Health Research Authority (HRA) through the South Central– Oxford C Research Ethics Committee (REC); REC reference 17/SC/0488; IRAS Project ID 221022 (Appendix B3). A substantial amendment to include PwP who were unsteady, with re-wording of the guide to this effect was approved on 13.03.2018 (Appendix B4).

4 The Needs and Preferences of People with Parkinson's and their Caregivers for the Effective Self-management of Falls (Phase One)

This study sought to explore the needs and preferences of community-dwelling People with Parkinson's (PwP), and their informal caregivers, for the effective self-management of falls.

4.1 Methods

4.1.1 Study Design

PwP and caregivers completed questionnaires, with a purposive sample taking part in semi-structured interviews. Semi-structured interviews allowed greater exploration of participant insights than open ended questions within a survey, which can restrict views to those dictated by the researcher (169).

This study sought to explore the experiences of falling amongst PwP and their caregivers to include:

- a) What it is like when someone with PD falls
- b) Thoughts and feelings about falling and its impact
- c) Self-management techniques to manage falls that have been adopted amongst this population.
- d) Unmet requirements for the effective self-management of falls.
- e) The presence and acceptability of different resources that are utilised by this population to address problems relating to falling.
- f) Barriers and facilitators to service users informing HCPs of their falls.
- g) The presence and acceptability of different resources that are utilised by this population for problems unrelated to their PD.

4.1.2 Participant Recruitment

4.1.2.1 Questionnaire Survey

Participants were recruited by myself through local groups supported by Parkinson's UK, a UK based Parkinson's charity. These groups, run by volunteers, are held in community settings. 14 groups, in 12 locations, were attended by myself between 14.03.17 and 05.06.17, with prior approval from Parkinson's UK. Initial screening for inclusion and exclusion criteria took place (Table 4-1). Where a PwP met the inclusion criteria for the study, if they had an informal caregiver, their caregiver was also invited to take part. Results from this study would later be used to support the development of a falls-based self-management intervention to support all community-dwelling PwP who fall and their caregivers (phase three, chapter six, page 155). Therefore, to reflect this, an inclusive approach to participant recruitment was adopted to include PwP with cognitive impairment/ dementia, and PwP were not excluded based upon PD severity. Cognitive impairment has been reported to be present in up to 80% of those with longstanding PD, it is therefore important that these PwP are included in research (13). Those with cognitive impairment are no less accurate at reporting falls than their cognitively intact peers when surveyed alongside their informal caregivers (28).

Those living in a residential or nursing home were excluded from this study as (i) professional caregivers may have received formal training about PD and falls, and (ii) the needs of professional caregivers would likely differ from those of informal caregivers. Results from this study were used to inform the development of a self-management intervention for community dwelling PwP and their informal caregivers (phase three, chapter six, page 155).

PwP meeting the criteria for inclusion were provided with a participant information sheet, two questionnaires (one for the PwP, one for the caregiver) and a prepaid envelope for their return (Appendix C1, 2, 3). 112 questionnaires were distributed to PwP.

Table 4-1 Inclusion and Exclusion Criteria

Inclusion criteria	Exclusion criteria
Diagnosis of idiopathic PD, with or without cognitive impairment	Diagnosis of a Parkinson's Plus syndrome
PwP living in their own home	PwP living in a residential or nursing home.
At least one fall in the preceding year, as reported by the PwP or the caregiver	No falls in the preceding year
Able to read a newspaper with glasses without severe difficulty	Participants not fluent in written and spoken English

Standard issue patient information sheets may leave participants without the information that they require to consent to a study. I designed participant information sheets that were easy to navigate, whilst providing all necessary written information about the study (Appendix C1) (170).

PwP could complete their questionnaire with the support of a close friend/ relative where required (Appendix C2). Questionnaires could be completed anonymously. However, individuals wishing to be considered for involvement in the semi-structured interviews, or in the later feasibility study of the intervention (phase four, chapter eight, page 179), were able to provide their contact details.

Questionnaires were distributed until responses had been received from 30-40 PwP. Due to the delay in time between questionnaires being distributed, and questionnaires being returned, completed questionnaires were received from 56 PwP.

4.1.2.2 Semi-structured Interviews

A combination of purposive, maximum variation and critical case sampling was used to invite a sample of PwP and caregivers who had taken part in the questionnaire survey. This heterogeneous sample provided a wide range of perspectives.

Maximum variation sampling aims to view a problem from all angles. Participants invited to interview included: (i) PwP with low and high concerns of falling and (ii) caregivers with low and high levels of caregiver burden (163). As questionnaires were returned, total short form Falls Efficacy Scale International scale (FES-I) scores were entered into an excel spreadsheet (a measure of concerns of falls), and participants with scores approaching the lower and higher limits were invited to interview. There are established cut off points for low, moderate and high concerns of falls on the short FES-I, and for low and high caregiver burden and the ZBI short version (171,172). However, these cut off points were not used to select participants to invite to interview as the sampling strategy aimed to invite those lying at the extremes of the population studied.

Critical case sampling aims to understand how those with a defined characteristic perceive a problem. Participants invited to interview included: (i) PwP with and without cognitive impairment or dementia, (ii) female PwP and (iii) PwP who lived alone (163).

The sample size was derived through the concept of 'Information Power' (173). Information power requires consideration of: (i) the scope of the research question, (ii) the characteristics of the participants and (iii) the researcher. Each of these variables affects whether a smaller or larger sample is likely to be required. Indicators for a larger sample size are a broad research question, participants that are not forthcoming and an inexperienced researcher. Indicators for a

smaller sample size are a narrow research question, participants who are likely to provide a plethora of information and an experienced researcher (173). The characteristics of this study meant that a larger sample of participants was likely to be required: the research question was broad; the quantity of information provided by some participants, particularly those with cognitive impairment, was likely to be small; and the interviews were performed by two researchers with little prior experience of qualitative interviewing.

Whilst the sampling schema was drawn a priori, as data-collection and analysis ran in parallel, this allowed me to ensure that the sampling technique was adequate to achieve data saturation. Data saturation describes the point in data analysis at which the data obtained provides sufficient breadth and depth such that no further patterns emerge (163,174).

4.1.3 Data Collection

4.1.3.1 PwP Questionnaire

This questionnaire sought to identify: (i) if participants met the inclusion criteria and purposive sampling criteria for the nested qualitative study and (ii) frequency and types of falls (Appendix C2).

Cognitive impairment and dementia were assessed through self-report. Participants were also asked about whether they had any concerns about their memory, and if these had been discussed with HCPs, aiming to capture undiagnosed cognitive impairment.

Through open ended questioning, PwP provided details of up to three recent falls, to include any difficulties getting up from the floor.

Concerns of falling were assessed by the Short Form FES-I, (34,175). A previous review cited the FES-I as the most appropriate tool to measure 'fear of falling' amongst PwP, and it has been validated for use amongst both cognitively impaired and cognitively intact individuals (34,175,176). The FES-I does not assess fall-related self-efficacy, as the name suggests, but measures 'concerns' about falling. However, scores have been found to directly correlate with those from the Swedish Falls Efficacy Scale (FES-S), which measures falls-related self-efficacy (34). The FES-I is comprised of 16 questions, which each assess concern of falls whilst performing a defined activity. Responses are graded from one: 'not at all concerned', to four: 'very concerned' (144). The Short Form FES-I consists of seven of the original 16 questions. It maintains excellent internal reliability and test-retest reliability and is more practical for research and clinical purposes (175,177).

The questionnaire also sought to identify the different mediums of information that this population regularly utilised to inform the development of the intervention (phase three, chapter six, page 155).

4.1.3.2 Caregivers' Questionnaire

This questionnaire consisted of the Zarit Burden Interview (short version) (ZBI) (Appendix C3). The ZBI is a commonly used measure to assess caregiver burden in PD research, and has been validated for use amongst informal caregivers of individuals with cognitive impairment (178). It seeks to identify the impact of caregiving on emotional, physical and social aspects of a caregiver's life. Originally consisting of 22 questions, a short version has been introduced, validated, and utilised in PD research (171,179). The short version consists of 12 questions, each scored from a scale of 0 (never) to five (nearly always) (171). A score of 17 or greater indicates high caregiver burden (171).

4.1.3.3 Interviews (PwP and caregivers)

Interview Schedule

A schedule of open questions and probes was developed by myself to allow exploration of the views and experiences of PwP who fall and their caregivers (Appendix C6). Views were sought about healthcare provision and falls management, and of resources available for PwP and their caregivers. Asking participants about their thoughts surrounding the content and format of the proposed intervention allowed development of an intervention that was more likely to be acceptable, and therefore more likely to be utilised, by this population.

During data collection, the interview schedule underwent minor changes to reduce ambiguity; multifaceted questions were broken down into individual questions and language was altered. The layout was altered so that it was easier for the interviewers to follow; this produced a more fluid conversation and increased the homogeneity of the questions between interviews.

Data Collection

Interviews were conducted between 27.03.17 and 11.07.2017 at participants' home address and at a time convenient to them. This provided an inclusive approach, as some PwP might find travelling to a research centre difficult, impossible or off-putting. When interviewed in their home environment, participants are more likely to feel comfortable and therefore more forthcoming with information (169).

Chapter Four: Needs and Preferences of PwP and Caregivers

Informed written consent was obtained prior to each of the interviews (Appendix C4). Where the person with Parkinson's was unable to provide informed written consent because of cognitive impairment, their caregiver was asked to act as a consultee (Appendix C5). All participants invited to interview agreed to participate. Interviews were conducted with 38 participants: 20 PwP, and 18 caregivers. In 16 PwP, one corresponding caregiver was interviewed. In one PwP, both their wife and their daughter were interviewed. Three PwP lived alone, and no corresponding caregiver was interviewed.

PwP and their caregivers were invited to be interviewed separately. It was acknowledged that caregivers may not want to discuss caregiver related stress in the presence of their relative or close friend with PD. However, participants were able to be interviewed together. Eight PwP were interviewed with their caregivers (five of these had a diagnosis of cognitive impairment or dementia), and nine PwP were interviewed separately to their caregivers in addition to the three PwP that were recruited into the study alone. Dyadic interviews may stimulate the expression of ideas that may otherwise be forgotten or facilitate the sharing of stories leading to increased detail of information (180). Interviewing PwP with cognitive impairment or dementia alongside their caregiver aimed to enhance participation, a method that has been used previously in dementia and intellectual disability research studies (180,181). Interview questions in single and dyadic interviews were congruous to allow for later combined analysis (180).

Interviews lasted between 18 and 61 minutes (mean 37 +/- standard deviation (SD) 10). 29 interviews were conducted by myself (n=16) and Christine Gaulton (CG) (n=13), an MSc student. I and CG underwent prior training in qualitative interviewing. I attended qualitative interview training organised through the Social Research Foundation. CG attended qualitative interview training organised as part of her master's degree through the University of Southampton. Together, I and CG familiarised ourselves with the interview schedule to ensure that we had a uniform and sound understanding of the questions. Prior to each interview, details were exchanged of participant characteristics, and of questionnaire responses which might be explored within the interview. Interviews were recorded with an audio-recorder. Field notes were completed by myself and CG and communicated throughout the data collection process to allow for emerging ideas and themes to be explored in subsequent interviews and to contextualise the findings, a technique referred to as 'memo-writing' (182).

4.1.4 Data Analysis

4.1.4.1 Questionnaires

Responses to open ended questions were entered by myself into excel. I double entered all other responses into Statistics Package for Social Scientists (SPSS) (version 24) and checked for discrepancies prior to analysis. The distribution of values was assessed. Descriptive statistics were used to describe the population studied, fall frequency, short form FES-I and ZBI short version scores and the mediums of information utilised.

Responses to open ended questions underwent content analysis led by myself, supported by utilising Microsoft Excel (169). Content analysis is often used to analyse responses to open-ended questions within surveys, as the level of detail in the data does not lend itself to thematic analysis (169). Data was analysed in the context that it was presented, rather than simply calculating the frequency of the words presented (169). Responses were assigned to low-level codes, which were derived from the data set and not pre-set variables. Test-retest reliability was achieved through re-coding by myself (169). Codes were then aggregated into categories and frequencies were calculated (169).

4.1.4.2 Semi-structured Interviews

Audio-recordings were transcribed verbatim into Microsoft Word for analysis by CG and Angela Dumbleton (ADu), a research administrator. I re-listened to the recordings to ensure that the transcripts were an accurate reflection of what had been said and to provide immersion in the data (169). I amended transcripts where they were not congruent with the audio-recordings. I imported transcripts of the interviews into NVivo software (version 11) and analysed them through thematic analysis (183). Subsequent to conducting this study, Braun and Clarke have described thematic analysis is an umbrella term to describe different approaches adopted by researchers (184). Braun and Clarke outline three broad approaches to conducting thematic analysis (i) coding reliability, (ii) codebook and (iii) reflexive thematic analysis (184). Coding reliability involves attempts to obtain objective and unbiased coding; multiple researchers code the data with inter-rater reliability a marker of quality, themes are summaries of topics and are often developed early (184). In reflexive thematic analysis coding is open, inter-rater reliability is not a marker of quality with the subjective nature of the researcher embraced as an analytical resource, and themes are developed as the final outcome and provide shared meaning (184). Lying between these two extremes is codebook (184). The approach taken within this analysis lies between codebook and reflexive thematic analysis as described below.

Chapter Four: Needs and Preferences of PwP and Caregivers

Descriptive codes were assigned to sections of text that contained information relating to the research question. Analysis was undertaken through an inductive method, meaning that codes were derived from the data rather than assigning pre-defined codes to sections of text. Codes were of a low-level, meaning that they stayed close to the raw data (169). In keeping with reflexive thematic analysis, coding was fluid and interpretative (184). Coding was undertaken by myself with input from my supervisor Laura Dennison (LD). Input from LD provided additional analytical insight given her extensive qualitative research experience and background in health psychology. It did not aim to achieve inter-rater reliability, but to aid data interpretation.

After 18 interviews had been coded, related codes were reviewed and grouped into 'aggregated codes' or 'clusters' and emerging subthemes and themes were discussed. In line with reflexive thematic analysis, I developed themes inductively, themes were not considered to be pre-existing entities lying within the data (184). The remaining 11 interviews were coded using these 'aggregated codes' where possible, but new codes were created if required. However, as data analysis continued, further codes were not created, implying that data saturation had been reached (163,174). Data saturation describes information redundancy (174,185). It is a concept developed from grounded theory, where data saturation corresponds with theoretical saturation (174,185,186). Data saturation is widely adopted and referenced by researchers conducting thematic analysis (163,174,185,186). However, Braun and Clarke have argued that data saturation is not compatible with their reflexive thematic analysis, as it implies that the themes are within the data rather than from the researcher (185). Marconi et al. describe that data saturation may refer to either 'code saturation': heard it all, or to 'meaning saturation': understand it all (186). In order to achieve meaning saturation, the researcher must conduct concurrent data collection and data analysis, with theoretical sampling of participants to obtain greater understanding (186). Whilst my analysis provides a deep and contextualised presentation of PwP and caregivers views and experiences of falls, without theoretical sampling, one cannot conclude that theoretical saturation has been achieved. However, obtaining code saturation allows for me to conclude that the key experiences of PwP and caregivers have been described to support the later development of the intervention (phase three).

Aggregated codes were grouped into 'themes' by myself with input from LD. Themes were reworked until a coherent set had been developed to describe the data. In keeping with reflexive thematic analysis, themes were developed as the final outcome with the majority providing shared meaning rather than topic summaries (184). However, one theme (theme six) provides a topic summary of participants views on the content and format of future interventions. Theme six was developed inductively in line with reflexive thematic analysis and was not pre-defined, but

reporting this data separate to that of participants' present views and experiences of falling provided the most coherent presentation of this information.

Statements such as 'a few participants' or 'many participants' were used to communicate how common an experience or opinion was amongst those interviewed (169). The exact number of participants holding these views is not helpful as qualitative research does not aim to provide data that is generalisable, but to provide insights into the perspectives and experiences of those who take part (164,169,187). Counting in qualitative research can inadvertently reduce the quality of data that is presented; converting subjective characteristics into numbers reduces the breadth and depth of data presented (187).

4.2 Results

4.2.1 Questionnaires

Of the 112 questionnaires that were distributed, 62 PwP completed and returned the PwP questionnaire. One PwP was excluded from the study as there was insufficient data to establish whether they met the inclusion criteria, thus 61 of 62 questionnaires were analysed from PwP. 56 of 61 PwP had a caregiver that completed and returned the caregiver questionnaire. All caregivers who returned and completed questionnaire two were included in the study.

4.2.1.1 Participant Characteristics

Characteristics of PwP are shown in Table 4-2. 67% of PwP were male and 33% were female. The mean age of the PwP was 74 years (SD 7, range 57-85), and mean time from diagnosis was 127.4 months (SD 69.6, range 10-324). 14% of PwP lived alone. 86% lived with somebody else, 77% lived with their spouse/ partner, 7% lived with children, 7% lived with others; 7% participants lived with their spouse/ partner and their children.

33% of PwP reported concerns in relation to their memory, 21% of these had a formal diagnosis of cognitive impairment or dementia (11.5% cognitive impairment, 9.8% dementia). 6.6% of PwP with concerns reported that they had not discussed these with a healthcare professional and did not have a diagnosis of cognitive impairment or dementia. The median Short Form FES-I score was 14 (range 8 to 28); a score of ≥ 14 indicates high concern of falls (188). In caregivers, the mean Zarit Burden Interview Score was 21 (SD 10, range 0-48). 71% of caregivers had ZBI scores of ≥ 17 , indicative of high caregiver burden.

Table 4-2 Characteristics of People with Parkinson's

Characteristics of PwP	Number (%)
Age (years) Mean (SD)	74 (7)
Gender (n=61) Male: Female	41 (67%): 20 (33%)
Living alone (n=59) Yes: No Live with spouse/ partner: Live with children: Live with others	8 (14%): 51 (86%) 47 (77%): 4 (7%): 4 (7%)
Time from diagnosis of PD (months) (n=61) median (IQR) (range)	120 (78-173) (10-324)
Cognitive impairment (CI) or dementia (n=61) CI: Dementia: Neither	7 (11%): 6 (10%): 48 (79%)
Memory Concerns (n=53) Yes: No: Response unclear	20 (38%): 30 (57%): 3 (5%)
Memory concerns, no CI/ dementia diagnosis, not discussed with HCP (n=61) Yes: No	4 (7%): 57 (93%)
Walking aid usage (n=61) Always: Sometimes: No Wheelchair: Zimmer frame: Walking stick	30 (49%): 26 (43%): 5 (8%) 24 (39%): 25 (41%): 44 (72%)
Number of falls in the last year (n=61) median (IQR) (range)	4 (2-11) (1 – 260)
Difficulties getting up from the floor (n=60) Yes: No	42 (70%): 18 (30%)
Near misses (n=60) Yes: No	49 (82%): 11 (18%)
Frequency of near misses (n=58) Daily: Weekly: Monthly: Occasionally Unclear: N/A	13 (23%): 10 (17%): 4 (7%): 3 (5%) 18 (31%): 10 (17%)
Particular situations leading to unsteadiness (n=53) Yes: No	47 (89%): 6 (11%)
Short Form FES-I score (n=58) median (IQR) (range)	14 (11-20) (8-28)

Abbreviations: CI= Cognitive Impairment; FES-I= Short Form Falls Efficacy Scale International; IQR- Interquartile Range; SD= standard deviation.

4.2.1.2 Frequency and Description of Falls

The median number of falls in the last year was 4 (range 1-260; Interquartile range (IQR) 2-11) (Figure 4-1).

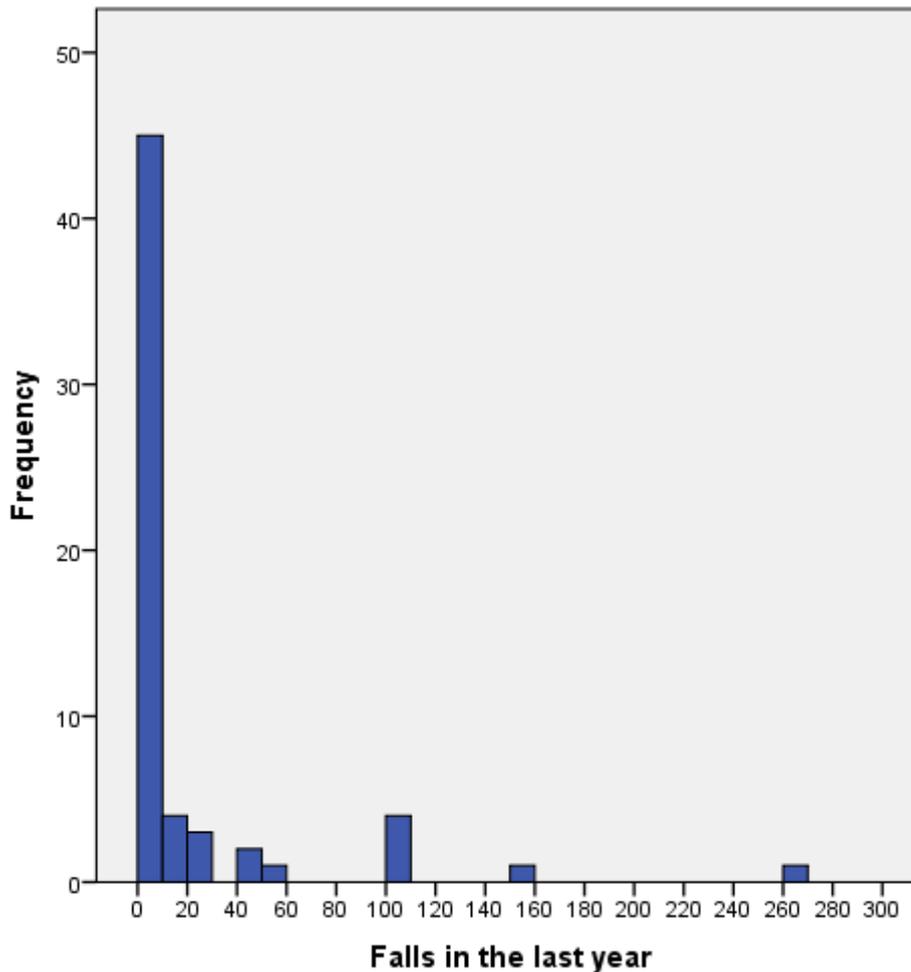


Figure 4-1: Number of Falls in the Last Year

The details of 149 falls were described by 61 participants. One fall from bed while asleep was excluded from the analysis in keeping with methods reported elsewhere (51). Content analysis of the falls described is presented below, with tabular representations of the data shown in Appendix C7.

Location

77% (n=114) of falls occurred within the home environment and 20% (n=29) occurred away from the home environment. Data was missing for 3% (n=5) of participants. Of the 114 falls occurring within the home environment, 87% (n=99) were inside the house, with the remainder being in the

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driveway or the garden. The most common locations were the lounge/ dining area, the bedroom, and the kitchen.

Of the 29 falls that occurred away from the home environment, 69% (n=20) were outside. The most common location of falling was a car park or a footpath.

Of all falls, 73% (n=108) occurred inside and 24% (n=35) outside. The location in 3% (n=5) was missing or illegible.

Before the Fall

Participants stated that they were walking at the time of 24% (n=36) of falls. Participants provided more information about 28% (n=10) of these falls; 8% (n=3) occurred when rushing, 11% (n=4) when the ground was uneven, 5% (n=2) in a small space and 3% (n=1) when changing direction. No additional information was provided about 72% (n=26) of these falls.

14% (n=21) of falls occurred when going from sitting to standing or from standing to sitting. Other common circumstances and environments included turning (11% (n=16)), climbing steps (8% (n=12)), reaching (9% (n=13)), and doorways (7% (n=11)). Other situations included playing golf, cutting grass, moving an object, gardening, cooking, washing, hanging clothes up, drawing curtains, making bed and multitasking. Three falls occurred when sitting or standing still.

42% (n=62) of falls occurred when PwP were with somebody else.

In most circumstances, participants felt able to attribute a cause for the fall (89% (n=133)). The most common cause was freezing, which was felt to be responsible for 35% (n=51) of falls. Other common causes were altered balance (16% (n=24)) and trips/ slips (15% (n=23)). Less frequent causes included overreaching, feeling dizzy, legs giving way, personal misjudgement, rushing, distraction, small spaces and dyskinesia.

After the Fall

When asked what happened after the fall, responses were often unclear. In 60% (n=68) of falls, participants required help from others. This was provided by paramedics, their spouse, friends or passers-by. Support could be for getting off the floor, or for injuries that they had sustained. 44% (n=65) of falls were associated with an injury and 22% (n=33) of falls required medical attention.

51% (n=76) of falls were felt to be preventable, 28% (n=42) were felt to be unpreventable. In 8% (n=11) the participant was unsure whether they could prevent the fall, and in 13% (n=19) the response was illegible or unclear. The most common way in which it was felt that a fall could have been prevented was through improved concentration, planning a journey and taking more

care. This was reported in 24% (n=35) of the 148 falls described. Other adaptations included not rushing 9% (n=14), alteration of defined activities such as not overstretching or avoiding small spaces 7% (n=11), adaptations to the home 5% (n=8) and equipment to aid their walking or transfers 5% (n=7). Less common alterations included changing footwear and keeping possessions nearby or asking others for help to reduce the distance that they mobilised.

Difficulty Getting Up from the Floor

70% (n=42) of PwP reported that they had previously had difficulties getting up from the floor.

44% (n=27) of PwP described situations where they had needed help from others, which was most commonly provided by their spouse/ close friend. Of the 18% (n=11) of participants that had needed physical support, in 64% (n=7) of these participants, this was provided by paramedics. Of those needing help from others, 7% (n=2) explicitly stated requiring only verbal instructions to get up, and 4% (n=1) described seeking support through pressing their pendant alarm.

7% (n=3) PwP had used nearby objects to get up after a fall.

21% (n=9) PwP described falling in an awkward position or a small space such that they were unable to get up unaided.

Situations Where PwP Feel Unsteady

82% (n=60) of participants reported that PwP could experience 'near misses'. 40% (n=23) of PwP had 'near misses' on an at least weekly basis. In 89% (n=47) of PwP there were particular situations that led them to feel unsteady.

A variety of situations were reported to cause unsteadiness; 72 responses were given by 52 participants, which lay within 24 categories. The most frequent causes of unsteadiness were turning 13% (n=9), navigating the stairs 10% (n=7), being in an 'off' state with their PD 8% (n=6), rushing 7% (n=5) and small spaces 7% (n=5). Other situations included freezing, dressing, walking backwards, standing and transferring, doorways, fatigue, multitasking, showering, a change in floor surface or colour, bending forwards, confusion, poor lighting, standing still and uneven surfaces.

4.2.1.3 Use of Information Formats

Participants were asked to rate how often they were likely to use different formats of information on a day-to-day basis through responses on a 5-point Likert scale. Data is presented in Table 4-3. Participants most frequently rated the internet as the format that they were most likely to use,

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with 59% (n=34) of participants stating that they were either 'likely' or 'very likely' to use this information format. Conversely, 36% (n=21) of participants stated that they would be either 'very unlikely' or 'unlikely' to use this information format. 52% (n=36) participants stated that they would be either 'very likely' or 'likely' to use a leaflet; 22% (n=13) stated that they would be either 'unlikely' or 'very unlikely' to use this information format.

Table 4-3: Preferences for the presentation of information in different formats

Format of Information	Likelihood of using the information format				
	Very unlikely	Unlikely	Not sure	Likely	Very likely
Internet (n=58)	n=12 (21%)	n=9 (15%)	n=3 (5%)	n=12 (21%)	n=22 (38%)
Smartphone/ tablet (n=59)	n=27 (46%)	n=5 (8%)	n=4 (7%)	n=9 (15%)	n=14(24%)
Youtube (n=58)	n=37 (64%)	n=10 (17%)	n=4 (7%)	n=5 (9%)	n=2 (3%)
DVDs (n=58)	n=31 (54%)	n= 11 (19%)	n=7 (12%)	n= 6 (10%)	n= 3 (5%)
Leaflets (n=58)	n=6 (10%)	n=7 (12%)	n=9 (15%)	n=25 (43%)	n=11 (19%)
Books (n=60)	n=10 (17%)	n= (21%)	n=7 (12%)	n=21 (35%)	n=9 (15%)

4.2.2 Semi-structured Interviews

4.2.2.1 Participant Characteristics

38 participants consisting of 20 PwP and 18 caregivers were interviewed (Table 4-4). All participants approached agreed to be interviewed. 20% of PwP interviewed (n=4) had a diagnosis of cognitive impairment/ dementia. In a further 30% of PwP interviewed (n=6), concerns were raised about their memory through self-report in questionnaire one (n=4), or through behaviours observed by the interviewer (n=2).

Table 4-4 Characteristics of People with Parkinson's and Caregivers Participating in Semi-structured Interviews

PwP ID	Caregiver ID	PwP Characteristics						Caregiver characteristics		Joint or separate interviews
		M/F	Age (Years)	Duration of PD (months)	Cognitive impairment/dementia diagnosis	FES-I	Number of falls / last year	M/F	ZBI	
P1	C1	M	78	90	No (Concerns at interview)	20	12	F	27	Joint
P3	C3	M	78	168	No (Concerns self-raised)	20	2	F	19	Joint
P5	C5	M	85	30	No (Concerns at interview)	11	2	F	19	Separate
P7	C7	M	67	96	No (Concerns self-raised)	10	3	F	29	Separate
P11	N/A Lives alone	F	73	216	No	13	12	M	N/A	N/A
P12	C12	F	57	258	No	12	4	M	20	Separate
P14	C14	M	73	140	No	20	4	F	24	Separate
P16	C16	F	73	228	Cognitive impairment	19	3	M	18	Separate
P18	C18	M	77	151	No	12	20	F	17	Joint
P20	C20	M	66	168	Dementia	25	3	F	33	Joint
P22	C22	M	75	120	No (Concerns self-raised)	9	4	F	34	Separate
P24	C24	F	65	216	No	11	4	M	12	Separate
P26	N/A Lives alone	F	70	36	No	15	4	M	N/A	N/A
P27	C27.1, C27.2	M	69	179	No (Concerns self-raised)	24	10	F, F	48	Joint
P31	C31	M	84	180	Dementia	9	100	M	29	Joint
P33	C33	M	72	61	Cognitive impairment	15	5	F	17	Joint
P37	N/A Lives alone	M	79	194	No	11	100	F	N/A	N/A
P45	C45	F	59	144	No	22	3	M	18	Separate
P80	C80	M	69	117	No	11	4	F	0	Joint
P84	C84	M	71	156	No	13	6	F	6	Separate

Abbreviations: Concerns at interview= Concerns about cognition raised during the interview by the participant; Concerns self-raised= concerns about cognition raised by the participant in the questionnaire; FES-I = short form falls efficacy scale international; ID= Participant Identification number; M/F =male/ female; ZBI= Zarit Burden Interview.

4.2.2.2 Themes Identified from Semi-Structured Interviews

Six themes were identified that provided a descriptive coherent representation of the data (Table 4-5). Data contributing to each of these themes is displayed within the coding manual (Appendix C8). There were five themes relating to the experiences of falling: “establishing reasons for falls; attributions and perceptions”, “initial responses, coping and adaptation”, “recognising and managing risks surrounding falling”, “concerns and worries about consequences” and “PwP and caregivers as case managers”. Data surrounding views of the content and format of the intervention are presented in theme six: “views on the content and format of future interventions”.

In the narrative below, each of the themes and its constituent subthemes are presented and explained along with illustrative quotations from participants. Where there were differences between PwP and caregiver views these are highlighted.

Table 4-5: Themes Identified from Semi-structured Interviews with PwP and their Caregivers

Theme	Subthemes
Theme 1 "Establishing reasons for falls; attributions and perceptions"	People are driven to try to identify reasons for falling and may encounter uncertainty Falling may be perceived as unrelenting, unpredictable and unpreventable
Theme 2 "Initial responses, coping and adaptation"	Initial reactions in response to falling Development of emotional coping strategies Acceptance and normalisation of falling over time
Theme 3 "Recognising and managing risks surrounding falling"	Adoption of problem-focused coping strategies, which are often self-taught Adaptations lead to transformation of the lives of PwP and caregivers
Theme 4 "Concerns and worries about consequences"	Despite coping strategies, significant concerns remain Impact on the relationship between the PwP and the caregiver Loss of pre-caregiver identity Support outside of the dyad is often inadequate
Theme 5 "PwP and Caregivers as case managers"	Parkinson's UK group provides little support for falling Healthcare provision is often insufficient for successful falls management Good Information isn't available or used Dyads may feel lost and not know where to look for support
Theme Six "Views on the content and format of future interventions."	Not applicable (no subthemes)

Theme 1: "Establishing Reasons for Falls; Attributions and Perceptions"**People are Driven to Try to Identify Reasons for Falling and May Encounter Uncertainty**

Following a fall, both PwP and caregivers frequently sought to identify the underlying aetiology. PwP and caregivers identified that falls occurred due to a multitude of reasons; recognised causes included freezing, altered balance, multitasking, impaired concentration, fatigue and dyskinesia. Many participants, PwP and caregivers, discussed the variability of PD symptoms, which could be related to time of day or time of medication. The heterogeneous nature of PD was reflected, with the primary reason for falling differing between participants, and many felt that their falls were multifactorial. Where PwP discussed episodes where they felt unsteady and had nearly fallen, these occurred in a similar context to occasions where a fall had occurred.

"It's the freezing before he falls." Caregiver 14

"If her tablets have worn off she's more prone to be falling." Caregiver 12

A few participants, predominantly PwP, appeared preoccupied with their PD medication. Amongst these participants, there was a sense that they perceived that further adjustment to their PD medication would improve their Parkinson's symptoms, including their falls risk.

"I just didn't think I got on with the drugs that [Parkinson's consultant] prescribed so I just went back to the previous ones... my gait actually improved."

PwP 7

A minority of PwP attributed some of their falls to be due to mis-stepping or tripping. Only one PwP felt that this was the primary cause of falling.

"They were caused by tripping more than anything". PwP 5

The majority of PwP and caregivers described environmental contributors to falling. The most commonly highlighted concerns were uneven ground and steps. Many participants highlighted that doorways and small or crowded spaces were associated with increased risk of freezing and subsequent risk of falling. Less frequent concerns included poor lighting and unfamiliar environments. Most PwP and caregivers acknowledged that it was the interaction between PD symptoms and environmental risks that led to falls. However, some PwP could perceive the environmental risk to be the key contributor.

"[People without Parkinson's] negotiate in and out of crowds easily, but [PwP] can't... [PwP] can freeze just going through a doorway." Caregiver 45

Some PwP and caregivers perceived that the PwP did not always acknowledge falls risks. These participants expressed that if the PwP had adapted their behaviour in accordance to these risks then falls could have been prevented. Often, the same participants attributing blame toward the PwP also discussed instances where falling was out of the control of the PwP, further highlighting the multifactorial nature of falling in PwP.

"His feet are too close together, if only he could get his legs apart... It's feasible. It's a bit disappointing". Caregiver 14

Both PwP and caregivers often encountered uncertainty when trying to attribute reasons for falling. Most participants appeared to be at ease with this unknown. However, amongst others this was associated with confusion and frustration.

"There are times when I find myself saying 'why?'... I always feel saddened and I feel frustrated." Caregiver 31

Falling May Be Perceived as Unpredictable and Unpreventable

Some PwP discussed the unpredictable nature of falling, which could cause frustration.

"I can't predict when it's going to happen, that's what I find very frustrating... I have a great day, I can have a bad day, and I can't see the difference between the two days."

PwP 7

Some participants, more caregivers than PwP, discussed how they perceived the risk of falling to be unrelenting and constant. This was often associated with anxiety.

"I sort of concentrate, worry about him, where he's going...what's gonna to happen. ... I get worked up." Caregiver 5

Amongst most PwP who reported 'near misses' these episodes were associated with concern, although a minority appeared dismissive.

"I do stumble a bit. But I don't really take much notice of that". PwP 7

All participants who discussed the preventable or unpreventable nature of falling felt that falls were, at least in part, inevitable. Where falling had been occurring for a long period of time, participants appeared more likely to perceive falling as unpreventable. One caregiver discussed how interventions to support PwP who fall may be more effective amongst PwP with less advanced PD.

"I don't think there is anything.... He's gonna fall, you know. So it doesn't matter what they say." Caregiver 27.1

Theme 2: "Initial Responses, Coping and Adaptation"

Initial Reactions in Response to Falling

Many PwP and some caregivers described a sense of shock when the PwP had their first fall. PwP had often received literature about falling and had observed falling in other PwP, but they felt unprepared when it happened to them. There was a sense that some PwP may not acknowledge the risks until they experienced their first fall.

"I suppose the best way of describing it, is that it was like falling off the edge of a cliff... you know realistically, that you're in for a downhill run, but you expect it to be a gentle slope". Caregiver 22

PwP frequently described frustration when they fell, with falling often leading to a decline in confidence and heightened worry. These concerns could be most apparent in the period immediately after a fall.

“For several days afterwards I was quite cautious.... Quite nervous of doing anything.”

PwP 12

Caregivers reported that they were often not with the PwP when they fell. Caregivers of a few male PwP reported that the PwP had previously concealed their falling from them, which could arise from embarrassment. This was more common when falling was new to the PwP.

“First time he fell, he didn’t call me. And I didn’t know anything about it...he was embarrassed.” Caregiver 84

Development of Emotion- focused Coping Strategies

Participants described emotion-focused coping strategies that they had developed to manage the negative impact of falling. The vast majority of PwP and their caregivers described seeking social support from within the dyad. Participants were rarely able to recall specific conversations that had taken place where they had discussed their worries or concerns. However, one female caregiver of a male PwP, spoke at length of the importance of effective communication within the dyad.

“He loses confidence.... his other means of excitement is to have sex more.... I think it's keeping an open dialogue between my husband and I...being honest and upfront about how it affects us both.” Caregiver 7

However, interaction with those outside of the dyad could be met with difficulty. One PwP described how she felt uncomfortable when her husband discussed her falling with his friends. Participants occasionally spoke of others not understanding the complexities of PD, which could be overcome through attendance at the local Parkinson’s group or carers group.

“[C24] does tell friends sometimes if there’s been a silly fall...which I find a little bit annoying cos I don’t like to feel that I am a subject of hilarity”. PwP 24

A few participants, two PwP and one caregiver described how they found it helpful to release their pent-up emotions. This could be encouraged by their spouse or by healthcare professionals (HCPs), whose advice they had sought to manage underlying negative emotional turmoil arising from PD and falling.

“Get it out instead of holding it in, the frustration and the bitterness and the anger.... we went to the psychologist” Caregiver 45.

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A minority of caregivers appeared to use humour as a coping strategy.

“He does a stumble and a wobble, like Mr Blobby I always think”. Caregiver 14

Some PwP and caregivers displayed thought distancing and distraction. This appeared to mostly be utilised by male PwP, who had often experienced significant physical consequences after a fall. These PwP spoke of the frustrating nature of falling and were likely to perceive falling, at least in part, as unpreventable. Whilst the large majority of both PwP and caregivers described concerns surrounding the progression of PD and falling, a few caregivers, male and female, preferred not to think about what the future might hold. Caregivers could feel that this would be unhelpful as they could not change the course of events.

“I don’t like to think about it. I get wrapped up in the sport on the telly or something.”

PwP 27

Most caregivers, including all of those of a PwP with cognitive impairment or dementia, discussed the importance of maintaining a sense of calm. Some caregivers described consciously trying to settle underlying frustrations after the PwP had fallen. Anxieties that the caregiver experienced in relation to why the fall had occurred, or how to get the PwP off the floor, were often alleviated through maintaining composure and thinking methodically. A few caregivers acknowledged that this was not always easy to achieve, and they could require support from others in situations where they experienced distress.

“Keep it calmer than I do! [Laughs]... Our daughter is very good, she says, “Calm down dad – you go out, I’ll deal with it” Caregiver 16

The perceived importance of keeping calm after a fall appeared to be recognised less amongst PwP than by caregivers. Caregivers frequently described how they encouraged the PwP to remain calm. A few caregivers described how this approach had previously led to greater success in aiding the PwP to get up from the floor without physical support from others.

“The times I’ve managed to [get] him up, I’ve made him comfortable on the floor to start with, just until he’s sort of got over the initial shock of falling.” Caregiver 20

One dyad discussed how the PwP had initially been apprehensive to attend psychological support sessions, and how they had become more receptive toward attendance at these sessions, and discussions about their thoughts following encouragement from their spouse.

“If I had the opportunity to go [to the psychologist] again now, I think I probably would.”

PwP 33....

“Have a look, because I think it was really good for you.” Caregiver 33

Acceptance and Normalisation of Falling Over Time

The majority of PwP and caregivers appeared to have developed a sense of acceptance of falling. This view appeared to be more established amongst participants within a dyad where the PwP had been falling for a longer period. A few participants discussed how not accepting or acknowledging that falling was likely to recur could lead to negative connotations.

“Well it’s a new life now.... I’ve got to sort of accept it really...Otherwise I’d go round the bend.... I know a lot of people who do.” PwP 45

Where the PwP had been diagnosed with PD for longer, or where falling was frequent, PwP and caregivers could normalise falling. A few caregivers normalised falling in PD through discussing how they too would have fallen in a similar circumstance.

“I tripped over that more times than he has (giggle).” Caregiver 14

Theme 3: “Recognising and Managing Risks Surrounding Falling”

Adoption of Problem-focused Coping Strategies, which are Often Self-taught

Behavioural Adaptations

PwP and caregivers often described how they had self-identified contributors to fall risk and implemented behavioural adaptations to overcome them. Nearly all PwP and many caregivers discussed the importance of taking care and being more methodical in their actions in order to reduce the risk of falling. Changes instigated by both PwP and caregivers were often specific to a defined setting or circumstance. Alterations included ensuring that the PwP did not over-reach or carry items whilst walking, and that they took care upon standing. Where the PwP had cognitive impairment or dementia, caregivers could instigate changes on behalf of the PwP.

“If he’s been lying down, I give him time to acclimatise rather than just standing him up straightaway.... And always make sure that he’s standing steadily before moving”.
Caregiver 20

Many participants, PwP and caregivers, discussed how they adapted to variability of PD symptoms. PwP often adjusted the timing and type of activity that they might undertake. When PwP self-assessed that they were at enhanced risk they took more care or used a different mobility aid. Caregivers also described how they provided more support at these times.

“To go out walking, I’d need to be at the right stage in my medicines...when they’re wearing off, I get more unsteady.” PwP 12

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Many caregivers described their key role in preventing and managing freezing episodes using strategies that were more often self-taught than acquired from HCPs. Caregivers ensured that the PwP took their PD medication on time and had learnt specific phrases to help the PwP to overcome a freezing episode. One caregiver described how they encouraged the PwP to push the trolley when in the supermarket to prevent freezing.

“You have to know how to say to him ‘stop, stand still. Think what you’re doing. Long slow stride’ (giggle). It gets him going again.” Caregiver 1

As described within theme one, PwP and caregivers often cited environmental contributors to falls. Many of these participants described practical adaptations to overcome these environmental challenges. A few participants discussed how fall risk may be greatest in environments that were new to the PwP, and how this could be reduced through enhancing familiarity.

“Everything has got to be in the same place.” Caregiver 1

PwP and caregivers discussed the importance of pre-planning journeys to reduce fall risk and to allow them to continue to partake in the activities that they enjoyed. A few participants discussed ensuring that the route had a place to rest in case the PwP became fatigued. Participants could describe taking an alternative route where the ground was more even. A few participants discussed how they planned all journeys, which including short distances such as crossing a room.

“We have to plan where there’s no stiles, where there’s a proper gravel path, like a biking track rather than just a walk through the woods.” Caregiver 33

Participants described how they took care on sloping or slippery ground, ensured that they were wearing appropriate footwear and used handrails on the stairs. Caregivers supported PwP in making these changes.

“Small number of steps in the lobby, so normally she holds the banister and I hold her under the arm, on the other side.” Caregiver 45

Both PwP and their caregivers recognised the need for wide spaces. Many participants discussed changes within their homes to increase space, such as reducing clutter and leaving doors open. These adaptations were mainly driven by caregivers.

“Make a wider space for him to walk round ...so he’s not going to bump into the furniture and stumble.” Caregiver 7

Many PwP and their caregivers, including all three married male caregivers, were keen that the PwP continued to be physically active. Caregivers often perceived that ongoing physical activity would maintain the level of mobility of the PwP at a higher level and reduce their fall risk. A few participants, the majority of whom were male caregivers, spoke of the importance of maintaining physical strength. These participants associated increased strength with reduced risk of falling, or of reduced risk of injury following a fall.

“Haven’t got the strength in my legs...so I fall.... I get plenty of exercise but my legs are as weak as hell.” PwP 37

PwP frequently spoke of trying to prevent a fall through holding onto objects nearby; two caregivers described holding onto the PwP to prevent them from falling.

“That doesn’t happen every day or every week, or every month, but it probably would do if I didn’t hold her when we were out.” Caregiver 12

The three PwP who lived on their own reported varying degrees of help from others. This was provided by supportive neighbours, a paid cleaner who also helped with household tasks and having shopping delivered to the house. However, there was a sense amongst all three of these participants that they were keen to maintain their current level of independence.

“He wrote to my GP and um in his words he said, ‘this lady continues to be fiercely independent and reluctant to have a carer’.” PwP 11

Practical Adaptations

Most caregivers and a few PwP spoke at length about the practical changes that they had instigated within their homes to manage the concerns or risk of falling. The most common adaptation described was grab rails, which had been installed in areas where the PwP had previously fallen or was perceived to be at greater risk from falling. Caregivers in particular spoke about the installation of grab rails in their homes. A few PwP explained how grab rails helped for them to feel more secure and less susceptible to fall. A few PwP discussed using the furniture to steady themselves when walking.

“Wife follows me round at times. Makes sure that I’m holding on.” PwP 5

Other adaptations to the home included toilet seat raisers, equipment to aid transfers, and changes to the bath or shower. Many participants spoke of how the adaptations that they required had evolved over time. A few participants, in particular caregivers, appeared pre-occupied with further practical changes to the house or equipment to aid transfers, but few appeared to plan ahead.

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"I can see him going tumbling outside, I'm not quite sure what we're going to do with that. I guess make it into a ramp." Caregiver 14

Where participants described practical adaptations, the majority were made following advice from HCPs such as occupational therapists. A few participants had made substantial changes to their living circumstances to reduce their risk of falling; some had moved to a new house; others had coordinated significant construction work. These sizeable changes often appeared to have been orchestrated by the caregivers themselves with little support from HCPs. Three male participants, two PwP and one caregiver, spoke at length of self-initiated adaptations, which often occurred when there had been a delay in assessment by occupational therapy, or where the advice from occupational therapy was deemed unhelpful.

"We moved in here.... cos it's a bungalow, we needed to get rid of the stairs. The next car we buy I'm gonna get one that's higher." Caregiver 24

The majority of PwP and caregivers discussed mobility aids. These allowed PwP to continue activities outside of the home, and helped them to feel safe and to maintain their independence

"I've got the mobility scooter that's changed our world... we take the scooter and go miles now." PwP 7

Many PwP described having access to multiple different mobility aids, and that the setting or intensity of the physical activity that they were to undertake would dictate which one that they would use. Some PwP discussed how rough or uneven terrain may lead them to use a different aid, and a few caregivers discussed how a wheelchair may be more suitable in a crowded environment or could provide a 'back-up' at times of reduced mobility.

"We keep a wheelchair in the car, though she hasn't used it for ages, because if she freezes with Parkinson's then we're stuck." Caregiver 16

Adaptations Lead to Transformation of the Lives of PwP and Caregivers

There was a sense that PD and falling led to a transformation in the life of PwP and their caregivers. Significant changes were described in the activities that they performed, either because of their increased risk of falling or a decline in their mobility. PwP and caregivers frequently described adapting their existing activities or switching to alternative activities to those that they felt more confident in performing.

"When I've played golf recently, I took the Golf buggy with me.... I used to play on me own, just practice, but I don't think I want to do that at the moment, because I fell over." PwP 7

However, many settings were deemed non-modifiable by both PwP and caregivers, which often resulted in the PwP avoiding them. These concerns related to uneven ground, small crowded spaces and unfamiliar environments. PwP and caregivers discussed the more sedentary lifestyle that these PwP had adopted. Many caregivers discussed how they would prefer for the PwP to avoid certain environments. A few discussed considerable anxieties associated with any physical activity of the PwP. They could go so far as asking the PwP to remain seated or to avoid going outside. One caregiver described how managing the risks associated with a lack of physical activity alongside elevation in falls risk required careful consideration.

"I am a Cathedral guide, or I was, and I can no longer do that because there's a risk of falling in the Cathedral. I'm sad not to be doing it." PwP 11

Caregivers often described the transformation of their lives arising from PD. The vast majority expressed concern of the PwP falling when they were alone in the house or when the PwP undertook outdoor activities independently. Caregivers eased these concerns through reducing the duration and frequency of these occasions and providing clear instructions as to what the PwP was allowed to do. Two younger male caregivers had altered their work commitments. Other strategies included the use of pendant alarms, timing outings to times when the PwP was asleep, and seeking support external to the dyad from either family members or social services.

"I go out running earlyish [PwP 12's] just getting out of bed and so it hasn't affected her too much." Caregiver 12

Many caregivers and PwP liked for the caregiver to be within a short distance should difficulties arise. A few caregivers described watching the PwP's every move, which could lead to frustration in the PwP themselves.

*"I have to tell him every step that he takes, [I'm] behind him, when he's walking."
Caregiver 1*

Conversely, a minority of caregivers, including all male caregivers, discussed the importance of the PwP undertaking activities away from the home and on their own. These caregivers felt this would maintain the independence and confidence of the PwP.

*"She ...has just has a little look round the shops. And I encourage her to do that ... if she doesn't do it on her own then she will lose all confidence.... it's good for her."
Caregiver 24*

A few caregivers discussed how they had adjusted their social activities to spend more time with the PwP. Some had adapted current hobbies and others switched to new activities that they were

both able to partake in. New hobbies included ballroom dancing, swimming and attending the day centre. These changes could be welcomed by one member of the dyad more than the other.

“I can spend more time with [P12] and we can do things. For instance, on Friday we go ballroom dancing in the afternoon.” Caregiver 12

Theme 4 “Concerns and Worries about Consequences”

Despite Coping Strategies, Significant Concerns Remain

Despite the emotion and problem-focused coping strategies described within themes two and three, all participants expressed ongoing concerns.

Most participants, including all PwP with high FES-I scores, and some caregivers, discussed concerns of falls-associated injuries. These concerns were not exclusive to those where the dyad discussed previous injuries that the PwP had sustained following a fall. Falls leading to injury appeared to be recalled more freely. Amongst some participants, there was a perception that falls were of varying severity, which was determined by whether an injury had, or was likely, to occur.

“I don’t really worry about falling in the garden, because it’s soft, you don’t hurt yourself when you fall over.” PwP 18

Many PwP discussed concerns regarding inability to get up from the floor, which could arise from previous experience. Concerns did not appear related to fear of falling as measured by the FES-I. Many PwP had previously required physical support or verbal guidance from others to get up, which was most commonly provided by caregivers. Where a caregiver was not present, support could be provided from friends or passers-by.

“If I have a bad fall, I have to call someone on the phone. (Laughs) “Come and pick me up”. PwP 37

Exclusively female caregivers voiced concerns that they would not be able to help the PwP physically off the floor should verbal prompting be insufficient. Many of these caregivers appeared uncertain as to what they could or should do if this situation were to arise. One female caregiver acknowledged that the physical support that she currently provided put herself at risk.

*“I’m also aware that it did put myself at more risk. And obviously if I was injured, I wouldn’t be of so much use.... I’m aware of the risks but I can’t make go away.”
Caregiver 20*

No male caregivers who discussed providing support to the PwP after a fall voiced concerns relating to their personal physical ability. However, a few were concerned that they could injure themselves, and a few were concerned for others who might be less physically able than themselves.

“Fortunately, I’m reasonably fit and strong, but there might be people of older years ...they might struggle to get them up off the ground by themselves.” Caregiver 12

Arising from this dependence on the support of the caregiver, many PwP expressed anxiety of being alone in the house. Some PwP drew from previous experiences where they had struggled alone.

“When I’m on the floor, I tend to panic. And especially if I’m in the house alone I think how long am I going to be here for?” PwP 3

Whilst a few caregivers acknowledged that they could not be with the PwP all of the time, this was often met with ongoing concern. Caregivers, where able to leave the PwP alone, could raise concern about the possible isolation of the PwP. This could also arise after moving to a house that the dyad felt was better equipped for the PwP but was in a new geographical area with a resultant loss of their social network.

“We moved over here They’re very insular around here”. Caregiver 33

Although the majority of both PwP and caregivers spoke positively about the physical changes instigated within their home, a few encountered difficulties. One caregiver discussed how it could be difficult to accept medical equipment within the home, another caregiver was concerned that a ramp outside their home would display vulnerability and attract crime. One PwP discussed how she resented adapting their home to plan for a possible decline in mobility.

*“If, heavens above, I have to go into a wheelchair or something like that the things are already in place which I resent slightly but I realise that you know it has to be done.”
PwP 24*

Many PwP raised difficulties with the use of mobility aids; in some circumstances they were deemed to increase the risk of falling. The most frequently reported problem was the continued forward movement of wheeled walking aid when a PwP experienced a freezing episode. Other difficulties included their perceived instability and problems in mounting a step.

“I had fallen on my knees, normally when pushing my rollator when it gets too far ahead of me and I can’t get it back.” PwP 1

Chapter Four: Needs and Preferences of PwP and Caregivers

A minority of participants expressed concerns that related to how the PwP would be viewed by others when using a walking aid. Some younger PwP and caregivers perceived that mobility aids were for older people, or for those with greater disabilities. This led to some PwP to avoid using a mobility aid. However, one dyad and one PwP were positive about the increased attention arising from use of a mobility aid.

“When they take me out, they walk with me and I hold their arm. So it’s not so obvious that I’m with a stick. Vanity really.” PwP 24

“When you have a stick, people give way.” PwP 26

A few caregivers voiced concerns that the use of a mobility aid or a wheelchair might lead to a decline in the independence of their spouse.

“We don’t want her to use a wheelchair... I think if you start doing that it becomes the norm, and suddenly you know she’ll lose muscles in her legs.” Caregiver 12

Impact on the Relationship Between the PwP and the Caregiver

Both PwP and their caregivers voiced frustration over their inability to prevent falling, and the impact that falling had had on their lives. The relationship within the dyad had often changed and some described friction.

“Virtually hardly ever had any cross words before Parkinson’s came along... And now it’s like sharing your life with a third person”. Caregiver 45

Caregivers occasionally appeared frustrated that the PwP called upon their support when they felt that the PwP would be able to perform an activity themselves.

“When she first had Parkinson’s, she sort of went into her shell a little bit I sometimes think [P16] leaves it to other people to do things for her...that makes me frustrated

“Caregiver 16

Many caregivers, all of whom had high caregiver burden and were from a dyad where the PwP had cognitive impairment/ dementia, voiced frustration when the PwP did not follow their advice or that of HCPs. This could relate to situations where the PwP performed an activity alone when they had been advised to ask for help.

“We went to the physiotherapist.... she just knew everything; it was just quite refreshing.... he’s not really taken that on board and kept it which is a great pity.”

Caregiver 14

Two caregivers, both of whom were from a dyad where the PwP had dementia, described how, over time, they had become more understanding of the difficulties that the PwP experienced.

"I try to consciously mentally step back and remember that [P31] has problems...I've learnt a high degree of patience." Caregiver 31

Caregivers often described how their share of responsibilities within the home and the personal care that they provided to PwP had increased. These findings were not exclusive to caregivers with high caregiver burden as measured by the ZBI. Re-allocation of chores could be met with discomfort in PwP; they could feel that they were still able to perform an activity, or that the caregiver was not performing it to the required standard.

"I enjoyed gardening very much indeed...I send [Caregiver 31]." PwP 31. "He's very good at um watching, and I can feel him thinking 'that's not the way to do it'." Caregiver 31

Loss of Pre-caregiver Identity

Amongst most caregivers, including all of those of a PwP with cognitive impairment/ dementia, there was a sense that they were defined by their caregiving role. These caregivers often appeared to display significant distress when discussing their role. In the majority of caregivers of PwP with cognitive impairment/ dementia, carer-associated stress did not appear to be exclusively related to falling.

"I don't feel that I'm in control of my time. It's like almost having a permanent, a full-time job." Caregiver 45

Many caregivers spoke at length of changes that they implemented to try to maintain their own social activities and relationships outside of the dyad. Amongst some caregivers there was a sense that they were trying to self-preserve their own identity.

"You've got to look after yourself, nobody else will". Caregiver 14

A few caregivers described how they maintained social interaction outside of the dyad and its perceived importance. One female caregiver discussed how her daughter had supported her through sourcing an activity away from the home environment that she enjoyed.

"I like company ... I've been stuck in... [My daughter] said 'I'm gonna come and pick you up and [take you] to the tea party'...I've been going ever since. It gets me out." Caregiver

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Chapter Four: Needs and Preferences of PwP and Caregivers

Some caregivers discussed how the PwP did not always acknowledge the changes that Parkinson's had had on the caregivers' life, which could cause frustration. A few described the transition from close friend/ spouse to 'caregiver', which could be met with unease.

"I am getting used to it. I don't like the role of, I don't like being a carer; I like to think of myself as the husband." Caregiver 45

One caregiver, who described the considerable support that she provided, went so far as to say that her inability to prevent falling led her to feel inadequate.

"Inadequate sometimes. Um tired because [the falling] is, it's just constant."
Caregiver 20

Support Outside of the Dyad is Often Inadequate

Friends, family and neighbours also provided support for PwP. This could be pre-organised to support the PwP in their day to day activities or to allow the caregiver to have time outside of the 'carer' setting, or 'ad hoc' at times of difficulty. Neighbours provided support through helping with shopping, putting the dustbin out and helping the PwP off the floor. Children provided support for their parent caregiver through the provision of care and encouraged caregivers to raise difficulties with HCPs.

"I'm only going away Monday...getting his shoes on is a problem.... our daughter lives nearby, so she'll come and help him". Caregiver 14

Where caregivers described support that was available to them, there appeared to be a consensus that they remained the primary caregiver. A few PwP and caregivers discussed difficulties when support was provided external to the dyad, which could be associated with the reduced knowledge of PD amongst others. Two PwP discussed how friends had attempted to pull them along. One PwP discussed her dislike of her friend's over-protective nature.

"Her perception of me as having Parkinson's, it was a case of she wanted to hold me, she wanted to mother me, smother me." PwP 24

A few caregivers with high caregiver burden discussed how paid support through social services allowed for them to have time to themselves. However, paid help was not always able to meet the individual requirements of the dyad.

"We phoned one of Care Agencies ...he said 'well actually what I really want is someone to help me up and down the stairs' ... 'ah! For health and safety reasons we don't send anyone to do that'." Caregiver 22

Theme 5: PwP and Caregivers as Case Managers

Parkinson's UK Provides Little Support for Falling

The majority of participants, more caregivers than PwP, described positive experiences from their attendance at Parkinson's UK support groups. Caregivers and PwP found it useful to speak with others who were in a similar situation to themselves. One participant discussed how the heterogeneous nature of PD meant that the advice provided from other dyads could be superior to that from HCPs.

"Parkinson's group, they're not professionals; we usually try and learn from each other. ...It's a very awkward for the consultants to give 100% advice on what you can do, because everybody's so different." Caregiver 16

Most participants were unsure of whether falling was a topic that had been discussed within the meetings. Amongst those who felt that falling had been discussed, very few were able to recall conversations or suggestions from their peers that they had found useful. One caregiver felt that given the progression of PD in her husband, it was them who provided advice to others.

"I think just ad hoc conversations with people at the support group meeting." PwP 7

"[PwP 27's] one of the worst ones there so a lot of them have just started falling whereas [PwP 27's] been doing it for a long time so we can probably tell them (giggle)." Caregiver 27.1

A few participants discussed the beneficial services that the support groups were able to offer, which included physiotherapy, organised talks about falling, meditation classes, and access to becoming a potential participant in a research trial.

"[The physiotherapist] comes to the Winchester Group if, if anybody needs a physio." PwP 11

Three participants, two PwP and one caregiver, spoke about the Parkinson's UK monthly magazine, but could not recall any falls specific details. One caregiver discussed how her husband felt positive when hearing about the experiences of other PwP, and the sense of rapport he felt on reading this.

"There was the guy who wrote The Vicar of Dibley... And because of his sense of humour, it was very very funny, because he found the funny side of it". Caregiver 3

Healthcare Provision is often Insufficient for Successful Falls Management

The vast majority of participants reported that they had informed HCPs that they had fallen and discussed the roles that HCPs played in the management of falling. Two caregivers, both of a PwP with dementia and with high caregiver burden, listed a considerable number of HCPs that they had informed. Where participants stated that they had not informed either their doctor or PDNS, some felt that falls were unpreventable and that there was nothing that HCPs could do.

"I don't think there's much point in telling [my consultant]. "Oh, I fell down yesterday". If I have to call an ambulance or a doctor. Ok, then I'll tell them. I just cope with it." PwP 16

When asked what role a specialist doctor might play in the management of falling, the majority were either unsure or felt that the primary role of specialist doctors and PDNS was medication management.

"Find a cure (giggle) ...I don't know how a doctor would [help]... I don't know because they're not there are, they." Caregiver 24

A few PwP and caregivers discussed that these professionals might be able to provide some verbal advice. However, one PwP recognised that they might not always put this advice into practice and one caregiver felt that the advice provided did not build upon their existing knowledge.

*"We had [PDNS] out once, didn't we? Just to talk about medication, falling and so on." Caregiver 31 [**"Any advice about falling you found useful?" Interviewer**] You want a frank answer, not really. Nothing we didn't already know." Caregiver 31*

One PwP felt that the PDNS role was primarily one of moral support.

"General reassurance that somebody's taking an interest in you but very non-specific.... that you're supported, people haven't written you off." PwP 22

A few participants, PwP and caregivers, discussed how specialist doctors and PDNS also had a role in signposting them to other services. The service most frequently mentioned was physiotherapy, and some participants discussed occupational therapy. One caregiver spoke positively of how their PDNS had referred them to a psychologist.

"I was heading for a bit of a nervous breakdown, and through the Parkinson's nurse, we both went and saw a psychologist.... Which was very helpful." Caregiver 45

One caregiver perceived that the PDNS' ability to visit and assess the home environment, and their reduced time constraints, led to them playing a greater role in falls management than a specialist doctor.

“A Parkinson’s Nurse would be able to help you more than maybe the doctor... the Parkinson’s Nurse has the ability to come into your home and see the situation. A doctor has 10 minutes.” Caregiver 3

Caregivers and PwP were often more positive about the role of physiotherapist in the management of falls than they were of specialist doctors and PDNS. Many discussed how physiotherapy classes had taught the PwP how to get up from the floor, strategies to overcome freezing and how to rise from a chair. One caregiver felt that all PwP should receive regular physiotherapy.

“We’ve been going to exercises cos they teach you to get up...they definitely help.” Caregiver 1

However, difficulties could be encountered with implementing physiotherapy strategies where the PwP had cognitive impairment/ dementia. One caregiver discussed how physiotherapy exercises could be adapted for her husband with dementia.

“It’s actually very difficult now to encourage [my husband] to do proper exercises he enjoys things like throwing and catching a ball which is great because he’s getting some core strength.” Caregiver 20

PwP and caregivers were positive about Tai Chi and Dance for Parkinson’s, however no participants elaborated as to how this had affected falls risk or falls management. Participants were also positive about their experience with occupational therapy, and the beneficial support that they had received in making changes to their home environment.

“Occupational Therapist is very helpful in that they’ve arranged to have rails put in and came to give advice when we had the extension built.” Caregiver 20

Some participants, both caregivers and PwP, voiced frustrations with their healthcare. This did not appear to be related to caregiver burden, fear of falling or the presence of cognitive impairment/ dementia. The most common complaint was that healthcare lacked a ‘joined up’ approach, and that communication between HCPs needed to be improved.

“The organisation is chaotic as far as I can see, actually trying to get information, or be told what might happen next ...nothing seems to be joined up, nobody seems to know what anybody else is doing.” Caregiver 22

A few participants voiced concerns surrounding the involvement of their GP with their Parkinson’s, which could relate to their perceived inexperience of PD.

“You had gone to the GP I would feel really nervous about him doing anything to do with his Parkinson’s.” Caregiver 80

Participants also discussed frustrations relating to the short duration of HCPs appointments, and the referral process between different HCPs and social services. Participants could be frustrated at the lack or delay of referral to other HCPs. Three dyads voiced their frustration surrounding the availability of therapy on the NHS.

“We have requested the occupational therapist to come and talk to us.... we’re waiting, we’re on the list and waiting, we’ve been referred, twice, but...” Caregiver 18

In response to a delay in physiotherapy assessment, three dyads had sought support for the PwP privately with positive response. In response to a delay in occupational therapy assessment, participants had often self-initiated changes as described within theme three. Amongst a few female caregivers, with high levels of caregiver burden, calling for support from paramedics appeared to be very much the last resort. A few caregivers appeared to try to manage in situations where external support might have been of benefit, which had raised concern in family members. Barriers included concerns about a call leading to a hospital admission and that it was not in the paramedics remit to help people up from the floor, thereby wasting paramedic’s time.

“I know that [the paramedics] have got other you know, lifesaving things to do... just making [Dad (PwP 27)] realise that just because someone comes out here to help him it isn’t going to mean he has to go to hospital.” Caregiver 27.2

Good Information is Not Available or Used

Only four participants, three caregivers and one PwP, described having read the Parkinson’s UK leaflet on falls without prompting from the interviewer. When prompted, the majority of participants were able to recall that there was a leaflet, but none were able to recall its contents or to describe whether they had found it useful. Where the leaflet had been read, some stated that this had been at a time that they felt it was not relevant to them, and one caregiver viewed that the material was for PwP only.

“They do have things on falls and things... I’ve not particularly, necessarily read them... I’ve more or less thought that they’re for people with, they’re for people with the condition.” Caregiver 45

Amongst some participants, both PwP and caregivers, there was a sense that they ‘collected’ information about Parkinson’s, which might be filed away. Nearly half of these participants were not aware of the Parkinson’s UK leaflet on falling. Two participants described difficulties engaging and absorbing information.

"I will look at [the information] because I'm conscientious, but not everybody is... and there's only so much you can take in really." PwP 26

A few PwP and caregivers felt that they had not received any verbal or written information about falls from HCPs. Most of these participants displayed ambivalence, feeling there was nothing that HCPs could offer, but one voiced frustration.

"So, we seem to be managing it ourselves...the powers that be don't seem to think it's necessarily bad enough to be sent to a Falls Clinic." Caregiver 33

Dyads may Feel Lost and Not Know Where to Look for Support

Most PwP and caregivers felt that additional information and resources might lead to improvement in their management of falling. Nearly all these participants were unable to identify what this support might be. Only one participant discussed how there was nothing more for her to learn.

"Until you know what the information is you don't know whether you need it...you can always pick up new information". Caregiver 31

Most participants reported that they had not self-sought information about falling. One participant, a retired HCP, had researched PD, whereas others were less inclined. Two participants, one PwP and one caregiver, elaborated that further information could lead to heightened worry or anxiety.

"I don't go to the [Parkinson's UK] website...I don't want to know. I suppose you could say I'm burying my head in the sand, um like an ostrich I suppose". Caregiver 31

The majority of PwP appeared to be very dependent upon their caregiver as a source of practical support and advice. PwP and caregivers frequently presented as a team. They reflected after a fall had occurred and both parties instigated changes to manage ongoing risk. Some PwP and caregivers discussed how they had only discussed their falls-related worries with their spouse. Some dyads appeared 'lost' and were unsure of where they might seek support. A few caregivers, with both high and low levels of caregiver burden, spoke at length about their concerns, with a sense that they soldiered on relentlessly.

"Going through the fall and actually saying, you know, well 'what do we think caused this one?' 'Okay, what could we do differently?'" Caregiver 7

"I just have to pull myself together and manage.... I think it's our generation and we just, you've just got to get on with it." Caregiver 84

Theme Six “Views on the Content and Format of Future Interventions”

When asked for their views about what information the proposed intervention should contain, participants gave a wide variety of responses. The most requested content was information about how to get the PwP off the floor, which was reported by three caregivers, one of which cited a lack of previous support.

“I don’t think she’s taught him how to get up off the floor...that might be a good, sort of description somehow to help yourself get up.” Caregiver 3

Other suggestions included general information about falling and Parkinson’s, alongside information about how to manage episodes of freezing. A few caregivers and PwP, all within a dyad of a PwP cognitive impairment/ dementia, discussed how the heterogeneous nature of PD led to differing information requirements for PwP and caregivers.

“Everybody with Parkinson’s is different. There’s isn’t such a thing as a textbook case of Parkinson’s.... what works for one person won’t necessarily work for another.” Caregiver 20

Both PwP and their caregivers commonly felt that information should be presented simply and without over-embellishment. Some highlighted that if too much information was provided this could lead to reduced engagement.

“Short and sweet. Short sentences, not too much overload, I think.” PwP 7

Four participants discussed that producing an intervention that was short may be difficult due to the heterogeneous nature of PD. These participants felt that through signposting users to other resources it would allow for the content of the intervention to be reduced. Two participants, one PwP and one caregiver, suggested an index to allow users to read the parts of the intervention that were relevant to them.

“An overview on paper and then directing people to specific pages on the internet...either the individual or the Carer to find in more detail...trying to put everything into a paper document would be impractical.” Caregiver 31

Some PwP and caregivers discussed the language that they felt should be used within the intervention. Participants raised that the intervention should avoid the use of medical jargon, whilst acknowledging that many PwP and their caregivers are often very knowledgeable about PD. A few raised that the intervention should have a positive tone, and two participants, one caregiver and one PwP, discussed how humour could increase engagement.

"I always thought humour and positivity are the two things that makes something interesting." PwP 84

When participants were asked about how they would like information presented to them, the vast majority, both PwP and caregivers, reported a preference for a paper-based intervention, and discussed how this would be the most accessible medium to them.

"Something that's easily accessible.... probably just a leaflet." PwP 12

Some participants, both PwP and caregivers, discussed how they did not have access to a computer. A few believed computers and the internet were not utilised amongst older individuals. Three caregivers of PwP with cognitive impairment/ dementia reported that although they used a computer, the PwP did not. Where participants did have access to a computer, they could feel that they lacked computer literacy. One caregiver discussed that a computer-based intervention might alienate some individuals.

"I think people have to be careful not to push the internet side of things at the risk of alienating some part of the population that's still clearly very very anti." Caregiver 20

Four participants, two caregivers and two PwP, described a preference for a computer-based intervention. However, when probed on how they would like for this to be delivered, they all described a non-interactive downloadable format that could be printed and then read. One of these participants felt that printing the information off would allow for it to be used in unplanned circumstances.

"If it was more of an emergency you're not going to say 'just wait there I'm just going to go and switch my computer on'.... Whereas if you've maybe got something in hard copy you might be able to quickly grab it ..." Caregiver 27.2

One caregiver, who had previously held the role of 'librarian' within a Parkinson's UK support group, highlighted that one difficulty they had experienced with written information was keeping up to date

"That's one reason the library failed, because things were being printed so sort of slowly and ... and things were changing so quickly". Caregiver 16

Participants who suggested the size of a paper-based intervention unanimously felt that it should be an A5 booklet, which would make it easier to hold and store. A few participants discussed that they felt that it would be important for the intervention to be in colour to enhance engagement of users. Amongst many participants there was a sense that a user's first impressions of an intervention would affect how likely they would be to use it.

“You need the print spread out on the page with perhaps coloured headings ...if you open a booklet up, and its dense black print all over you tend to switch off.” PwP 22

Many PwP and caregivers placed importance on the inclusion of pictures and diagrams within the intervention, and perceived that this would make it more interesting. Two caregivers discussed how pictures could enhance the concentration of PwP with dementia. One of these caregivers discussed how their husband with dementia had found pictures within a previous falls booklet useful.

“As time’s gone on actually being able to process what he’s read has got harder and harder. Whereas something visual, is much easier”. Caregiver 20

Some participants, both PwP and caregivers, discussed how the intervention should contain text of a reasonable size to make it easier to read. One dyad discussed how the PwP co-existing eye problems made small print difficult to read.

“He has some trouble reading leaflets. He’s under the hospital”. Caregiver 1

4.3 Discussion

4.3.1 Overview of This Study

This mixed-methods study, which explored the experience of falling amongst PwP and their caregivers, took an inclusive approach to participant recruitment. Many previous studies exploring the experiences of PwP have excluded those with cognitive impairment (15–21). Few studies have previously considered the experiences of PwP and caregivers as interacting entities (17,19,53). The inclusion of caregivers facilitated the inclusion of PwP with dementia, who would have otherwise been unable to take part. Conducting dyadic interviews stimulated participants’ thoughts; concepts were discussed that might not have been remembered, and the sharing and contrasting of ideas enhanced the depth of the data (180). Six of the eight PwP interviewed with a caregiver had either a diagnosis of cognitive impairment/ dementia or raised concerns about their cognition through response to the questionnaire or during the interview. During interview, with the assistance of prompts, most of these PwP were able to provide the researcher with information about their personal experiences of falling, and rarely appeared overshadowed by the opinions of their caregiver.

4.3.2 Perceptions of Falling in PwP and their Caregivers

Through questionnaires and interviews, PwP and caregivers highlighted awareness of the multitude of reasons for unsteadiness and falling in PD, as has been reported previously (26). In keeping with previous findings, falls most commonly occurred inside the home environment (51). A few participants were pre-occupied with their medication and falling could have adverse effects on impulse control symptoms, highlighting that falling interacts with other symptoms that PwP experience. The majority of PwP and caregivers identified environmental contributions to falling, which were felt to be largely non-modifiable. When designing an intervention to help PwP who fall, it is important that the heterogeneity of falling in PD is considered so that the intervention is relevant to all PwP.

Some PwP and Caregivers attributed blame toward the PwP as a cause of falling, which has been reported previously (189). A meta-ethnography reported that older people without Parkinson's disease may attribute falls due to personal error to maintain their identity as a non-faller (27). Through non-acknowledgement this could place PwP at heightened risk of further falls due to non-adaptation of behaviour, or not informing HCPs of their falls history.

PwP and caregivers often tried to attribute a reason for the fall. This search for understanding of symptoms has previously been reported by caregivers of PwP (190). In this earlier study caregivers often self-sought information prior to discussion with HCPs (190). When participants encountered uncertainty as to the reason for a fall, or spoke of its unpredictable nature, this could lead to frustration. Perceived uncertainty amongst caregivers and PwP has previously been shown to lead to increased caregiver distress (191). In this study, differences were found in the amount of information that caregivers wanted in relation to the progression of PD, which is in line with what has been published previously (43). Managing the uncertainty that PwP and their caregivers experience in combination with their individualised information requirements requires a holistic approach.

Amongst dyads where the PwP had been diagnosed for a longer period, PwP and caregivers could perceive falling as unpreventable. These participants were often accepting of falling, with normalisation occurring over time. Acceptance has been found to be a more prevalent coping strategy amongst attendees of Parkinson's UK support groups, which could explain the prevalence of this finding in this study (15).

Concerns of falling, as measured by the short form FES-I, were similar to those reported in previous studies of older adults, with and without cognitive impairment, who did not have PD (175,176). However, participants in these earlier studies fell 0-1 times in the last year, which is

considerably less frequent than those within this study. Whilst the short form FES-I scale has been validated in PwP, comparisons of scores between adults with and without PD have not been made (34). It could be suggested that the apparent comparative non-elevation of FES-I scores despite increased fall frequency could arise from the acceptance of falling that was displayed by many PwP and caregivers in this study.

PwP and their caregivers discussed considerable negative emotional connotations of falling. Falling was often associated with a decline in confidence and mobility. Whilst this has been reported previously, participants within this study described how these concerns were often greatest within the immediate period following a fall (24,26,31,42).

4.3.3 Coping Strategies Adopted by PwP and their Caregivers

In response to a stressor, an individual may develop emotion or problem-focused coping strategies (192). Emotion-focused strategies regulate how an individual feels about a situation. They can be either behavioural, e.g. alcohol, drugs, social support, or cognitive e.g. denial, avoidance or redefining of symptoms (192). Problem-focused strategies aim to expand the resources that an individual has to manage or to change the situation (192). The 'matching hypothesis' suggests which strategy an individual is likely to adopt (193). It proposes that an individual is more likely to use emotion-focused strategies where a stressor is deemed non-modifiable, and an individual is more likely to use problem-focused strategies where a stressor is deemed modifiable (193). Participants in this study described a range of emotion and problem-focused coping strategies that they had adopted. Previous studies have linked the adoption of emotion-focused strategies to depressive mood in PwP, and perceived distress in both PwP and caregivers (189,191).

Participants in this study highlighted the difficulties in interacting with those who were less informed about PD. Lack of understanding of PD has previously been highlighted as a barrier to physical activity in PwP (194). Participants in this study described how they overcame this difficulty through attendance at Parkinson's UK or carers support groups. Support groups in general commonly provide 'information', 'love' and 'status'; 'love' defines warmth and comfort from peers, 'status' describes the elevation in esteem following the provision of information that others find helpful (195). Many participants described positive experiences from the Parkinson's UK support group, which were most often related to social support, or 'love', and not information provision. This is in line with findings from previous studies of attendees experiences of Parkinson's support groups (15,196).

Only a few participants reported utilising thought distancing and distraction as a coping strategy. This could be explained by the recruitment strategy utilised within this study. A study by Charlton et al reported that distraction was more common amongst those who do not attend Parkinson's UK support groups (15). Studies of the effect of PwP adopting thought distancing and distraction have reported conflicting results. Whilst Hobson et al found that avoidance strategies in PwP were associated with improved HR-QOL in PwP, others have reported that distancing strategies are associated with reduced emotional well-being, social functioning and QOL (16,18,197). Most caregivers highlighted the importance of maintaining a sense of calm, which they could try to invoke amongst PwP. Relaxation amongst caregivers of PwP has been linked to reduced caregiver stress (196).

Problem-focused coping strategies were utilised by both PwP and their caregivers and were often self-taught. Whilst the role of caregivers and close friends as a facilitators for ambulation in PwP has been reported previously, this study highlighted their central role in supporting the PwP to manage their day-to-day activities, particularly where the PwP has cognitive impairment (194). A few participants in this study described occasions where they had adjusted their activities to incorporate more time together. Joint spousal recreational activity has previously been linked with a reduction in avoidance coping strategies and depressive mood in PwP (189).

Participants discussed the importance of planning activity in line with medication timings and physical ability, as has been reported previously (21). A few caregivers discussed the importance of the PwP maintaining physically active. These caregivers felt that a decline in activity could either increase the PwP risk of falls or reduce their independence. Conversely a few caregivers, and in particular those of a PwP with cognitive impairment/ dementia, were keen that the PwP avoided all activity to manage caregiver concerns of falls. However, as a decline in physical activity can lead to increased fear of falling, increased falls, and reduced mobility this strategy could be counter-intuitive (24,31,198).

The adaptability of PwP was highlighted through adjustment of their social activities to those which they felt more confident, and their flexibility in choosing a mobility aid to suit a defined circumstance. However, where risk factors were considered non-modifiable, such as crowded environments, PwP often avoided these as has been reported previously (20,194).

Many PwP and caregivers described the practical changes that they had instigated within their homes, which is in line with the previous literature (42,53). This study highlighted how these adaptations were able to reduce the concerns of falling in both PwP and their caregivers. A previous study found that home adaptations may alleviate caregiver stress through reducing the caregiver's workload (53). In this study, caregivers could appear pre-occupied with adjustments

to the house, which could be considerable in size and were often self-instigated. Whilst maintaining a problem-focused approach may lead to improved sense of control, reduced mental stress and improved health outcomes, undertaking changes alone without the support of HCPs could result in either ineffective or inappropriate results (192).

Highlighting the progressive nature of PD, home adaptations often changed over time, but few caregivers appeared to plan ahead. A previous study by McLaughlin et al found that caregivers may struggle to initiate discussions about advancing PD. This could suggest that caregivers were aware that adaptations would be likely to change, but felt uncomfortable planning ahead or discussing these with HCPs (199).

Despite the considerable emotion and problem-focused coping strategies adopted by PwP and caregivers, numerous concerns remained. Amongst many PwP and caregivers there was a sense that they were defined by falling. Falling often led to considerable transformation of the lives of both PwP and their caregivers. PwP and caregivers experienced a marked detrimental effect on many instrumental activities of daily living, which often lead to a loss of independence and social isolation. A few PwP were reluctant to use a walking aid for fear of how they were perceived by others. PwP could view walking aids for people who were older or who had greater disabilities than themselves. In older people without PD, falling has been identified as a threat to independence; people may not accept falling risk for fear of a new identity where they are labelled as 'old' and 'infirm' (27).

4.3.4 Negative Impact on Caregivers

In this study, most caregivers had scores on the ZBI of 17 and above, indicative of high caregiver burden (171). In a previous study where caregiver burden was also assessed through the ZBI, most caregivers of PwP had scores indicative of low caregiver burden (179). In this earlier study, 33% of PwP had cognitive impairment (vs 21% in this study), but falls prevalence was unknown (179). Falling has previously been reported to negatively impact caregiver burden (52). Findings from this study may suggest that falling has a greater influence on caregiver burden than cognitive impairment.

The key role of caregivers in helping PwP after a fall was highlighted through questionnaire and interview responses. Support was provided through verbal instructions or physical assistance. Some female caregivers spoke of the physical risk to themselves in helping the PwP up, but were often reluctant to ask for external support, as has been reported previously (42,199). This study identified that caregivers could deem that post-falls support did not lie within the remit of the paramedic service.

There were several occasions where caregivers recalled occasions where a neighbour or a close friend had supported the PwP. Whilst the support of other family members as a facilitator to the maintenance of physical activity in PwP has been reported previously, this study identified that these individuals often played a supporting role with the caregiver remaining central to the management of PD and falls (53). Whilst the benefits of paid support were highlighted, it was not always able to meet the needs of the caregiver, leaving them no option but to struggle on regardless. This general lack of support was highlighted in the 2015 audit by Parkinson's UK, where only 21% of caregivers reported having received support from HCPs related to their caregiver role (200).

Caregivers appeared to feel defined by their caregiving role. A previous study reported that caregivers felt that it was their duty to care for their spouse (199). In this study, whilst caregivers provided considerable support for the PwP, they could encourage the PwP to be independent to reduce their caregiver load. The relationship between PwP and their caregiver had often changed. Caregivers discussed difficulties arising from a decline in social interaction outside of the dyad, and in the transition from 'spouse' to 'caregiver'. Friction could arise within the relationship, which could be exacerbated by the PwP not understanding how PD had affected the caregiver. These findings contrast those of a previous study, where the majority of dyads described how the changes that had taken place within their relationship had led them to feel closer (17). In this earlier study, falls status of PwP was not reported, the participants were younger and had a shorter duration of PD compared to those in this study. This could suggest that characteristics of PwP and their PD symptoms may impact how relationship changes are perceived by caregivers.

4.3.5 The Pitfalls of Current Healthcare Provision

PwP and caregivers often presented a 'team front' and provided many examples of where they had attempted to self-manage falling with little input from HCPs. This strategy was often adopted in response to a delay in HCP assessment, or where HCPs had made adjustments that were deemed inadequate. There was often a sense that PwP and caregivers felt lost within the healthcare system, and unsure of the information they needed or where to seek support. PwP and their caregivers have previously reported benefit from signposting to appropriate health and social care services, and support in communicating with HCPs (119–121).

The vast majority of participants reported that they had discussed falling with HCPs, which contrasts with what has been reported previously (28,200). The recruitment methods utilised within this study may have resulted in a group of participants who had greater concerns about

falling or were more proactive. Most participants were uncertain as to how HCPs could help with falls, and felt HCPs role was medicines management or finding a cure for PD. Where participants had not informed HCPs of falling, they could perceive falling as unpreventable, or be unaware of the support that HCPs could provide. Through altering this perception and educating PwP and their caregivers of HCPs roles this may improve patient- professional communication.

Participants voiced many frustrations with current healthcare provision. Some felt that communication between HCPs required improvement, which PwP have reported previously (44). Participants commonly highlighted difficulties with limited appointment frequency and duration and long waiting times for referral to physiotherapy, occupational therapy and social services. These concerns are all echoed within the latest Parkinson's UK audit report, where 31% of PwP reported a requirement for physiotherapy but a lack of its provision (200). A few participants in this study described positive experiences when they had sought physiotherapy privately, which is in line with PwP experiences in a previous study (199). However, given the personal expense associated with private healthcare this is unlikely to be an option for many PwP.

The Parkinson's UK falls leaflet was often not remembered, and information could be stored away without appearing to have been utilised. A few PwP and caregivers reported not receiving any falls-based information. Where participants had received information about falling, they were often unable to recall advice that they had received or had received it at a time when they felt it was not relevant to them. In other studies caregivers have reported a lack of information about many aspects of PD, and not just falling (42,43,199)

4.3.6 Views on the Content and Format of the Intervention that is to be Produced

In keeping with the heterogeneity of falls in PD, participants showed variety in the information that they would want in a future intervention. The most commonly discussed topic, was information to support caregivers in helping PwP up off the floor, which caregivers have previously highlighted as an unmet need (42,51).

Whilst many participants reported using the internet daily, 36% were either unlikely or very unlikely to do so. Whilst internet use amongst older people is increasing, in 2019 the Office of National Statistics reported that only 47% of people over the age of 75 had used the internet recently (201). During the interviews, where participants elaborated on the potential intervention being in electronic format, they stated that they would like for this to be in a downloadable format. No participants spoke of an interactive intervention. Through questionnaire, paper-

based information was more universally acceptable to PwP. The most acceptable format for an intervention to be delivered to this population would be paper based, with the option for it to be available in a non-interactive downloadable electronic format.

4.3.7 Limitations

Little clinical data was collected from PwP; where it was obtained it was through self-report. No demographical data was collected from caregivers. More research is needed to elucidate whether clinical characteristics of PD, including PD severity, and caregiver characteristics including age and medical co-morbidities, impact upon the beliefs and experiences reported in this study.

PD is a heterogeneous condition. Open ended questions were utilised within the questionnaire so that participants were not restricted by their responses. However, PwP frequently report difficulty writing due to micrographia. Consequently, some responses within the questionnaire were illegible. In addition, some responses to open ended questions could be ambiguous. To overcome this, subsequent questionnaires developed for this programme of research will be designed to have an opening question, with response on a Likert scale, followed by an open-ended question to explore the concept further.

The recruitment strategy adopted within this study may have attracted those who have strong views about the experiences of falling and its management. Findings could provide a more negative representation of the experience of falling than that of the true population of PwP and caregivers. Participants were all recruited through Parkinson's UK support groups, which may have resulted in non-representation of those who are less engaged with support services, including those who are house bound. These participants could be represented through utilising a different recruitment strategy, or interviewing HCPs who are involved in the provision of care to PwP who fall to indirectly explore these patients' falls-related experiences. Chapter Five (phase two, page 121) will report interviews conducted with HCPs to provide an important overall perspective of the difficulties experienced by PwP and caregivers. Locally, considerable physiotherapy research has been conducted amongst PwP. Participants in this study may have had access to research interventions that are different to what PwP nationally would typically have. It would be valuable to explore whether the findings from this study are generalisable to those in other geographical locations.

Whilst conducting the interviews it was acknowledged that dyads may feel uncomfortable speaking of difficulties in front of one another. Where possible, PwP and caregivers were invited to be interviewed separately. However, some participants, particularly those with cognitive impairment or dementia, asked to be interviewed together. When interviewed as a dyad,

Chapter Four: Needs and Preferences of PwP and Caregivers

caregivers rarely appeared to answer on behalf of the PwP or appear uncomfortable when discussing caregiver burden in the presence of the PwP, indeed difficulties arising from caregiver burden and friction between parties were identified despite the use of dyad interviews. This method was also necessary to include those with cognitive impairment/ dementia, who might otherwise have been unable to take part.

4.4 Key points

- This mixed methods study aimed to establish the experiences, needs and preferences of PwP who fall and their informal caregivers, for the effective self-management of falls. PwP with cognitive impairment and dementia were included.
- Six themes were identified from semi-structured interviews with PwP and their caregivers. Five themes related to needs and experiences of falling: (1) 'establishing reasons for falls; attributions and perceptions', (2) 'initial responses, coping and adaptation', (3) 'recognising and managing risks surrounding falling', (4) 'concerns and worries about consequences' and (5) 'PwP and caregivers as case managers'. A further theme related to the content and format of the guide: 'the proposed intervention: implications for its design and development.'
- Dyads displayed a range of problem and emotion-focused coping strategies to manage falling.
- 70% of PwP reported difficulty getting up from the floor, with support often provided by the caregivers. Caregivers played a key role in the management of falling, particularly in the setting of cognitive impairment/ dementia.
- Falling was often associated with considerable impact on the relationship within the dyad, with loss of caregiver identity. 71% of caregivers reported high levels of caregiver burden.
- Participants displayed heterogeneity in their unmet needs for the effective self-management of falls. Dyads frequently require support in attributing reasons for falls, and in communicating with HCPs.
- Use of electronic communication was often limited and a paper-based format would be the most widely accepted amongst the population.
- Results from this study will be combined with results from a qualitative study with HCPs (phase two, chapter five, page 121) to inform the development of a falls-based self-management intervention (phase three, chapter six, page 155).

5 Healthcare Professional's Experiences of Falls and Falls Management in PwP (Phase Two)

This study sought to explore healthcare professionals (HCPs) experiences of falls, current falls management in PwP, and their views on suitable future self-management materials. This included their own experiences of helping to prevent and manage falls in this population as well as their interpretations of PwP and caregiver experiences. HCPs were able to draw on their wide experience of the problems experienced. They provided a different perspective of the problem and were able to supplement the findings from PwP and their caregivers (phase one, chapter four).

The results from this study were later combined with the results from the study with PwP and their caregivers (phase one, chapter four) to support the development of the falls-based self-management intervention to support PwP who fall and their caregivers (phase three, chapter six, page 155). This self-management intervention aimed to support all community dwelling PwP who fall and their caregivers. This study with HCPs helped to provide a greater understanding of the problems encountered by PwP who fall and their caregivers, to include PwP and caregivers who might have been less willing/ able to take part in phase one, and included the perspectives of those who do not attend Parkinson's UK support groups.

5.1 Methods

5.1.1 Study Design

Through semi-structured interviews with HCPs the following were explored:

- a) Reported experiences of those who fall, as acknowledged by HCPs.
- b) Ways in which HCPs attempt to help PwP to overcome difficulties relating to the self-management of falls
- c) The presence and acceptability of different resources that are utilised by PwP and their caregivers to address problems relating to falling.
- d) Perspective of HCPs in relation to the barriers encountered by PwP and caregivers to informing HCPs of falls.
- e) HCPs views on suitable future self-management materials

5.1.2 Participant Recruitment

Parkinson's disease nurse specialists (PDNS) and therapists, comprised of physiotherapists and occupational therapists, were invited to take part. A combination of sampling strategies was used to identify HCPs: convenience, critical case and snowball sampling (163). Convenience sampling refers to the selection of individuals who are easily accessible to the researcher (163). Snowball sampling identifies individuals with similar characteristics to pre-existing participants; new potential participants are identified through those who are already taking part (163). Critical Case sampling seeks to identify those with defined characteristics (as described in phase one, chapter four, page 73).

5.1.3 Data Collection

Data collection took place in two streams. In the first stream, I interviewed ten participants, identified through convenience, critical case and snowball sampling. HCPs were invited through their role as a member of the Wessex Parkinson's Excellence Network, which is supported by Parkinson's UK. This network aims to unite HCPs to further the knowledge of PD and the care provided to PwP. I contacted 20 HCPs and provided them with information about the study (Appendix D1). Of these 20 HCPs, 11 were happy to take part, consisting of eight PDNS and three physiotherapists. Selected by job title, five of these PDNS and all three physiotherapists were invited to take part (critical case sampling). Two further participants, one PDNS and one physiotherapist, were identified through snowball sampling.

After I had coded the data from the first ten participants and emergent themes had been discussed with my supervising team, I appreciated that a second stream of data collection was required to explore therapists' views further. Critical case sampling was utilised, and one physiotherapist and one occupational therapist, both working local to the research centre, were invited and took part in the study.

The estimated sample size was derived through the concept of 'Information Power', as described in the mixed methods study with PwP and caregivers (phase one, chapter four, page 73) (173). Participant and researcher characteristics suggested that a smaller number of participants was likely to be required to achieve 'data saturation' (173,174). HCPs were likely to offer considerable breadth and depth of data given their substantial experience in the provision of healthcare to PwP who fall. Secondly, interviews were performed by myself, and I had developed expertise as a qualitative interviewer through experience, supervision and reflective practice during the mixed methods study with PwP and caregivers.

Participants provided informed written consent (Appendix D2). Interviews were recorded with a digital audio-recorder. Interviews were conducted by myself between 20.07.2017 and 07.12.2017. I developed a schedule of open questions and probes to allow exploration of the views and experiences of PwP who fall, and their caregivers, as perceived by HCPs (Appendices D3 and D4). Views were sought about healthcare provision and falls management, and of resources available for PwP and their caregivers. The interviews explored the same topics as those conducted in phase one with PwP and their caregivers. This allowed later triangulation of data obtained from PwP, their caregivers and HCPs to produce a more comprehensive picture of the problem (202).

Interviews took place at a time and place convenient to the participants and began by asking them to introduce themselves to create a relaxed atmosphere and encourage participants to speak openly (169,180). A pragmatic approach was taken when choosing if participants were interviewed alone, or with other participants. Where more than one individual from a geographical location wished to participate, they were invited to be interviewed as a dyad. Dyadic interviews are of particular relevance when the researcher wishes to allow for the stimulation and sharing of ideas between participants who have busy schedules or are geographically dispersed (203). Dyads were composed of two professionals working in the same or similar professional discipline and were acquainted with one another prior to participating in the study. Through adopting this approach it was felt that participants would be more likely to be comfortable speaking in front of one another (180,203). Interview questions were congruent between single and dyad interviews to allow for later data analysis (Appendices D3 and D4) (180).

5.1.4 Data Analysis

Audio-recordings were transcribed by ADu, imported into NVivo software (version 11) by myself and analysed through inductive thematic analysis, as described within the mixed methods study with PwP and caregivers (phase, one, chapter four, page 77) (183). The approach adopted within this analysis lies closest to codebook analysis (184). The person-based approach favours understanding the end users perspective, rather than using HCPs/ experts interpretations of these (22). This study explored HCP's experiences of falls and falls management and their perceptions of PwP and caregivers experiences. Therefore, the analysis from this study placed greater emphasis on the identification of patterns and commonalities within the data, as opposed to providing a subjective contextualised interpretation of HCPs' experiences.

Coding commenced after the first stream of interviews. In keeping with reflexive thematic analysis, coding was fluid and interpretative (184). 119 initial codes were identified. As data was

coded, it was felt that no further concepts were emerging from PDNS. However, as described above, therapists' viewpoints required further exploration, and two further therapists were identified via critical case sampling. Data from these two therapists was coded without restriction to the existing codes. However, no further codes were produced, implying data saturation (174). The concept of data saturation is described in phase one (chapter four, page 77). Here the term data saturation relates to code saturation: heard it all (186).

Analysis was undertaken by myself with input from my supervisors Dr Sarah Kirby (SK) and Professor Helen Roberts (HCR) into emerging codes and themes to ensure that results stayed close to the data (162). This also provided additional analytical insight given SK's extensive qualitative research experience and background in health psychology, and HCR's research and clinical experience in PD.

In keeping with reflexive thematic analysis, themes were developed as the final outcome. However, themes two, four and six provide topic summaries as opposed to shared meaning, which is in keeping with coding reliability/ codebook thematic analysis (184)

Themes and subthemes from this study were then compared with those from the mixed methods study with PwP and their caregivers (phase one, chapter four, page 87), a process referred to as triangulation. Triangulation describes the comparison of data collected from either more than one population, method, investigator or theory (202). Triangulating the findings from PwP, caregivers and HCPs provided a more comprehensive picture of problems encountered (202). Outcomes from the triangulation process are presented within the discussion of this chapter.

5.2 Results

5.2.1 Participants

12 HCPs took part comprised of six PDNS, five physiotherapists and one occupational therapist. Seven interviews were conducted; ten participants were interviewed as a dyad and two were interviewed alone. Four dyads were composed of HCPs working in the same discipline, one of the dyads was composed of a physiotherapist and an occupational therapist who worked in the same locality. The two single interviews lasted 21 and 29 minutes. Dyad interviews lasted between 25 and 51 minutes (mean 40 minutes).

5.2.2 Themes Identified

Six themes were identified that provided a descriptive coherent representation of the data (Table 5-1). Data contributing to each of these themes is displayed within the coding manual (Appendix D5). Five themes related to the perceived experiences of PwP and their caregivers, and their interactions with HCPs. One theme compiled views surrounding the content and format of the proposed intervention. Statements such as 'a few participants' or 'many participants' have been used to display the prevalence of opinion amongst the population interviewed as described within the mixed methods study with PwP and caregivers (phase one, chapter four, page 77). Where the term 'therapists' is used, this signifies that the view presented is that of both physiotherapists and the occupational therapist.

Table 5-1: Themes Identified from Semi-structured Interviews with HCPs

Theme	Subthemes
Theme 1: "Causes of falls and their consequences on PwP and their caregivers."	<ul style="list-style-type: none"> • Multitude of reasons for falling in PwP • Consequences of falling on PwP and their caregivers
Theme 2: "Healthcare provision."	<ul style="list-style-type: none"> • Roles of HCPs and MDT working • Provision of education • Signposting to third sector organisations
Theme 3: "Personalised Healthcare."	<ul style="list-style-type: none"> • Adapting to the heterogeneity of PD • Adapting to personal characteristics
Theme 4: "Limitations of healthcare in meeting patient needs."	<ul style="list-style-type: none"> • Barriers to the implementation of management strategies • Approaches to overcome barriers to the implementation of management strategies • Healthcare provision often leaves many needs unmet
Theme 5: "Engagement versus disengagement with healthcare."	<ul style="list-style-type: none"> • Degree of self-management practices • Barriers to accessing healthcare and information about falling
Theme 6: "Views surrounding the content and format of future interventions."	Not applicable (no subthemes)

Abbreviations: HCPs= healthcare professionals, MDT= multidisciplinary team

5.2.2.1 Theme 1: Causes of Falls and Their Consequences on PwP and their Caregivers

Multitude of Reasons for Falling in PwP

All HCPs discussed at length the multifactorial nature of falling. All highlighted Parkinson’s specific and non-Parkinson’s specific contributions to falls.

“It’s the whole thing when you say falling.... your lack of heel strike and all the normal things...home hazards...freezing” Participant 12 (Physiotherapist)

Most HCPs, including all physiotherapists, highlighted impaired balance as a Parkinson’s related contributor to falling. Other contributors commonly highlighted by both PDNS and therapists included freezing, multitasking and postural hypotension. Less commonly raised aetiologies were motor fluctuations, rushing, turning, doorways and dyskinesia.

“Their balance...Parkinson’s patients fall when they freeze...their legs stick, and they think they’re going to move forward, and they don’t” Participant 1 (PDNS)

Nearly all HCPs described how cognitive impairment led to additional risks of falling in PwP. Cognitive impairment was felt to contribute through reduced insight, and PwP performing more ‘risky’ activities. Other effects included impaired visuospatial skills, reduced concentration, non-

compliance with walking aids, fatigue, and hallucinations. Where HCPs did not discuss the effect of cognitive impairment on risk of falling, they raised how it affected caregivers or the implementation of management strategies.

“People with cognitive impairment are at high risk of falls...they lack insight...they become more risky, they don’t take their equipment.” Participant 7 (PDNS)

A few HCPs, including therapists and PDNS, discussed how Parkinson’s affected how PwP interacted with their environment. Altered perception could lead to over-reaching and instability.

“They don’t step near enough to something ...their perception is wrong.” Participant 4 (PDNS)

Non- PD specific contributors were raised more frequently by therapists than PDNS. The most described risks were associated with reduced vision, poorly fitting footwear, clutter within the home, medications, and difficulties with walking aids. A few therapists discussed how inappropriate maintenance of walking aids amongst PwP contributed to falls risk. Other causes included long toenails, constipation, hearing, poor lighting and incontinence.

“Are your glasses clean and are you shoes fitting... I often clean glasses.” Participant 3 (PDNS)

Two participants, one PDNS and one therapist, discussed how PwP and their caregivers were not always aware of potential causative factors.

“We’re asking them about foot-care and eyesight and hearing ... they kind of look at us like you know, ‘but you’re a physio why are you asking me about my eyes’?” Participant 5 (physiotherapist)

Consequences of Falling on PwP and their Caregivers

A few physiotherapists described how some PwP felt unprepared at the onset of falling.

“I think people can be quite shocked.” Participant 6 (physiotherapist)

Most HCPs, including all physiotherapists, discussed the significance of fear of falling, which could be greatest amongst those who were cognitively intact. This often led to a decline in confidence, a reduction in physical activity and avoidance of defined settings. One therapist went so far to say that PwP could use their diagnosis as an excuse to remain immobile and discussed the adverse effects of immobility on muscle mass.

“People use Parkinson’s as an excuse...I’ve got Parkinson’s, so I just need to sit in my chair and not do anything...that obviously then leads to the muscle-wasting and bad balance.” Participant 6 (physiotherapist)

Chapter Five: Healthcare Professionals Experiences

Two PDNS described how they perceived that the most common problem experienced by PwP in association with falling was inconvenience, which could rise in line with increased fall frequency.

“The frequency of falling; you know just the pure inconvenience of it I think, even if they’re not injuring themselves.” Participant 4 (PDNS)

Few HCPs spoke of concerns that PwP might have of falls related injuries. Where this was discussed, participants did not feel that it was significant or unique to PwP.

“That’s across the board with the elderly...everybody is a bit worried that they’re going to fracture their hip.” Participant 1 (PDNS)

All HCPs discussed the significant role that caregivers played in the management of falls. Most PDNS and one therapist felt that caregivers helped to increase the compliance of PwP with HCPs advice. PDNS discussed how through providing caregivers with information about falling, there was an increased likelihood of it being retained within the PwP/ caregiver dyad. HCPs also raised how caregivers helped the PwP to mobilise safely and supported them with their physiotherapy exercises.

“It does make a big difference if you’ve got a supportive husband or wife...that’s willing to kind of go through the exercises with them at home and take on board the advice.” Participant 5 (physiotherapist)

HCPs frequently described concerns that the caregiver had of the PwP falling. Many HCPs, both PDNS and physiotherapists, discussed how some caregivers did not want to leave the PwP alone for fear that they would fall in their absence. This could lead to a decline in social interactions of caregivers, and resultant isolation.

“They kind of lose their social interaction because they don’t like to leave the patient at home.” Participant 5 (physiotherapist)

Caregivers could also restrict the activities that PwP performed to manage their concerns of falling. One PDNS discussed how this restriction could lead to heightened anxiety in the PwP, especially in the presence of cognitive impairment. Two PDNS recalled occasions when these restrictions had been so severe to trigger a safeguarding referral.

“Sometimes we end up having to get adult social services involved if we think that they’re being retained too much; safeguarding.” Participant 8 (PDNS)

Most HCPs, including nearly all PDNS, discussed how the development of cognitive impairment in the PwP was associated with heightened difficulties for the caregiver. These HCPs commonly

raised difficulties with caregiver fatigue, which could arise from day/night reversal in the PwP. This could in turn lead to caregiver fatigue and the PwP moving to a care home.

“Wandering at night...lack of sleep for a caregiver... falling at night... It’s very often number one reason they go into a care home.” Participant 7 (PDNS)

All HCPs discussed how caregivers often displayed inappropriate manual handling practices, and how they required training in their new role.

“A lady asked me ‘how do you just get mum out of a chair safely without me heaving her up?’ ...when you have a baby [you have] antenatal classes, why can’t we have elderly persons classes like how to safely manual handle people.” Participant 11 (occupational therapist)

Whilst most HCPs discussed how caregivers experienced difficulties when trying to get the PwP off the floor after a fall, a minority, who were all therapists, felt that this was not something which caregivers assisted with. Where this was discussed, participants described how caregivers could struggle trying to get the PwP off the floor themselves, which could be heightened amongst caregivers of a smaller build. This could lead to injury to the caregiver or result in inadequate medical attention for the PwP. Some HCPs raised that caregivers could inappropriately pull the PwP either when trying to help PwP out of a chair or when mobilising. HCPs discussed how this arose from a lack of understanding of PD amongst caregivers.

“Injuries, due to lifting, hauling, dragging, pushing.” Participant 4 (PDNS)

“Lots of carers pulling people around, to get them moving... hoiking their legs about to stop them freezing.” Participant 10 (physiotherapist)

All HCPs described the physical and psychological difficulties that caregivers experienced as a result of falls. Most therapists discussed how reduced activity in PwP led to an increased level of responsibility amongst caregivers, which could adversely affect the PwP-caregiver relationship. Consequently, these therapists could perceive that the high caregiving workload made PwP that they were a burden.

“The caregiver duties are upped... they are just getting frazzled and then that relationship breaks down because they’re too exhausted to try and have that caring relationship.” Participant 9 (physiotherapist)

5.2.2.2 Theme 2: Healthcare Provision

Roles of HCPs and Multi-disciplinary Team (MDT) Working

All HCPs described always monitoring falls at clinical review. PDNS commonly described assessing falls risk through observing how PwP mobilised. Two PDNS, who worked in the same locality, acknowledged that falls had not always been monitored, and outlined how a previous audit had led to changes in their practice.

"I think it's been hit and miss up until now... the audit for Parkinson's UK made us look at what we were doing...we weren't consistent." Participant 2 (PDNS)

All PDNS described gathering information about falling, providing brief advice and then signposting to other HCPs or resources. The role of the PDNS appeared to be that of 'case manager'. Only a few PDNS spoke of trying to identify the aetiology of falling, and when PDNS' made medication changes, they perceived this to be a minor role.

"Generally, my role is referral to more specialist Services, Physiotherapists and Occupational Therapists if it's practical issues and things." Participant 4 (PDNS)

Therapists described how their role was to help to reduce the PwP's falls risk or to manage the consequences of falling. Strategies to address falls risk included cueing techniques to manage freezing and provision of walking aids. Most therapists motivated PwP to remain active, aiming to increase their confidence and reduce muscle wasting. Most therapists taught PwP to get up from the floor, and some described providing caregivers with moving and handling training, which could help to manage caregiver anxiety.

"If possible, we would like to teach backward chaining... how to get up from the floor." Participant 12 (physiotherapist)

All HCPs described how the needs of PwP were best met through involvement of different members of the multidisciplinary team (MDT). This included PDNS, physiotherapy, occupational therapy, social services and doctors. In some localities communication was through a formal referral process.

"It's a multidisciplinary clinic, so patients will come in fairly regularly and access Physio Services much more easily than they would do if they had to go through the community." Participant 6 (physiotherapist)

Whilst all HCPs described referring PwP and caregivers to other HCPs, reasons for referral varied. All PDNS referred PwP/ caregivers to physiotherapists; half of PDNS referred for advice in helping the PwP get off the floor, and half referred for balance training. Only one PDNS referred PwP to

physiotherapy to manage reduced confidence in association with falls. Two PDNS discussed referring caregivers to therapists for assistance with manual handling.

“I refer to Physio... Specifically for that, can you give them some instructions on how to get up from the floor.” Participant 2 (PDNS)

Few HCPs discussed specific benefits provided by other HCPs or services. Where described, they included: the provision of locality specific information by social services, ‘practical support’ by occupational therapy, and a comprehensive falls assessment to include non-PD risk factors by the falls service. Some PDNS stated that they were unclear of the services provided by other HCPs.

“I would refer generally for anybody with cognitive problems to the Mental Health team... what their resources can provide, I couldn’t say.” Participant 4 (PDNS)

Provision of Education

All HCPs perceived education of PwP to lie within their role as a healthcare provider. HCPs described ‘information packs’ that were distributed to PwP at the time of diagnosis by PDNS. The breadth and depth of information contained within these varied between the localities in which the HCPs worked. Information about falls was not uniformly included. Few HCPs described whether PwP engaged with these. One PDNS thought that they were often left unread, another described reducing the quantity of information that they contained to increase their acceptability.

“The information packs.... Information about movement...exercise... groups that they can go to...a little bit about Parkinson’s...but most people don’t read it.” Participant 1 (PDNS)

“They’re given an information pack...we wanted to keep it short and simple...otherwise it’d be overwhelming... not specifically about falling.” Participant 8 (PDNS)

One PDNS described formal group education sessions organised for PwP and their caregivers within the locality that they worked. These took place soon after diagnosis, covered a range of topics, and included information about falls. Whilst the PDNS perceived that the information was comprehensive, they did not elaborate on the views of PwP and their caregivers.

*“New diagnosis session... part of it is a physio and an occupational therapist joint talk on managing falls and getting up from the floor... it’s quite a comprehensive block”
Participant 4 (PDNS)*

Nearly all HCPs described education embedded within routine clinical review, which was targeted toward PwP and their caregivers. Many HCPs thought caregivers needed the same information as PwP; a view more prevalent amongst PDNS than therapists. These HCPs perceived that caregivers could help to overcome difficulties with PwP forgetting advice.

“Usually we’re telling them both at the same time, so hopefully the carer is the backup at home.” Participant 3 (PDNS)

Some HCPs, including most therapists, described encouraging a shift of responsibility from HCPs to PwP and their caregivers. These HCPs provided PwP and caregivers with personalised information to empower them to take control of their condition. This included teaching PwP to recognise patterns of symptoms in association with their medication, conservative measures to manage postural hypotension, and recognition of their limitations and adaptation of activities.

“A bit of reassurance with respect to managing their Parkinson’s and having good days and bad days... if you don’t feel like going for swimming, yet you feel the need to be active, go for a walk instead.” Participant 9 (physiotherapist)

Signposting to Third Sector Organisations

All HCPs signposted to third sector organisations, which provided services not available within the NHS. Most participants, including all therapists, discussed the benefits of Parkinson’s UK support groups, which provided PD related information, and subsidised Tai Chi sessions.

“The local Parkinson’s Group will subsidise, some of these groups...Tai Chi, or the exercise groups.” Participant 7 (physiotherapist)

Most HCPs, PDNS and therapists, discussed signposting PwP to the Parkinson’s UK website for further information. PDNS often described the plethora of information that was available and sensed that it was easily accessible.

“The Parkinson’s UK website is quite a good resource for lots of different things that happen in Parkinson’s... obviously anybody can go on the website at any point”
Participant 1 (PDNS)

A few therapists, and one PDNS, discussed other third sector organisations. Age (UK) had previously provided volunteers to support physiotherapists in helping PwP to become more active, which had in turn increased the confidence of PwP. Community exercise classes could increase the confidence of PwP, although the same HCPs that referred to them were unsure of their content.

“We’ve got the Steady and Strong classes, which are run by the Council... [we don’t know] much that goes on in them, just that people enjoy them.” Participant 4 (PDNS)

5.2.2.3 Theme 3: Personalised Healthcare

Adapting to the Heterogeneity of PD

All HCPs described undertaking a comprehensive assessment in PwP who fall. Physiotherapists emphasised the complexity of PD and how adopting this approach allowed identification of each PwP's individual needs. Some HCPs highlighted that concerns experienced by the PwP or the caregivers may not be brought forward without probing.

"People with Parkinson's are quite different, and they fall for quite a number of different reasons, so I think it's quite hard to be very generic." Participant 5 (physiotherapist)

Following identification of a PwP's individual needs, HCPs tailored the assessments performed and the management plans instigated. Where PwP experienced freezing, cueing techniques were provided. Where PwP experienced postural hypotension, lifestyle measures and monitoring were suggested. Signposting to other health and social care services was also guided by each PwP's individual requirements.

"Frequent fallers I would be monitoring quite closely...get the District Nurses or the Nursing Homes to monitor their blood pressure" Participant 7 (physiotherapist)

Most therapists described the importance of considering the intra-individual variability in PD symptoms that PwP could experience. In response, therapists provided some PwP with multiple walking aids to adapt to these variations. Other therapists described encouraging PwP to recognise this variability, and to adapt their activities accordingly.

"Patients can be variable... you don't want to be confining somebody to using a frame when actually at some points in the day they might be okay with a stick." Participant 5 (physiotherapist)

Another consideration described by most therapists and one PDNS was the duration for which the PwP had been diagnosed. These HCPs outlined how the risk of falling changed over time, resulting in differing needs and interventions that were likely to benefit.

"You've made that home as safe as possible...you can't be providing stuff they don't need yet ... we tend to discharge them but give them our contact telephone details so they can get back in touch with us." Participant 12 (physiotherapist)

All HCPs discussed how management strategies required adaptation in the setting of cognitive impairment/ dementia. A few HCPs described referring PwP to the mental health team; although the same HCPs were often unsure of the additional support that this service provided. Therapists often provided PwP with cognitive impairment/ dementia with one walking aid to enhance

compliance. This contrasts with the approach taken toward those who are cognitively intact where PwP are advised to switch between different aids as determined by variation in mobility.

“If patients have got problems with cognition, then it does just confuse them if they’ve got all these different [walking aids]; it’s much better just to have one [walking aid].”

Participant 5 (physiotherapist)

Adapting to Personal Characteristics

All therapists, but no PDNS, described how assessment of a PwP in their home environment allowed identification of risks pertinent to that individual. Some raised that these risks might not have been identified during an assessment within the hospital setting.

“Go in see how their home environment is, see if there’s any hazards. See if there’s any equipment that can help with them at home managing their daily activities.”

Participant 11 (occupational therapist)

Some PDNS and therapists discussed the importance of providing PwP with realistic advice, to include physical activity and exercises. Two therapists described how some PwP lacked confidence, whereas others were ‘risk takers’; identification of where an individual lay on this continuum was required to assess and address falls risk.

“You have the people that are more risk takers...or they’re the other end of the spectrum where they’ve completely reduced their mobility.”

Participant 10 (physiotherapist)

A few therapists raised the need to adapt information in accordance to the PwP and caregiver’s perceptions of falls. These therapists recognised that some PwP experience shock at the outset of falling, which could make them less receptive to new information.

“I don’t think that necessarily straight after [a fall] is the right time... [PwP] are processing what’s happened or they’ve got an injury ... sometimes people need a little bit of time.”

Participant 6 (physiotherapist)

Another adaptation included modification of language to make advice more relevant to the individual.

“[Whilst talking about cueing strategies] We’ll start 1, 2, 1, 2, and somebody will say, no, they were in The Forces, so they’re left, right, left, right.”

Participant 3 (PDNS)

Some participants, PDNS and therapists, described how assistive technology was able to support caregivers, and aimed to reduce anxieties that they might have in relation to the PwP being alone.

“You leave them asleep in the chair, you just want to do half hour of something for yourself, and the sensor mats have allowed people to do that.”

Participant 2 (PDNS)

Amongst nearly all HCPs, caregiver difficulties appeared to be identified through a reactive rather than a proactive approach. Two PDNS discussed how locally adopted pre-emptive strategies had enhanced the identification and management of caregivers' problems.

"I generally see them sat in clinic with a plaster on, or an arm in a sling, or looking uncomfortable or, and then you realise that something's not quite right." Participant 4 (PDNS)

5.2.2.4 Theme 4: Limitations of Healthcare in Meeting Patient Needs

Barriers to Implementation of Management Strategies

All HCPs identified barriers relating to PwP and caregivers translating information and advice into practice. Most HCPs discussed how some management strategies may be less feasible for some PwP and their caregivers. Some PwP and caregivers encountered difficulties relating to the acceptability of walking aids, equipment within the home or physical exercise. Other HCPs discussed the complexity of PwP learning new skills and using compression stockings.

"Multitasking... that's really hard isn't it to relearn." Participant 2 (PDNS)

Some participants, therapists and PDNS, discussed problems with walking aids. The most frequently discussed problem was that PwP could be reluctant to use walking aids, which could arise from a perception that they were for people older than themselves.

"They don't want to use a four-wheel walker outside...it delineates them doesn't it...normality isn't there with a walking aid." Participant 6 (physiotherapist)

A few PDNS, but no therapists, discussed how some PwP and their caregivers were reluctant to accept or use equipment in the home. Difficulties related to the size of the equipment, perceptions of intrusion, and the length of time that it took to operate. This could result in caregivers performing unadvised manual handling practices.

"The equipment isn't necessarily convenient to use in the home... it's to do with the size of the equipment... the speed of use...it's easier just to yank them up by the arm, easier in their perception." Participant 4 (PDNS)

All therapists and some PDNS identified barriers in relation to physical activity. These HCPs described how fear of falling could lead to a reduction, or even avoidance of physical activity. These concerns were often perceived to be greatest amongst those who were cognitively intact.

"I think the ones without cognitive impairment worry more and become more immobile...Because of the fear of falling." Participant 8 (PDNS)

All HCPs identified barriers pertinent to PwP with cognitive impairment or dementia. The most common area discussed related to the use of a pendant alarm. Most HCPs discussed that PwP with cognitive impairment/ dementia may either forget to carry the alarm or forget to press it after a fall. More therapists than PDNS discussed how those with cognitive impairment may forget to use their walking aid. Other difficulties included reduced implementation of cueing strategies for freezing, and reduced engagement with therapy.

“Pushing the actual button...they forget to press it.” Participant 11 (occupational therapist)

Most HCPs, including all therapists, highlighted that PwP and caregivers could experience information overload due to the plethora of information available. Consequently, written information could be left unread, and verbal advice not translated into practice. All therapists, and a few PDNS, perceived that PwP may not read information if deemed irrelevant to their circumstances. Some HCPs discussed the reduced ability of PwP to recall information, which was not limited to PwP with cognitive impairment/ dementia. A few PDNS discussed how some PwP may not want to engage with their diagnosis and were perceived to resist changing their behaviour.

“I’ve had people that haven’t picked up leaflets before because they are very active and it’s got someone sitting in a chair on the front of it, so they then think it’s not for them,” Participant 10 (physiotherapist)

Approaches to Overcome Barriers to the Implementation of Management Strategies

All HCPs described adapting their practice to overcome reduced engagement of PwP and caregivers. All PDNS, and most therapists, provided PwP and caregivers with information to read at home, which was specific to the participants, re-enforced discussions, and provided a reference to refer to later. PDNS were most likely to provide information published by Parkinson’s UK. Therapists were more likely to provide generic falls literature, or information to support cueing strategies.

“If you give them a load of leaflets they’re going to think ‘oh, I can’t be bothered to read all that’...If you had a couple of leaflets that are actually appropriate to you, they might think ‘oh actually yes, I will read that’.” Participant 11 (occupational therapist)

Most therapists, and a few PDNS, described repeating information or training of tasks to enhance compliance, with one PDNS going as far to say that they ‘nagged’ PwP. Therapists and PDNS described that information should be relevant to the individual and delivered in manageable

stages and at appropriate times. A few PDNS described adapting advice to enhance its acceptability.

“Some people...they’re not happy walking with a stick...sometimes you offer then walking poles...it’s trying to find an alternative that is suitable.” Participant 1 (PDNS)

Healthcare Provision Often Leaves Many Needs Unmet

Most HCPs perceived that current management strategies left many PwP’s needs unmet. Only two participants, both PDNS, felt that adequate interventions were in place, and that the unresolved difficulties arose from the reluctance of PwP to change.

“Quite prompt at getting help aren’t we...I think it’s more the resistance to change.” Participant 2 (PDNS)

Many HCPs perceived that problems related to the reduced availability of healthcare resources, rather than their ineffectiveness. All therapists and a few PDNS described difficulties encountered by PwP and caregivers in accessing physiotherapy. Prolonged waiting times were commonly highlighted, difficulties included ineligibility of PwP related to locality-specific or age cut-off criteria.

“Our Service is an over-sixty-five Service...in under-sixty-five’s there’s that bit of a black hole in terms of treatment.” Participant 5 (physiotherapist)

A few PDNS described ways in which they tried to support PwP and caregivers whilst awaiting physiotherapy review. These included the provision of cueing strategies or signposting to private physiotherapy or community exercise groups. Whilst most PDNS referred PwP to physiotherapy to support them getting off the floor, and advised caregivers not to lift the PwP, none gave PwP/caregivers information about this prior to therapy review. However, one PDNS did refer PwP and caregivers to the pendant alarm service.

“We get Careline involved...I don’t have a lot of input once they have fallen...as to, how to, what to do next.” Participant 8 (PDNS)

Most therapists regarded the current provision of therapy to be inadequate. These therapists perceived that physiotherapy should be provided for longer, which would lead to improved clinical outcomes. One therapist discussed that current services were often non-compliant with NICE guidelines.

“They may see a generalist physio. If they’re very lucky they’ll see a specialist physio...the NICE guidelines have now just told us that we should all have specialist physios.” Participant 10 (physiotherapist)

Few HCPs had sought feedback about the written information that they provided or the resources that they referred to. HCPs were often unsure whether PwP and their caregivers had found written information useful. PDNS could be unsure of whether PwP had benefited from being referred to other HCPs. PDNS and therapists could be unsure whether PwP and their caregivers had attended exercises classes or carers groups that they had recommended. One PDNS went so far as to say that no news was good news.

“We try and encourage them to move onto the Community classes... I should follow them up and see whether they’ve actually taken up that opportunity.” Participant 5 (physiotherapist)

“I generally hear if the referral hasn’t happened rather than if it has. Because if it has and it’s successful, then it all goes quiet. So, no news is definitely good news when it comes to falls.” Participant 4 (PDNS)

5.2.2.5 Theme 5: Engagement Versus Disengagement of Service Users with Healthcare

Degree of Self-management Practices

Only a few HCPs, who were all therapists, perceived that PwP and caregivers self-sought information about PD and falls. These therapists thought information was most likely to be obtained from Parkinson’s UK. Where described, this practice was thought to be limited to PwP and caregivers who were pro-active, with information related to all aspects of PD and not falls specifically.

“Proactive ones may search on the internet and think I am falling more, where can get help, and therefore it’s probably Parkinson’s UK.” Participant 10 (physiotherapist)

Most HCPs, and all PDNS, perceived that the majority of PwP did not self-seek falls information. A few participants, PDNS and therapists, discussed how PwP could have a pessimistic outlook, or strive for paternalistic healthcare.

“It’s whether it’s half full or half empty glass of water... I spend a lot of my time you know sort of positive thinking; you know encouraging them.” Participant 7 (PDNS)

In two PDNS, who earlier described the benefits of HCPs being proactive to identify caregiver needs, there was a sense that they expected caregivers to ask for any information that they required.

“There’s enough staff for them to ask to be honest. If they have any queries, and I do find that the carers are very proactive with our patients.” Participant 3 (PDNS)

Many HCPs, both PDNS and therapists, discussed how PwP and caregivers benefited from social support. HCPs often described how PwP and their caregivers benefited from sharing their experiences of falling with others in a similar position to themselves. Opportunities included PwP attending the day hospital or community strength and balance classes, and caregivers attending carers groups. Whilst all participants discussed signposting to Parkinson’s UK support groups, only one participant, a physiotherapist, described the social support that they provided.

“People chatting to each other about falls actually gives them a lot of confidence and to see that other people fall as well and how other people have got over it.” Participant 5 (physiotherapist)

Barriers to Accessing Healthcare and Information About Falling

All HCPs perceived that PwP and caregivers may not seek appropriate timely support, which could have adverse consequences for the PwP and the caregiver. Many participants described the stoical nature of some caregivers, and how difficulties might only be recognised through a proactive approach.

‘There’s an issue with people wanting to have extra help, to reduce the carer stresspeople will tend to put that off quite a lot and try and deal with a lot of it themselves...and then get into a bit of a crisis situation.’ Participant 6 (physiotherapist)

Most HCPs, including all therapists, discussed how PwP could view falling as unpreventable, which made some PwP less likely to inform or seek advice from HCPs about falls. Some of these HCPs appeared frustrated when discussing these perceptions and wished that all PwP would take their falls seriously to allow for PwP to receive the appropriate interventions in a timely manner.

“People don’t realise that there’s actually anything you can do about falling as well... it’s just part of my Parkinson’s, oh I’m just old so I fall.” Participant 5 (physiotherapist)

A few participants perceived that PwP may be embarrassed of falls, one therapist went as far to say that PwP could feel ashamed. This could relate to feeling that they were too young to fall. These thoughts could in turn lead to delays in alerting others that a fall had occurred. Most HCPs identified barriers to caregivers not calling 999 after a fall. Half perceived that caregivers wanted to try to manage themselves before seeking support, which could arise out of ‘natural instinct’. When caregivers did seek support, some experienced a delay before help arrived, which led some caregivers to attempt to manage in the interim. Other HCPs described how PwP and caregivers

could be concerned that 999 would automatically result in admission to hospital, or that the management of falling was within the remit of the ambulance service.

“People are very worried...feeling that if you call for an ambulance you’ll be taken to hospital, and nobody wants to go to hospital.” Participant 5 (physiotherapist)

“There’s been a few incidences where they almost feel very guilty...they’ve sort of come across, for whatever reasons, a slightly abrupt ambulance driver, and it really has put them off phoning again.” Participant 8 (PDNS)

A few participants identified barriers to PwP and caregivers accessing support from other services. Some therapists suggested that some PwP and caregivers did not know where to seek support from. Where available, PwP may not be aware that they can self-refer to therapy, and consequently wait until they have been referred by another HCP. One therapist described how the delay between being referred and assessed by another HCP could lead to PwP being unable to recall the details of their falls, which could lead to less effective outcomes. Another HCP discussed how caregivers might not want to ask for support in their caring role due to financial concerns or a perception of intrusion.

“Financial issues or intrusion into their life...I think people will tend to put that off quite a lot and try and deal with a lot of it themselves.” Participant 6 (physiotherapist)

Most HCPs, including PDNS and therapists, discussed signposting PwP to the Parkinson’s UK website for further information. PDNS often described the plethora of information that was available, with a sense that it was easily accessible. A few of these participants later described expecting PwP to ask for printed information and perceived that the internet was not acceptable to many PwP.

“Some patients will say to you yes, I’ve been online and got it. Other patients will say could you print me stuff off... you have to remember the age-group of these people, and many aren’t online.” Participant 2 (PDNS)

Over half of HCPs, including all physiotherapists, described concerns held by PwP in relation to the progression of PD. PwP could avoid exercise groups that were not PD specific due to experiencing embarrassment in relation to their PD symptoms. Conversely a few participants outlined how some PwP could be deterred from attending Parkinson’s-specific support groups due to concerns of seeing those with more advanced PD.

“(Mr X) didn’t want to go [to the Parkinson’s support group] cos he was frightened of what he would see, of what may happen to him.” Participant 11 (occupational therapist)

5.2.2.6 Theme 6: Views Surrounding the Content and Format of Future Interventions

Content of the Self-management Intervention

All HCPs described the considerable PD specific and non-PD specific causes of falling in PwP and felt that information about both components to falls should be included within the intervention to be developed.

“Concentrating on one task at a time...how to get up if you do fall... if you can’t get up dial 999.” Participant 2 (PDNS)

However, all participants described that they thought that the intervention should be short, to the point, and not contain too much information. Most thought that the intervention should provide an awareness of the causes of falling, with signposting for further information and support. One therapist suggested that providing information prior to clinical assessment might reduce the therapist’s workload.

“Some of the things that people can understand, and actually implement on their own... by the time they actually do land up seeing a physio, hopefully the list is not enormous.” Participant 9 (physiotherapist)

Therapists had conflicting views about whether the intervention should contain instructions for undertaking exercises. Whilst some suggested that the intervention should contain a few generic exercises, some felt that the inclusion of these could lead to adverse outcomes.

“There are guides out there that give kind of general balance exercises, but I am always a bit nervous about that...you obviously don’t want patients to do be doing exercises that are too high a level for them and then cause them to fall.” Participant 5 (physiotherapist)

Some participants, mainly therapists, discussed the importance of ensuring that the intervention contained realistic suggestions, to increase its acceptability. Therapists, but not PDNS, raised that the intervention should acknowledge the limitations that PD placed on an individual, and provide suggestions of adaptations to overcome these difficulties.

“Reassurance with respect to managing their Parkinson’s and having good days and bad days. A lot of people I speak to feel their absolute need to do the very best every single time.” Participant 9 (physiotherapist)

Most therapists, but no PDNS, thought that the intervention should be able to be individualised. These HCPs perceived that this would increase the likelihood of the intervention being used. A

few therapists described how this might be achieved through including an index, guiding users to read relevant sections.

“Every individual is so different ...being able to kind of pick and choose the relevant information inside a guide I think would be quite good.” Participant 5 (physiotherapist)

All participants thought the intervention should contain signposting, to remind PwP and caregivers of advice provided by HCPs. Parkinson’s UK resources were commonly suggested; others included physiotherapy and an optician. A few HCPs suggested including a list of telephone numbers within the intervention for PwP/ caregivers’ future reference. Only one HCP, a physiotherapist, suggested that this list should be specific to the geographical location of the PwP.

“If you’ve got a problem with your eyes, see your optician, if you’ve got a problem with strength and balance, actually get a referral to a physio.” Participant 5 (physiotherapist)

Most therapists, and some PDNS, thought that the intervention should emphasise the importance of PwP informing HCPs that they had fallen. Most physiotherapists suggested that the intervention should aim to improve communication between PwP and HCPs, which would be supported through stressing the preventable nature of falls. A few HCPs described how including a falls diary would also facilitate patient-professional communication. These participants discussed how a falls diary might support accurate falls-related history taking or improve compliance of PwP/ caregivers with the intervention.

“[Falling’s] not an inevitable part of the condition, because I come across that a lot...it is potentially reversible.” Participant 10 (physiotherapist)

“Think about what happened... While it’s still fresh in their mind...it might be really helpful in terms of developing a management strategy for that particular person.” Participant 6 (physiotherapist)

All participants described the vital role that caregivers played in the management of PD and falls and thought that caregivers needed information and support too. When asked what information caregivers needed, most HCPs believed that they needed similar information to the PwP, which could act as a ‘backup’.

“Telling them both at the same time, so hopefully the carer is the backup at home.” Participant 3 (PDNS)

Most physiotherapists, and a few PDNS, described encouraging caregivers to raise any concerns and to seek time for themselves. However, few HCPs detailed specific support services available for caregivers, such as carer support groups. Some believed that the intervention should contain

manual handling techniques and emphasise the importance of caregivers recognising their limitations.

“Any carer groups, where they can go for sort of psychological support themselves and accepting the diagnosis.” Participant 11 (occupational therapist)

A few HCPs, PDNS and therapists, discussed potential benefit of targeting the intervention toward those who feel unsteady but have not previously fallen. However, one HCP raised how PwP who were yet to fall might not be ready to engage with falls-based information, related to fears of PD progression.

“Starting your self-management guide before a fall... getting the attention probably a step, a couple of steps before... because it’s almost like the ship has sailed.” Participant 9 (physiotherapist)

“Patients can get quite upset if you mention something that they haven’t thought of they’ve already, they haven’t got there yet.” Participant 1 (PDNS)

Format of the Self-management Intervention

All participants perceived that a paper-based intervention would be the most acceptable format to PwP and caregivers.

“Our client group like paper... you can dip in and out of [it]” Participant 8 (physiotherapist)

Many HCPs thought an online platform might be less accessible to PwP and caregivers, which some HCPs attributed to PwP and caregivers’ advancing age. Where participants were positive of an online platform, they described an intervention produced in a format that could be downloaded.

“You definitely need a paper copy... or you know certainly downloadable [so it’s] easily accessible.” Participant 10 (physiotherapist)

All participants discussed the importance of presenting information clearly. Many raised the importance of considering font size, and that PwP/ caregivers may have reduced visual acuity from pathologies such as macular degeneration. HCPs suggested colour and pictures to enhance engagement of PwP and caregivers.

“For ease of use, it would have to be a written format, or pictures... pictures makes things much more interesting... the more text the less inclined they are to read it.” Participant 4 (PDNS)

5.3 Discussion

5.3.1 Overview of the Results of this Study

This study explored HCP's experiences of falls, falls management in PwP and their views on suitable future self-management materials. This included their own experiences of helping to prevent and manage falls in this population as well as their interpretations of patient and family experiences.

There were 12 participants in this study comprised of six PDNS, five physiotherapists and one occupational therapist. Perspectives of the occupational therapist were congruent with those of the physiotherapists taking part. HCPs were able to provide an important overall perspective of the difficulties that PwP and caregivers experience in relation to falls, to include those who do not attend Parkinson's UK support groups.

From this study five themes were identified that provided a coherent representation of the data: (1) causes of falls and their consequences on PwP and their caregivers; (2) healthcare provision; (3) personalised healthcare; (4) limitations of healthcare in meeting patient's needs and (5) engagement versus disengagement of service users with healthcare. One further theme detailed participant's views of the proposed intervention. Throughout this discussion, the findings of this study will be discussed in the context of present literature, and will be compared and contrasted to the findings of the mixed methods study with PwP/ caregivers (phase one, chapter four) through the process of triangulation to provide a more comprehensive picture of the overall problem (202).

5.3.2 Perspectives of Fall Risk

HCPs described the heterogeneous nature of falling in PwP, congruent with the views expressed by PwP and caregivers in phase one and with the published literature (25,26). HCPs, PwP and caregivers all discussed non-PD specific contributions to falling. HCPs often described how these non-PD-specific risks were modifiable, whereas PwP and caregivers in phase one were more likely to perceive them as non-modifiable. When designing falls-based literature for PwP and their caregivers it would be important to educate them of how fall risk may be amenable to change.

Nearly all HCPs described additional risks that cognitive impairment placed on fall risk, as has been highlighted in published literature (28). HCPs discussed how this heightened risk arose through reduced insight of PwP, with a lack of compliance with walking aids and HCPs advice.

Similarly, in phase one, caregivers with high caregiver burden, and caregivers of a PwP with cognitive impairment/ dementia voiced frustration when describing how the PwP did not always follow their advice or that of HCPs. A few HCPs, including PDNS and therapists, described how executive dysfunction increased fall risk. When designing falls-based interventions, it would be important to ensure that the difficulties associated with cognitive impairment/ dementia are recognised.

All HCPs described the negative emotional consequences of falling on PwP. When discussing fear of falling, PDNS and therapists felt that this was greatest amongst those who were cognitively intact. Triangulating the results from phase one and phase two, a few therapists echoed PwP in describing a sense of shock that PwP experienced at the onset of falling, suggesting a key period of vulnerability and time for intervention targeting.

5.3.3 Perspectives of the Role of Caregivers

All HCPs described the key role that caregivers play in the management of falls, echoing the results from PwP/ caregivers in phase one and the existing literature (42,199). In phase one, caregivers described supporting PwP up from the floor and acknowledged the personal risk of physical injury to themselves, as has been reported in the previous literature (42). In this study, PDNS often described advising caregivers not to lift the PwP up from the floor and referring them to physiotherapy for ongoing support. However, physiotherapists within this study did not always recognise this risk that caregivers placed upon themselves. HCPs described how caregivers could restrict the activity of the PwP to manage concerns of falling, and therapists discussed the adverse physical consequences of this such as muscle wasting (24,198). However, in phase one, not all caregivers appeared aware of the negative consequences associated with sedentary behaviour. In relation to injury concerns, these appeared significant amongst PwP and their caregivers, whereas HCPs could be dismissive. These discrepancies highlight areas of impaired inter-professional and patient- professional communication.

Caregivers have previously reported that HCPs are ignorant of their needs (49). In this study, HCPs perception of caregiver difficulties appeared incongruent with the degree of difficulties reported by caregivers in phase one. This inconsistency may be explained by the method through which caregivers were recruited in phase one. Caregivers in phase one may have been more likely to participate if they were experiencing greater difficulties; the perspective provided by HCPs may be more in line with the true overall level of difficulties experienced by caregivers. Another explanation may relate to the reactive process through which HCPs identified caregiver difficulties; suggesting a true discrepancy between caregiver and HCPs views. Furthermore,

caregivers within phase one were often reluctant to ask for external support from HCPs, as has been reported in previous studies (42,199). Reactive behaviour of HCPs has also been described in relation to palliative care discussions in PwP and restrictions of care in other chronic neurological conditions (204,205). In this study, a minority of HCPs described how adopting a more proactive approach had led to positive outcomes.

5.3.4 Perspectives of Healthcare Provision and the Role of the Multi-disciplinary Team (MDT)

All HCPs described how falling was routinely monitored at the time of clinical review, congruent with the views of most participants in phase one. However, previous comparison of retrospective and prospective falls data has identified that PwP do not always inform HCPs of their falls (28). PDNS described their role as a 'case manager', providing information to PwP, signposting and acting as a point of contact. The ability of nurses to act as mediators in explaining information to patients, has been identified as a facilitator to patient-centred care and shared decision making (206). However, in phase one, PwP and caregivers frequently described appearing lost within the healthcare system, and perceived they themselves were the case managers, which may suggest that there is not an effective system in place for the management of falls.

Previous literature has highlighted that PwP may not discuss falling with HCPs (28). Some HCPs in this study attributed this to PwP perceiving falls as unpreventable or embarrassing. A few HCPs described how PwP may not like to be labelled as a 'faller', and may not accept falls risk due to concerns of altered identity, consistent with the reported literature (27). Stigma of falling was also acknowledged by PwP and caregivers in phase one; this has also been reported previously (27). When designing falls literature, it is important that terminology is used that is identifiable to PwP to enhance its acceptability (207).

HCPs from all disciplines described how therapists managed the risks and consequences of falling. Physiotherapists expanded on the information provided by PDNS and described empowering the PwP to become their own health coach through teaching them problem-focused strategies to overcome difficulties that they could experience. A few HCPs discussed how PwP may be unsure of the roles that HCPs can play in falling, in keeping with the results from phase one. Misperceptions held by PwP of HCPs roles has previously been highlighted as a barrier to PwP accessing specialist palliative care (205).

In line with NICE guidelines, and the published literature, HCPs reported that PwP's needs were best met through the involvement of the multidisciplinary team (MDT) (38,208). However, HCP's

descriptions of the MDT were often fragmented, with suboptimal information flow between professionals, which has previously been identified as a barrier to patient-centred care in PwP, and to empowerment of older people in their healthcare (44,84,206). There was a sense that HCPs were unsure of the roles of other professionals within the MDT, with PDNS perceptions of the therapist role differing to that described by the therapists themselves. This discrepancy has been reported previously in relation to the role of HCPs in palliative care in PD (205). HCPs rarely described how they followed up the outcome of a referral, and often presumed that no news was good news. However, in phase one, PwP and their caregivers described feeling lost within the healthcare system and could self- instigate significant adaptations to their house in response to a lack of HCPs support. A previous review of integrated care programmes for chronically ill patients found those containing self-management support and patient education were able to improve fragmentation of care (209).

The NICE guidelines recommend that HCPs consider early referral of PwP to generalised physiotherapy, with specialist physiotherapy when PD- specific problems arise (38). In phase one, PwP often reported unmet therapy requirements, consistent with the latest national audit of PD care conducted by Parkinson's UK (200). In this study, many HCPs discussed how long waiting times to access therapy could lead to adverse outcomes for the PwP. A previous study conducted in the Republic of Ireland, found that long waiting times were also a barrier to PwP accessing specialist palliative care and led to adverse outcomes in PwP (205).

Given the varied and comprehensive roles that HCPs can play in falls management, it is imperative that PwP and caregivers are supported to communicate with HCPs about falling so that they are able to access these services. It is important to challenging the stigma associated with falling and the perception that falling is unpreventable to ensure that PwP and their caregivers receive access to timely advice and support. Education of the roles of HCPs in falls-management, could allow PwP and their caregivers to act as facilitators for joined up healthcare and improved professional-patient communication.

PwP have previously reported a preference for holistic healthcare; HCPs should be encouraged to recognise the individual needs of PwP and encourage them to become engaged with their healthcare (44,82). Holistic care has been identified as a facilitator to the empowerment of older patients in shared-decision making (84). HCPs in this study described adapting management plans to the heterogeneity of the condition and to intra-individual variations. HCPs identified barriers to PwP transforming HCPs advice into practice, which could be more pronounced in those with cognitive impairment/ dementia. HCPs described delivering advice in manageable chunks and repeating information to enhance the likelihood of it being implemented. HCPs raised that PwP

may not use a walking aid due to perceptions of how they would be viewed by others, which was also raised by PwP in phase one. HCPs often altered their advice so that it was acceptable, realistic and attainable for PwP, which has previously led to improvements in HRQOL in PwP who fall (139). Assessment of PwP in their home was valued by HCPs for its ability to identify insights into personal risk. The benefits of home assessment have previously been highlighted by GPs in the setting of advanced PD (112). When designing falls-based literature for PwP it must recognise the heterogeneity of PD and provide realistic and achievable recommendations.

5.3.5 Information Provision as a Facilitator of Patient-centred Care

PwP have reported a preference for information about PD and for autonomous decision making (112,113). Enhanced patient-professional communication, and involvement of PwP in their care has led to improvements in treatment compliance, clinical outcomes and patient satisfaction (82,114). To be actively involved in decision-making, PwP require information about their condition in order to make informed decisions about their treatment goals and preferences (82,210). In line with the NICE guidelines, all HCPs described providing PwP and caregivers with information about PD, but the provision of information about falling could be associated with unease or uncertainty (38). HCPs could be concerned that providing information about falling could lead PwP to feel overwhelmed. Feeling overwhelmed may lead PwP to experience anxiety and to become dis-engaged (90). HCPs often discussed concern of triggering or exacerbating worries that the PwP might have in relation to PD progression. Concerns relating to discussions about disease progression have previously been reported by HCPs involved in the care of people with multiple sclerosis (211). In phase one, some PwP described how they adopted distancing as a coping strategy, and caregivers have previously reported difficulty in initiating discussions in relation to advancing PD (199). The current strategy adopted by many PwP, caregivers and HCPs may mean that patient's information requirements and concerns are left unmet. Encouraging PwP, caregivers and HCPs to participate in discussions about falling is required to ensure that PwP and their caregivers have access to timely advice and support.

Written information can provide an aide memoire of discussions held with HCPs to facilitate shared-decision making (206). HCPs in this study described information packs that were distributed by PDNS at the time of PD diagnosis. However, falls-related information was not always included and engagement of PwP with this information was often perceived to be limited. In phase one, PwP and caregivers occasionally described having never received falls-based information; where they had received it, some caregivers had not read it as they had thought that

it was not addressed to them. Falls-based literature for PwP and their caregivers should be engaging and explicitly addressed to both parties to increase the likelihood of it being read.

5.3.6 Engagement of PwP with Healthcare and Third Sector

Support

In this study, some PDNS and therapists described perceiving some PwP to be disengaged or to adopt a passive role with their healthcare. Advancing age and dementia have previously been highlighted as a barriers to shared-decision making (82,206). Additionally, those who are older may view HCPs as authoritative figures who are not to be questioned, and those with dementia may be less able to contribute (82,206). HCPs in this study described imparting substantial information on PwP and caregivers without consideration of how this information was received or acknowledging possible disempowerment as a barrier to participation. Triangulating the findings from phase one and phase two, the extensive self-taught coping strategies described by PwP and caregivers did not appear to be acknowledged by HCPs. Ignorance of HCPs in relation to the knowledge and self-management skills held by people with other LTCs has been reported previously (85). For patient-centred care to take place, patients must feel able to influence decision making processes (206). When designing falls-based literature for PwP and their caregivers it is imperative that their individual needs and pre-existing knowledge and skills are recognised to encourage patient empowerment and involvement in decision-making processes.

In this study, HCPs perceived few PwP and caregivers to have accessed information independently, which is congruent with the findings from PwP and caregivers in phase one. PwP have previously reported benefits of signposting, and HCPs in this study often signposted to information available on the Parkinson's UK website (119). However, HCPs had received little feedback about these resources and often acknowledged a lack of computer use in PwP and caregivers, which is in keeping with the results from phase one and what has been reported elsewhere (212–214). HCPs perceptions of the resources that local Parkinson's UK groups were able to provide contrasted the descriptions provided by PwP and their caregivers in phase one. HCPs described that support groups delivered education about PD and therapy services not available within the NHS, whereas PwP and caregivers were more likely to describe how they provided social support. The perceptions of PwP and their caregivers are in keeping with PwP perceptions of Parkinson's UK groups in the existing literature (15,196).

HCPs identified that concerns about disease progression could prevent PwP from attending Parkinson's UK support groups, where they could meet with those with more advanced PD. A qualitative study with PwP and their caregivers, in which all PwP participants had a Hoehn and

Yahr stage of one to three, identified that whilst PwP liked contact with their peers, this was on the premise that it was tailored to their disease stage (44). It is important that these concerns are recognised and that individuals can access support outside of Parkinson's UK groups where PwP deem them unacceptable.

5.3.7 Perspectives about the Self-management Intervention to be Produced

When describing the intervention to be produced, HCPs thought that information should be focused to increase the likelihood of it being used. The provision of relevant, patient-centred information has been reported to be associated with enhanced empowerment and engagement (84,90). PwP, caregivers and HCPs felt that an online medium would be less acceptable to PwP, which is in keeping with what has been reported previously (212,214). PwP, caregivers and HCPs all perceived the use of colour would increase the acceptability of the intervention, which is in keeping with the published literature (120).

HCPs perceived that the intervention should aim to facilitate enhanced communication between PwP and HCPs and suggested that this might be achieved through the inclusion of a section for PwP and caregivers to log falls. Increased frequency of symptom checking has previously been associated with improved self-management in PwP (94). PwP have previously reported that they would be interested in logging their symptoms, and that this might enhance their understanding of their symptoms, communication with the healthcare team and their ability to cope (113).

5.3.8 Limitations

HCPs were invited to participate through their involvement in the Wessex Parkinson's Excellence Network which may have introduced selection bias. This recruitment strategy may have attracted those who have strong views about the experiences of falling and its management. HCPs in this study may have had a greater understanding of the difficulties experienced by PwP and their caregivers, than those of other HCPs. Therefore, the mismatch between the difficulties that PwP and caregivers experience, and how they are perceived by HCPs without such experience in PD may be greater than those reported in this study. Where HCPs discussed their role in the management of falling, these may be more expert in comparison to HCPs who did not participate. Furthermore, locally, considerable research has been conducted in the PD population, which participants in this study may have been involved with. Overall selection bias might have

produced an overly positive account of interest in and involvement in falls management by HCPs who work with PwP.

The sample size was estimated through the concept of 'information power', participants provided a rich data set and at later stages of data analysis no further concepts were forthcoming, suggestive of data saturation (173,174). However, the perspectives of HCPs from other geographical regions and those with less experience of PD were not explored.

Through the recruitment method that was adopted, only one occupational therapist elected to take part in this study. In comparison to PDNS and physiotherapists, occupational therapists are likely to have a reduced frequency of clinical encounters with PwP and caregivers. Therefore, the breadth and depth of the information that they provide of their own experiences of falls, and their perception of the experiences of PwP and caregivers, is likely to be lower than that of PDNS and physiotherapists. Whilst the views of the occupational therapist were congruent with those of the physiotherapists who took part, and allowed for conclusions to be drawn, occupational therapist's views could be explored further through interviewing additional occupational therapists identified through different recruitment methods.

Data was collected from a combination of dyad and single participant interviews. Dyads often provided enhanced information through the exchange of stories and discussion. Whilst this could not be reproduced in single participant interviews, I attempted to overcome this by using probes and prompts to achieve a comprehensive data set. Dyads rarely expressed differences in their opinions. Through congruency in the questions asked in single and dyadic interviews, data were able to be combined for data analysis (180).

5.4 Key points

- This qualitative study aimed to explore HCPs experiences of supporting PwP and caregivers in the management of falls, and views on future self-management interventions. This included their own experiences of helping to prevent and manage falls in this population as well as their interpretations of PwP and caregiver experiences.
- Five themes were identified that provided a coherent representation of the data: (1) causes of falls and their consequences on PwP and their caregivers; (2) healthcare provision; (3) personalised healthcare; (4) limitations of healthcare in meeting patient's needs and (5) engagement versus disengagement of service users with healthcare. One further theme described participant's views about the proposed intervention.
- HCPs described the heterogeneous nature of the difficulties experienced by PwP, and the key role that caregivers play in falls management. In the setting of cognitive impairment or dementia, falls risk and caregiver difficulties were increased.
- HCPs addressed the needs of the dyad through personalised care that was provided through the MDT. However, HCPs were sometimes unsure of other HCPs roles, and communication within the MDT could appear fragmented.
- HCPs identified barriers to dyads accessing and implementing HCP advice and support. PwP could be perceived to view falling as unpreventable, with non-acknowledgement of falls risk. Caregivers were perceived as stoical, but their needs were frequently identified reactively.
- Dyad's engagement with current falls-based literature was often recognised as poor; HCPs sought to overcome this through providing relevant information in manageable stages.
- Current healthcare provision may leave the varied needs of dyads unmet. Challenging dyad's misperceptions of falling, and engaging them with falls-management, may enhance communication between them and HCPs. This may in turn lead to greater identification and management of their needs.
- Results from this study together with relevant insights from the background literature (chapter one), the results from my systematic review of falls-based self-management interventions for PwP (chapter two) and the results from my mixed methods study with PwP and caregivers (phase one), were triangulated to inform the development of a falls-based self-management intervention for PwP and caregivers (chapter six).

6 Development and Usability Testing of the Intervention (Phase Three)

This chapter reports the development and usability testing of a prototype of the self-management intervention. The intervention aimed to support the self-management of falls in all community dwelling PwP and their caregivers, to include those with cognitive impairment/ dementia and those with more advanced PD. Modifications were made to the intervention through an iterative approach to produce the self-management intervention which was evaluated in the subsequent feasibility study (phase four, chapter seven, page 179).

6.1 Methods

This phase was conducted through the following stages (Figure 6-1):

- (i) Development of the prototype of the self-management guide
- (ii) Development of a logic model
- (iii) Usability testing of the prototype of the self-management guide
- (iv) Modification of the intervention

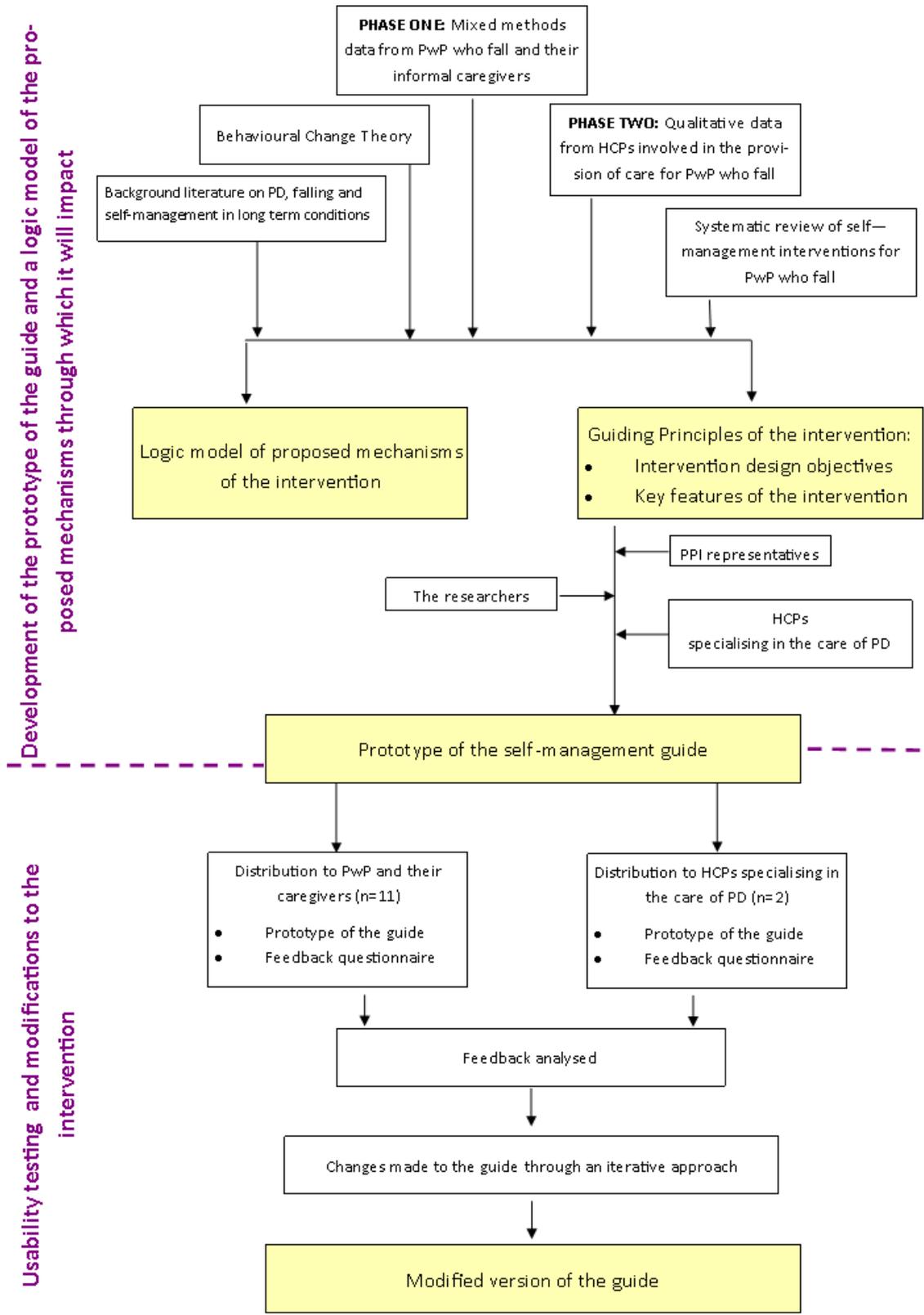


Figure 6-1 Overview of Phase Three

(i) Development of the Prototype of the Self-management Intervention

A key phase of designing an intervention via the Person- Based Approach (PBA) is to use all the evidence available to generate guiding principles (22,153,155–157,159,215). I triangulated the data from the background literature, the systematic review of falls-based self-management interventions, and phases one and two to describe the issues, needs and challenges experienced by PwP who fall and their caregivers (22). These were termed the ‘Intervention design objectives’ (Appendix E1). ‘Key features of the intervention’ were identified to meet each of these objectives (Table 6-1). Together the ‘intervention design objectives’ and the ‘key features of the intervention’ formed the ‘guiding principles of the intervention’ from which the intervention was developed (Table 6-1).

A prototype of the intervention was developed through an iterative approach with incorporation of feedback from patient and public representatives (PPI), experts in behavioural change, and HCPs specialising in the care of PwP. The intervention consisted of a paper-based guide alongside telephone calls providing support (Appendices E2 and E3). PPI feedback was provided from individuals with either a diagnosis of PD, or prior experience in a caregiving role. These PPI representatives contributed to the language, presentation and content of the paper-based guide.

(ii) Development of a Logic Model

Drawing from the MRC guidance of process evaluation of complex interventions, a logic model was developed (216). A logic model provides a visual representation of the current problems experienced by PwP and their caregivers, and the hypothesised mechanisms through which the intervention will act to achieve the intended outcomes (152,153,157,217).

(iii) Usability Testing of the Prototype of the Self-management Guide

Study Design

The prototype of the paper-based self-management guide underwent usability testing. PwP, caregivers and HCPs provided feedback through questionnaire-based survey. Participants did not use the guide during this period, and they did not receive the support telephone calls.

Participants and Data Collection

A convenience sample of PwP, caregivers and HCPs involved in the care of PwP who fall took part. I recruited PwP and their caregivers from local NHS PD outpatient clinics and a Parkinson's UK support group, which I attended between 13.12.2017 and 10.01.2018. All individuals, with the exception of those who had taken part in phase one, who attended these services were invited to participate irrespective of a history of falls. I recruited HCPs through convenience sampling.

PwP and caregivers were provided with an information sheet about the study, a copy of the prototype of the guide and a feedback questionnaire (Appendices E2, E4 and E5). PwP and caregivers were asked to provide feedback about the content and format of the guide to include whether they would be likely to use it, if the guide altered any of their concerns about falls, and if they would be confident applying the information to their daily routine (Appendix E5).

HCPs were provided with the same questionnaire but could provide feedback in a narrative.

Data Analysis

I entered responses to questionnaires into Microsoft Excel, which were double checked for discrepancies. I calculated mean values of responses to Likert-type questions and analysed responses to open ended questions through content analysis (described in phase one, chapter four, page 77).

(iv) Modification of the intervention

The intervention, consisting of a paper-based guide alongside telephone calls providing support, was modified using an iterative approach, to produce the version that was evaluated in the feasibility study (phase four, chapter seven, page 179) (Appendices E6, E7, E8).

6.2 Results

6.2.1 Development of the Prototype of the Intervention

6.2.1.1 The guiding principles of the intervention

Data from the background literature, my systematic review of falls-based self-management interventions for PwP and phases one and two were triangulated. Five intervention design objectives were identified: (i) the intervention should provide information about falling, challenge

common misperceptions and suggest strategies for the successful management of falls, (ii) the intervention should recognise the key role that caregivers play in the management of falls, (iii) the intervention should be presented in a clear and acceptable format using appropriate language that encourages user autonomy, (iv) the intervention should motivate the adoption of self-management strategies through using the appropriate theory and (v) suggestions should be described clearly to increase their adoption amongst PwP and caregivers (Appendix E1). To meet the intervention design objectives, 30 Key features of the intervention were identified (Table 6-1). A narrative of the data contributing to each the intervention design objectives and how these will be addressed is presented below.

Table 6-1 Guiding Principles of the Intervention

Intervention Design Objective	Key Feature of the Intervention
<p><u>Intervention design objective one:</u> The intervention should provide information about falling, challenge common misperceptions and suggest strategies for the successful management of falls</p>	<ul style="list-style-type: none"> • The intervention will contain information about falling and how falls can be managed • The intervention will discuss the different aetiologies of falling in PD to include the most raised difficulties. It will provide suggestions of how to manage in each of these different situations. • Within the guide, each potential cause of falling will provide several suggestions as to possible ways that might help, and ask for users to think about which of these might help them • The guide will seek to address the commonly held concerns that PwP and caregivers hold in relation to falls management, and try to re-frame commonly held misperceptions • The guide will challenge the idea that falling is unpreventable • The guide will promote ongoing physical activity of PwP, address the barriers to this, and provide evidence as to why this is important • The guide will contain information about non-PD specific causes of falling, challenge the idea that these are unpreventable, and suggest ways in which PwP and caregivers can address these • The guide will contain information and strategies that can be performed independent to HCPs, whilst awaiting, or as a reminder of HCPs opinion • The Guide will provide advice and support for helping PwP and their caregivers when the PwP is on the floor. It will seek to challenge the perception that caregivers should help the PwP up from the floor • The guide will inform of the roles of HCP in falls management, suggest ways that they are able to help and promote interaction with them • The guide will provide signposting to additional resources for support. • The guide will promote sources of social support for PwP and their caregiver, to and advise of their benefits
<p><u>Intervention design objective two:</u> The intervention should recognise the key role that caregivers play in the management of falls</p>	<ul style="list-style-type: none"> • The guide will be targeted toward and contain information for both PwP and caregivers • The guide will emphasise the importance of caregivers

Chapter Six: Development and Usability Testing

Intervention Design Objective	Key Feature of the Intervention
	<p>having time for themselves and in supporting the PwP to mobilise</p> <ul style="list-style-type: none"> The guide will seek to promote communication between the PwP and the caregiver
<p><u>Intervention design objective three:</u> The intervention should be presented in a clear and acceptable format using appropriate language that encourages user autonomy</p>	<ul style="list-style-type: none"> The guide will seek to empower PwP and their caregiver to take control of falls management The guide will aim to increase the confidence of PwP and caregivers through management of falls through promoting autonomy and competence. It will provide suggestions as to what might help, alongside the evidence basis as to why it might work. The guide will be able to be individualised by users The language within the guide will be without the use of medical jargon and will have a positive tone The guide will explain the positive consequences associated with suggestions within the guide, as identified through phase one and phase two The guide will be made available in paper format. The guide will seek to engage through the appropriate use of colour and pictures, and will be easy to navigate The guide will be interactive
<p><u>Intervention design objective four:</u> The intervention should motivate the adoption of self-management strategies through using the appropriate theory</p>	<ul style="list-style-type: none"> The guide will promote the use of problem-focused coping through suggesting strategies that might help, and user identification of those that might help them. The guide will contain quotes from other PwP and caregivers of how they have successfully managed to adapt or change a situation to manage their falls risk The guide will contain an action plan for falls management The guide will require minimal researcher input and will provide ongoing support. It will encourage PwP/ caregivers to seek further review with HCPs should their needs change. It will provide information about how these HCPs can help them
<p><u>Intervention design objective five:</u> Suggestions should be described clearly to increase their adoption amongst PwP and caregivers</p>	<ul style="list-style-type: none"> The guide will suggest strategies through a step by step approach The guide will acknowledge the intra-individual variability of PD and will encourage PwP to persist with changes should they not initially succeed.

Intervention Design Objective One: The intervention should provide information about falling, challenge common misperceptions and suggest strategies for the successful management of falls

For a self-management programme to be effective, it is imperative that PwP and their caregivers are provided with the appropriate knowledge and skills to allow for them to make informed decisions about their care (40). PwP and Caregivers have reported a paucity of information about falling, and may feel unprepared when the PwP starts to fall (data from phase one, phase two and (43)).

The paper-based guide contained information about the varying aetiology of falls in PD and how to manage them. The aetiologies of falling described included the most common difficulties raised by PwP, caregivers, and HCPs in phases one and two, to include freezing, postural hypotension, multitasking, turning, perceptions of tripping and rushing.

To increase engagement and the effectiveness of the intervention, the intervention sought to address user's commonly held concerns, and reframe possible misperceptions (218). Self-efficacy can be improved through reframing of symptoms, to allow for exploration of symptoms to manage a situation (79). Phases one and two identified how PwP are commonly fearful of falling, which can lead to avoidance of defined activities, reduced social interaction and exacerbation of falls risk. Given that a decline in physical activity can lead to increased fear of falling, increased falls, and reduced mobility, this strategy is likely to be counter-intuitive (24,31,198,219). Similarities exist between individuals who fall and individuals with chronic pain, in that both groups exhibit avoidance behaviours in relation to activities that they perceive to provoke their symptoms (219,220). Vlaeyen et al. hypothesised that in many individuals with chronic pain there is a vicious cycle, whereby individuals avoid activity due to fear of (re)injury, leading to adverse physical and psychological consequences, which in turn maintains pain (220). Figure 6-2 depicts adaptation of cycle to falling in PwP. The guide sought to intercept this cycle and encouraged PwP to remain active, through addressing the 'belief' that engagement in any physical activity leads to falling. The guide explains the benefits of physical activity and suggests adaptations to achieve this.

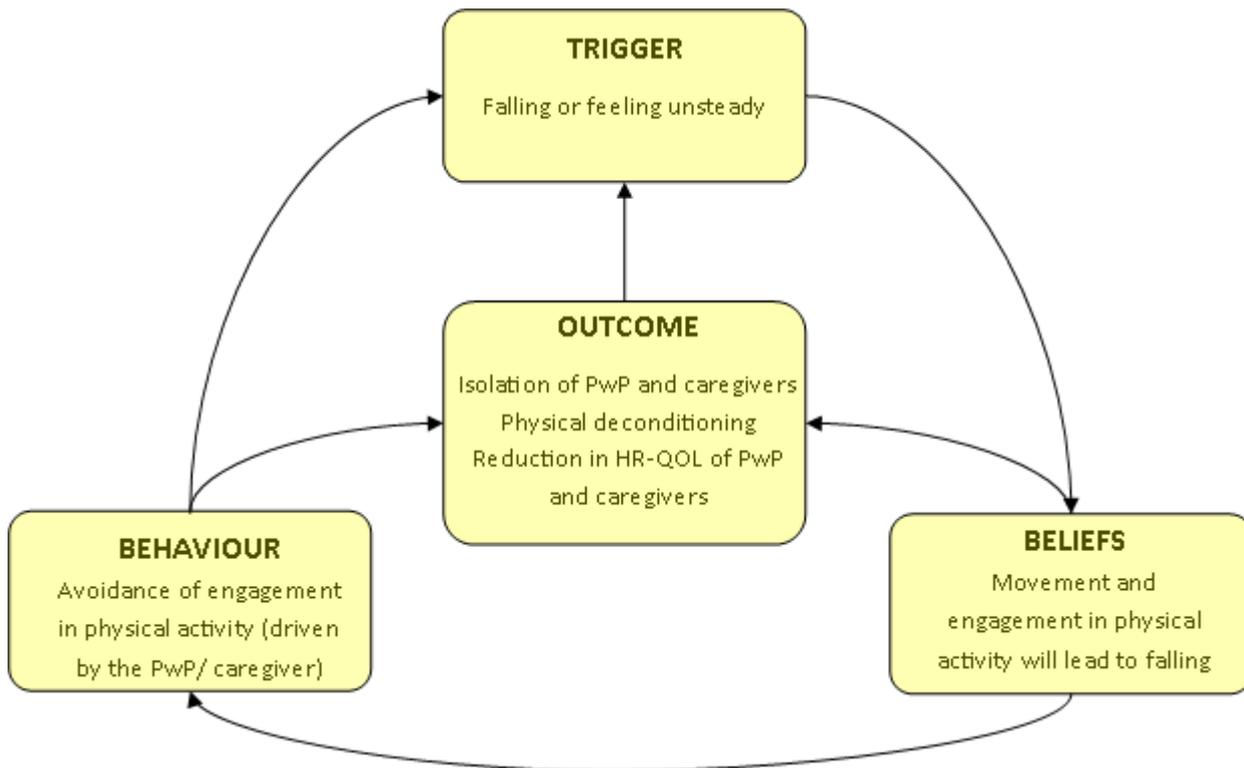


Figure 6-2 Cycle of fear of falling leading to activity avoidance experienced by PwP

Source: Adapted from Vlaeyen et al (220)

In line with the previous literature, in phases one and two it was discussed how PwP and caregivers could believe that environmental contributions to falling are non-modifiable or that falling is unpreventable (20,194). The guide sought to challenge these misperceptions.

PwP and caregivers may be unsure of the roles that HCPs play in the management of falls (phase one and (112)). They may not inform them of falls or fail to seek timely access to support following a fall (phases one and two, (28,42,43). The guide provided advice for PwP and caregivers as to what to do after a fall, to include calling 999. It described HCP’s roles in falls management and suggested ways that they might be able to help, aiming to improve patient-professional communication, which may enhance physical and psychological outcomes (28,79,200).

The guide provided signposting to additional sources of support. PwP and their caregivers have previously been positive of signposting to health and social care services, and the Corbin and Strauss Framework states that for effective self-management an individual requires knowledge of the resources that are available, in addition to how they can help and how to access them (79,119). In phase two, HCPs described signposting/ referring without full understanding of what the service they were referring to provided. In contrast, the guide described how third-party

sources of information might support PwP/ caregivers, to allow PwP and caregivers to understand how these resources might benefit.

Intervention Design Objective Two: The Intervention Should Recognise the Key Role that Caregivers Play in the Management of Falls

Caregivers play a significant role in the management of falls, which often increases in the setting of cognitive impairment or dementia. Falling increases with increased caregiver burden, and caregiver needs are often left unmet (phase one, (42,52,200). Through addressing the concerns of caregivers, the guide may help them to feel better equipped to manage falls, which could potentially reduce caregiver burden. Effective family member support has been reported to improve measures of general self-efficacy in PwP (94). Targeting the intervention toward caregivers may lead to improvements in caregiver's ability to provide PwP with support and could impact on PwP's self-efficacy.

Phases one and two described reduced social interaction amongst caregivers arising from a fear of leaving the PwP alone. Reduced social interaction is a significant contributor to caregiver burden (52). The guide emphasised the benefits of ongoing physical activity in caregivers and suggested strategies to allow continuation of their current hobbies and interests.

The guide promoted discussion of falls within the dyad. Distancing, an emotion-focused coping strategy, has been associated with negative outcomes (16,18,197). In phase one (chapter four), PwP and caregivers spoke positively of the discussion of falls with each another and described how it had helped them.

Intervention Design Objective Three: The Intervention Should be Presented in a Clear and Acceptable Format Using Appropriate Language that Encourages User Autonomy

In phase two, therapists described encouraging PwP to take control of their diagnosis through teaching strategies to overcome difficulties that might be encountered. The guide suggested strategies that might help to reduce fall risk in different circumstances and sought to empower PwP and caregivers to take control. Empowerment is associated with improved health outcomes and greater satisfaction (91,92).

Underpinned by self-determination theory (SDT), the guide used language to promote autonomy. PwP have reported a preference for autonomous decision making, and respecting autonomy increases the likelihood of a behavioural change being initiated and maintained (95,112). The guide explained the positive consequences that may arise following adoption of the strategies

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that it described. Behavioural change is more likely to be initiated and maintained if associated with personally valued outcomes (93). The guide described how adopting the strategies within it might enhance PwP/caregivers' understanding and control of falls; these objectives were identified as important to PwP and caregivers in phase one (chapter four).

When information is deemed relevant is more likely to be read, and users are more likely to be empowered to instigate change (120,149). The majority of PwP, caregivers and HCPs in phases one and two were keen that the guide remained succinct. Users were encouraged to identify and read only the content relevant to them. Given the considerable breadth and depth of information that could be contained within an information resource about falling in PD, I utilised signposting to reduce disengagement and information overload (90). The guide was developed to be interactive, which HCPs in phase two felt would enhance user engagement. The guide contained sections to fill in or activities to complete.

The guide avoided medical jargon, and language was positive. People who fall may not self-identify as a 'faller' (27,207,221). Therefore, the guide utilised the word 'steady' to increase acceptability. Acceptability was also increased through producing it in a colour, paper-based format (phase one, (120,212,214)).

Intervention Design Objective Four: The Intervention Should Motivate the Adoption of Self-management Strategies Through Using the Appropriate Theory

The guide promoted problem-focused coping strategies, which are required for effective self-management and are associated with improved psychological outcomes in both PwP and caregivers (79,189,191). Problem-focused coping strategies are more likely to be adopted over emotion-focused coping strategies when a situation is deemed modifiable. The guide described the preventable nature of falls and suggested strategies that might help (193). In phase one, PwP and caregivers described frustration when they were unsure of the aetiology of a fall. The intervention promoted the use of problem-solving to support PwP and caregivers to understand the aetiology of their falls, it encouraged users to think about why the PwP might have fallen and how they might feel more in control (191).

The guide contained quotations from other PwP and caregivers (sourced from the interviews in phase one). These quotes described how they had successfully been able to adapt or change a situation to manage their falls risk to provide a 'model' for social learning to take place (79,222). Promoting accurate perceptions of a condition and the strategies through which an individual can initiate change, with previous examples of success, can increase adherence with self-management

interventions (218). In phase one, participants spoke fondly of their discussions of living with and coping with PD with other PwP at Parkinson's UK support groups. The guide aims to create a sense of connection with other PwP and caregivers via the use of quotes and stories.

The guide contains two interactive sections: (i) a falls diary and (ii) an action plan. PwP have reported that they would be interested in logging their symptoms, and how this might facilitate an increased understanding of their condition and their ability to cope (113). Increased symptom checking in PwP is an independent predictor of improved self-management in PwP (94). Self-efficacy can be improved through 'performance mastery', which involves the production of an action plan to execute the targeted skill. Successful completion of an action plan may increase user's self-belief that they are able to manage falling and provide them with a sense of control over the outcome (79). Including an action plan might also improve patient-professional communication; adopting a collaborative approach has led to cost-effective improvements in the quality of care provided to older patients with LTCs (82).

The guide requires minimal interaction with HCPs. The engagement of users, and the health and behavioural outcomes achieved, are likely to be greater when an intervention is delivered with human contact and support (223). However, an intervention that requires minimal researcher/clinician input is more likely to be cost-effective than formal education programmes due to reduced professional-patient contact time, and is also more likely to be feasible and replicable on a larger scale to be available to all PwP (59,72,224). In addition, group-based self-management interventions in other LTCs have led to feelings of participant isolation or relapse in the improvements observed at programme end (37,85,102).

Intervention Design Objective Five: Suggestions Should be Described Clearly to Increase their Adoption Amongst PwP and Caregivers

Caregivers in phase one discussed the benefits of maintaining a calm approach, and relaxation amongst caregivers has been associated with reduced caregiver stress (196). The guide suggested strategies through a step-by-step approach.

In phase two, all HCPs highlighted barriers encountered when translating information and advice into practice. Some HCPs placed importance on the intervention containing realistic suggestions and acknowledged the limitations placed on an individual arising from PD. The guide acknowledged the intra-individual variability of PD and encouraged PwP to persist with changes should they not initially succeed.

6.2.1.2 Overview of the Prototype Produced

The self-management intervention produced consisted of a paper-based guide alongside brief structured telephone support. The paper-based guide was designed to contain the active components of the intervention (217) (Appendix E2). However, an important part of whether these components are in any way helpful is whether the person looks at them and engages with them. Therefore, the telephone support contains components specifically to achieve this through promoting use of the guide by participants through describing how it might be able to help them (Appendix E3).

The Paper-based Guide

The paper-based self-management guide provided information about falling and strategies to support PwP and caregivers (Appendix E2). A summary of each of the sections is described below.

Introduction

Information in this section sought to relate to PwP and caregivers' perceptions of falls, aiming to increase user engagement. The introduction outlined who the guide had been designed for, a summary of its contents and how to use it.

Section One: What Causes Falling and What Can I Do to Help

This section provided knowledge relevant to all PwP who fall. It sought to provide information about falling in PD, and to address commonly held concerns and misperceptions. Falling was described as common, but not a certainty in PD; seeking to challenge the view that falling is inevitable and unpreventable. The guide encouraged PwP to remain active, with explanation of why this might help and suggestions as to how it might be achieved.

The guide described the different roles that HCPs play in the management of falls and addressed barriers to PwP/caregivers seeking HCPs support, as identified in phases one and two.

The intra and inter-individual variability of falling and PD was described, and users were encouraged to identify the parts of the guide likely to be relevant to them. There was a description of how using it might help PwP and caregivers to feel more in control of their symptoms, thereby acknowledging 'identified motivators' to change (93,95).

Section Two: Unsteadiness and Falls Diary

This section contained a diary to complete when the PwP felt unsteady or fell. It asked users to answer the following questions:

1. What were you trying to do?
2. Why do you think you felt unsteady or fell?
3. What worried you?

The diary facilitated individualisation of the intervention and promoted problem-solving, through encouraging users to identify the parts of section three that might help. Users were asked to take the diary to meetings with HCPs.

Section Three: Common Concerns and Suggestions

Eight topics were discussed within section three, informed by the needs and experiences of PwP and caregivers identified during phases one and two. Users were encouraged to identify and read the topics relevant to them. Each subsection provided possible suggestions routinely recommended by HCPs, alongside adaptations that other PwP and caregivers had found helpful. After identification of any strategies that they might want to try, users were encouraged to complete the action plan in section four. Discussion with HCPs about falls was encouraged throughout, with clear descriptions of this might help them.

Section 4: Personal Action Plan

Users were encouraged to self-identify difficulties, and strategies to try to overcome them, and to develop an action plan through completion of a table, which asked:

1. Their concern of interest
2. A suggestion that they would like to try
3. Outcome of any changes implemented

The guide encouraged users to modify strategies if they had not initially been successful.

Section 5: Useful contacts

This section contained information about how and why the following resources could be sourced/ contacted:

1. Parkinson's UK
2. Pendant alarms

3. Key safe
4. Social services
5. Blue badge application

Brief Structured Telephone Support

Alongside the self-management guide, the intervention planned to include brief (5-10 minute) phone calls to participants from myself at two, four and eight weeks (Appendix E3). During the telephone call, I planned to speak to both the PwP and the caregiver.

Telephone calls aimed to identify any difficulties experienced in using the guide and offer support and encouragement for the strategies that it contained. Brief structured telephone support has been reported to enhance the engagement of participants with self-management interventions (218,225).

6.2.2 Logic Model of the Proposed Mechanisms that the Intervention will Act to Produce Change

A logic model of the proposed mechanisms through which the self-management intervention would act to produce change was developed (Figure 6-3).

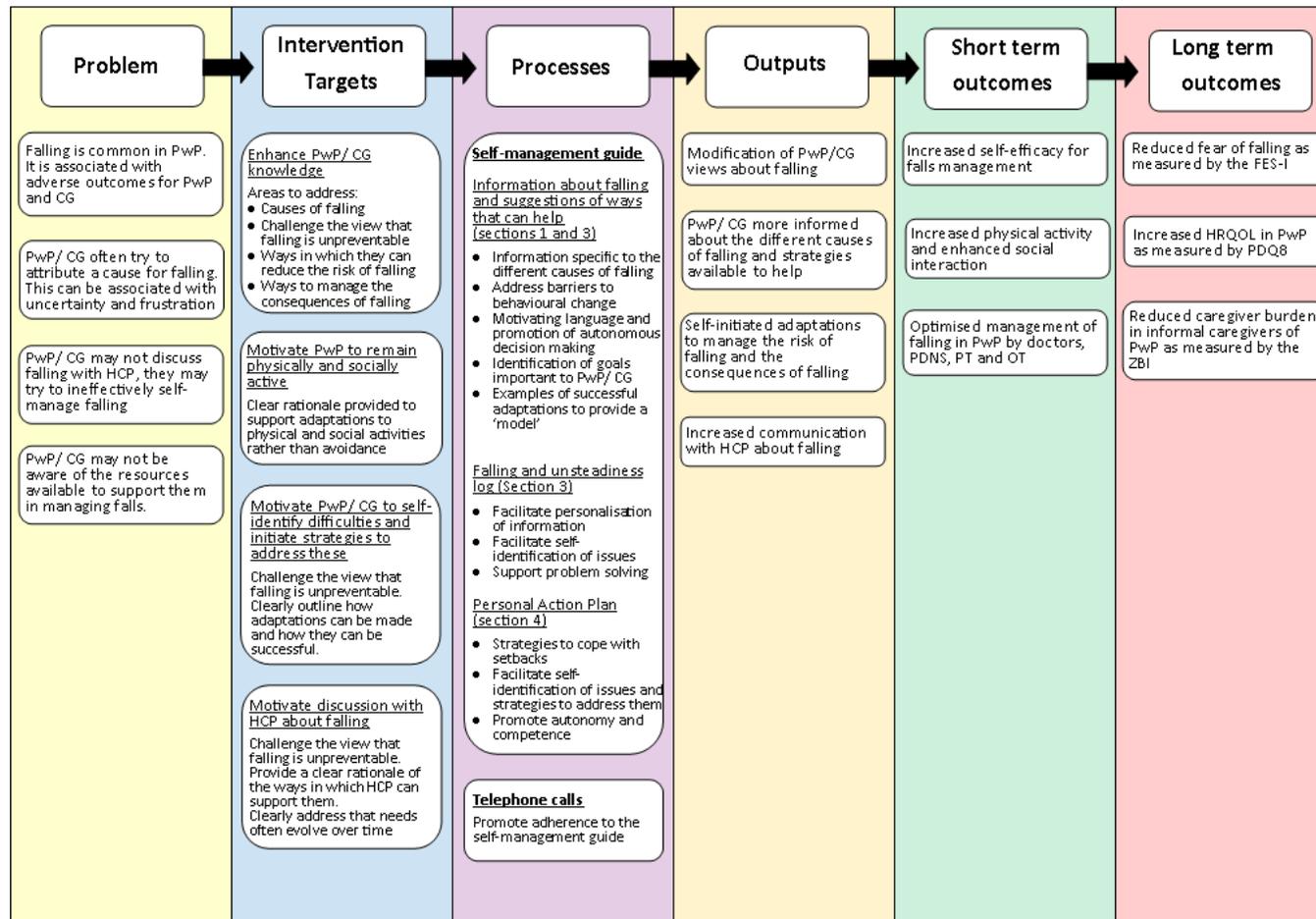


Figure 6-3 Logic model of the self-management intervention

Abbreviations: CG= caregivers; FES-I= Falls Efficacy Scale- International; HCPs= Healthcare professionals; HRQOL: Health Related Quality of Life; OT= Occupational Therapy; PDNS= Parkinson's disease nurse specialists; PT= Physiotherapy; PDQ-8: Parkinson's disease Questionnaire 8; ZBI: Zarit Burden Interview

6.2.3 Usability testing of the Prototype of the Intervention

6.2.3.1 PwP and their Caregivers

Characteristics of Participants

11 of the 33 feedback questionnaires distributed to PwP and their caregivers were returned. Participants included men and women, those with and without a history of cognitive impairment/dementia and those with and without a history of falls (Table 6-2).

Table 6-2 Characteristics of Participants Completing the Feedback Questionnaire

Participant Number	M/F	Cognitive impairment/ Dementia	Falls History	Presence of a caregiver	Recruitment Source	Questionnaire Completed by
1	M	Yes	Yes	No	Outpatient Clinic	Both
2	M	No	Yes	No	Outpatient Clinic	Caregiver
3	M	Yes	No	No	Outpatient Clinic	PwP
4	F	No	No	Yes	Outpatient Clinic	PwP
5	M	No	Yes	No	Outpatient Clinic	PwP
6	M	Yes	Yes	Yes	P (UK) support group	Caregiver
7	F	Yes	Yes	No	Outpatient Clinic	Caregiver
8	M	No	No	No	P (UK) support group	PwP
9	M	No	No	No	Outpatient Clinic	PwP
10	M	Yes	Yes	No	P (UK) support group	PwP
11	F	Yes	Yes	Yes	P (UK) support group	Caregiver

Abbreviations: M/F= Male/ female; P (UK)= Parkinson's UK

Feedback Received

PwP and caregiver responses to the questions are displayed in Table 6-3.

Table 6-3: PwP and Caregiver Feedback of the Prototype of the Intervention

Question (n)	Mean response* (SD)	Range of responses*
Do you think the content is useful? (n=11)	4.6 (0.5)	4-5 (n=11)
Does the guide increase your knowledge about falling and Parkinson's? (n=11)	3.8 (1.2)	2-5 (n=11)
How do you find the way in which the information is presented? (n=11)	4.4 (0.5)	4-5 (n=11)
Do you think the guide would be easy or difficult to use? (n=11)	3.8 (1.0)	2-5 (n=11)
Would you feel confident applying the information to your daily routine? (n=9)	4.3 (0.5)	4-5 (n=9)
Do you feel that the guide would alter any of the concerns you have about falling? (n=11)	3 (1.3)	1-5 (n=11)
Do you feel that this guide would alter your ability to manage your falls? (n=11)	3.7 (1.1)	2-5 (n=11)
Does the guide worry or concern you in any way? (n=11)	3.28 (1.0)	1-4 (n=11)
How likely is it that you would use the guide? (n=11)	4 (0.9)	3-5 (n=11)

*Response options were 1-5, higher scores indicate more favourable/positive responses

All felt the content within the guide was useful or very useful. When asked out the least useful part of the guide, responses were 'Section 4. Not sure it would be used', 'concerns of close friends and family', and 'repetition'.

Most (n=7) participants felt that the guide increased their knowledge about falling and Parkinson's. One who did not feel that it increased their knowledge said that it provided 'timely reminders'. None of the participants who felt that the guide did not increase their knowledge described information that they felt was missing. One participant, who felt that the guide did increase their knowledge, said that the guide needed more information about medications.

All were positive of the way in which the information was presented. Participants found the guide 'friendly but not condescending' and 'easy to understand'. Most (n=7) participants felt that the guide would be 'somewhat easy' or 'very easy' to use. Three were undecided. Only one participant felt that the guide would be 'somewhat difficult' to use, which was related to remembering to consult the guide in the future.

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All participants who responded (n=9) felt that they would be confident in applying the information to their daily routine. Three reported barriers. One described needing to become more familiar with the guide and one caregiver was concerned that they might not remember to use the guide as problems arose. One participant, a PwP who had not fallen, felt the guide might be difficult to use where a PwP had a high frequency of falls.

Five of the Eight participants who were from a dyad where the PwP had fallen, felt that the guide would alter concerns that they had about falling. One caregiver stated that the guide did not alter their concerns because they were already aware of the information that it contained.

Five of the eight participants who were from a dyad where the PwP had fallen felt that the guide would alter their ability to manage falls. One caregiver reported that the information within the guide was good, but the issue lay with getting the PwP to follow the advice. One PwP, who felt that the guide would be unlikely to alter their ability to manage falls, reported they had not had any falls since having the guide.

Only one participant stated that the guide led to concern. However, when this participant was asked whether there was anything that could be done to reassure them, they stated 'draws attention to the perils but also makes you more aware'. This suggests that the Likert scale (a quantitative measure) fails to capture the complexity of how concern (as a negative outcome) and awareness (a positive outcome) co-occur/ interact. One participant felt that they would be reassured through 'keeping in touch regularly'.

Six of the eight participants who were from a dyad where the PwP had previously fallen, including all participants where it was the PwP who completed the questionnaire, felt that they would be 'likely' or 'very likely' to use the guide. Two caregivers of PwP who had fallen were undecided. One caregiver explained that the difficulty was in relation to the PwP taking the information on board.

6.2.3.2 Healthcare Professionals

Two HCPs, one PDNS and one research physiotherapist with an interest in PD provided feedback in the form of a narrative. Tabulation of the comments and suggested changes from these HCPs is displayed in Table 6-4.

Table 6-4: Responses Received from Healthcare Professions Following Usability Testing of the Self-management Guide

Category of feedback	Healthcare professional one: Comments and Suggestions	Healthcare professional two: Comments and suggestions
Content	<ul style="list-style-type: none"> • Useful information: Info re staying active and prevention of falls and risk avoidance • I would have liked for it to clarify that falls and freezing do not respond to changes in PD medication • If falls are frequent then consider leaving a blanket, cushion and a flask at a low level in case of a long wait for assistance 	<ul style="list-style-type: none"> • The freezing section looks good, I like the flow! You may wish to add information about: <ul style="list-style-type: none"> - Freezing common on turning - Additional brief information about physiotherapy strategies to overcome freezing - De-cluttering home to keep areas obstacle free
Layout	<ul style="list-style-type: none"> • Clear language and layout • I am not clear how the 'concerns of close family and friends' section related to the title of the guide 	Suggest adding more bullet points to the section on how to keep physically active to make it clearer for the reader.
Usability	I suspect few people would complete or refer back to action plans	

6.2.4 Modifications Made to the Intervention

6.2.4.1 Modifications Made to the Paper-based Guide

The guide was modified in response to feedback from PwP, caregivers and HCPs (Appendix E7). A log of the changes made is presented in Appendix E6. Key changes are described below.

A few participants were unsure if the action plan would be utilised. Rationale of how the action plan and falls diary might help was enhanced, to include identified regulators as motivation to change, thereby aiming to increase compliance of PwP and caregivers. Whilst no participants provided feedback specific to the falls diary, it is an important component as it facilitates interaction and individualisation of the intervention.

The section targeted toward caregivers was re-located and moved toward the front of the guide to enhance the flow of information. A few PwP and caregivers perceived that this subsection might not be read. It was modified to include additional information, including information about potential sources of financial support, aiming to increase its relevance to caregivers.

One HCP felt that the 'How can I stay active' section would benefit from editing to make it more coherent. In response, the content and layout of the whole of the guide was reviewed. The layout and content of the information were adjusted, to include additional subheadings to enhance ease of use, and the re-ordering of the topics in section three so that the more common

difficulties encountered by PwP and caregivers were presented first. Where participants described that subsections required expansion, additional information and potential strategies to manage falls were added, which was informed by the results of this study in addition to phases one and two.

6.2.4.2 Modifications Made to the Support Telephone Calls

The telephone calls aimed to provide a reminder to use the guide. However, results from the usability testing suggested that PwP and caregivers may need support and encouragement to use the guide. During phase one and two of this programme of research there was a sense that PwP and their caregivers did not prioritise falls management and could be unable to recall written information that they had been given, or advice that they had received.

In response, the outline of the telephone calls was altered to provide structured support and encouragement for the suggestions provided within the guide (Appendix E8). The key intervention ingredients remained within the self-management guide to ensure fidelity.

The telephone calls incorporated the 'Congratulate, ask, reassure, encourage' (CARE) model. This model is underpinned by self-determination theory and aims to improve adherence with self-management interventions (217). It provides a structured framework through which behavioural change support can be provided by those who lack the knowledge or experience in behavioural counselling skills through the following format (217):

- Congratulate: Provide positive feedback to the participant on however far they have managed to get with the intervention
- Ask: Ask the participant how they are getting on. When asking participants if they are experiencing any difficulties using the guide, they will be asked to think of any ways in which they might be able to tackle them, promoting autonomous motivation and shared decision making. Through enacting their own ideas, rather than those imposed on them, this will enhance their competence.
- Reassure: Reassure the participant about any concerns that they might have. Acknowledgement of their feelings and reassurance of any difficulties that they are experiencing promotes autonomy. Providing an explanation and education for their symptoms can increase participant satisfaction.
- Encourage: Encourage the participant to keep going with their efforts to achieve their goal and provide evidence as to how this might help through identification of introjected regulators to motivation.

6.3 Discussion

During this third phase of the programme of research, the self-management intervention was developed and underwent usability testing.

The self-management intervention was developed through the PBA, with the content and format of the guide informed by guiding principles (22,153). Guiding principles were identified through incorporating information from the background literature, my systematic review (chapter two), mixed-methods data from PwP and caregivers (phase one, chapter four) and qualitative data from HCPs (phase two, chapter five) to enhance the acceptability of the intervention (22). The intervention was underpinned by SDT and SCT to increase the probability of the suggested behaviours being initiated and maintained (72,79,93,97). A logic model was developed to provide visual representation of the current problems experienced by PwP and their caregivers, and the hypothesised mechanisms through which the intervention will act to achieve the intended outcomes (216).

The intervention consists of a paper-based falls guide, delivered alongside brief structured telephone support, which aims to improve the self-management of falls in PwP and caregivers. The key features of the intervention are contained within the booklet to maintain fidelity, and the telephone calls aim to encourage PwP and caregivers to engage with it (217).

Usability testing with 11 PwP and their caregivers, and two HCPs suggested that the intervention was likely to be acceptable. Incorporating feedback, changes were made to increase the relevance of information contained within the guide, and the likelihood of users engaging with it. The outline and aims of the support telephone calls was altered, with incorporation of the CARE model, which provides a structured framework to increase the adherence with the guide (217). PwP and caregivers were asked to provide brief feedback about the guide. They were not asked to put suggestions within the guide into practice, to log their falls or to create action plans. Some participants fed back that they felt that PwP and their caregivers may have difficulties in these practical applications.

The modified version of the intervention produced from this phase was taken forward to a feasibility study, during which engagement with the guide was explored in detail (phase four) (Appendices E7 and E8).

6.3.1 Limitations

Very little demographic and clinical data was collected from participants who formed a convenience sample. It is unknown whether the population studied was representative of the wider population of PwP who fall and their caregivers. Not all participants were from a dyad where the PwP had fallen. Participants from a dyad where the PwP had not experienced falls may have provided feedback less relevant to that provided by dyads where the PwP had experienced falls.

Two thirds of feedback questionnaires were not returned. It is unknown whether this led to positive or negative skewing of the results received. Participants were not asked to use the guide and feedback was provided through response to a questionnaire; these factors are likely to have reduced the quality of the data collected. However, this study did not aim to obtain detailed feedback about the guide, but to identify any major and significant errors or omissions prior to being taken forward to thorough mixed methods feasibility study (phase four, chapter seven).

Previous interventions developed using the PBA have obtained in-depth qualitative feedback at this stage, using methods such as think aloud, to understand how users interpret the intervention and if, when and how it is likely to be used (22,154,155,158). Researchers developing these interventions have described iterative modification of their respective interventions throughout the data collection process, to enhance the acceptability and engagement of users. It was not possible to use similar methods in this study due to the limitations on the time allocated prior to commencing the mixed methods feasibility study.

6.4 Key Points

- During this phase, the intervention was developed and modified in response to a usability study.
- Data was triangulated from the background literature, the systematic review and from earlier phases of this programme of research to describe the issues, needs and challenges experienced by PwP who fall and their caregivers. These were termed the 'Intervention design objectives'.
- 'Key features of the intervention' were identified to meet each of the 'intervention design objectives'. Together the 'intervention design objectives' and the 'key features of the intervention' formed the 'guiding principles of the intervention' from which the prototype intervention was developed.
- The prototype intervention consisted of a paper-based guide and telephone calls providing brief structured telephone support.
- A logic model of the proposed mechanisms through which the self-management intervention would act to produce change was developed.
- The prototype of the paper-based guide underwent usability testing; 11 PwP and caregivers, and two HCPs provided feedback through completion of a questionnaire. Feedback from the usability testing was largely positive. Suggested improvements included: a greater rationale as to how the falls diary and action plan might benefit PwP/caregivers, increased information about freezing, and changes to the layout and grammar used within the guide.
- Results from the usability testing suggested that PwP and caregivers may need support and encouragement to use the guide. In response, the schedule of the telephone calls was modified to incorporate the 'Congratulate, ask, reassure, encourage' (CARE) model. This model is underpinned by self-determination theory and aims to improve adherence with self-management interventions.
- The modified version of the intervention developed during this phase was taken forward to the feasibility study (phase four, chapter seven).

7 Mixed Methods Feasibility Study of the Self-management Intervention (Phase Four)

In this chapter, the findings from the feasibility study of the self-management intervention are described and discussed. PwP experiencing unsteadiness/ falls and their caregivers were asked to use the paper-based falls guide for 12 weeks, during which they received three brief telephone calls at two, four and eight weeks providing standardised support.

7.1 Methods

7.1.1 Study Design

This mixed methods study assessed the feasibility of the intervention developed within phase three: a paper-based falls self-management guide delivered alongside brief telephone support. The intervention aimed to support the self-management of falls in all community dwelling PwP who fall and their caregivers. PwP and their informal caregivers were asked to use the guide over 12 weeks, during which they received three brief telephone calls providing standardised support (Figure 7-1).

Feasibility studies assess whether an intervention is relevant and sustainable (226). This study assessed:

1. The acceptability of the intervention; the satisfaction, suitability and appropriateness of the intervention, to include feedback about the content and the format of the guide.
2. The demand for the intervention; the extent to which the intervention was used or would be likely to be used in the future.
3. Implementation of the intervention; the extent to which it can be implemented within the context of the study.

The feasibility of the intervention was explored through:

1. Questionnaire of all participants
2. Analysis of the field notes of the telephone calls, conducted with all participants
3. Semi-structured interviews with a purposive sample of participants

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The study also explored the potential impact of the intervention to include any effect that the guide had on PwP and caregivers’ concerns of falls or falls self-efficacy. Assessments at baseline and 12 weeks included:

1. In PwP, Health Related Quality of Life, as measured by the Parkinson’s Disease Questionnaire 8 (PDQ8)
2. In PwP, concerns of falling as measured by the Short form Falls-efficacy scale international (FES-I)
3. In caregivers, caregiver burden as measured by the Zarit Burden interview short version (ZBI)
4. In PwP and caregivers, falls self-efficacy as measured by a single-item falls self-efficacy question, developed for use in this study



Figure 7-1 Overview of Phase Four

Abbreviations: FES-I= Falls Efficacy Scale International, PD8= Parkinson’s disease Questionnaire 8

7.1.1.1 Intervention

The intervention consisted of the paper-based falls self-management guide, developed during phase three, alongside brief structured telephone support (Appendices E7 and E8).

Brief Structured Telephone Support

PwP and caregivers received brief (5-10 minute) telephone calls from myself at two, four and eight weeks (Appendix E8). Calls aimed to identify any difficulties that participants were experiencing with the guide and provide support and encouragement for the self-management strategies that it described following the 'congratulate, ask, reassure, encourage' (CARE) framework as described on page 174. The CARE framework is underpinned by self-determination theory and aims to improve adherence with self-management interventions (217). Telephone calls promoted engagement with the guide and were also a data gathering tool. Data was collected about any falls and HCP contact, and their views and experiences of the guide onto a pre-defined data collection form (Appendix F1). The telephone calls provided additional insight into events rather than a true recording, adding weight to the findings overall.

7.1.2 Participant Recruitment

Participants were recruited from the Parkinson's UK Research Support Network (RSN), local Parkinson's UK support groups and specialist NHS PD outpatient clinics. Parkinson's UK sent an invitation email to local members of the Research Support Network on 08.02.2018. I attended 16 NHS outpatient clinics in four locations between 14.02.2018 and 25.05.2018 for recruitment purposes. I also attended six local Parkinson's UK support groups between 13.02.2018 and 04.06.2018, with prior approval from Parkinson's UK.

The self-management intervention aimed to support the self-management of falls in all community dwelling PwP who fall and their caregivers. To reflect this, an inclusive approach to recruitment was adopted to produce results that were representative of the population of PwP who fall (Table 7-1). Initially only those who had fallen in the last year were invited to take part. However, early informal feedback from PwP enrolled into the study was that the intervention might be more suited toward those who are unsteady but had not yet fallen. Subsequently, the inclusion criteria were modified to include those who had fallen more than one year ago, or who were unsteady and had not previously fallen. A substantial amendment was submitted and granted ethical approval (Appendix B4). This did not significantly delay recruitment of

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participants into the study. Consequently, all community-dwelling PwP with a history of falling or unsteadiness, irrespective of PD severity or the presence of a diagnosis of cognitive impairment/dementia were invited to take part (Table 7-1).

Recruitment of PwP from NHS Parkinson's outpatient clinics in addition to Parkinson's (UK) support groups, aimed to provide a sample more representative of the PD population than that studied in the mixed methods study with PwP and caregivers (phase one, chapter four). Participants in phase one often described information seeking behaviours and coping strategies that they had adopted to manage falls. Consequently, I thought that PwP and caregivers who attend Parkinson's UK support groups might deem the guide less relevant. I felt that these adaptive behaviours may be less developed in PwP and caregivers who do not attend Parkinson's UK support groups, which may lead to enhanced relevance of the guide.

Those expressing an interest in the study were screened for inclusion and exclusion criteria (Table 7-1). Where the PwP met the criteria for inclusion in the study, if they had a caregiver then they were also invited to take part. Potential participants were provided with:

1. Participant information sheet (Appendix F2)
 1. Consent form(s) + / - consultee declaration form (Appendices F3 and F4)
 2. Baseline questionnaires:
 - a. PwP Questionnaire (Appendix F5)
 - b. Caregiver Questionnaire (Appendix F6)
 3. A copy of the self-management guide (Appendix E7)
 4. A prepaid envelope.

Table 7-1 Inclusion and Exclusion Criteria

Inclusion criteria	Exclusion criteria
Diagnosis of idiopathic PD, with or without cognitive impairment	Diagnosis of a Parkinson's Plus syndrome
PwP living in their own home	PwP living in a residential or nursing home.
Unsteadiness or a history of falling	No history of unsteadiness or of falls
Able to read a newspaper with glasses without severe difficulty	Participants not fluent in written and spoken English

A follow up telephone call was made 48 hours after potential participants had received information about the study. Those wishing to take part were guided through the informed consent form (Appendix F3). Where PwP were unable to provide informed consent because of

cognitive impairment, caregivers were asked to act as a consultee and to complete a consultee declaration form (Appendix F4).

7.1.3 Data Collection

7.1.3.1 Baseline Questionnaires

PwP Questionnaire

This questionnaire sought to confirm whether PwP met the inclusion criteria for the study and to describe the population (Appendix F5). Demographic data included participant gender, age, place of residence (own home/ care home) and whether they lived alone/ not. Clinical data included time since PD diagnosis, the presence/ absence of cognitive impairment/ dementia and frequency of falls/ near misses.

Health related quality of life (HR-QOL) was measured by Parkinson's Disease Questionnaire 8 (PDQ-8). PDQ-8 is an eight-item questionnaire used to measure HR- QOL in PwP. It is a validated shortened version of the 39-item questionnaire (PDQ-39) (227). PDQ-39 has been cited as the most appropriate instrument to assess HR- QOL in PD, with good internal consistency, test-retest reliability, construct validity and sensitivity (39,228). A license was obtained from Oxford University Innovation for the use of PDQ-8 in this study.

PwP concern of falls was assessed by the Short Form (FES-I) (175). The Short Form FES-I assesses concerns of falls across seven domains, and was also used in the mixed methods study with PwP and caregivers (phase one, chapter four, page 74). I also aimed to assess falls self-efficacy, however, on review of the literature, there is no validated measure to assess falls self-efficacy. Previous studies of non falls-related self-management interventions for PD and other chronic diseases have used the the 'Self-Efficacy for Managing Chronic Disease 6-Item scale' to assess participants' self-efficacy. This scale does not contain any falls-related questions (37,121). It consists of six questions, which each ask the respondent to self-rate how confident they feel in managing a defined circumstance, for example fatigue or emotional distress. Response is through a 10-point Likert Scale, with one corresponding with 'not at all confident, and ten corresponding with 'totally confident'. I developed a question to assess PwP and caregivers' self-efficacy of falls management using the same sentence structure as the questions within the the 'Self-Efficacy for Managing Chronic Disease 6-Item scale', with response also on a 10-point Likert Scale. The question read *'How confident are you that you can keep your falls from interfering with the things*

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that you want to do?'. This question was included within the baseline PwP questionnaire.

Validation of this question was beyond the scope of this thesis.

Caregiver Questionnaire

This questionnaire sought to identify caregiver's demographic details, caregiver burden, as measured by the Zarit Burden Interview: short version (ZBI), and falls self-efficacy, as measured by the single-item falls self-efficacy question (Appendix F6) (171). The ZBI seeks to identify the impact of caregiving on emotional, physical and social aspects of a caregiver's life, and was also used in the mixed methods study with PwP and caregivers (phase one, chapter four, page 75). The single-item falls self-efficacy question was the same as the question used within the baseline PwP questionnaire.

7.1.3.2 Telephone Calls

I telephoned PwP and caregivers at two, four and eight weeks. Where participants did not answer the telephone, I attempted to contact them for up to one week after the scheduled telephone call date, after which, if no contact was made then I did not attempt to contact them until the next scheduled telephone call.

I made handwritten notes during each of the telephone calls onto a predefined data collection form (Appendix F1). Notes included date and duration of the telephone call, frequency and types of any falls or contact with HCPs, and participant's views of the intervention to include any barriers to its use.

7.1.3.3 Follow-up Questionnaires

Follow-up questionnaires were posted to all participants at 12 weeks. In the event of non-return, participants received telephone calls after two, three and four weeks to identify any potential difficulties. Where participants had not returned questionnaires, the researcher offered to visit those residing within the local area to aid completion. Visits were offered to six participants, three accepted.

PwP Questionnaire

PwP were asked to complete a follow-up questionnaire which sought to identify the incidence of falls and near misses during the study and contained the Short Form FES-I, PDQ-8 and the single-item falls self-efficacy question (Appendix F7).

Caregiver Questionnaire

Caregivers were asked to complete a follow-up questionnaire that contained the ZBI (short version) and the single item falls self-efficacy question (Appendix F8).

Feedback questionnaire for PwP and caregivers

PwP and caregivers were asked to complete a feedback questionnaire that sought to identify views about the content, format, adoption and acceptability of the intervention (Appendix F9).

7.1.3.4 Semi-structured Interviews

A purposive sample of participants were invited to take part in semi-structured interviews using maximum variation sampling and critical case sampling, as described in the mixed methods study with PwP and caregivers (phase one, chapter four, page 73) (163). Participants included: (i) PwP with and without cognitive impairment, (ii) PwP with low and high concerns of falling, (iii) caregivers with high and low levels of caregiver burden, and (iv) dyads who did and did not use the guide during the 12-week period. This heterogeneous sample provided a wide range of perspectives. Participants' concerns of falls, as measured by the FES-I, were classified as high or low using the cut off points utilised within the mixed methods study with PwP and caregivers (phase one, chapter four, page 73). Caregiver burden was classified as low or high using established cut off points on the ZBI short version (171). I conducted interviews at the participants' home address at a time convenient to them. Data collection and analysis were conducted in tandem; participants were invited to take part in later interviews to explore concepts emerging from the initial data analysis. Data was collected until the point of data saturation (as described on page 73) (163,174).

Interviews were audio-recorded with prior informed written consent. PwP and their caregivers were invited to be interviewed separately. However, participants were able to be interviewed as a dyad where preferred. Through open ended questioning with prompts, the interviews sought to explore participants' thoughts and feelings in relation to the content, format, adoption and acceptability of the intervention (Appendix F10).

7.1.4 Data Analysis

7.1.4.1 Questionnaires

Data was double entered and analysed by myself using the software programme Statistical Package for the Social Sciences (SPSS) version 24. Demographic and clinical details were described using summary statistics (mean (SD); median (IQR); number (%)) as appropriate).

Participants' responses to the feedback questionnaire were presented in a table and the pertinent points described in a narrative summary. Feedback was broken down by PwP and caregiver demographics and clinical features. The distribution of the responses provided on the feedback questionnaire was assessed visually using a histogram; all continuous outcomes had a non-normal distribution. Where the feedback data was continuous and the dependant variable was binary, the Mann-Witney *U* Test was used. Where feedback data was continuous and the dependant variable was continuous, Spearman's Rank Correlation was used. Where both the feedback data and the dependant variable were binary, Fisher's Exact Test was used. Where feedback data was binary, and the dependant variable was continuous, logistic regression was used.

Participants' PDQ-8 single index scores (PDQ-8-SI) were calculated from their responses to the PDQ8 (227). Distribution of scores on the continuous measures of FES-I, PDQ-8-SI, ZBI and the single item falls self-efficacy question at baseline and 12 weeks was assessed. Data on all variables had a non-normal distribution. Median values were calculated, and the Wilcoxon Signed Rank Test was used to perform before and after analyses.

Responses to open ended questions on the feedback questionnaire were entered into Microsoft Excel and analysed through content analysis.

7.1.4.2 Telephone Calls

The duration of the telephone calls was double entered by me into SPSS (version 24). I assessed the distribution and calculated median values.

During each telephone call, where participants described barriers to using the guide, I assigned these to a one of the four components of the 'Problematic Experiences of Therapy Scale' (PETS) at the time of the telephone call (229). The PETS is designed to assess barriers to adherence to behavioural, self-management and psychological interventions, and provided a broad means to assess problem areas (229). The components of the PETS are: (1) symptoms too severe or

aggravated by therapy, (2) uncertainty about how to carry out the treatment, (3) doubts about treatment efficacy, (4) practical problems such as lack of time or forgetting what to do.

I transcribed and imported field notes from each the telephone calls into NVivo software (version 11). I analysed the data using content analysis to provide a coherent description of the data.

7.1.4.3 Semi-structured Interviews

Audio-recordings were transcribed by ADu into Microsoft Word. I re-listened to the interviews to immerse myself in the data and to check transcriptions for discrepancies. I imported the transcriptions into NVivo software (version 11) and analysed them using inductive thematic analysis as described in the mixed methods study with PwP and caregivers (phase one, chapter four, page 77) (183).

The approach taken within this analysis lies between codebook and reflexive thematic analysis. In keeping with reflexive thematic analysis, coding was fluid, with input from LD, SK and HCR to provide additional analytical insight and aid data interpretation (184). Data collection and analysis took place in tandem to allow for theoretical sampling (as described on page 186), and data was collected until the point of data saturation (as described on page 77). Braun and Clarke argue that the concept of data saturation is not in keeping with reflexive thematic analysis as this infers that themes lie within the data itself (185) (page 77). In this analysis, the type of data saturation achieved lies between code and meaning saturation (186). In accordance with reflexive thematic analysis, themes were developed as the final outcome, and the majority provided shared meaning rather than topic summaries (184).

7.1.4.4 Triangulation of Findings

Findings from the questionnaires, telephone calls and interviews were triangulated using a triangulation protocol. This method has previously been successfully used to combine mixed methods data (167).

I identified independent key findings from each of the four analyses:

- Questionnaire quantitative analyses: Feedback questionnaire Likert responses, and before and after analyses on (i) FES-I, (ii) PDQ-8-SI, (iii) ZBI and (iv) the single item falls-self-efficacy question.
- Questionnaire content analysis: Feedback questionnaire content analysis.
- Semi-structured interview analysis

- Telephone call analysis: Content analysis of the field notes and PETS components from the telephone calls.

Independent key findings from the four analyses were entered into Microsoft Excel. For each key finding, comparisons were made between each of the separate analyses. Six comparisons were made for each of the independent key findings (Figure 7-2). For each comparison, there were five possible outcomes: (i) agreement; (ii) partial agreement; (iii) dissonance, where the analyses disagreed; (iv) silence, where the key finding was identified in only one of the analyses undergoing comparison; and (v) not applicable (N/A) where the finding was not identified in either of the analyses undergoing comparison. Where a key finding was identified in more than one analysis, this led to a reduction in the number of overall findings. Then full results from this comparison process are presented in a convergence matrix (Appendix F18) and the pertinent results are presented, described and discussed within the discussion of this chapter.

	Questionnaire Quantitative analysis	Questionnaire content analysis	Semi-structured Interview analysis	Telephone call analysis
Questionnaire Quantitative analysis	N/A	Comparison 1	Comparison 2	Comparison 3
Questionnaire content analysis		N/A	Comparison 4	Comparison 5
Semi-structured Interview analysis			N/A	Comparison 6
Telephone call analysis				N/A

Figure 7-2 Triangulation Protocol: Comparisons Made Between Each of the Data Analyses

7.2 Results

7.2.1 Participants

Of the 108 PwP and 80 caregivers approached, 74 PwP and 57 caregivers were recruited between 13.02.2018 and 21.06.2018 (Figure 7-3, Appendix F11). Following informed consent and completion of baseline questionnaires, one dyad was excluded as the PwP was no longer unsteady.

26 participants, consisting of 15 PwP and 11 caregivers, took part in semi-structured interviews. All participants invited to interview agreed to participate.

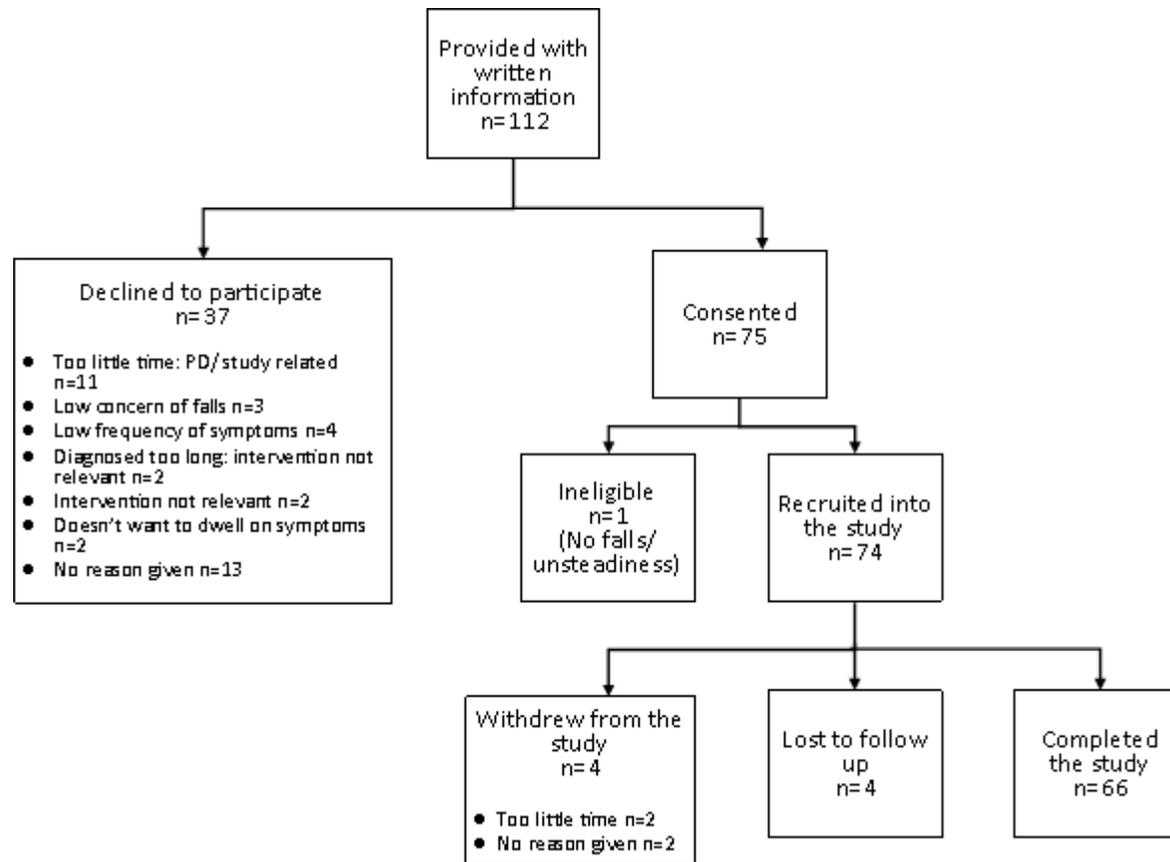


Figure 7-3 Flow Diagram Depicting the Outcome of Participants Approached, Consented and Recruited into the Study

7.2.2 Characteristics of Participants

Characteristics of PwP and caregivers are shown in Table 7-2 and Table 7-3.

Mean age of PwP was 72. As expected, PwP were predominantly male (5). Fall rate was high; 85% of PwP had previously fallen, 78% within the last year. 15% had a diagnosis of cognitive impairment/ dementia. Median Short Form FES-I score was 14, which reflects high concern of falls (172). Median PDQ-8-SI score was 31; PDQ-8-SI scores can vary between one (no effect of PD on HR-QOL) to 100 (maximum impact of PD on HR-QOL), there are no validated cut-off points (227). Median score on the single-item falls self-efficacy question was seven; a score of one reflected low falls-self efficacy and 10 reflected high falls self-efficacy.

77% of PwP were recruited alongside a corresponding caregiver. 98% lived with the PwP, and 95% were the PwP's spouse/ partner. 79% were retired, 11% were in full or part-time employment. Median ZBI was 14.5 (IQR 8.3-21.0, range 3-38); 37% had a ZBI score ≥ 17 indicating high caregiver burden (171). Median score on the single-item falls self-efficacy question was six.

Frequency of unsteadiness and falls during the study are shown in Table 7-4. 69% of PwP fell during the study, 89% experienced near misses.

Table 7-2 Baseline Characteristics of PwP

Baseline characteristic of PwP	Number (%)
Recruitment source Parkinson's UK: NHS Outpatient Clinics	47 (64%); 27 (36%)
Age (years) Mean \pm SD (range)	72 \pm 7.3.(55-88)
Gender Male: Female	48 (65%); 26 (35%)
Time since PD diagnosis (nearest year) (n=71) Median (IQR); Range	7 (4-13); 0-27
Employment status Full-time: Part-time: retired: other	1 (1%); 2 (3%); 68 (92%); 3 (4%)
Live alone (n=73)	10 (14%)
Recruited alongside a caregiver	57 (77%)
Memory Diagnosis of CI or dementia	11 (15%)
Discussed memory with family and concerns raised (n=73) Yes: No	14 (19%); 59 (81%)
Use a walking aid Always: Sometimes: No	23 (31%); 33 (45%); 18 (24%)
Type of walking aid used** Mobility Scooter Wheelchair Walking Stick Walking Frame/ rollator Other	15 (20%) 15 (20%) 48 (65%) 23 (31%) 2 (3%)
Falls Ever Fallen Fallen in the last year Fall Frequency (n=70) Daily: Weekly: Monthly: Occasionally: N/A Admitted to hospital following a fall (n=73) Informed specialist about falls (n=72) Informed PDNS about falls (n=72)	63 (85%) 58 (78%) 2 (3%); 8 (11%); 6 (9%); 40 (57%); 14 (20%) * 16 (22%) 46 (64%) 42 (58%)
If unsteady only, frequency of symptoms (n=11) Daily: Weekly: Monthly: Occasionally	4 (36%); 3 (28%); 0 (0%); 4 (36%)
Near misses (n=74) Yes: No Frequency (n=65) Daily: Weekly: Monthly: Occasionally	67 (91%); 7 (9%) 8 (11%); 18 (25%); 5 (7%); 34 (47%)
FES-I (n=74) Median (IQR); Range	14 (11-19); 7-26
Single Item falls self-efficacy question*** (n=74) Median (IQR); Range	7 (5-8); 1-10
PDQ-8-SI (n=73) Median (IQR); Range	31.3 (18.8- 43.8); 0-75

N=74 unless otherwise stated

*N/A given as participant response; **Several participants reported using more than one walking aid; *** High Scores reflect high falls self-efficacy

Abbreviations: CI= cognitive impairment; FES-I= Short Form Falls Efficacy Scale-International; HCP= healthcare professional; IQR= interquartile range; PDNS= Parkinson's disease nurse specialist; PDQ-8-SI= Parkinson's Disease Questionnaire 8 Single Index; SD= standard deviation

Table 7-3 Baseline Characteristics of Caregivers

Baseline characteristic of caregiver	Number (%)
Age (years) Median (IQR): Range	69 (63.0-75.5): Range 42-93
Gender Male: Female	18 (32%): 39 (68%)
Employment status (n=56) Full-time: Part-time: Retired: Other	4 (7%): 3 (5%): 44 (79%): 5 (9%)
Live with the PwP	56 (98%)
Relationship to the PwP Spouse/ partner: Child/ stepchild: other	54 (95%): 2 (4%): 1 (1%)
ZBI Score (n=56) Median (IQR); Range Score \geq 17 (High Caregiver Burden)	14.5 (8.3-21.0); 3-38 21 (37%)
Single Item falls self-efficacy question* Median (IQR); Range	6 (4-8); 1-10

N=57 unless otherwise stated; * High scores reflect high falls self-efficacy

Abbreviations: IQR= Interquartile range; PwP= Person with Parkinson's; ZBI= Zarit Burden Interview short form

Table 7-4 Symptoms Experienced by PwP during the study

Characteristic of PwP during the study	Number of participants (%)
Fall whilst had access to the guide (n=65)	
Yes	45 (69%)
1 fall	11 (24%)
2-5 falls	18 (40%)
6-10 falls	9 (20%)
More than 10 falls	7 (16%)
No falls	9 (14%)
Never Fallen	11 (17%)
(Missing	1)
(Lost to Follow-up	8)
Near misses whilst had the guide (n=66)	
Yes	59 (89%)
No	7 (11%)
(Lost to Follow-up	8)
Frequency of near misses whilst had the guide (n=66)	
Daily	11 (17%)
Weekly	16 (24%)
Monthly	4 (6%)
Occasionally	28 (42%)
N/A	7 (11%)
(Lost to follow-up	8)
In those unsteady only at baseline, with no previous falls, the frequency of unsteadiness whilst had access to the guide (n=11)	
Daily	5 (46%)
Weekly	2 (18%)
Monthly	0 (0%)
Occasionally	4 (36%)

7.2.3 Study Completion Rates

66 PwP (88%) and 53 caregivers (93%) completed the study (Figure 7-3). Four PwP and three caregivers formally withdrew from the study, comprised of three dyads, two PwP who lived alone and one caregiver of a PwP. One of the PwP who lived alone withdrew as they were no longer concerned about falls, the other participants cited time constraints; where described these time constraints were not related to their PD. There were no unifying characteristics of these participants.

In line with the protocol, I attempted to contact participants who had not returned the follow-up and feedback questionnaires on up to three occasions. Participants from 35 of the 70 dyads enrolled received at least one telephone call reminder, the majority of whom cited a lack of time leading to non-completion. Six dyads accepted support from the researcher to complete the questionnaires. Four PwP and one caregiver could not be contacted and were lost to follow-up.

The feedback questionnaire about the guide was completed by 67 participants; one caregiver of a PwP who was lost to follow-up completed follow-up questionnaires two and three, with non-return of follow-up questionnaire one.

7.2.4 Questionnaires

7.2.4.1 Questionnaires: Participants' Views of the Intervention: Feedback from Questionnaire Likert Scores

Feedback about the self-management guide and the telephone calls is displayed in Table 7-5.

The majority found the content useful and were positive of the way that the information was presented. Whilst most reported that the guide increased their knowledge of unsteadiness and falls, 33% reported that the guide did not increase their knowledge, and 20% felt that information was missing. Responses as to the type of information reported missing are analysed within the content analyses of the questionnaires (page 200).

Most reported that they had used the guide. An equal number of PwP used it alone as used it as a dyad with their caregiver. The majority used the unsteadiness and falls diary (79%), and 41% used it whenever they fell, or they felt unsteady. Whilst most used the action plan at some point during the study (77%), usage was very often limited; 69% of dyads used it 'never', 'rarely' or 'once in a while'. 55% of participants stated that they would be likely to continue to use the guide in the future.

71% of participants felt that the guide was easy to use, and 75% were confident in applying the information. 41% of participants said that the guide had altered their concerns of unsteadiness and falling, and 54% said that it had altered their ability to manage them. Where participants provided additional information through answering the open-ended questions, they elaborated that alterations led to an improvement, as is described in the content analysis of the open-ended questions (page 200).

Participants provided mixed feedback about the usefulness of the telephone calls.

Table 7-5 Responses to the Feedback Questionnaire for PwP and Caregivers

Feedback domain	Feedback question	Feedback response options	Number of participants (%)
Feedback about the content at the layout of the guide	Did you find the content useful (n=67)	Not at all	0 (0%)
		Not really	10 (15%)
		Undecided	4 (6%)
		Somewhat	41 (61%)
		Very Much	12 (18%)
	Do you think that there is information that we have missed out and should be included within the guide (n=63)	No	10 (48%)
	Undecided	20 (32%)	
	Yes	13 (20%)	
How did you find the way in which the information was presented? (n=66)	Was the guide easy or difficult to use? (n=65)	Very Poor	0 (0%)
		Poor	2 (3%)
		Not sure	6 (9%)
		Good	46 (70%)
		Very Good	12 (18%)
		Very difficult	0 (0%)
	Somewhat difficult	2 (3%)	
	Neither difficult nor easy	17 (26%)	
	Somewhat easy	22 (34%)	
	Very easy	24 (37%)	
Did the guide worry or concern you in any way? (n=64)	Did the guide increase your knowledge about unsteadiness and falling in Parkinson's (n=67)	Very Much	0 (0%)
		Somewhat	6 (9%)
		Undecided	1 (2%)
		Not really	19 (30%)
		Not at all	38 (59%)
		Not at all	2 (3%)
	Not really	20 (30%)	
	Undecided	4 (6%)	
	Somewhat	28 (42%)	
	Very Much	13 (19%)	
Feedback relating to outcomes	Did you feel confident in applying the information to your daily routine? (n=63)	Not at all	2 (3%)
		Not really	4 (6%)
		Undecided	10 (16%)
		Somewhat	30 (48%)
		Very Much	17 (27%)
		Do you feel that the guide has altered any of your concerns about unsteadiness and falling? (n=66)	Do you feel that this guide has altered your ability to manage your unsteadiness and falling? (n=63)
Not really	25 (40%)		
Undecided	6 (9%)		
Somewhat	19 (29%)		
Very Much	9 (14%)		
Not at all	10 (16%)		
	Not really	12 (19%)	
	Undecided	7 (11%)	
	Somewhat	26 (41%)	
	Very Much	8 (13%)	
Feedback relating to use during the study and hypothetical ongoing use	Did you use the guide? (n=66)	Never	1 (2%)
		Rarely	12 (18%)
		Once in a while	16 (24%)
		Sometimes	33 (50%)
		Most days	4 (6%)
	If you used the guide, who used the guide? (n=65)	PwP	27 (42%)
	Caregiver	8 (12%)	
	Both	28 (43%)	
	Didn't use the guide	2 (3%)	

Feedback domain	Feedback question	Feedback response options	Number of participants (%)
	Did you complete the unsteadiness and falls diary in the guide? (n=66)	Never	14 (21%)
		Sometimes	25 (38%)
		Whenever I felt unsteady or I fell	27 (41%)
	Did you use the personal action plan? (n=65)	Never	15 (23%)
		Rarely	16 (25%)
		Once in a while	14 (21%)
		Sometimes	19 (29%)
		Most days	1 (2%)
	How likely is it that you would continue to use the guide? (n=64)	Very Unlikely	8 (12%)
Unlikely		10 (16%)	
Undecided		11 (17%)	
Likely		28 (44%)	
Very Likely		7 (11%)	
Feedback about the telephone calls	Did you find the telephone calls useful? (n=65)	Not at all	0 (0%)
		Not really	15 (23%)
		Undecided	13 (20%)
		Somewhat	32 (49%)
		Very Much	5 (8%)

Association of PwP and Caregiver Characteristics on Use and Impact of the Intervention

To better understand how PwP and caregiver baseline characteristics related to feedback about the guide I used statistics to explore the relationships between these variables. As this is a feasibility study these analyses are not adequately powered but are intended to indicate trends, which alongside qualitative data and expert and clinical experience may tentatively suggest issues relevant for future improvements to the intervention. Full results of these analyses are presented in Appendices F12, F13 and F14, and key results are described below while recognising that this is a feasibility study and not powered for such detailed sub analyses.

Recruitment Source

Participants recruited from NHS outpatient clinics, when compared to those recruited through Parkinson's UK, were significantly more likely to report altered concerns of falls arising from the guide. Although failing to reach statistical significance, those recruited through the NHS were more likely to (i) complete the falls diary and the action plan, (ii) feel that the guide had altered their ability to manage falls and (iii) find the telephone calls more useful. Subsequent content analysis of the open-ended responses to the questionnaires (page 200), showed that where participants reported altered concerns and went on to provide a free text response, they described this alteration as a reduction.

PwP Characteristics

Age had no significant effect on participants' use and perception of the guide, but increased time from PD diagnosis was associated with a reduced likelihood of gaining knowledge from the guide.

Participants from a dyad where the PwP had a diagnosis of cognitive impairment/ dementia were significantly less likely to use the falls diary. Although failing to reach statistical significance, these participants were also less likely to use the guide and the action plan and find the guide more difficult to use.

Those with lower HRQOL, as measured by PDQ-8-SI, were significantly more likely to report improved knowledge from the guide compared to those with higher HRQOL.

Falls History and Concern of Falls

Although failing to reach statistical significance, a history of falls was associated with a trend to increased use of the guide, and completion of the falls diary and action plan. However, a history of falls was also associated with reduced likelihood of ongoing use the guide at the end of the study. Although not significant, participants from a dyad where the PwP had a history of falls reported greater (i) confidence in applying the information, (ii) alteration in their concerns of falls and (iii) altered ability to manage falls.

Participants from a dyad where the PwP fell during the study were significantly more likely to use the guide. Although failing to reach statistical significance, these participants also reported greater use of the falls diary, but reduced use of the action plan. Although not significant, participants who experienced falls or near misses during the study reported greater alteration in their concerns of falls and their ability to manage them and found the telephone calls more useful.

Effect of Co-recruitment of a Caregiver

Compared to those who were recruited alone, PwP who were recruited alongside a caregiver were statistically more likely to complete the falls diary and the action plan. Although failing to reach statistical significance, co-recruitment of a caregiver was associated with increased likelihood of altered knowledge of falls and their ability to manage them; however, these participants perceived the telephone calls less useful.

Caregiver Characteristics

Increasing caregiver burden significantly negatively correlated with the perceived usefulness of the guide, completion of the action plan and continued use of the guide after the study.

7.2.4.2 Questionnaire: Content Analysis of Open-ended Responses

64 of 67 participants (96%) completing the follow-up questionnaires provided additional information through response to the open-ended questions, which was analysed through content analysis (Appendix F15). 53 responses, from 23 participants, were illegible or unclear. Many of the responses to the open-ended questions added no additional information to that provided by the Likert-type question. The most common and pertinent components of the analysis are discussed below.

Question One: Did you Find the Content Useful?

Feedback was provided by 56 participants; there was considerable heterogeneity between the components that participants described as most and least useful.

29 participants (43%) described a specific component of the guide that they found most useful. The most common areas were information about freezing (n=6), 'section three' (which contained information about the different aetiologies of falls and suggested strategies)' (n=6) and 'slips and trips' (one of the subsections within section three) (n=5). Seven participants (10%) stated that content deemed useful related to their personal circumstances, and six (9%) that the guide provided a useful reminder of information.

13 participants (19%) stated that the guide was useful because it enhanced their knowledge and promoted reflection and adaptation; these are all recognised skills required for effective self-management. Eight participants (12%) stated that the interactive components (the falls diary and the action plan) were the most useful.

12 (18%) participants stated that the least useful part of the guide was that they perceived it to provide little new information; two expanded that this related to the long duration that they had been diagnosed with PD. Nine (13%) stated that the interactive components were the least useful components; five of these participants stated that there was too little space to write. Eight participants (12%) stated that the information was not relevant to their circumstances. Six participants (9%) listed specific components of the guide; all described a different area.

Question Two: Did the Guide Increase Your Knowledge About Unsteadiness and Falling in Parkinson's?

Feedback was provided by 57 participants. 19 (28%) stated the guide had not increased their knowledge because it provided no new information.

Where participants stated that the guide had increased their knowledge, seven (10%) attributed this to enhanced awareness and focus on their symptoms. Information about freezing was the component of the guide most frequently cited to lead to enhanced knowledge (n=4).

Question Three: Do You Think That There is Information That we have missed out and should be included in the guide?

Feedback was provided by 38 participants, of which 17 (25%) listed information that they felt was missing, which showed considerable variation. Nine stated that this related to a need specific to themselves, or detailed information that they had learnt elsewhere. Three felt that the falls diary or action plan required adaptation; this included requesting more space (n=2) or a more detailed diary (n=1).

Question Four: How Did You Find the Way That the Information was Presented?

Feedback was provided by 46 participants. 21 provided information about the language used within the guide; 19 were positive, describing it clear and easy to understand. 18 (27%) participants provided feedback about the format and the layout of the guide, all were positive, with 15 participants positive of the use of colour and the separation of information into sections.

15 participants (22%) provided feedback about the guide content. Responses were mixed, whilst four perceived that the guide was concise, two perceived it to be too vague, and one commented negatively about repetition within the guide.

Question Five: Did You Use the Guide?

Feedback was provided by 49 participants. 22 participants' (33%) response provided information about how often they used it or how they used it. Nine (13%) of whom stated that a new problem had triggered them to use the guide. However, another nine participants stated that they had used the guide less as the study progressed.

14 participants' (21%) response stated that the information was not new or was not relevant to their circumstances, which led to reduced use. Two stated that the information would be more relevant to them in the future.

Eight participants (12%) described practical constraints to using the guide. The most common barrier described was lack of time (n=6).

Question Six: If You Used the Guide, Who Used the Guide?

Feedback was provided by 39 participants. 15 participants' (22%) responses described why they had used the guide or outcomes obtained from using the guide. Responses varied; the most

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common responses were that it was used for reference of information (n=3) and that they read and discussed it together (n=3).

11 participants (16%) described how one party drove the use of the guide; in eight dyads (12%) this was the caregiver, which could arise from difficulty of the PwP in comprehending the information (n=3) or the PwP deeming the information not relevant (n=2).

Question Seven: Did You Complete the Unsteadiness and Falls Diary in the Guide?

Feedback was provided by 47 participants. 12 participants (18%) described difficulties using the diary; these included forgetting to complete it or insufficient time to complete it (n=4), high frequency of symptoms (n=3), or insufficient room within the guide (n=2). Further barriers, each described by one participant, included difficulties writing, not noticing it within the guide, and self-perceived laziness.

Eleven participants (16%) deemed that the diary was not relevant or necessary. Seven of these participants stated that they had not fallen or had a low frequency of falls-related symptoms, and three stated that they already problem-solved the cause of their symptoms.

Five participants described why they had used the diary. Enablers included a reminder of fall risks (n=2), an aide memoire for the telephone calls (n=1), to support discussions with HCPs (n=1), to keep track of symptoms (n=1) and to identify a pattern (n=1)

Four participants described how they used the diary. Two participants had completed a separate diary deeming that there was insufficient room within the guide, and one had completed the diary on their iPad due to writing difficulties.

Question Eight: Did You Use the Personal Action Plan in the Guide

Feedback was provided by 33 participants. 18 (27%) identified barriers to using the action plan, which led to reduced use. The most common barriers were a lack of time or forgetting to complete it (n=5), already knowing the actions that they needed to implement (n=4) and writing difficulties (n=2).

11 participants (16%) identified drivers to using the action plan. Five used the action plan to think about ways of addressing their problems. Other drivers included a communication tool with HCPs (n=2), increased focus (n=1) and a place to document their concerns (n=1).

Question Nine: Was the Guide Easy or Difficult to Use?

Feedback was provided by 32 participants. All 21 participants (31%) who commented on the layout or language of the guide were positive.

Six participants (9%) discussed barriers to using the guide. These included writing difficulties, the guide causing frustration between the PwP and the caregiver, and difficulty working out how to use the guide.

Two participants commented on difficulties implementing the information within the guide related to participants' memory impairment.

Question Ten: Did You Feel Confident in Applying the Information to Your Daily Routine

Feedback was provided by 29 participants. Of those participants who stated that they were confident applying the information, seven described why. The most common reasons were that the information was useful (n=2), and that they had learnt to slow down and concentrate (n=2). One participant described that they felt confident applying the information in combination with physiotherapy.

Five participants (7%) described barriers to implementing the information, two cited time constraints, two had difficulty comprehending the information and one had difficulties implementing the strategies. 11 participants (16%) commented that the information was not new or relevant to them.

Question Eleven: Do you Feel that the Guide has Altered any of the Concerns that you Have about Unsteadiness and Falling?

Feedback was provided by 36 participants. Where participants responded via the Likert-type question that their concerns had altered, open-ended responses described a reduction in concerns. In three participants this reduction was linked to an increase in their knowledge of falls, in two participants this arose from the knowledge that falls were preventable and awareness that they were not alone.

Of those participants who responded to the Likert-type question to state that their concerns were not altered, three commented that guide had enhanced their awareness of falls. Two commented that they felt that their concerns were non-modifiable. Four stated that they had no current concerns of falls, one of whom thought the guide may help in the future.

Question 12: Do you Feel That This Guide Has Altered Your Ability to Manage Your Unsteadiness and Falling?

Feedback was provided by 33 participants. Where participants responded via the Likert-type question that their ability to manage their unsteadiness and falling had altered, open-ended responses described how their ability to manage had improved.

Thirteen participants (19%) commented how their enhanced ability to manage arose from heightened knowledge or awareness of unsteadiness and falls. Eight (12%) described approaches that they had implemented with success, which included strategies to overcome freezing (n=2), enhanced concentration and care (n=2) and getting up from the floor (n=1). One commented how their enhanced ability to manage falls had reduced their frequency of falls, another stated that they now had increased control over their symptoms.

Eight (12%) commented that the guide had not altered their ability to manage unsteadiness and falling as they perceived the guide to be irrelevant to their personal circumstances. Amongst these participants, two perceived that they had no difficulties to alter, one stated that their high frequency of symptoms meant that the guide was unhelpful, one discussed reduced engagement of the PwP, one commented that they were unsure why the PwP fell, and one attributed the lack of change to arise from a deterioration in the PwP's cognition.

Question 13: Did the Guide Worry or Concern You in Any Way?

Feedback was provided by 17 participants. Two commented that their concerns with the guide arose from difficulties problem-solving. Other responses did not provide any additional information to that provided in the response to the Likert-type question.

Question 14: How Likely is it That You Would Continue to Use the Guide in the Future?

Feedback was provided by 17 participants. 12 (18%) stated that the guide provided them with a reminder, 10 of whom (15%) felt that they would be likely to use the guide in the future. Ten participants (15%) described how they would be likely to continue to use the guide arising from their positive experience of using it.

Six (9%) commented that they would be unlikely to use the guide as they did not feel it was relevant to them. Three of whom felt that the information was not relevant to their circumstances, and one perceived that they had no current problems. Four participants described difficulties using the guide, which could lead to reduced ongoing use.

Six participants (9%) stated that a change in their symptoms would trigger ongoing or future use of the guide.

Question 15: Did You Find the Telephone Calls Useful

Feedback was provided by 34 participants. 13 (19%) stated the telephone calls provided them with a reminder, of these, 11 (16%) stated that this was a reminder to look at the guide, and one stated that it was a reminder to implement strategies.

Four (6%) felt that the calls were helpful and supportive and a further four (6%) liked the discussion within the telephone calls, to include the opportunity to provide clarification of points that they did not understand.

Nine participants (13%) provided responses that were consistent with the view that telephone calls were primarily for research purposes. Amongst these participants, three would have liked scheduled calls so that they could prepare, one stated that they felt anxious that they needed to give the 'correct' answer. Two reported guilt that they were not using the intervention as it had been designed.

7.2.4.3 Questionnaires: Impact of the Intervention on Clinical Outcome Measures

This was a feasibility study and therefore these analyses are not adequately powered but were intended to indicate trends which, alongside qualitative data and expert and clinical experience may tentatively suggest issues relevant for future improvements to the intervention. Change in FES-I, PDQ-8-SI, ZBI and the single item falls self-efficacy question between baseline and 12 weeks for both PwP and caregivers was assessed (Table 7-6).

Among PwP, there was no change in either concerns of falls, measured by the FES-I, in falls self-efficacy, measured by the single-item falls self-efficacy question or HRQOL, measured by PDQ-8-SI.

In caregivers there was no change in either caregiver burden, measured by the ZBI or in falls self-efficacy, measured by the single-item falls self-efficacy question.

Complete cases analysis was performed. Three measures (PwP FES-I, PwP PDQ-8-SI and caregiver single-item falls self-efficacy) had missing data at follow-up. Last observation carried forward analysis was performed and there was no change in the conclusions.

Table 7-6 FES-I, PDQ-8-SI, ZBI and Single Item Falls Self-efficacy Question Scores at Baseline and 12 weeks

Participant Group	Outcome measured	Statistic	Complete Cases Analysis
PwP	FES-I	N	66
		Pre-intervention median (IQR)	14 (11-19)
		Post- intervention median (IQR)	14 (11-18)
		Test Statistic (Z value)	-1.40
		P value	0.16
	PDQ-8-SI	N	61
		Pre-intervention median (IQR)	31.25 (18.8-43.8)
		Post- intervention median (IQR)	32.8 (21.9-50.0)
		Test Statistic (Z value)	1.66
P value		0.10	
Single item falls self-efficacy question	N	63	
	Pre-intervention median (IQR)	7 (5-8)	
	Post- intervention median (IQR)	7 (5-8)	
	Test Statistic (Z value)	-0.19	
Caregiver	ZBI	N	52
		Pre-intervention median (IQR)	14.5 (8.3-21.0)
		Post- intervention median (IQR)	15.0 (8.0-23.5)
		Test Statistic (Z value)	-1.10
		P value	0.27
	Single item falls self-efficacy question	N	52
		Pre-intervention median (IQR)	6 (4-8)
		Post- intervention median (IQR)	7 (4.3-8.8)
		Test Statistic (Z value)	-0.88
		P value	0.38

Abbreviations: IQR= interquartile range; PDQ-8-SI= Parkinson's disease questionnaire 8 single index; Z value=Wilcoxon Signed Rank Test statistic

7.2.5 Semi-structured Interviews

All participants who were invited to interview agreed to participate. 26 participants, consisting of 15 PwP and 11 caregivers, took part in semi-structured interviews (Table 7-7). The sampling strategy was successful and all participant groups that I wanted to reach were interviewed.

19 face to face interviews took place. Of the 11 PwP recruited with a caregiver, four were interviewed alone and seven with their caregiver as a dyad. Three of the Four PwP with cognitive impairment/ dementia were interviewed as a dyad with their corresponding caregiver. Three of the four caregivers who had high caregiver burden were interviewed alone.

Interviews lasted between 12 and 91 minutes (median 41).

Table 7-7 Characteristics of PwP and Caregivers Who Participated in the Semi-Structured Interviews

PwP ID	Caregiver ID	Interviewed alone or with caregiver as a dyad	Recruitment Source	Used the guide	PwP Characteristics				Caregiver characteristics	
					M/F	CI/ dementia	FES-I	Previous Falls	M/F	ZBI
1	N/A	Alone	P (UK)	Yes	M	No	High	Within 1 year	N/A	N/A
5	N/A	Alone	P (UK) RSN	No	M	No	Low	Within 1 year	N/A	N/A
11	12	Alone	P (UK) RSN	Minimal	F	No	Intermediate	Within 1 year	M	High
17	18	Alone	P (UK) RSN	Yes	M	No	Intermediate	Within 1 year	F	High
19	20	Dyad Interview	NHS Clinic	Yes	M	No	Intermediate	Within 1 year	F	Low
41	42	Dyad Interview	P (UK)	Minimal	M	Yes	High	Within 1 year	F	High
45	46	Alone	P (UK)	Yes	M	Yes	High	Within 1 year	F	High
57	58	Alone	NHS Clinic	PwP- yes, CG- no	F	No	High	Within 1 year	M	Low
97	98	Dyad Interview	NHS Clinic	Yes	M	No	Intermediate	Within 1 year	F	Low
123	124	Dyad Interview	P (UK)	Yes	M	Yes	Low	Within 1 year	F	Low
125	N/A	Alone	P (UK)	Yes	F	No	Low	Never	N/A	N/A
149	150	Dyad Interview	P (UK)	No	F	No	Intermediate	>1 year ago	M	Low
155	156	Dyad Interview	P (UK)	PwP- no, CG- yes	M	Yes	Low	>1 year ago	F	Low
167	N/A	Alone	Clinic	Yes	F	No	Low	Within 1 year	N/A	N/A
177	178	Dyad Interview	Clinic	No	F	No	Intermediate	Never	M	Low

Abbreviations: CG: Caregiver; CI= cognitive impairment; F=female; FES-I= short form Falls-efficacy scale international; M=male; N/A= Not applicable; P (UK)= Parkinson’s UK; ZBI= Zarit Burden Interview (short version).

7.2.5.1 Themes Identified

Two over-arching themes were identified which provided a descriptive coherent representation of the data: 'Engagement with the guide: enablers and Barriers' and 'Impact of the Intervention' (Figure 7-4 and Table 7-8). Within the first overarching theme 'Engagement with the guide: enablers and Barriers' there were six themes. Within the second overarching theme 'Impact of the intervention' there were five themes. Subthemes contributing to each of the themes is outlined in Table 7-8. The coding manual outlining the data contributing to each theme and subtheme is presented in Appendix F16. Statements such as 'a few participants' or 'many participants' have been used to display the prevalence of opinion amongst the population interviewed, as described in the mixed methods study with PwP and caregivers (phase one, chapter four, page 85).

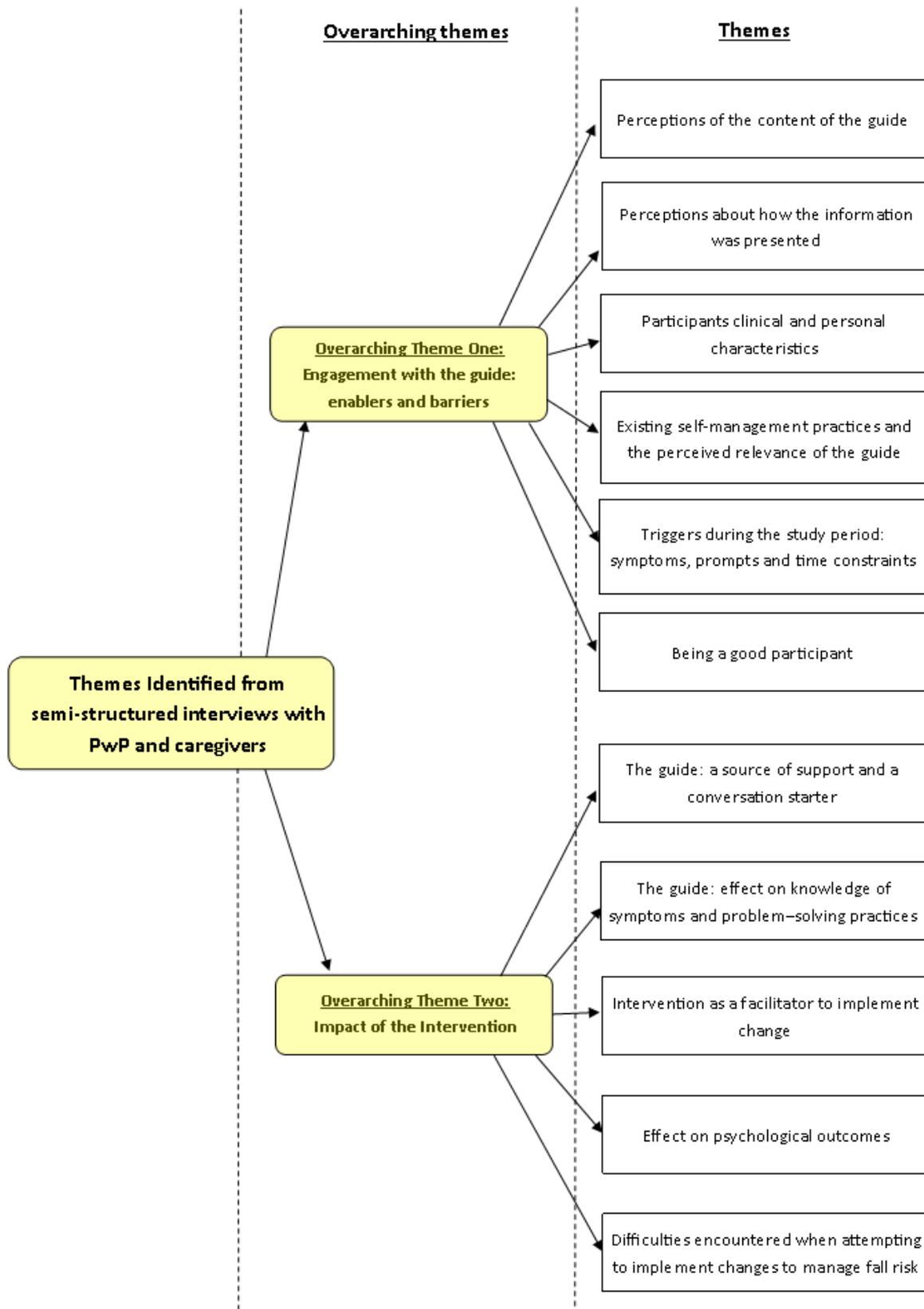


Figure 7-4 Over-arching Themes and Themes Identified From the Semi-structured Interviews with PwP and Caregivers

Table 7-8 Overarching Themes, Themes and Subthemes Identified From the Semi-structured Interviews

Overarching Theme One: Engagement with the guide: Enablers and barriers	
Theme	Subthemes
Perceptions of the content of the guide	Topics within the guide and their perceived relevance
	Factors influencing use and non-use of interactive components
	How the intervention embeds into current healthcare provision
Perceptions about how the information was presented	Perceptions of the paper-based format and suggested changes
	Perceptions of the layout and suggested changes
Participants' clinical and personal characteristics	Perceived relevance of the guide related to time from PD diagnosis and the presence of CI/ dementia
	Engagement of the guide related to participants perception of falls
	A drive for a greater understanding of unsteadiness and falls
	Personality traits and communication preferences
Existing self-management practices and the perceived relevance of the guide	
Triggers during the study period: symptoms, prompts and time constraints	
Being a good participant	
Overarching Theme Two: Impact of the Intervention	
Theme	Subthemes
The guide: a source of support and a conversation starter	Intervention as a source of social support
	The guide as a facilitator to communication within the dyad
	The guide as a facilitator to communication between the dyad and HCPs
The guide: effect on knowledge of symptoms and problem-solving practices	
Intervention as a facilitator to implement change	Telephone calls as a driver to instigate change
	Adopting a more strategic and proactive approach
Effect on Physical and Psychological Outcomes	Effect on fall rate and physical symptoms associated with falls
	Confidence in managing falls-related symptoms
	A more positive outlook versus ongoing concerns of falls and their consequences
Difficulties encountered when attempting to implement changes to manage fall risk	

Overarching Theme One: Engagement with the Guide: Enablers and Barriers

Theme: Perceptions of the Content of the Guide

Subtheme: Topics within the Guide and their Perceived Relevance

PwP and caregivers' perceptions of information deemed most useful varied considerably, which often related to their current symptoms. The most common elements considered useful were information about freezing and quotations from other PwP and caregivers. One PwP, who had not previously fallen, discussed how they had been able to apply information out of each topic to their individual circumstances.

"How to prevent yourself falling by standing up and waiting a few minutes before moving along...feeling lightheaded, I've had quite a lot of that." PwP 167

Equal numbers of participants perceived the guide was comprehensive, as perceived that the guide was missing information. Areas where participants felt that the guide required expansion varied in accordance with the PwP symptoms. Two caregivers wanted greater explanation of what caused PD, why PwP fall, and why the strategies suggested could benefit them. A few participants discussed how adding more information could lead users to experience problems concentrating, or to feel overwhelmed or disengaged.

"Everything that we've been told by different people you managed to put it into a booklet form which I think is very helpful...if we've been away for a few days we take it with us, it's like taking your Passport." Caregiver 98

"I think it's a nice size because you don't want to be too overwhelmed with information cos you're not going absorb anything." Caregiver 42

Two caregivers and one PwP described that they thought that the guide would benefit from splitting into two, with one targeted toward PwP and one toward caregivers. This could arise from the perception that the current layout interrupted the flow within the guide, or that PwP and caregivers had different information requirements. These viewpoints did not appear to affect the engagement of users with the guide.

"The layout of book I thought the bit about Carers and professionals breaks up the flow... It would be better being at the beginning or the end." PwP 19

Subtheme: Factors Influencing Use and Non-use of Interactive Components

Some participants who described reduced engagement with the falls diary and the action plan were unclear as to their proposed benefit or stated that they were waiting for a significant event

to trigger initiating using them. Barriers to completion of the diary included high frequency of symptoms, and that analysing events could be perceived as negative.

“You just try and live as normal as you can... if you were picking at everything you did all day long it would drive you mad.” PwP 150

Barriers to completion of the action plan included deeming writing unnecessary, self-perceived laziness and an inability to identify strategies that might help.

“We picked up the tips that were in there and started running with the ones we could use...what we didn’t do was write an action plan...Idleness...we can do it anyway without writing it all down’.” Caregiver 18

Subtheme: How the Intervention Embeds into Current Healthcare Provision

Many participants described successful support that they had received from HCPs, most of which had taken place prior to the study. This support was largely from physiotherapists, but also included education classes organised by PDNS. A few of these participants discussed how delivering the intervention in association with the support that they had received elsewhere would be beneficial.

“Understanding more from going to [local PD education sessions]... [the guide] is really to help you get through, perhaps more to say ‘you know, you’re not unique in this’...maybe this book coupled with [the sessions] given to new patients would help tremendously.” Caregiver 98

Some PwP and caregivers discussed how, although not needed during the previous 12 weeks, they would have liked the option of being able to discuss things in further detail if required. The majority of participants expressing these views had been diagnosed within the last five years, discussed limited Parkinson’s-related healthcare provision within their locality and had lower FES-I or caregiver burden scores.

“There needs a reference point...there’s no nurse now...that’s pretty crucial...somebody available for you to ask questions.” Caregiver 150

Theme: Perceptions About How the Information Was Presented

Subtheme: Perceptions of the Paper-based Format and Suggested Changes

Nearly all who discussed the format of the guide were positive about its delivery in a booklet, which was often deemed more acceptable and accessible than an electronic format. However, a

few participants discussed difficulties to include its reduced availability if filed away or not being with them when needed.

“We tend to drown in a sea of paper...I would find it more useful if [the action plan] was in chart form and I could pin it on a noticeboard.” PwP 11

Where discussed, PwP and caregivers were positive about the language used. A few participants felt diagrams would help to illustrate points.

“Section which talked about what to do if you fall, how to get up. It would probably help with a diagram.” PwP 5

Two PwP discussed that the cover of the guide needed to be more engaging and felt that this would enhance use. Views surrounding the use of colour were mixed; whilst a few felt it aided navigation, one felt too many were used, and another felt it made it more difficult to read.

Where negative, these views did not appear to effect engagement with the guide.

“Personally, I find black text on yellow background a lot easier to read than the black on pink.” PwP 1

Subtheme: Perceptions of the Layout and Suggested Changes

Most PwP and caregivers were positive about the layout of the guide and felt that it was easy to read and to navigate, bullet points were deemed to provide useful step-by-step advice. However, some felt that the diary and the action plan required development. The most common difficulty was that the space to write within the falls diary and the action plan were too small, which could relate to PD-associated writing problems. In response, two PwP described recording separate to the guide, either on a separate piece of paper or electronically. Reduced writing ability was cited as a contributor to future non-engagement with the guide.

“It was just set out in a way that it was easy to understand and that your next step each time was.” PwP 125

“I can’t write anyway so I did it on the iPad.” PwP 19

Where participants described how they used the guide, they most often described reading it cover to cover, before selecting and re-reading the parts that they felt were most relevant to them. A few participants who read the guide from cover to cover felt it contained unnecessary repetition; however, this did not appear to affect their engagement.

“Cover to start with... when I had something that sort of crops up...you go through and then think ‘oh yeah that’s what I’ve got, that page’.” PwP 97

Two caregivers felt that rearranging the guide could enhance engagement with it. One PwP did not notice the action plan until it was highlighted by the researcher during the telephone calls. One PwP, who had gained from completing an action plan, discussed that the guide required greater explanation of the potential benefits that an action plan might have.

“When there’d been trips or stumbles...we used the Action Plan...but...perhaps it [would be] more beneficial if you started with your Action Plan... [and then] looking through the Guide.” Caregiver 124

Theme: Participants’ Clinical and Personal Characteristics

Subtheme: Perceived Relevance of the Guide Related to Time from PD Diagnosis and the Presence of Cognitive Impairment/ dementia

PwP and caregivers frequently discussed how their information requirements reduced as time from PD diagnosis increased. Participants diagnosed longer could view the guide more relevant to those nearer to the start of their journey as they had already learnt a lot about PD and falls.

*“[My husband] has had Parkinson’s for a long time...some of those tips if we’d known earlier, could have been helpful cos we’ve not had an awful lot of advice really.”
Caregiver 18*

A few PwP and caregivers discussed how providing the guide prior to the onset of unsteadiness and falls could facilitate preparation and adaptation. However, others raised that they had felt overwhelmed at this stage, and those who had been diagnosed more recently could view that the guide was more relevant to those with greater symptoms. A few participants raised that if giving the guide to those earlier in the trajectory of PD it would be important to avoid exacerbating any concerns of PD progression, which could be minimised through allowing users to select information that was relevant to them.

“...diagnosis no, you’re already on overload anyway...after a while you become more investigative.” Caregiver 124

“I’m sure the Guide is more applicable to, in inverted commas, other people you know. But, um, at the moment it’s not affecting us too much” Caregiver 150

A few PwP and caregivers, including caregivers from all dyads where the PwP had cognitive impairment/ dementia, discussed how the guide was less relevant in the setting of cognitive impairment/ dementia due to difficulties with the recall of information and its translation it into practice.

"[My husband's] understanding, he can read and take it all in, it's just the connections don't work." Caregiver 46

Subtheme: Engagement of the Guide Related to Participant's Perception of Falls

Participants' perception of falls could affect their engagement with the guide. A few participants, comprised of PwP with low FES-I scores and one caregiver with low caregiver burden, could normalise or dismiss their symptoms leading to reduced engagement with the guide. A few PwP, who did use the intervention, discussed previous denial of their symptoms, and how if they been provided with the guide at this earlier time point then they may not have used it.

"If you say 'everything is absolutely fine, there are no problems I don't ever feel unsteady, I'm not concerned about falling' then you're not going to be wanting to record it." Caregiver 156

The vast majority of PwP and caregivers discussed concerns relating to medical issues aside from falls including PD medications, fatigue and PD progression. Where these difficulties were associated with greater anxiety than that arising from unsteadiness and falls, participants described reduced engagement with the guide. A few caregivers, the majority of whom were from a dyad where the PwP had cognitive impairment/ dementia, discussed how they perceived falls to be, at least in part, unpreventable, which could lead to reduced use.

"I have read it and I don't think there's anything else we can do... [Healthcare Professionals] all say 'there's nothing we can do'." Caregiver 46

Subtheme: A Drive for a Greater Understanding of Unsteadiness and Falls

Participants from over half of dyads, the majority of whom were PwP with lower falls self-efficacy, described how they had been driven to use the guide to try to achieve a greater insight into the management of unsteadiness and falls. A few caregivers with high caregiver burden discussed how they had hoped that the guide might provide reassurance that they were doing all that they could.

"I don't think you can ever know enough. None of us know everything. And, we all want reassurance that we're doing the right thing." Caregiver 42 (Caregiver of a PwP with dementia)

Some PwP and caregivers described previous experiences which led them to perceive the guide less relevant, this included participation in other PD falls research projects, or employment as a nurse. However, the engagement of these participants with the guide did not appear to have been adversely affected.

“It says that you can ring for an ambulance to get somebody up. I think that is so useful...I used to be a nurse.” Caregiver 124

Where caregivers discussed the relevance of the guide to each of PwP and caregivers, all but one perceived that the guide was more relevant to caregivers due to their greater information requirements. These caregivers had varying degrees of caregiver burden.

“Most useful for Carers...they, in truth, should be the observers and the facilitators...the Carers could perhaps have more comprehensive information.” Caregiver 156 (Caregiver of a PwP with dementia)

Subtheme: Personality traits and Communication Preferences

Participants who perceived themselves to have an optimistic or analytical mind-set, were positive about the guide and described enhanced engagement with it.

“It’s really sort of um made me stop and think...I just try and look in the bright side of things.” PwP 57

However, one caregiver discussed how they wished that the guide provided more specific advice, rather than promoting a problem-solving approach.

“I think I’d almost like to be able to turn to a certain page and had it listed as to what I was meant to do.” PwP 178

A few PwP raised difficulties with telephone conversations, to include a lack of non-verbal communication and anxiety when unscheduled contact was made. These concerns related to telephone conversations on a wider basis and were not limited to those within study.

“The Parkinson’s Nurse now tends to be done on the phone and I really miss having someone there... If I just get your voice, there’s a lot missing there.” PwP 5

Theme: Existing Self-management Practices and the Perceived Relevance of the Guide

The vast majority of PwP, and all caregivers, described an array of practical and behavioural strategies to manage unsteadiness and falling that they had adopted prior to the onset of the study. A few participants described how this led them to view the guide less relevant.

“I really didn’t find any of it relevant to me because I really do try and be wary. I count stairs. I try not to fall.” PwP 149

Some PwP and caregivers, who were all recruited from Parkinson’s UK support groups, described information seeking behaviour adopted prior to the study. Two PwP discussed how they already

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analysed their symptoms to try and gain greater understanding. Participants who described information-seeking behaviour or analytical thinking prior to the study could deem the guide less relevant. A few PwP and caregivers, all recruited from Parkinson's UK support groups, reported initial reduced motivation to use the guide.

"Initially I thought I wasn't going to be using [the guide] ...but then...it was just reinforcing everything." PwP 125

Theme: Triggers During the Study Period: Symptoms, Prompts and Time Constraints

Some PwP and caregivers described how symptoms during the study had triggered them to use the guide, hoping that it would provide reassurance or strategies to manage their symptoms. Where PwP and caregivers described low engagement with the guide, they often described how future symptoms might trigger them to use it and hoped that the guide might help to increase their understanding and management of any new symptoms.

"[The PDNS] said I seemed to be prone to freezing...and I thought 'hang on it mentioned freezing in your booklet'." PwP 1

The majority of PwP and caregivers described the telephone calls an aide memoire to use the guide. Most of whom thought that they would have used the guide without the telephone calls, but the calls increased the frequency that they used it.

"[The telephone calls] do remind you that [the guide] is there and each time caused me to pick [the guide] up." Caregiver 156

Some participants, the majority of whom were caregivers, discussed time constraints that reduced their engagement with the guide. Most of these caregivers had high caregiver burden. Time limitations related to pre-existing commitments within the caregiving role, bereavement and caregiver illness.

"Well a time thing really...when you care for somebody 24/7 you want a bit of life yourself as well...I concentrate a lot with [my husband] as it is." Caregiver 46

Theme: Being a Good Participant

Around half of PwP and caregivers appeared to have engaged with the guide more because they were enrolled in a research study. Some expressed guilt when describing how they had not used certain components of the guide or perceived that their low frequency of symptoms made them inferior research participants. Where participants had not used the falls diary or the action plan, some appeared to perceive that these components of the guide were for the benefit of the

research project alone. A few participants discussed feeling unprepared for the telephone calls and stated a preference for communication to be at a pre-arranged time.

"I'm very bad. And I didn't diary them and I know I should have done for your research and I apologise for that...it's my fault I didn't." Caregiver 42

Overarching Theme Two: Impact of the Intervention

Theme: The guide: A Source of Support and a Conversation Starter

Subtheme: Intervention as a Source of Social Support

Some PwP and caregivers, the majority from a dyad where the PwP had either high concern of falls or low HRQOL, were positive when discussing how the guide and/or the telephone calls, allowed for them to feel that they were not alone. A few participants discussed how the quotations allowed for them to hear how others had overcome difficulties, and a couple said they would now be more open to attending a Parkinson's UK support group.

"Everybody feels like you do, that's what like kind of came across; you're not alone."
PwP 125

However, two male PwP, diagnosed for seven and fourteen years, and had previously attended Parkinson's UK support groups did not find the quotations helpful.

Subtheme: The guide as a Facilitator to Communication Within the Dyad

Nearly all caregivers described that the guide had led to them providing additional support or reminding the PwP of strategies to implement. In two caregivers, the guide had prompted them to discuss falls with family members outside of the dyad.

"I just walk at her pace...I tell me daughter not to pull her along either." PwP 58

Often, one member of the dyad described using the guide and instigating changes more than their spouse. This lead role could be adopted by either PwP or caregivers. Most caregivers adopting this role were from a dyad where the PwP had cognitive impairment/ dementia. A few caregivers described becoming frustrated when encouraging the PwP to engage with the guide or when reminding them of strategies to implement.

"[my wife] got irritated with me sometimes... It was difficult to encourage [her] to engage in [the guide] [she] weren't really too interested." Caregiver 178

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In some, the guide increased discussion about falls. These conversations primarily took place within the dyad, but also with friends and children. In caregivers, these conversations sometimes led to enhanced awareness of falls and of the PwP's falls-related concerns.

"It has made us more aware, cos he's had some falls after I've gone to bed...Apparently he fell over in the bedroom right next to me and I slept through it." Caregiver 18

Some participants, PwP and caregivers, discussed how the guide supported them in discussions that they had with their spouse through providing 'backup' for their views.

"Something written down by a professional is actually good because I can pick it up and say... 'have you thought about going to see a Physiotherapist?', 'Um no I don't think we need to do that'...then I could say...'it does say talk to a Physiotherapist'...And we did... which is a real plus." Caregiver 156 (Caregiver of a PwP with dementia)

Subtheme: The Guide as a Facilitator to Communication Between the Dyad and HCPs

Most participants described limited contact with HCPs during the study. Of the three PwP who had a scheduled review with HCPs, two described increased confidence to raise issues with them. One participant described how the diary had facilitated falls history taking; a few participants without cognitive impairment/ dementia discussed how they would continue to use the falls diary for this purpose. A few caregivers described how the guide had prompted them to seek further advice and support from occupational therapists and physiotherapists.

"If I didn't have the book to write it down, I probably wouldn't have remembered...I make notes of it when I come to see [the doctor]." Caregiver 98

A few PwP discussed difficulties in communicating with HCPs. Some of these participants described disliking the signposting to HCPs within the guide, and one went so far as to say that the guide was 'batting off' their concerns. A few discussed difficulties they had previously encountered trying to navigate the healthcare system, one stated that locality specific information of services needed to be included.

"The references to Social Services and OT...a bit incomplete...There is a route to getting help and I found that quite tough at times." PwP 11

Theme: The Guide: Effect on Knowledge of Symptoms and Problem-solving Practices

Many PwP and caregivers described the guide increasing their knowledge. There was variation in information considered new; the most common topics were freezing strategies and how to get up from the floor. The greatest perceived benefits were amongst PwP who had been diagnosed more recently. Where the PwP had been diagnosed for longer, or had taken part in previous PD

falls research, participants were more likely to remark that the guide contained little new information. However, those who had been diagnosed for longer did often describe that was new to them or stated that the guide was the first written information that they had received about falls.

“If I can get the wheels to him, and he can get up on one knee, like it says in the book...we can often get him onto his feet... I don’t think anybody had specifically given us any instructions before... [My husband] has had it for 15 years now.” Caregiver 42

Many participants, the majority of whom PwP, described how the guide had led them to try to problem-solve the cause of their symptoms. These PwP included those with both high and low concerns of falls, with no apparent relationship to time from diagnosis. Most of these participants described how writing their symptoms down within the falls diary had led to greater reflection, understanding and management of their symptoms. Two PwP described modifying the diary to aid problem-solving.

“Writing down helped me...when I had a fall and I come and wrote it down, it gave me time to think... I could sort of see if I had perhaps slowed down... and concentrated.” P57

However, a few had difficulty attributing a cause of their symptoms, and one caregiver found no benefit from writing within the guide.

“We wouldn’t sort of sit and formally write something down if we weren’t on a study...it doesn’t mean we wouldn’t look at the ‘why’ of something rather than just accepting that you’ve got Parkinson’s you’re going to trip over.” PwP 124 (Caregiver of a PwP with cognitive impairment)

Two dyads where the PwP had been diagnosed for more than 10 years described using the diary to simply document that a fall had occurred, and not as a tool to trigger reflection and understanding.

“Somewhere to fill in when she did fall...It really was just a record... [My wife] wrote a few things maybe to watch out for but it was more a record that she used.” PwP 12

Theme: Intervention as a Facilitator to Implement Change

Subtheme: Telephone Calls as a Driver to Instigate Change

Most participants described the telephone calls as an aide memoire to use the guide and/or allowed them to feel that they were not alone. However, in a few caregivers, the telephone calls triggered reflection of current difficulties, or enhanced their focus toward strategies that they needed to implement.

“You’d rung and said ‘how you getting on’? And I thought ‘actually it is now time I brought in somebody else’.” Caregiver 42 (Caregiver of a PwP with dementia)

Subtheme: Adopting a More Strategic and Proactive Approach

Nearly all participants described implementing strategies to manage falls during the study. Only one caregiver and one PwP, who did not use the guide and described previous engagement with Parkinson’s (UK) and other PD falls research projects, stated that they had made no changes. Participants described a wide range of strategies that they had implemented in keeping with their personal circumstances. Changes were made in response to reflection, problem-solving or information within the guide. Some participants described how through emphasising why a strategy was important, the guide led them to implement strategies that they had not previously explored. The most common changes made included: enhanced concentration and care, slowing down, care when multitasking, and adjustment of activities to modify falls risk.

“Keeping the floor space clear... its stupid things like I didn’t realise how important it was to keep the floors, you know, free.” PwP 1

Some participants, most of whom used the falls diary, described using the action plan to document strategies that they planned to implement. A few participants, all without cognitive impairment/ dementia, described how completion of an action plan allowed for greater focus on any planned changes.

“Writing down the Action Plan...there’s little things that happen all the time and you think ‘oh I must remember that I must never do that’...if you don’t have anything you forget and go and do it again.” PwP 167

Some participants described adopting a more proactive approach in response to the guide. This included planning for future possibilities, such as considering how to best manage fall risk on journeys away from the home.

“The idea of preparing yourself beforehand if you were going to go somewhere...one of the trips was a nightmare, but the others, because I kind of pre-empted what could have happened, worked out.” PwP 125

Theme: Effect on Physical and Psychological Outcomes

Subtheme: Effect on Fall Rate and Physical Symptoms Associated with Falls

Amongst those who used the guide, all reported successful strategies that they had adopted, or improvement in physical or psychological outcomes. Some participants felt that the PwP was now

falling less frequently. This perception of reduced falls did not appear to relate to time from PD diagnosis and included PwP with low and high fall frequency. Participants attributed improvements to changes instigated in response to using the guide.

“It’s made me aware that I can be more in control if it...Instead of thinking ‘at some point I’m going to fall’ I kind of think... ‘well if I do this perhaps I won’t.’” PwP 125

A few other PwP, including two PwP who had never fallen, discussed improvement in their symptoms of unsteadiness. Participants attributed this to arise from changes that they had implemented to manage light-headedness, adaptations within the home and professional advice that they had sought.

“I did actually get a grab rail put on the wall... I was quite pleased when [my wife] said that it did help [her].” Caregiver 178

All but one of the participants who had used the guide during the study reported that they would be likely to continue to use it. Ongoing use appeared to be driven by perceived benefits obtained from the using the guide. The one participant who reported that they would not continue to use the intervention reported no benefits in association with the intervention.

“The Action Plan and what you could do, try to do about it and how it helped, that I found very handy...definitely [continue to use it] ...because of [the action plan].” PwP 167

Some participants, PwP and caregivers, discussed how the PwP now got up from the floor after a fall. Two PwP discussed how they had previously been unaware of how to get up or had been physically assisted by their caregiver. These PwP described how they would now stand up via the step-by-step approach described within the guide. Conversely, two caregivers of PwP who had been diagnosed for 14 and 15 years, described that they continued to lift the PwP up from the floor themselves related to the perception that they would be perceived a nuisance calling for paramedic support.

“It was far beyond my capabilities...ambulance drivers are far too busy you don’t want to be a nuisance.” Caregiver 42 (Caregiver of a PwP with dementia)

Many PwP and caregivers reported ongoing falls-related symptoms. These participants were more likely to have been diagnosed with PD for longer and included those with both low and high frequency of falls. The most common ongoing difficulties related to small spaces and unpredictability of symptoms.

Subtheme: Confidence in Managing Falls-related Symptoms

Many participants, PwP and caregivers, described an increase in their confidence of falls managed that they attributed to using the guide. PwP with higher concern of falls were over-represented in this group; there was no apparent relationship to time from diagnosis. Participants commonly credited enhanced confidence to arise from improved knowledge or ability to manage their symptoms.

“It starts to get bad in the evening and then I need to sort of concentrate on strategies for dealing with falls... [the guide’s] made me a little bit more confident.” PwP 17

A few participants, most of whom were caregivers with high caregiver burden, discussed increased confidence in managing falls related to the guide reassuring them they had already been managing falls correctly. However, as a caveat to this, one caregiver discussed how this could leave them to feel that there were no further options available to them.

“I thought gold stars all round...we’re doing the right thing. We can’t do anything more than we’re doing. I think in a way that can be quite depressing as well... [My husband] wants it to go away rather than have to live with it.” Caregiver 18

Some PwP and caregivers were positive of the presentation of falls risk as modifiable, which could lead PwP to feel more in control of their symptoms, and ease caregivers’ worries of future PD progression. One PwP discussed that this contrasted previous resources that they had accessed.

“If this doesn’t work, try this...before, everything you’ve read would be ‘do this, do that’ but [the guide] sort of gave you – ‘it doesn’t matter if it doesn’t work for you, you might find something else that does’. And that helped.” PwP 125

Subtheme: A More Positive Outlook Versus Ongoing Concerns of Falls and their Consequences

Some PwP, the majority with low HRQOL, discussed feeling more positive. Participants could attribute this to greater perceived control of their symptoms, understanding falls risk as modifiable, additional support from HCPs and the positive outlook presented within the quotations. Participants from two dyads, both of which the PwP had been diagnosed for less than four years, viewed the guide to have a calming influence when using it to manage the PwP’s symptoms or to reflect on an event.

“[My husband] wanted to get up but couldn’t move...We were both panicking... his legs wouldn’t move... I got the book out and said to him ‘right now this is what you’ve got to do... And [he] did it on [his] own.” Caregiver 98

Where described, the effect of the guide on fear of falling was mixed. Equal proportions of PwP reported that their fear was unchanged as reported that their concerns had reduced. Where PwP reported reduced fear of falling, this was attributed to arise from an enhanced understanding of their symptoms, increased awareness of fall risk or adaptations that they had instigated to manage falls.

"I'm not quite so worried as I was a while back...Now I've realised what's been causing it...that's helped a bit...Not made me quite so nervous." PwP 57

Some caregivers, with both low and high levels of caregiver burden, discussed ongoing worries of the PwP being alone. Two caregivers described heightening of these concerns as they were now more aware of the PwP's risk of falls. Caregivers could try to reduce the activity of the PwP or restrict the duration and/or frequency of times that the PwP was alone to try and manage these concerns.

"[The guide] certainly made me more concerned about her...because I could see situations...I dread sort of coming back and finding [my wife] on the floor...it would certainly make me think twice about ever going out for more than a couple of hours." Caregiver 178

Some participants, caregivers more than PwP, also raised ongoing concerns of injury in association with a fall.

"We've got to be very careful not to fall and break anything because once that starts happening life gets really a lot more difficult." Caregiver 178

Theme: Difficulties Encountered When Attempting to Implement Changes to Manage Fall Risk

All participants who described instigating changes encountered difficulties. The most frequent issue related to environmental circumstances that were perceived non-modifiable. This frequently resulted in ongoing difficulties in mobilising outside, which could lead to avoidance of physical activity, or ongoing falls risk.

I think that's been the most dramatic fall he's had, because that was outside...He has got a fear of falling, which is making him not want to go out of the house very often." Caregiver 18

The second most frequent discussed problem related to cognitive impairment/ dementia. At least one member of all dyads where the PwP had cognitive impairment/ dementia discussed how this led the PwP to have difficulty learning new information and to forget strategies to manage their

symptoms. Some PwP with cognitive impairment/ dementia were perceived to fail to accept their limitations.

“It’s so very difficult... he doesn’t automatically get the Zimmer frame and he just goes off and walks. And that’s why he falls... [My husband] just does these silly things.”
Caregiver 46 (Caregiver of a PwP with dementia)

A lack of acceptance of limitations was also described in some PwP who were cognitively intact, with some linking this to PwP striving to maintain their current level of independence. PwP and caregivers frequently described difficulties in PwP changing their behaviour to include improvements to the way that they turned, increasing ground clearance and taking longer strides when walking, slowing down and concentrating. A few caregivers described difficulties in changing their own behaviour, to include not talking to the PwP whilst walking.

“He’ll start walking...I’m jabbering away and then he stops... [My husband] will say ‘[Caregiver 20] don’t talk to me please’ because he’s got to concentrate... it’s so difficult.”
Caregiver 20

Some PwP raised concern of how they were viewed by others. This appeared to act as a barrier to change in two PwP, who discussed not wanting to make home adaptations linked to the perception that they were for people who were ‘disabled’ than themselves.

“I feel I don’t want to turn the house into a sort of, disabled person’s house.... I feel instinctively that I give into some of these ideas that I’m going down that route.”
PwP 155

Only two participants described adapting management strategies following initial failure. Where other participants raised barriers or limitations, they did not go on to describe how or if they had overcome these.

“I had trouble counting...I wasn’t walking straight...then somebody suggested getting a sort of, not a marching song but a slightly slower tempo.” PwP 1

7.2.6 Telephone Calls

Telephone calls at two, four and eight weeks aimed to identify any difficulties that participants were experiencing with the guide and provide support and encouragement for the self-management strategies that it described. The telephone calls were also used to collect data about any falls or HCP contact, and participant’s views and experiences of the guide.

7.2.6.1 Number of Telephone Calls Participants Received

82% of PwP and 70% of caregivers received all three telephone calls (Table 7-9).

Table 7-9 Number of telephone calls completed with participants

Number of telephone calls received by participants	PwP n (%)	Caregivers n (%)	All participants n (%)
Zero	3 (4%)	1 (2%)	4 (3%)
One	2 (3%)	5 (9%)	7 (5%)
Two	8 (11%)	11 (19%)	19 (15%)
Three	61 (82%)	40 (70%)	101 (77%)

7.2.6.2 Barriers to Using the Guide as Assessed by the Components of the Problematic Experiences of Therapy Scale

Where participants reported a difficulty with using the guide, this was grouped into the components of the Problematic Experiences of Therapy Scale (PETS) by myself at the time of the telephone call. The four components of the PETS are (i) symptoms too severe to try the suggestions or symptoms are aggravated by suggestions, (ii) uncertain about how would do the suggestions, (iii) doubt that suggestions will help/ they are not relevant, and (iv) practical problems: lack of time/ opportunity/forgetting what to do (229). Data contributing to each of the four components is outlined in Table 7-10 .

Table 7-10 Barriers Reported by Participants and the Corresponding Component of the PETS

PETS Component	Contributing information reported by PwP and caregivers
Symptoms too severe to try the suggestions or symptoms are aggravated by suggestions	<ul style="list-style-type: none"> • Have not trialled the advice because PwP does not follow advice provided with, often arising from dementia • Discussed how PwP was unable to go outside due to fear of falling • PwP freezes without warning • Symptoms are unpredictable and cannot predict when they will occur so cannot instigate strategies to prevent them
Uncertain about how would do the suggestions	<ul style="list-style-type: none"> • Uncertain what to log • Uncertain how could go about instigating strategy e.g. difficulty calling 999, and difficulty changing behaviour
Doubt that suggestions will help/ they are not relevant	<ul style="list-style-type: none"> • Guide provides no new information • Information within the guide is not relevant to them, to include a perceived lack of symptoms • Participant feels that the strategies within the guide, and using the log and the action plan will not help • Guide is not relevant to them, could be viewed more pertinent for others to include more beneficial for PwP than caregivers, and more beneficial for those who have had PD for less time
Practical problems: lack of time/ opportunity/forgetting what to do	<ul style="list-style-type: none"> • Writing difficulties leading to difficulty using the guide • Difficulty using the guide as forgetting what to do- to include forgetting to log the falls, PwP forgetting the strategies due to dementia (as opposed to not trialled the strategies due to dementia, coded within 'symptoms too severe'). Caregivers could describe reminding the PwP to implement strategies when they forgot them. • Difficulty using the guide arising from a lack of time, to include symptoms too frequent or caregiver unwell. • Guide was lost by participants

Frequency of participants reporting each of the PETS components is displayed in Table 7-11. The main issues, which were widely held, were doubts that the intervention would help and practical problems, to include a lack of time. Yet only a small proportion of participants reported that their symptoms were too severe to try the suggestions or that they were not sure how to enact them. This could suggest individuals reporting barriers have the potential for future behavioural change. However, with successive telephone calls, participants were more likely to report doubts that the intervention would help, but less likely to report a lack of time.

Table 7-11 Barriers to Using the Guide Grouped by PETS Component

PETS Component	Participant group	Number (%) of participants reporting PETS component			
		Telephone Call One n (%)	Telephone Call Two n (%)	Telephone Call Three n (%)	Across all telephone calls n (%)
Symptoms too severe to try the suggestions or symptoms are aggravated by suggestions	PwP	2 (3%)	1 (1%)	5 (7%)	8 (11%)
	Caregivers	3 (5%)	7 (12%)	2 (4%)	10 (18%)
	All	5 (4%)	8 (6%)	7 (5%)	18 (14%)
Uncertain about how would do the suggestions	PwP	5 (7%)	3 (4%)	4 (5%)	11 (15%)
	Caregivers	4 (7%)	0 (0%)	2 (4%)	6 (11%)
	All	9 (7%)	3 (2%)	6 (5%)	17 (13%)
Doubt that suggestions will help/ they are not relevant	PwP	29 (39%)	32 (43%)	41 (55%)	56 (76%)
	Caregivers	16 (22%)	17 (23%)	26 (35%)	42 (74%)
	All	45 (34%)	49 (37%)	67 (51%)	98 (75%)
Practical problems: lack of time/ opportunity/forgetting what to do	PwP	25 (34%)	24 (32%)	19 (26%)	42 (57%)
	Caregivers	21 (37%)	19 (33%)	19 (33%)	39 (68%)
	All	46 (81%)	43 (75%)	38 (51%)	81 (62%)

7.2.6.3 Qualitative Analysis of the Telephone Calls

Handwritten field notes of the telephone calls were analysed through content analysis. Four key findings were identified (Table 7-12): (i) the guide as a facilitator to enhance focus and understanding of symptoms, (ii) development and implementation of management strategies to manage unsteadiness and falling, (iii) engagement with the guide: enablers and barriers and (iv) limitations delivering and implementing the intervention and subsequent adaptation. Data contributing to each of the key findings is outlined in Appendix F17.

Table 7-12 Key Findings Identified from the Telephone Calls

Key Finding	Sub-findings
Key finding one: The guide as a facilitator to enhance focus and understanding of symptoms	<ul style="list-style-type: none"> • The guide as a conversation starter • Effects of the guide on understanding of symptoms
Key finding two: Development and implementation of management strategies to manage unsteadiness and falling	<ul style="list-style-type: none"> • Self-management practices developed before the study • Guide as a facilitator to the development and implementation of management strategies • Difficulties implementing management strategies • Management strategies often resulted in improved PwP symptoms, but concerns frequently remained
Key finding three: Engagement with the guide: enablers and barriers	<ul style="list-style-type: none"> • Variations in engagement across time and user characteristics • The importance of PD duration • Engagement could be limited by participants' general capacity • Being a good participant and researcher identification of introjected regulators
Key finding Four: Limitations delivering and implementing the intervention and subsequent adaptation	Not applicable. No sub-findings

Key Finding One: The Guide as a Facilitator to Enhance Focus and Understanding of Symptoms

The Guide as a Conversation Starter

The unsteadiness and falls diary could jog participants' memory of events that had occurred. Some PwP and caregivers used the diary to prompt themselves of events during the telephone calls and three described how the diary had aided their interaction with HCPs, which had led to subsequent enhancement of HCPs management plans. These behaviours were not limited to those from a dyad where the PwP had a diagnosis of cognitive impairment/ dementia.

A few PwP and caregivers, all from dyads where the caregiver had high caregiver burden, described how the guide prompted conversations about falling within the dyad or with family members. These participants described how they had reflected on episodes of unsteadiness and falling, which could be facilitated by the diary.

Effects of the Guide on Understanding of Symptoms

Many participants, PwP more than caregivers, described increased focus on falls. These participants often described problem-solving to ascertain the cause of their symptoms; frequently the falls diary was a facilitator. A few were able to identify a pattern to their symptoms through the diary. These participants varied in time from PD diagnosis, scores on the FES-I or single-item falls self-efficacy question. Conversely, some participants, the majority PwP, used the diary as a

simple record that a fall had occurred. This could arise from the perception that they already knew how to manage falls.

A few participants, PwP and caregivers, described using the guide to re-visit events they had previously dismissed. This reflective practice could enhance their understanding of their symptoms.

Key Finding Two: Development and Implementation of Management Strategies to Manage Unsteadiness and Falling

Self-management Practices Developed Before the Study

Where PwP and caregivers described behaviours to manage falls, it was often difficult to ascertain whether these were developed prior to or during the intervention period. Behaviours varied considerably; the most common included (i) enhanced care and concentration, particularly in circumstances they felt vulnerable and (ii) ensuring that they remained physically active. Most caregivers supported with balance and falls, which was more often provided through verbal reminders as opposed to physical assistance.

Guide as a Facilitator to the Development and Implementation of Management Strategies

Participants from around half the dyads, and twice as many PwP as caregivers, described strategies to manage unsteadiness and falls that were developed during the study period. These were often instigated in response to an episode of unsteadiness or a fall. Behaviours varied considerably; the most common were enhanced care and concentration, conservative measures to manage postural hypotension and rearranging furniture. It was often difficult to ascertain whether behaviours were self-instigated or derived from the guide.

Eleven participants, comprised of both PwP and caregivers, and without cognitive impairment/dementia, described how the diary or the action plan provided an aide memoire for strategies that they had implemented to manage unsteadiness and falls.

Difficulties Implementing Management Strategies

Many PwP and caregivers described difficulties implementing strategies to manage unsteadiness and falls. Those diagnosed longer tended to report: (i) strategies to overcome freezing and light-headedness within the guide did not help, and (ii) difficulties in getting up from the floor using the step-by-step approach within the guide. Some participants, PwP and caregivers, discussed difficulties in the PwP accepting their limitations and making changes to their behaviour; caregivers could perceive these PwP to be in denial. A few caregivers were concerned that they

could be perceived as nagging the PwP when reminding them of strategies to implement.

Caregivers of PwP with dementia often discussed how the PwP did not follow advice provided by themselves or HCPs.

A few participants described self-identified strategies to manage fall risk that were later deemed ineffective. Few participants described adaptation of management strategies following initial setback; where described, this often followed a trial and error approach.

Some PwP and caregivers, most from a dyad where the PwP had been diagnosed for longer than five years, discussed how although the guide promoted discussion with HCPs, they had previously encountered difficulties. These related to concerns of intrusion, uncertainty of how to contact HCPs, or a perception that HCPs had too little time.

Management strategies often resulted in improved PwP symptoms, but concerns frequently remained

Some PwP and caregivers described that PwP symptoms had improved following management strategies that they implemented. Strategies that were attributed to have led to an improvement in symptoms varied considerably; the most common were (i) the freezing strategies described within the guide and (ii) enhanced awareness and care. A few participants described successful strategies that had been instigated after self-identification of symptoms when using the unsteadiness and falls diary.

A few PwP and caregivers perceived that the changes that they had instigated were small. Some participants were reassured by this, others could feel that changes instigated were insignificant.

A few caregivers discussed positive outcomes for themselves arising from the guide. Caregivers who perceived that the PwP was reluctant to change could discuss how the guide provided 'professional back up' for their views during discussions with the PwP.

However, many dyads described ongoing concerns. This seemed common in participants from a dyad where either the PwP (i) had cognitive impairment/ dementia, (ii) was diagnosed within the last five years, or (iii) had not fallen within the last year. Many participants were unsure of how to manage the PwP symptoms; the most common unmet concerns related to freezing and light-headedness. Some PwP and caregivers discussed ongoing fear of falling in the PwP, which was more common where the PwP had a high baseline FES-I score.

Key Finding Three: Engagement with the Guide: Enablers and Barriers**Variations in Engagement Across Time and User Characteristics**

Around two thirds of participants described using the diary or the action plan. Use was greatest amongst those who fell during the study; the majority of PwP who fell, and around half of their respective caregivers, used the diary. Fewer participants used the action plan than the diary, and the majority of those using the action plan also used the diary. Only seven caregivers described using the action plan, nearly all were from a dyad where the PwP had cognitive impairment/dementia.

Whilst many PwP and caregivers reported not using the intervention during at least one of the telephone calls, seven PwP and eight caregivers, derived from fourteen dyads, described non-engagement at all three time points. The proportion of those describing non-engagement was similar at each of the three time points. Some reported only one member of the dyad engaged with the intervention, here, use was greater amongst PwP than caregivers. The guide was lost by two PwP who were recruited alone and one dyad; these participants received a replacement.

The Importance of PD Duration

Around half of participants, more PwP than caregivers, which included participants from a dyad where the PwP had and had not fallen within the last year, described the guide as good, interesting or helpful. There was considerable heterogeneity of content reported to be helpful; information about freezing was most discussed.

Where participants stated that the guide provided them with new information this did not appear related to PD duration. Information within the guide considered new varied considerably. Some PwP and caregivers discussed how the guide provided a useful reminder of information. These participants were more likely to be from within a dyad where the PwP had had PD for longer, and the vast majority were from a dyad where the PwP had fallen in the last year.

Conversely, some participants, the majority of whom were caregivers, felt the guide provided little new information. A few perceived it was common sense and described behaviours that they did automatically. All but two of the participants raising these views were from a dyad where PD had been diagnosed more than five years ago. Some of these participants felt the guide was more appropriate to those nearer to the start of their journey. Equally, some of those from a dyad where the PwP had not fallen in the last year felt that the guide would be more relevant to those who had been diagnosed for longer, who they perceived to have greater problems than themselves.

Some PwP described that guide addressed their concerns of unsteadiness and falls. However, a few PwP and caregivers, the majority of whom from a dyad where the PwP had been diagnosed for more than ten years, described ongoing concerns. These participants discussed information that they perceived to be missing from the guide, which was often very specific to their individual requirements.

Some participants, more PwP than caregivers, expressed doubt that the interactive components of the guide would provide benefit. Doubts were more frequent amongst those from a dyad where the PwP had been diagnosed for longer or where the PwP had fallen within the last year. These participants could perceive that the diary would not help to either identify patterns of symptoms or ways of managing, that writing things down would not help, and reduced relevance in the setting of dementia. A few caregivers perceived that the guide was primarily for the PwP, and that completion of the diary and the action plan was the PwP's responsibility.

Perceptions of the language and layout of the guide were mixed. Where negative, participants could feel that the guide was too long, required less text and less repetition.

Engagement with the Intervention and Participants' Perceptions of Falls

PwP and caregivers frequently described concerns of unsteadiness and falls, which often appeared to drive their engagement with the guide. A few, PwP more than caregivers, discussed how they had been prompted to look at the guide following an episode of unsteadiness or a fall. A few PwP, including attendees and non-attendees of Parkinson's UK support groups, perceived the guide to provide a sense of rapport, some of which cited this to arise from the quotations that it contained.

Where participants perceived their symptoms as minimal or unchanged, engagement was often low. Many PwP and caregivers from a dyad where the PwP had not fallen in the last year described limited engagement. Some PwP and caregivers, the majority of whom were male and had been diagnosed within the last five years, appeared to normalise falls or to describe them as unpreventable. Where falls were normalised, reduced use of the diary and action plan was often described. A few caregivers, the majority of whom had high caregiver burden, could appear frustrated when discussing reduced interaction of the PwP with the guide. These caregivers could perceive the PwP to be in denial of their fall risk or reluctant to change their behaviour. Conversely, three caregivers discussed how use of the guide could be perceived as dwelling on the PwP symptoms, and lead to a deterioration in the PwP's mood.

Most caregivers described support that they provided for PwP. A few caregivers perceived their concerns of falls to be greater than those of the PwP, some of whom described using the guide more than the respective PwP and encouraging the PwP to use it.

Engagement Could be Limited by Participants' General Capacity

Nearly half of participants, with an equal split of PwP and caregivers, described limitations in their time arising from existing Parkinson's and non-Parkinson's related activities. Some described acute illness, and a few PwP discussed PD-associated fatigue. These limitations could reduce their engagement with the guide. A few PwP who perceived themselves to have a high frequency of symptoms, discussed that diarising their symptoms would be too time consuming.

Being a Good Participant and Researcher Identification of Introjected Regulators

PwP and caregivers frequently enquired about the conduct of the study. Some participants appeared to express guilt when discussing non-completion of the falls diary. These participants could state that they would attempt to use it for the benefit of the research study, with no apparent thought that it might help themselves. Some participants expressed concern that they were not helping with the study, which could relate to their perceived low frequency of symptoms. Participants often thanked the researcher for completing the telephone call and for expressing an interest in their condition and symptoms.

Key Finding Four: Limitations Delivering and Implementing the Intervention and Subsequent Adaptation

A few PwP and caregivers without a diagnosis of cognitive impairment/ dementia described difficulty reading the guide arising from reduced concentration and memory.

Some, the majority of whom were cognitively intact PwP, described barriers to completion of the falls diary and action plan. These included difficulty writing, a lack of space to write, forgetting to complete the diary after an event, and uncertainty about what to record. A few PwP and caregivers described initially completing the diary but had ceased doing so as it was repetitive and perceived futile. A few participants described completing an action plan within their head, but not documenting this within the guide. These participants could view documentation as unnecessary, be unsure of what to write, or want to try a strategy before putting pen to paper.

A few participants, PwP more than caregivers, described adaptations that they had made to the diary and the action plan. Changes made to the diary included adding a date/ time to facilitate identification of patterns of symptoms, completing the diary on a computer to overcome difficulty with their writing and producing a generalised diary due to their perceived high symptom

frequency. A few participants wrote on a separate piece of paper before transferring it to the diary as it allowed for refinement of their thought processes before writing within the guide.

7.2.7 Triangulation of Findings

Data from each of the four data analyses was amalgamated and summarised through a triangulation protocol as outlined in the methods of this study (167). A total of 149 findings were identified from across the four data analyses: (1) questionnaire quantitative data in the Likert responses and scores on FES-I, PDQ-8-SI, ZBI and single item falls-self-efficacy question, (2) questionnaire content analysis, (3) semi-structured interview analysis and (4) telephone call analysis (including the PETS analysis). A convergence matrix was created, which identified 59 independent different key findings from the four separate analyses (Appendix F18). Seven independent key findings drew information from one analysis, 23 independent key findings drew information from two data analyses, 20 independent key findings drew data from three data analyses, and nine independent key findings drew data from all four data analyses.

For each of the 59 independent Key findings, six paired comparisons were made between the four potential sources of data (the four data analyses); 354 paired comparisons were made. There were 174 instances of silence (where one data source contributed and one did not), 94 instances of partial agreement (where one data source partially agreed with the other), 30 instances of agreement (where both data sources provided the same information) and 15 instances of dissonance (where the two data sources disagreed with each other). There were 38 instances where neither of the data sources being compared contributed to the key finding undergoing scrutiny (silence). The majority of instances of partial agreement arose where one data analysis helped to explain or expand on the findings of another analysis, which was linked to the underlying different methodologies used, an acknowledged benefit of mixed methods research (164). Instances of silence often arose from the design of the study, as each of the data sources had different aims and objectives. The pertinent findings from the triangulation protocol are presented, described and discussed within the discussion of this chapter. The complete results are outlined in Appendix F18.

7.3 Discussion

This mixed methods study assessed the feasibility of a self-management intervention for community dwelling PwP who experience unsteadiness or falls, and their caregivers. The findings from qualitative and quantitative analyses were integrated through a triangulation protocol, which allowed exploration and a credibility check, enhancing the quality of the findings presented

(167,230). Credibility checks are performed in qualitative research to enhance the integrity of the findings presented (230).

7.3.1 Principal Findings

7.3.1.1 Feasibility of Trial Procedures

There was good recruitment through both NHS Outpatient Clinics and Parkinson's UK Support Groups. This may have been helped by the close relationship between the University Research Department, specialist PD clinicians and Parkinson's UK networks. A representative sample of PwP and caregivers were recruited, to include men and women, and those with and without cognitive impairment/ dementia. PwP were not excluded by disease severity. This inclusive sample increases the external validity of the findings presented.

The majority of those who were provided with written information consented to take part in the study. The retention rate of participants was high; 88% PwP and 93% of caregivers enrolled completed the study. Those who were lost to follow-up had no unifying characteristics. All participants invited to interview agreed to participate. These features suggest that the intervention and the collection methods were acceptable to participants. Many previous studies exploring the experiences of PwP have excluded those with cognitive impairment (15–21). 15% of the PwP in this study had a diagnosis of cognitive impairment/ dementia, suggesting that PwP with cognitive impairment/ dementia are keen to participate in research, and are no less able than their cognitively intact peers when supported by caregivers, as has been reported previously (28).

Most telephone calls were completed following the CARE approach. During the telephone calls, I was often able to provide personalised advice as to how the intervention might benefit. For example, where participants discussed how they had not used an element of the guide, I provided advice as to how it might help them. There was a high uptake of participants' engagement with the telephone calls. However, both members of the dyad did not always wish to talk. Other difficulties included difficulties with recall, which was not exclusive to those with cognitive impairment/ dementia, and fragmented conversation arising from speech or hearing problems. A few participants expressed a preference for the telephone calls to be at a pre-arranged time. This could relate to work commitments, fatigue or wanting to prepare for the encounter.

7.3.1.2 Feasibility of the Intervention

This study focused on the feasibility components of acceptability, demand and implementation (226). The following sections summarise conclusions drawn about each of these aspects and discusses future adaptations that might be necessary/could be explored.

Acceptability of the Intervention

The following components of acceptability were explored: affective attitude, burden, intervention coherence, perceived effectiveness and self-efficacy of the intervention (231).

Affective Attitude

Affective attitude defines how an individual feels about an intervention (231).

Participants from a dyad where the PwP had cognitive impairment/ dementia could deem the intervention less relevant due to underlying perception that falls were inevitable. However, these individuals are often at enhanced risk of falling (28). A few participants in the interviews discussed concerns that giving the guide to those earlier in the trajectory of PD could heighten worry of PD progression. However, reassuringly, none of the participants in the subgroup of those who were yet to experience a fall reported such anxieties.

One of my a priori hypotheses outlined that PwP and caregivers attending Parkinson's UK support groups would be more likely to have developed behavioural strategies to manage falls compared to participants recruited from NHS outpatient clinics, which may lead them to view the guide less useful. In keeping with this hypothesis, in the interview analysis, some participants recruited from Parkinson's UK support groups described pre-existing information seeking behaviour, which could lead them to deem the guide less relevant. Regression analyses to assess the possible effect of participant's baseline characteristics on FES-I scores, to include recruitment source, were beyond the remit of this study, these could be explored in a future appropriately powered RCT.

Most participants were positive of the paper-based format. Participants often reported that an electronic format would be less acceptable, consistent with preferences previously reported by PwP (120,214). Most participants were positive of the way that information was presented in all analyses. In the interviews, where participants had chance to elaborate, a few participants suggested that diagrams would help to illustrate points.

In all three qualitative analyses, participants discussed the limited space to write in the guide and raised difficulties with their writing. Only a few described adaptations to overcome these difficulties. Given that micrographia affects around half of all PwP, and the interactive

components of the guide are key to supporting the self-management of falls through aiding problem-solving and action planning, the guide requires modification to increase its acceptability (79,232).

Burden

Burden defines the perceived amount of effort required to participate with the intervention (231).

Participants in this study often described limitations in their capacity. Those with a higher perceived frequency of symptoms and higher caregiver burden (as measured by the ZBI) described limitations in their capacity that led to reduced use of the intervention. Caregivers' time was limited by activities linked directly to their caregiving role, as well as non-caregiving activities. Those with increasing caregiver burden have previously been highlighted to have a higher illness related workload, referred to as their 'burden of treatment' (233).

Previous research has discussed the concept of 'cumulative complexity', which arises when an individual's capacity cannot meet the demand arising from both illness related and non-illness related activities (234). Following the cumulative complexity model, those with a higher burden of treatment, will have comparatively less capacity available to implement self-management interventions (234). This was found in this study, where PwP with a high frequency of symptoms and caregivers with a high caregiver burden reported using the intervention less. Those with a higher burden of treatment, such as those with a high frequency of symptoms, or greater caregiver burden, are the very individuals that a self-management intervention would seek to support. Therefore, it is imperative that the potential benefits of self-management interventions are described coherently to allow for these individuals to understand how it might help them.

Whilst the retention rate of participants was good, 50% received telephone calls reminding them to return the follow-up questionnaires. Delay in completion was often attributed to a lack of time. For any future study, it would be imperative to review all study documentation to ensure that participants are not required to complete any unnecessary paperwork to enhance the study's acceptability.

Intervention Coherence

Intervention coherence describes the extent to which an individual understands the intervention and how it works (231). Falling in PD is heterogeneous (26). To overcome the potential barrier of information overload, and to allow for the intervention to be individualised, participants were encouraged to select the parts of the guide that were relevant to them (79,90). Some information was duplicated within the guide as it was relevant to more than one section. This led some

participants, particularly those who had read the guide cover to cover, to perceive the guide repetitive, which might have reduced engagement.

To effectively self-manage a LTC individuals require the key skills of problem-solving and action-planning (79). The guide aimed to improve these skills through completion of a falls diary and the action plan. Some perceived writing unnecessary or that the interactive components were for research purposes only. Modification of the guide to provide clearer rationale of the potential benefits of using the falls diary and the action plan might enhance their use and in-turn increase problem-solving behaviours.

Perceived Effectiveness

Perceived effectiveness describes the extent to which participants perceive an intervention to achieve its purpose (231). For a self-management programme to be effective it must address the beliefs and concerns of the individual and provide vital knowledge about their illness and its available treatment (40,72,79,82,84).

In all three qualitative analyses, most participants reported finding at least some of the content of the guide useful. In keeping with the heterogeneity of PD, information found useful related to participants' varying personal circumstances (26). Applicable knowledge has been cited as important in those with other LTCs to include colorectal cancer, diabetes and stroke (151). Some PwP and caregivers perceived the guide contained little new information, leading to reduced relevance, engagement and knowledge obtained. This view was greater amongst caregivers than PwP, and in dyads where the PwP had been diagnosed for longer. This may suggest that the guide may be more relevant for those diagnosed more recently, who by their very nature are likely to have had less contact with HCPs, and therefore less information and support for falls. However, the qualitative analyses highlighted that participants who had been diagnosed longer could describe the guide as a useful reminder, and a few participants discussed that through emphasising why a strategy was important, the guide had led them to implement changes. These results highlight how participant's views about an intervention can be explored more comprehensively through in-depth qualitative research as opposed to response to questions on a Likert-type scale.

Participants' views of the comprehensiveness of the guide across the four data analyses displayed dissonance. In both the questionnaire quantitative analysis and the telephone call analysis few participants perceived that information was missing from the guide, however, a similar number of participants reported that there was missing information versus it was comprehensive in the interview analysis. Whilst in-depth qualitative interviews are more suited to the deeper

exploration of participants' views, participants may have felt more able to present their true feelings through an open-ended questionnaire as the interviews were performed by the same individual who had delivered the intervention (myself). Topics reported as missing varied in line with the heterogeneous nature of PD and falls (26). To meet the needs of all PwP the guide would need to be very lengthy, which could lead to information overload and disengagement (90). This difficulty might be overcome through modification to the guide to include more explicit or detailed signposting of where additional information and/ or support could be accessed, or through using an electronic format.

Whilst difficulties were encountered with the interactive components, in the interviews, many PwP described problem-solving to try to understand the cause of their symptoms; often facilitated by the interactive components. The majority of those who discussed using the falls diary reported that the act of writing had supported their problem-solving process.

The telephone calls aimed to provide structured behavioural change support to improve adherence with the guide (217). Whilst most participants found the telephone calls useful, this was generally attributed to the calls providing a reminder to use the guide, rather than support for self-management practices. Some participants wanted lengthier telephone discussions, which largely related to generalised support for their Parkinson's, rather than being falls specific, and a few discussed how the telephone calls could lead them to feel that they were no longer alone. This feedback may relate to underlying feelings of loneliness, which is common in older people, with over-representation of those with LTCs (235).

Self-efficacy

Self-efficacy refers to the participant having the confidence to perform the behaviours required to participate in the intervention (231).

Participants' self-efficacy of behaviours required to participate in the intervention, such as confidence in problem-solving and action planning were not assessed prior to the study. During qualitative analyses, where participants discussed increased ability to manage falls, this was often cited to arise from increased problem-solving behaviour. However, many participants encountered uncertainty in problem solving the cause of their falls and creating an action plan thereafter. The Patient Activity Measure is a 22-item scale that assesses patient knowledge, skill, and confidence for self-management of their healthcare. A tool such as the Patient Activity Measure could be used to assess who is likely to benefit from using the intervention (236).

Demand of the Intervention

The demand of the intervention describes the extent to which an intervention is likely to be used (226).

Most participants reported using the guide during the study. However, in the questionnaire quantitative analysis only 55% reported that they would be likely to continue to use it. Conversely, in the interview analysis, nearly all who had used the guide stated that they would be likely to continue to do so. Guilt that they had not used the intervention as designed was more frequently expressed by participants in the telephone calls and interviews than in the questionnaire. These discrepancies may suggest that participants felt a sense of 'duty' to take part in the study and to be a good participant, which might relate to the involvement of myself in both the delivery and analysis of the intervention.

In all four data analyses, participants were more likely to use the guide if they experienced symptoms during the study. Additionally, those with a lower frequency of symptoms could perceive that the guide was suited to those with a higher frequency of symptoms. This is consistent with the findings within the published literature, where studies of self-management interventions in other LTCs have been utilised at times when deemed most relevant (237).

Where the PwP was cognitively intact, a few caregivers perceived the guide to be the PwP responsibility. Given the important role that caregivers play in supporting PwP, and the progressive nature of PD, the guide should include a clearer message of the importance of caregivers and how they may use the guide instead/as well as the PwP. Providing a clearer rationale for how the caregiver stands to benefit from using the guide might support their engagement with it.

Most participants described using the interactive components of the guide. However, use was often infrequent, particularly in the setting of cognitive impairment/ dementia, and caregivers regularly drove the process. Cognitive impairment is common in PwP, and is often associated with executive dysfunction, which leads to impaired planning and mental inflexibility (238,239). Consequently, completion of the interactive components within the guide and implementation of any changes may be difficult for PwP with cognitive impairment/ dementia, heightening the importance of the presence of caregiver support for these individuals. Executive dysfunction often increases in prevalence in PwP as PD progresses, and those who were from a dyad where the PwP had been diagnosed for longer were also more likely to report difficulties with the interactive components (238). Furthermore, a few PwP did not complete the interactive

components due to self-perceived laziness, this may relate to apathy, which is a feature of executive dysfunction (238).

A previous study of a self-management intervention for weight loss also reported reduced use of the self-management components (237). In the weight loss study, participants cited a lack of feedback for the self-management components as a barrier to their use (131,240). Feedback was not provided to participants whilst they used the falls self-management intervention in this study. It would be important to explore the perceived importance of this to PwP and caregivers as providing this would affect the practicality of the intervention if implemented within the NHS (226).

Implementation and Practicality

Implementation defines the extent to which the intervention can be successfully delivered to participants as intended (226). Practicality refers to the extent that the intervention can be implemented without a need for additional resources or support (226).

In this study, participants received three telephone calls, which aimed to identify any difficulties that participants were experiencing with the guide and provide support and encouragement for the self-management strategies that it described. Most received all three telephone calls. Median durations of the three telephone calls were all less than five minutes and were therefore shorter than the five to ten minutes that had been proposed. Limited duration of support telephone calls was also reported in a study of an to support weight loss (223). Additionally, a recent review of telephone coaching interventions to support those with other LTCs reported that telephone conversations did not improve adherence with medical treatment (240).

Before implementing the intervention within the NHS, it would be important to further explore the possible benefit of the telephone calls: to tease apart issues relating to the dual nature (intervention prompt and information gathering) of the calls, and to control for any effect that the participants might have had in trying to support me in delivering the intervention. In this study, those who were recruited through the NHS were more likely to perceive the telephone calls as useful when compared to those recruited through Parkinson's UK. It might be possible to reduce the number of telephone calls, through either only delivering them to those who find them beneficial (asking people to opt in, or offering only to those with low social support, for instance) or reducing the number of calls made to each participant, thereby reducing the associated resources required to deliver the intervention.

7.3.1.3 Impact of the Intervention

Increased Focus on Falls Management

In all qualitative analyses, participants commonly described increasing their attention toward the management of falls. Participants could describe starting to problem-solve the cause of their symptoms to facilitate a greater understanding of them and adopting a more proactive approach in response to using the action plan. These PwP included those with both high and low concerns of falls, with no apparent relationship to time from diagnosis. Benefits associated with group-based self-management programmes have shown decay after programme end (37,102). It would be important to consider whether the benefits observed in this study persisted given participants had ongoing access to the intervention. The adoption of problem-solving behaviours is important for clinicians and researchers interested in PD, as it suggests that self-management interventions do have a place in PD management.

Falls communication between PwP and HCPs is often poor (28). The logic model developed within phase three (chapter six, page 169), hypothesised that the intervention studied might lead to improved communication between PwP, caregivers and HCPs. Participants discussed how the guide had led to increased discussion about falls, primarily within the dyad, but also with HCPs. These conversations led to enhanced awareness of falls and falls related concerns within the dyad, and occasionally heightened confidence to communicate with HCPs. A few participants discussed how the guide provided 'professional backup' for their pre-existing viewpoints, which supported them in these discussions.

Changes implemented

Through response to Likert-type question most participants stated that they felt confident in applying information within the guide to their routine. In keeping with the heterogeneous nature of falling in PD, participants described a wide variety of management strategies that they had implemented. However, difficulties were described by participants in all three qualitative analyses, which were often heightened where the PwP had been diagnosed longer or had cognitive impairment/ dementia. This likely relates to the high prevalence of executive dysfunction present in PwP (238).

Where management strategies were implemented successfully, participants often described improvements in their symptoms. It would be important to quantitatively assess any effect that the intervention might have on participants' symptoms through asking participants to diarise their symptoms.

Rarely did participants describe adaptations to management strategies when they had not been initially successful. Going forward, it would be important to emphasise the potential benefit of responding to barriers and adapting management strategies to try and support PwP and caregivers to self-manage the PwP difficulties.

Concerns of falls and Falls Self-efficacy

41% of participants completing the questionnaire described reduction in their falls related concerns. Conversely, although no power calculation was performed, there was no change in PwP concerns of falls as measured by the Short Form FES-I, which identifies an individual's concern of falls in seven set circumstances. In the interviews, where participants described reduced concerns of falls, these often appeared generalised and were not specific to a defined setting. Therefore, the dissonance between the findings from the quantitative and the qualitative data sets could relate to the Short-Form FES-I measuring a different outcome than that reported by participants in the interviews.

In this feasibility study, participants with lower baseline falls self-efficacy or recruited through the NHS were more likely to report a reduction in concern of falls. One of my a priori hypotheses outlined that PwP and caregivers attending Parkinson's UK support groups would be more likely to have previously self-sought information to support their management of falls in comparison to those recruited through the NHS. In keeping with this hypothesis, participants recruited from Parkinson's UK groups were more likely to describe that the information within the guide was not new to them, which led them to deem the guide less relevant. Therefore, these findings suggest that the intervention would be most beneficial to those who are the most vulnerable, to include (i) those who feel least in control of their symptoms (lower falls self-efficacy) and (ii) those have accessed the least support. Regression analyses to assess the possible effect of participant's baseline characteristics on FES-I scores, to include recruitment source, were beyond the remit of this study. These could be explored in a future appropriately powered RCT.

Comparison of scores on the single-item falls self-efficacy question at baseline and at 12 weeks showed no significant change in PwP or caregivers. However, in the questionnaires, many PwP and caregivers described increased control or confidence in falls management, and interestingly those with higher concerns of falls, as measured by the FES-I, were over-represented. In the interview analysis, a few caregivers, the majority of whom had high caregiver burden, described increased confidence in managing falls because the guide provided reassurance that they were managing falls correctly. Whilst this was a feasibility study and this analysis was not adequately powered to draw conclusions, the dissonance between the findings from the quantitative and qualitative findings may relate to the methods used. Quantitative assessment of falls self-efficacy

was assessed through PwP and caregiver response to one single question, which was designed for use in this study and has not been validated. In addition, exploration of PwP and caregiver views surrounding self-efficacy through qualitative methods is more comprehensive and allows for insights and ideas to be explored.

Psychological Well-being

This was a feasibility study and was not designed to show significant results on quantitative analyses; no power calculation was performed. There was a non-significant deterioration in PwP HRQOL as measured by the PDQ-8-SI, which was below the threshold of clinical importance (241). Conversely, in the interview analysis, some PwP (the majority of whom had reduced HR-QOL) described feeling more positive as a result of the intervention, which arose from increased control of their symptoms, perceiving falls risk as modifiable, quotations within the guide and additional HCP support sought. Similarly, comparison of before and after scores on the ZBI short version showed a non-significant deterioration in caregiver burden. Yet, caregivers could describe benefit from the intervention to include social support and reassurance that they were managing falls correctly.

The dissonance between the quantitative and qualitative findings may relate to the measures assessed. The PDQ-8 asks PwP to self-rate the effect of PD on eight aspects of their day to day life; many components including communication and muscle cramps are not falls-related, and were therefore not explored in the interviews (227). Similarly, whilst the ZBI short version is validated and widely used in PD research, many of the questions within the questionnaire are not relevant to the intervention studied (171). With increasing disease duration and severity, caregiver burden increases and HR-QOL decreases (39,47). It would be important to explore any effect that the intervention might have on HR-QOL and caregiver burden, such as through a RCT, which would allow control for the natural impact of disease progression (47,242). However, given that many of the measures of the PDQ-8 and the ZBI are not related to falls, it might not be realistic to expect the guide to have a significant effect on these broad outcome measures.

7.3.1.4 Adverse effects of the intervention

The intervention was associated with few adverse effects. Participants occasionally raised difficulties with the telephone calls to include participant anxiety, a lack of non-verbal communication and a preference for scheduled contact. Issues with telephone communication have previously been raised by older patients with multimorbidity (243). In comparison to face to face support, HCPs have previously described that whilst more practical for those who have

difficulties in getting to appointments, telephone calls may lead to less fruitful conversations (244).

Qualitative data shed insights into concerns associated with the intervention. Participants occasionally raised frustration within the dyad when discussing falls, and concerns of dwelling on PwP difficulties. The guide aimed to increase knowledge of falls and their management in caregivers. However, in some caregivers this occasionally inadvertently increased their concerns. Future research should ensure that caregivers are encouraged to discuss any concerns that they might have to avoid negative psychological consequences.

7.3.2 Effect of the Researcher on Data Collection and Data

Analysis

The characteristics of the researcher should be described to understand the personal perspective from which the data is collected and analysed (230,245).

Within this study, I introduced myself as both a clinician and a researcher, which may have led some participants to believe (despite participant information sheets) that taking part would be medically advised and thereby affected their willingness to take part. A small minority of participants recruited from NHS outpatient clinics were seen by me in a clinical capacity. Those recruited through the NHS were more likely to complete the interactive components of the guide, which could suggest that they might have been more willing to help. Whilst acknowledging that this may have hindered the openness of participants; they appeared comfortable providing honest feedback to include barriers and difficulties with the intervention (230).

During the telephone calls a minority of participants asked questions relating to their clinical care. I had seen these participants in a clinical capacity in an NHS outpatient clinic. Where this arose, I explained that I was not able to provide clinical advice in my researcher role, and the telephone call continued in accordance with the schedule outlined in Appendix E8. In the few instances where this occurred, I made a subsequent telephone call to these participants to explore and address the clinical issues raised.

Successive telephone calls increased in duration, which may relate to my ability to build up a rapport, building upon skills developed in clinical practice (246). Conversely, clinicians have previously been identified to adopt a less exploratory approach during qualitative semi-structured interviews, which might reduce the quality of data obtained (246). My skills in semi-structured interviews were developed through attendance at relevant courses, practice in phases one

(chapter four) and two (chapter five) and reflection of my practice through listening to the audio-recordings and discussion with my supervisors.

As the intervention was designed and implemented by me, this may have created bias during qualitative data collection and analysis. Conscious effort was made to minimise this through encouraging participants to be open and honest. However, participants were more likely to express guilt that they had not used the guide, or to report that they would be more likely to use the guide, when face-to-face with the researcher. The effect of this could be minimised through having data collected and analysed by a third party. The supervisors for the research project were involved in overseeing and discussing emergent codes, themes and interpretations from the data, thereby enhancing the credibility of the findings presented (230).

7.3.3 Study Strengths and Limitations

7.3.3.1 Participants Recruited

This study had several strengths. An inclusive approach to participant recruitment was adopted to enhance the external validity of the findings. PwP with cognitive impairment/ dementia are at heightened risk of falling and its negative physical and psychological outcomes; unlike previous studies of interventions to support PwP who fall, these individuals were included (28). Caregivers who play a pivotal role in falls management were also included (28,43). In keeping with the published literature, initial feedback provided in the telephone calls suggested that the guide may be more beneficial to those earlier in their diagnosis, and the inclusion criteria were amended to include those who felt unsteady (63).

A strength of this study was that most PwP had experience of having fallen previously and had significant concern of falls. Most experienced symptoms during the study; 89% had near misses and 69% fell. The majority of PwP had high concerns of falls, as indicated by a score on the short form FES-I of 14 or more at baseline (172).

Another strength was the recruitment of participants from more than one setting. In the mixed methods study with PwP and caregivers (phase one, chapter four) participants were recruited from Parkinson's UK support groups. However, in this feasibility study, PwP and caregivers were also recruited from NHS outpatient clinics. It was hypothesised that those attending Parkinson's UK support groups may have had a longer duration of diagnosis and be more engaged with their healthcare. This approach was successful as the median time from diagnosis in this feasibility was 7 years, compared to 12 years in phase one (chapter four).

There were several limitations. Only 15% of PwP recruited into this feasibility study had a diagnosis of cognitive impairment/dementia. Caregivers of PwP with cognitive impairment/dementia could decline to take part stating that they were too busy, likely related to their 'burden of treatment' (233). Therefore, the results of those from a dyad where the PwP had cognitive impairment/ dementia may overestimate the benefit of the intervention in these participants.

Another limitation of this study is the geographical region in which this study was conducted. Locally, considerable research has been conducted into PD and falls. Some of the participants from this feasibility study have been involved in previous studies; these participants may have different knowledge or adaptive behaviours than those from other regions. It would be important to establish whether the benefits observed within this study are generalisable to other locations.

7.3.3.2 Methodological Comments

This study had several strengths. Mixed methods allowed exploration of process evaluation measures and the impact of the intervention. Incorporating the findings from the qualitative and quantitative findings using a triangulation protocol provided a comprehensive schematic through which the findings from the separate analyses could be compared and presented in a narrative.

With hindsight there were several methodological limitations. Little participant clinical data was collected, and where obtained it was through self-report. To formally assess the effectiveness of the guide, clinical data would need to be obtained from medical records. For completeness, it might have been helpful to know whether participants had a diagnosis of cognitive impairment/dementia (as by its very nature, participant's might not be able to recall their diagnosis).

A limitation that could have impacted on the sample recruited was that participants could view the intervention before deciding whether to take part. Some of those who opted out of the study stated that the guide provided little new information. This may have resulted in a sample population that deemed the guide more acceptable than that of the wider population of PwP. However, this method of recruitment was necessary for the rapid recruitment required to complete the overall programme of research within the timeframe available.

There were several methodological limitations that impacted data analysis. The unsteadiness and falls diary and the action plan were not collected at the end of the study. To better assess participant's use of these sections, copies of the guides could have been collected at the end of the study. The single-item falls self-efficacy question within the questionnaires was developed for use in this study. Validation of this question was beyond the remit of this thesis; it would be important to do so prior to using the question to assess the effectiveness of the intervention in a

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RCT. Additionally, telephone calls providing structured support were not audio-recorded. Whilst every effort was made to create accurate field notes, data collection and analysis would be of higher quality if audio-recordings had been obtained.

Finally, participants may have behaved differently because they were enrolled in a research study. A few participants displayed guilt when they had not used the intervention as designed, and in the telephone calls, participants often thanked me for completing the telephone call and for expressing an interest in their condition and symptoms. This could reflect the 'Hawthorne Effect': participants behave differently because they are enrolled into a research study, rather than because of the intervention itself (247).

7.4 Key points

- In this chapter, the findings from the feasibility study of the self-management intervention are described and discussed.
- 74 PwP experiencing unsteadiness/ falls and 57 caregivers were asked to use the paper-based falls guide for 12 weeks, during which they received three monthly telephone calls of standardised support.
- 66 PwP (88%) and 53 caregivers (93%) completed the study. All completed two baseline questionnaires and three follow-up questionnaires. A purposive sample took part in semi-structured interviews.
- The results from the questionnaires, field notes from the telephone calls, and the semi-structured interviews, were integrated through a triangulation protocol. This allowed exploration of the findings and a credibility check, enhancing the quality of the findings presented.
- Most participants felt that the guide was useful. Results suggested that the guide may be viewed more beneficial amongst PwP who were more recently diagnosed, such as those who do not attend Parkinson's UK support groups, and those without cognitive impairment/ dementia.
- Participants commonly described an increase in their focus on falls management to include discussion of falls within the dyad and with HCPs. Participants often described a reduction in their concerns surrounding falls; this was more likely in those who (i) had lower falls self-efficacy and (ii) those who had previously accessed the least support.
- Participants described enhanced falls-related problem-solving, which was often facilitated by the interactive components of the guide. However, use of these components could be limited; barriers cited included (i) a lack of clarity surrounding their potential benefit, or (ii) a higher treatment burden.
- There was a suggestion of who might benefit most from using the intervention. This included PwP were recruited from the NHS rather than Parkinson's UK support groups, PwP without a diagnosis of cognitive impairment/ dementia, PwP who had been diagnosed more recently, and PwP who experienced symptoms during the study.

8 Overall Discussion

8.1 Summary of Thesis

PD is a progressive condition with no cure. Current treatments are focused on symptom control, which are often variably addressed with pharmacological and physiotherapy (7,108–110). Self-management has been proposed as a potential strategy to help PwP and their caregivers to identify and address problems relating to how Parkinson's affects them (111).

I conducted a systematic review, which shone light on the limited number and quality of studies to support the self-management of falls in PwP (126). All studies reported the effect of a self-management intervention in association with physiotherapy. Reporting of the content of the interventions was poor, and the components of an effective intervention remained unclear.

This thesis reports the development and feasibility testing of an intervention to support the self-management of falls in PwP and their caregivers. The intervention was developed using the Person Based Approach (PBA) for the development and evaluation of health behavioural interventions, which incorporates in-depth qualitative research at each stage of intervention development to enhance the acceptability, use and effectiveness of the intervention (159). The PBA has been used to support the development of self-management interventions for other LTCs (154–159,217).

To ascertain the needs and preferences for the effective self-management of falls in PwP and caregivers two studies were conducted: (i) a mixed methods study with PwP and caregivers (phase one, chapter four), and (ii) a qualitative study with healthcare professionals (HCPs) (phase two, chapter five). These studies explored some of the key knowledge gaps in relation to PwP, caregivers', and HCPs experiences of falls and their views of the content and format of future interventions.

In the mixed methods study with PwP and caregivers, an inclusive approach to participant recruitment was adopted. Cognitive impairment/ dementia is common in PwP and associated with increased falls (14,25). However, previous falls studies have commonly excluded PwP with cognitive impairment/ dementia (15–21,53). Those with cognitive impairment/ dementia were included, as were caregivers, who play a key role in the day to day management of the condition (42). PwP and caregivers' perspectives were often explored through dyadic interview. The majority of previous qualitative studies in this population have considered either PwP or caregiver perspectives, rarely have both been studied in tandem (17,19,53). Dyadic interviews stimulated

Chapter Eight: Overall Discussion

participants' thoughts leading to the discussion of concepts that might not have been remembered, and facilitated the sharing and contrasting of ideas to enhance the depth of the data (180). The inclusion of caregivers facilitated the inclusion of PwP with cognitive impairment/dementia, who would likely have otherwise been unable to take part.

The qualitative study with HCPs (phase two, chapter five) explored their own experiences of helping to prevent and manage falls in this population as well as their interpretations of PwP and caregiver experiences, to provide a different perspective of the problem. Whilst it is important that HCPs are not considered a proxy of PwP and caregivers who did not take part, they provided important insights that would not otherwise have been obtained. Other researchers might want to explore this approach, as it facilitates important insights into the views of those who are less forthcoming to take part in research.

Results from phases one and two were triangulated to provide a comprehensive overview of the problem. PwP, caregivers and HCPs all described the heterogeneous nature of falling in PwP and the key role that caregivers play. It is vital that caregivers' perspectives are considered by both researchers and clinicians working with PwP given their considerable involvement in the day to day management of the condition (40,42). Previous literature has highlighted that PwP may not discuss falling with HCPs (28). Phases one and two identified many barriers to effective patient-professional communication, which included the perceived unpreventable or embarrassing nature of falls amongst PwP, and HCPs ignorance of the knowledge and coping strategies that PwP and caregivers had developed. Healthcare provision appeared fragmented; PwP and caregivers were often unsure of where how or when to seek support, whereas HCPs often perceived no news was good news. Identification of these differing perceptions will help researchers and clinicians working with PwP to facilitate the design and implementation of interventions, and the delivery of effective holistic healthcare (44,82). HCPs were often uncertain of other HCP's roles for falls management, and suboptimal information flow between professionals was described. It is important that clinicians seek to improve these communication channels as care delivered by an effective multidisciplinary team has been associated with improved outcomes in PwP (208).

Inadequate detail in the reporting of the content and delivery of complex interventions has led to difficulties in drawing clear conclusions about what works and why (93,131,133). Consequently, an intervention development phase (phase three, chapter six) has been reported within this thesis in sufficient detail to help other researchers to understand the context and mechanisms through which the intervention was developed and modified. During this phase, data from the background literature, my systematic review and phases one and two were triangulated. Using the PBA, detailed guiding principles were created from which an intervention was developed. The

intervention was initially developed with an aim to support the self-management of falls in all community dwelling PwP who fall and their caregivers, irrespective of PD severity or the presence of cognitive impairment/ dementia. The prototype underwent usability testing and was modified prior to being taken forward to a feasibility study.

The fourth phase of this thesis (chapter seven) reported the mixed methods feasibility study of the self-management intervention. The intervention studied consisted of a paper-based guide delivered alongside brief structured telephone support. A representative sample of PwP and caregivers were recruited, to include men and women, and those with and without cognitive impairment/ dementia. Participants were not excluded based upon PD severity. A flexible approach was taken, and when initial participants reported that the guide might benefit those who are yet to fall, the inclusion criteria were modified to include those who felt unsteady. The study had a good retention rate, and no participant characteristic was identified to lead to increased likelihood of the participant withdrawing from the study. This is important for researchers working with PwP, as it suggests that those with more advanced PD, to include those with cognitive impairment/ dementia, are keen to participate in research, and are no less able than their cognitively intact peers when supported by caregivers, as has been suggested previously (28).

The findings from the qualitative and quantitative analyses of the feasibility study (phase four, chapter seven) were integrated through a triangulation protocol, which allowed exploration and a credibility check of the findings, enhancing the quality of the results presented (167,230). Whilst the intervention was initially designed to support all community dwelling PwP who fall and their caregivers, the results provided suggestions of the characteristics of PwP that would predict greater use or benefit from it. Most participants felt that the guide was useful. Participants often described increased focus on falls management to include discussion of falls within the dyad and with HCPs. Some described a reduction in their concerns of falls; this was more likely in those who (i) had lower falls self-efficacy and (ii) those who had accessed the least support previously. Results suggested that the guide may be viewed more beneficial to PwP who are more recently diagnosed. This is an important insight, as anecdotal evidence suggests that these individuals may be less likely to attend Parkinson's UK support groups, which provide an avenue of opportunity and support for many PwP and caregivers. It is important that researchers seek to involve those who do not attend these groups in future studies of interventions, as the results from this study suggest that these PwP may obtain the greatest benefit.

Some participants described enhanced falls-related problem-solving, which was often facilitated by the interactive components of the guide. In keeping with the findings from studies of self-

management interventions to support individuals with other LTCs, PwP and caregivers from a dyad where the PwP had symptoms during the study were more likely to use the intervention (237). However, use of these components was often limited; barriers included (i) a lack of clarity of their potential benefit, or (ii) limitations in their capacity arising from PD and non-PD related activities (233,234). Given the potential benefits associated with completion of the interactive components, future iterations of the guide should provide a clearer rationale of their potential benefit. Secondly, it is important that researchers and clinicians working with patients with LTCs recognise the limited capacity of the patient and those close to them.

Finally, participants from a dyad where the PwP had a diagnosis of cognitive impairment/dementia often perceived the guide to be less relevant and frequently described limitations in the PwP's ability to comprehend the information and to implement changes. However, participants from these dyads often described benefits, which included caregivers feeling reassured or supported, and increased falls-related problem solving. This is important for researchers and clinicians interested in PD, as the intervention was able to benefit individuals where many risk factors leading to falls are likely to be less modifiable (71,73–75,77,78,126).

8.2 Suggestions for Future Research

Little clinical data was collected on participants recruited into the studies reported within this thesis. Where clinical data is presented, it was obtained through self-report. More research is needed to elucidate whether clinical characteristics of PD, including PD severity, and caregiver characteristics including age and medical co-morbidities, impact upon the beliefs and experiences reported.

During the development of the guide (phase three, chapter six) following the PBA, best practice would have been to incorporate think aloud studies on earlier prototypes of the guide, with changes made through an iterative process to increase the acceptability of the intervention (154–156,159). Alternatively, adopting quality improvement methodology with more Plan, Do, Study, Act (PDSA) cycles would have led to additional prototypes of the guide prior to being taken forward to the feasibility study (chapter seven). PDSA cycles provide a structured approach to analyse an intervention on a small scale, facilitating greater understanding of what does and doesn't work before being implemented more widely. Cycles consist of (i) planning an activity, (ii) doing it, (iii) studying what happens and (iv) acting on any changes. Incorporating think aloud studies or using multiple PDSA cycles might have led to improvements in the feasibility of the intervention studied in phase four (chapter seven) (248). However, due to time constraints associated with the programme of research this was not possible (159).

Several methodological approaches could be adapted if the intervention studied within the feasibility study (chapter seven) were to be explored further. Regression analyses to assess the possible effect of participant's baseline characteristics on scores on validated scales (FES-I, ZBI and PDQ-8), were beyond the remit of the feasibility study; these could be explored using methodology such as an appropriately powered RCT. The benefits arising from each of the paper-based guide and the telephone calls providing standardised support remained unclear; this could also be explored through further research. Obtaining a greater understanding of the importance of the telephone calls, to include whether they should be delivered to all participants, and how many are required, would help to inform how the intervention might be implemented into routine clinical practice.

Prior to the feasibility study (chapter seven), participants' self-efficacy of behaviours required to participate in the intervention, such as confidence in problem-solving and action planning were not assessed. During qualitative analyses, where participants discussed increased ability to manage falls, this was often cited to arise from increased problem-solving behaviour. However, many participants encountered uncertainty in problem solving the cause of their falls and creating an action plan thereafter. The Patient Activity Measure is a 22-item scale that assesses patient knowledge, skill, and confidence for self-management of their healthcare. A tool such as the Patient Activity Measure could be used to assess who might be likely to benefit from using the intervention (236).

In the feasibility study (chapter seven) PwP and caregivers often described limitations in their capacity arising from their burden of treatment. This burden of treatment often led to reduced engagement with the intervention and delayed completion of the follow-up questionnaires. Those with a higher burden of treatment are the very individuals that a self-management intervention would seek to support. Therefore, it is imperative that the potential benefits of any intervention are described coherently to allow individuals to understand how it might help. For any future study it would be imperative to review all study documentation to ensure that questionnaires are no longer than necessary to enhance participant retention and satisfaction (234).

Participants may have behaved differently because they were enrolled in a research study. The 'Hawthorne Effect' describes how participants behave differently because they are enrolled into a research study, rather than because of the intervention itself (247). A few participants described guilt where they had not used the intervention as designed. A few were known to myself in a clinical capacity as well as a research capacity, and participants were aware that the intervention had been designed by myself in conjunction with my supervisors, PPI and experts in behavioural

change theory. If the intervention were to be studied further in a future trial, the effect of the researcher could be minimised through data collection and analysis being conducted by separate individuals.

Finally, the studies reported within this thesis took place in the South of England. Within the local area considerable research has been conducted into PD and falls. If participants had been recruited outside of the local area, it might have been possible to establish whether the views and experiences of PwP and caregivers described, and if the results from the feasibility study are generalisable to other locations.

8.3 Next steps for optimising and implementing the intervention

8.3.1 Optimising the Intervention

8.3.1.1 Suggested Changes in Response to the Findings from the Mixed Methods Study

Results from the mixed methods study suggested that the guide requires modification to increase its acceptability, use and likely effectiveness. Key changes are described below and in Appendix G1.

Some participants read the guide cover to cover; these participants might have been more likely to read only the parts relevant to them if there was clearer information about how to use the guide. Participants reported a range of information as missing from the guide, which was often very specific to their individual circumstances. If the guide were to provide greater recognition of the heterogeneity of PD, and more information about third-party resources that might be of benefit, this might lead these individuals to obtain support for their unmet needs. Whilst many participants were positive about the 'how to get up from the floor' section, a few felt it would be helpful to include pictures corresponding to each of the steps.

The falls and unsteadiness diary and the action plan are key components of the guide for the support and development of PwP and caregivers' self-management behaviours. They encourage problem-solving, decision making, action planning and re-interpretation of symptoms. Additional supporting information is required about the rationale of how the diary and action plan might benefit PwP and caregivers, clarification of when to use them, and encouragement to modify strategies if they are initially unsuccessful. The tables within the diary and the action plan require increased space to write, and alteration of the column headings to increase their ease of use.

8.3.1.2 Further work that has happened beyond this thesis

Subsequent to the mixed methods feasibility study, seven PwP, five of whom had a corresponding caregiver, one physiotherapist and two Parkinson's Disease Nurse Specialists provided page by page feedback about the guide. All of the PwP and caregivers providing feedback also took part in the mixed methods feasibility study (phase four, chapter seven).

Findings were in keeping with those from the semi-structured interviews. However, participants provided more specific details about where they felt information was missing or was unclear. Examples of participant feedback, and strategies to address these comments, are described below and outlined in Appendix G2.

Examples of how to stay active could be deemed less relevant to those with earlier PD. By emphasising the suggestion that PwP modify their current activities, this may increase the perceived relevance of this section. One PDNS discussed the statement 'speak to a physiotherapist' and was concerned that PwP may dismiss advice if they did not currently have access to physiotherapy support. This concern could be alleviated through clearly stating that doctors and PDNS can refer PwP to physiotherapists.

Three participants perceived that the falls diary would benefit from additional information. This included a date column, which would allow PwP and caregivers to identify if falls were happening in quick succession and would enhance discussion with HCPs about falls/ episodes of unsteadiness. Five participants felt that the 'Useful Contacts' section required additional information to include more details about attendance allowance, and a space to write their PDNS's number/ other locality specific information.

8.3.2 Implementing the Intervention

The feasibility study of the intervention assessed the self-management guide and telephone calls in tandem. The telephone calls were delivered by myself and had a dual role of data collection and self-management support. The results of the feasibility data provide insufficient information to build a business case for implementation of the telephone calls by a healthcare professional outside of the research project. There was a suggestion of those that would benefit from the intervention most, which included PwP who were cognitively intact, PwP who were earlier in the trajectory of their condition, did not attend Parkinson's UK support groups, and had symptoms during the course of the study.

Elsewhere, researchers have often encountered barriers to the dissemination and implementation of other behavioural change interventions that have undergone thorough evaluation (249). To enhance use, researchers have sought to promote their intervention to HCPs and patients using appropriate and accessible channels (249). Discussions will take place with professionals working with PwP, to include NHS HCPs and charities, to make the self-management guide widely available to PwP and caregivers, such as through the Parkinson's UK Excellence Network. Obtaining buy-in from HCPs involved in the provision of care to PwP might promote use of the guide and enhance patient-HCP falls communication.

8.4 Closing Remarks

PwP and their caregivers described considerable difficulties in relation to falls management, with their needs often left unmet. The intervention developed during this programme of research has the potential to partially address these as part of a wider package of PD management driven by a multi-disciplinary team. Some PwP and their caregivers described a reduction in their concerns of falls and an increased focus towards falls management. Some described enhanced falls-related problem-solving, suggesting that self-management is an acceptable strategy to PwP and caregivers. There are also key take home points for researchers. Dyadic interviews facilitated the inclusion of PwP with cognitive impairment/ dementia alongside their caregivers and were acceptable to busy HCPs who were geographically dispersed. Conducting research with HCPs provided a more comprehensive overview of the problem, to include their perceptions of PwP who were less forthcoming to take part in the study themselves. However, the most pertinent point is that PwP with more advanced PD, to include PwP with cognitive impairment and dementia, were keen and able to take part in the research studies forming this thesis when supported by their caregivers. It is vital that other researchers seek to include these individuals to increase the external validity of their findings.

Appendix A Systematic review appendices

A.1 PROSPERO Registration

UNIVERSITY *of York*
Centre for Reviews and Dissemination

NHS
National Institute for
Health Research

PROSPERO International prospective register of systematic reviews

What is the effectiveness of falls-based self-management interventions for people with Parkinson's disease in improving psychological and health-related outcomes?

Charlotte Owen, Helen Roberts, Kinda Ibrahim

Citation

Charlotte Owen, Helen Roberts, Kinda Ibrahim. What is the effectiveness of falls-based self-management interventions for people with Parkinson's disease in improving psychological and health-related outcomes?. PROSPERO 2017:CRD42017052585 Available from http://www.crd.york.ac.uk/PROSPERO_REBRANDING/display_record.asp?ID=CRD42017052585

Review question(s)

What is the effectiveness of falls-based self-management interventions for people with Parkinson's disease in improving psychological and health-related outcomes?

Searches

We will search the following electronic bibliographic databases:

MEDLINE via Ovid

EMBASE via OVID

The Cochrane Central Register of Controlled Trials (CENTRAL)

Cumulative Index to Nursing and Allied Health Literature (CINAHL)

Allied and Complementary medicine database (AMED)

PSYCInfo

Science Citation Index Expanded (Web of Science) (Institute for Scientific Information SP)

Our search strategy will include only terms relating to the intervention and the population. We are to include trials of all designs in our study.

The MEDLINE search strategy will be adapted for use with other bibliographic databases, including the use of database specific filters where available.

Other resources:

The Database of Abstracts of Reviews of Effects (DARE) via The Cochrane Library will be searched to identify relevant reviews, and the reference lists screened to identify primary studies.

Scoping searches will be performed in Delphis and we will search the grey literature through www.openrey.eu.

We will search the relevant research registers for ongoing clinical trials: the World Health Organization's (WHO) International Clinical Trials Registry Platform (ICTRP) (www.apps.who.int/trialsearch/) and the National Institutes of Health Clinical Trials Database (www.clinicaltrials.gov).

We will screen the reference lists of relevant retrieved articles and reviews to locate potential additional trials for inclusion in the review. If necessary, we will attempt to contact principal investigators for clarification or to request missing information. Searches will be re-run just before the analyses to ensure that all studies meeting the inclusion

criteria are included in our review.

Types of study to be included

We will include studies regardless of study design if they meet the inclusion criteria.

Condition or domain being studied

Idiopathic Parkinson's disease. Falls-based self-management interventions.

Participants/ population

We will include studies where the participants have a diagnosis of idiopathic Parkinson's disease, as defined by the authors of the study. We will include studies where the participants have conditions other than Parkinson's disease only when there are subgroup analyses presented for those with idiopathic Parkinson's disease alone. We will include studies where the participants are people with Parkinson's alongside the caregivers of people with Parkinson's. We will exclude studies which are targeted toward caregivers only.

There will be no restrictions on the basis of participant age, disease duration, the presence of cognitive impairment or depression, or medication regimen.

Intervention(s), exposure(s)

We will include studies that aim to support individuals to self-manage falling in Parkinson's disease. We will use a broad definition of self-management to include increased responsibility for condition management or increased confidence. We will make no prior assumptions about the types of interventions that might affect patient self-management. Self-management programmes may target different elements of these core skills and may vary in their delivery, being lay-led or professional-led. They may also take the form of different modes of delivery and be group-based, one-to-one or online. We will include multi-modal interventions as long as one component of the intervention is aimed at supporting individuals to live with PD. We will include studies that aim to help to support individuals with multiple aspects of their PD, so long as one component of the intervention is specifically targeted toward falling.

We will include studies where the intervention is exercise or physiotherapy based only where there is an explicit self-management component. Studies where the intervention is a drug will be excluded from the review.

Comparator(s)/ control

The studies may compare either a self-management intervention with usual care or compare one self-management based intervention with another. Usual care refers to the care that PwP would normally receive in the setting in which the study was conducted.

Outcome(s)

Primary outcomes

1. Quality of life and health-related quality of life on validated scales such as PDQ-38 or PDQ-8.
2. Psychological health outcomes, including depression and anxiety
3. Skill and technique acquisition, including knowledge about PD and how symptoms can be managed
4. Attitude and approaches to PD, including perceptions about impact of PD on participant's life. This may be measured through validated scales such as the generalised self-efficacy scale or the falls efficacy scale.

Where available, we will assess both short-term and long-term outcomes.

Secondary outcomes

To determine the effect of self-management interventions for PwP on:

1. Physical measures related to their Parkinson's disease, this may be through measurement on validated scales such as the UPDRS or through self-reporting.
2. Caregiver outcomes amongst informal primary caregivers. This may be assessed through validated scales such as the

carer strain index or the Zarit Burden Interview, which measures caregiver burden.

3. Healthcare utilisation. This may be assessed through measures including number of visits to the GP or Parkinson's disease specialist or through admissions to hospital.

4. Activity levels: including participation in exercise and ability to perform activities of daily living

5. Any reported adverse events of the intervention

6. Any reported costs of the intervention

Where available, we will assess both short-term and long-term outcomes.

Data extraction, (selection and coding)

Data will be extracted by CO from the selected studies into a predefined collection form. The following characteristics will be extracted:

- Author name and date
- Study design
- Intervention studied
 - Intended audience
 - What was the intervention? E.g lecture-based, balance training, leaflet based
 - Modality (individual or group based)
 - Delivery method (face-to-face, online, audio, video, written)
 - Leader of the intervention (lay or professional led)
 - Setting of the intervention (home, hospital, community setting)
 - Duration and frequency of the intervention
- Description of the comparator
- Duration of the study
- Demographical data of the participants: age, sex, country, setting
- PD characteristics of the patients: Severity of PD, duration of PD, cognitive impairment
- Total number of participants in the intervention and comparator groups
- Drop out participants, reasons for drop out, handling of missing data
- All relevant outcomes

Where data is missing, we will contact the corresponding authors to request this.

Risk of bias (quality) assessment

Assessment of risk of bias in included quantitative studies:

Two researchers will independently assess the risk of bias in each included study against key criteria. Randomised

Analysis of subgroups or subsets

There is likely to be considerable heterogeneity between the studies included in our review, in terms of characteristics of the intervention, the comparator, the participants enrolled and the outcomes studied. Before conducting meta-analyses and combining data from across the studies, each will be assessed for similarities. Those judged to be too different will be assessed in sub-group analyses or described separately in the narrative synthesis.

Dissemination plans

We will upload the report of our findings onto PROSPERO. We will also submit a paper of our findings to relevant peer-reviewed journals, such as Age and Ageing, the journal of the British Geriatrics Society.

Contact details for further information

Charlotte Owen

University Hospital Southampton

Academic Geriatric Medicine, Room CE114B

Tremona Road

Southampton

SO16 6YD

c.Lowen@soton.ac.uk

Organisational affiliation of the review

University of Southampton

Review team

Dr Charlotte Owen, University of Southampton

Dr Helen Roberts, University of Southampton

Dr Kinda Ibrahim, University of Southampton

Collaborators

Dr Emma Stack, University of Southampton

Dr Laura Dennison, University of Southampton

Anticipated or actual start date

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Anticipated completion date

01 December 2017

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NIHR Academic Clinical Fellowship Programme

NIHR CLAHRC Wessex

Conflicts of interest

None known

Language

English

Country

England

A.2 Medline searching strategy

1. Parkinson Disease/
2. Parkinson*.mp,hw.
3. 1 or 2
4. Patient education as topic/
5. exp Consumer health information/
6. educat*.tw.
7. exp self care/
8. (self adj (assess* or care or help or manag* or monitor* or efficacy or evaluat* or concept or direct*)).tw.
9. exp self concept/
10. self evaluation/
11. exp adaptation psychological/
12. psychological adjustment/
13. (Psychologic* adj (adjust* or adapt*)).tw.
14. social learning theory.tw.
15. exp health behavior/
16. consumer behavior/
17. behavior therapy/
18. (behav* adj (adapt* or alter* or chang* or therap*)).tw.
19. attitude to health/
20. health knowledge, attitudes, practice/
21. coping behavior/
22. (cope or copes or coping).tw.
23. exp decision making/
24. (decision* adj (making or made)).tw.
25. (inform* adj (choice* or decision*)).tw.
26. problem solving/
27. (problem adj solving).tw.
28. ((patient* or consumer* or client* or participant*) adj (monitor* or adjust*)).tw.
29. "power (psychology)"/
30. empower*.tw.
31. ((improv* or increas*) adj2 confiden*).tw.
32. social support/
33. (social adj (support* or network* or engagement*)).tw.
34. "Patient Satisfaction"/
35. disease management/
36. animal/
37. human/
38. 36 not (36 and 37)
39. 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34 or 35
40. 3 and 39
41. 40 not 38
42. limit 41 to yr="1986- current"

A.3 Characteristics of Articles Included in the Review

Article	Participants						Intervention including Self-Management			Comparison Intervention	
	Study design	N	Mean age (SD)	H+Y Stage (%)	Mean years since diagnosis (SD)	Mean MMSE (SD)	Fallen in the last year	Description	1. Frequency and duration 2. Setting 3. Delivered by	Description	1. Frequency and duration 2. Setting 3. Delivered by
Peteet (137) RCT	27	Int 58 (7.0) Control 63 (9.5)	II 74% III 26%	Int 8.8 (3.9) Control 7.0 (4.4)	All ≥25	No data	1. Behavioural based self-management education programme. Week 4 contained a 20-25-minute group discussion about fall prevention and safety. 2. Exercise programme	1.5hrs/ wk. for 6 wks. Hospital Therapist with physical therapy assistance	Exercise programme only	1.5hrs/ wk. for 6 wks. Hospital Therapist with physical therapy assistance	
Tickle-Degnen et al. (139) 3 arm RCT	117	66.3 (9.0)	<III 84% III 16%	7.1 (5.7)	29.3 (1.0)	No data	<u>Intervention 1 and 2</u> Twice weekly 'Group clinic sessions' Motion, flexibility and strength exercises (25 minutes) Speech exercises (10 min) Daily function training examples (15 min) Gait training (10 min) Group discussion (30min), including 'preventing falls' <u>Intervention 2 only</u> Additional weekly transfer sessions	<u>Group sessions:</u> 2x1.5 hr/wk. for 6 wks. Hospital Physical therapist <u>Transfer sessions</u> 1.5hr/wk. for 6 wks. Home Physical therapist	'Social group sessions' including ice breaker activities, refreshments and conversation	1.5 hr/week for 6 weeks Hospital Physical therapy student	

Article	Participants						Intervention including Self-Management		Comparison Intervention		
	Study design	N	Mean age (SD)	H+Y Stage (%)	Mean years since diagnosis (SD)	Mean MMSE (SD)	Fallen in the last year	Description	1. Frequency and duration 2. Setting 3. Delivered by	Description	1. Frequency and duration 2. Setting 3. Delivered by
White et al. (139)		74	Int 65.6-68.2 Control 65.4-66.0	<III 85% III 15%	Intervention 5.1-6.9 Comparison 5.6-6.7	No data	No data	[as per Tickle-Degnen et al. (139)]			
Canning et al. (140) RCT		231	Int 71.4 (8.1) Control 69.9 (0.3)	Int II 30% III 67% IV 3% Control II 35% III 60% IV 5%	Int 7.5 (5.8) Control 8.3 (6.0)	Int 28.6 (1.5) Control 28.7 (1.4)	78 %	<u>Physiotherapy</u> Progressive balance and lower limb strengthening exercises and cueing strategies (PD-WEBB), exercise classes and physical therapist home visits PLUS <u>Education:</u> Received the booklet 'Don't fall for it, falls can be prevented'.	Over 6 months: PD-WEBB 40-60 mins 3x/wk.; Exercise class monthly 2-4 home visits PD-WEBB and exercise class at the hospital. Physical therapist led	Received the booklet 'Don't fall for it, falls can be prevented'.	
Morris et al. 2015 (141) 3 arm RCT		210	67.9 (9.6)	<III 59% III 30% IV 11%	6.7 (5.6)	28.2 (1.8)	55%	<u>Physiotherapy</u> EITHER: Movement Strategy Training (MST) OR Progressive resistance strength training (PRST) PLUS <u>Education</u> Based on the booklet	Physiotherapy: 2 hrs/ wk. for 8 wks. plus home practice session. Falls education delivered weekly. Hospital Physical therapist led	Life skills program. Included social activities, practical advice, information sessions and group discussions but no falls content.	

Appendix A: Systematic Review Appendices

Article	Participants						Intervention including Self-Management		Comparison Intervention		
	Study design	N	Mean age (SD)	H+Y Stage (%)	Mean years since diagnosis (SD)	Mean MMSE (SD)	Fallen in the last year	Description	1. Frequency and duration 2. Setting 3. Delivered by	Description	1. Frequency and duration 2. Setting 3. Delivered by
							'Don't fall for it. Falls Can be prevented.' Elements explained to each participant and given a copy to take away				
Morris et al. 2017 (142) RCT	133	71 (9)	<III 66% III 29% IV 5%	No data	28.3 (1.6)	55%	<u>Physiotherapy</u> Progressive resistance strength training Movement strategy training PLUS <u>Education</u> Individualized falls education based on the booklet 'Don't fall for it, Falls can be prevented'. Participants given a copy to take away.	Physiotherapy: 2 hrs/ wk. for 6 weeks. Falls education delivered weekly. Home Physical therapist led	Life skills program. Weekly guided education and discussion sessions followed by self-directed homework. No falls content. A standard help sheet from Parkinson's Victoria and a generic falls information sheet.		

Abbreviations: hrs=hours; H+Y= Hoehn and Yahr staging; Int=Intervention; mins=minutes; MMSE= Mini Mental State Examination score; RCT= Randomized controlled trial SD= Standard Deviation; wk.=week

A.4 Outcomes of Articles Included in the Review

Article	Statistical comparisons made		Quality ^a	Falls Outcomes	FES-I	QOL		Other Outcomes measured	
	Summary of Intervention containing self-management	Summary of comparator				Outcome	Results	Outcome	Results
Peteet (137)	Self-management plus exercise programme	Exercise Programme	8/13	-	-	-	-	Physical Activity Scale for the elderly (PASE), TUG, FRT	No change at 6 wks. or at 12 wks.
Tickle-Degnen et al. (139)	Self-management plus PT	Social Group sessions (No self-management or PT)	7/13	-	-	PDQ-39	Improved post intervention and at 6-month follow-up (p =0.02)	-	-
White et al. (138)	Self-management plus PT	Social Group sessions (No self-management or PT)	9/13	-	-	-	-	Total time spent walking and number of walking periods	No change
Canning et al. (140)	Self-management plus PT	Self-management	9/13	No difference in rate of falls or in the number of fallers over 12 months.	Improved post (p<0.01)	SF6D	Improved post intervention (p<0.01)	Short physical performance battery and sit to stand.	Improvement post intervention (p<0.05)
						SF-12 physical, SF-12 mental, PDQ-39	No change	Mean knee extensor strength, co-ordinated stability test, 4m fast walk test, FOG, Exercise hr/wk., ADL hr/day	No change
Morris et al. 2015	Self-management plus PT (MST)	Life Skills Programme (No self-	8/13	Reduced rate of falls over 12	-	PDQ-39	PRST: Improvement at 12	UPDRS ADL	MST and PRST: Improvement at 12 months (p<0.01).

Appendix A: Systematic Review Appendices

Article	Statistical comparisons made		Quality ^a	Falls Outcomes	FES-I	QOL		Other Outcomes measured	
	Summary of Intervention containing self-management	Summary of comparator				Outcome	Results	Outcome	Results
(141)	or PRST)	management or PT)		months associated with MST (P<0.05) and PRST (P<0.01) No difference in number of fallers or multiple fallers over 12 months.			months (p<0.05) MST: no change	UPDRS Motor	MST: Improvement at 12 months (p<0.05)
						EQ-5D VAS	MST and PRST: no change	Walking speed (derived from 6m walk test) and TUG	No change
Morris et al. 2017 (142)	Self-management plus PT	Life Skills Programme (No self-management or PT)	7/13	No difference in the rate of falls or number of fallers or multiple fallers over 12 months.	-	PDQ-39	No change	UPDRS	No change
						EuroQoL-5D	No change		

Abbreviations: ADL= Activities of Daily Living; EQ-5D VAS= EuroQoL 5 Dimensions Visual Analog Scale; FES-I= Falls Efficacy Scale International; FOG= Freezing of gait; FRT= Functional Reach Test; MST= Movement Strategy Training; PASE= Physical Activity Scale for the elderly; PDQ39= Parkinson's Disease Questionnaire 39; PRST= Progressive resistance strength training; SF-6D= Short form 6 dimension; SF-12 physical/ SF-12 mental= Short form 12 physical/ short form mental component summary; TUG= Timed up and Go; UPDRS= Unified Parkinson's Disease Rating Scale

^a Quality assessment performed using the JBI Critical Appraisal Checklist for RCTs. Summary scores are out of 13 possible quality criteria.

Appendix B Methodology: Ethical Approvals

B.1 Ethical Approval for Mixed Methods Study with PwP and Caregivers (Phase One)

Owen C.L.

From: ERGO <ergo@soton.ac.uk>
Sent: 07 March 2017 09:02
To: Owen C.L.
Subject: Your Ethics Submission (Ethics ID:25364) has been reviewed and approved

Submission Number: 25364
 Submission Name: Development and evaluation of a self-management guide for community-dwelling people with Parkinson's disease who fall and their informal caregivers: Phase One
 This is email is to let you know your submission was approved by the Ethics Committee.

You can begin your research unless you are still awaiting specific Health and Safety approval (e.g. for a Genetic or Biological Materials Risk Assessment)

Comments

1. Dear Charlotte, RE: 25364 - Development and evaluation of a self-management guide for community-dwelling people with Parkinson's disease who fall and their informal caregivers: Phase One Thank you for submitting your revised application relating to the above research study and for your helpful detailed cover letter. I am pleased to inform you that full approval has now been granted by the Faculty of Medicine Ethics Committee. Approval is valid from today until 31/12/2018, which is the end date specified in your application. Please note the following points: – the above ethics approval number must be quoted in all correspondence relating to your research, including emails; – if you wish to make any substantive changes to your project you must inform the Faculty of Medicine Ethics Committee as soon as possible. Please note that this email will now constitute evidence of ethical approval. Should you require a paper signed copy of this approval, please contact the FoMEC Administrative Team via email at: Medethic@soton.ac.uk. We wish you success with your research. Yours sincerely Dr Catherine Hill Chair of the Faculty of Medicine Ethics Committee

[Click here to view your submission](#)

Coordinator: Charlotte Owen

 ERGO : Ethics and Research Governance Online
<http://www.ergo.soton.ac.uk>

 DO NOT REPLY TO THIS EMAIL

B.2 Ethical Approval for Qualitative Study with Healthcare Professionals (Phase Two)

Your Ethics Submission (Ethics ID:25988) has been reviewed and approved <https://www.outlook.soton.ac.uk/owa/?ae=Item&t=IPM.Note&id=Rg...>

Your Ethics Submission (Ethics ID:25988) has been reviewed and approved

ERGO [ergo@soton.ac.uk]

Sent: 23 May 2017 07:19

To: Owen C.L.

Submission Number: 25988

Submission Name: Development and evaluation of a self-management guide for community-dwelling people with Parkinson's disease who fall and their informal caregivers: Phase Two

This is email is to let you know your submission was approved by the Ethics Committee.

You can begin your research unless you are still awaiting specific Health and Safety approval (e.g. for a Genetic or Biological Materials Risk Assessment)

Comments

1. Dear Charlotte, RE: ERGO 25988 Development and evaluation of a self-management guide for community-dwelling people with Parkinson's disease who fall and their informal caregivers: Phase Two
Thank you for submitting your revised application relating to the above research study and for your helpful cover letter detailing your revisions. I am pleased to inform you that full approval has now been granted by the Faculty of Medicine Ethics Committee. Approval is valid from today until 31.12.2018, the end date specified in your application. Please note the following points: the above ethics approval number must be quoted in all correspondence relating to your research, including emails; if you wish to make any substantive changes to your project you must inform the Faculty of Medicine Ethics Committee as soon as possible. Please note that this email will now constitute evidence of ethical approval. Should you require a paper signed copy of this approval, please contact the FoMEC Administrative Team via email at: Medethic@soton.ac.uk. We wish you success with your research. Yours sincerely Dr Catherine Hill Chair of the Faculty of Medicine Ethics Committee

[Click here to view your submission](#)

Coordinator: Charlotte Owen

ERGO : Ethics and Research Governance Online

<http://www.ergo.soton.ac.uk>

DO NOT REPLY TO THIS EMAIL

B.3 Ethical Approval for Mixed Methods Feasibility Study of the Intervention (Phase Four)



South Central - Oxford C Research Ethics Committee

Level 3, Block B
Whitefriars Building
Lewins Mead
Bristol
BS1 2NT

Telephone: 0207 104 8049

Please note: This is the favourable opinion of the REC only and does not allow you to start your study at NHS sites in England until you receive HRA Approval

08 December 2017

Professor Helen Roberts
Academic Geriatric Medicine, Mailpoint 807
University Hospital Southampton
Southampton
SO16 6YD

Dear Professor Roberts

Study title: Feasibility study of a falls-based self-management guide for people with Parkinson's disease and their informal caregivers
REC reference: 17/SC/0488
IRAS project ID: 221022

Thank you for your letter of 30 November 2017, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information was considered by a Sub-Committee of the REC. A list of the

Appendix B: Ethical Approvals

Sub-Committee members is attached.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this opinion letter. Should you wish to provide a substitute contact point, require further information, or wish to make a request to postpone publication, please contact hra.studyregistration@nhs.net outlining the reasons for your request.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Mental Capacity Act 2005

I confirm that the committee has approved this research project for the purposes of the Mental Capacity Act 2005. The committee is satisfied that the requirements of section 31 of the Act will be met in relation to research carried out as part of this project on, or in relation to, a person who lacks capacity to consent to taking part in the project.

Conditions of the favourable opinion

The REC favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise).

Guidance on applying for NHS permission for research is available in the Integrated Research Application System, www.hra.nhs.uk or at <http://www.rdforum.nhs.uk>.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of management permissions from host organisations

Registration of Clinical Trials

Sub-Committee members is attached.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this opinion letter. Should you wish to provide a substitute contact point, require further information, or wish to make a request to postpone publication, please contact hra.studyregistration@nhs.net outlining the reasons for your request.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Mental Capacity Act 2005

I confirm that the committee has approved this research project for the purposes of the Mental Capacity Act 2005. The committee is satisfied that the requirements of section 31 of the Act will be met in relation to research carried out as part of this project on, or in relation to, a person who lacks capacity to consent to taking part in the project.

Conditions of the favourable opinion

The REC favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise).

Guidance on applying for NHS permission for research is available in the Integrated Research Application System, www.hra.nhs.uk or at <http://www.rdforum.nhs.uk>.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of management permissions from host organisations

Registration of Clinical Trials

Appendix B: Ethical Approvals

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publicly accessible database within 6 weeks of recruitment of the first participant (for medical device studies, within the timeline determined by the current registration and publication trees).

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non-clinical trials this is not currently mandatory.

If a sponsor wishes to request a deferral for study registration within the required timeframe, they should contact hra.studyregistration@nhs.net. The expectation is that all clinical trials will be registered, however, in exceptional circumstances non registration may be permissible with prior agreement from the HRA. Guidance on where to register is provided on the HRA website.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Ethical review of research sites

NHS sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Non-NHS sites

The Committee has not yet completed any site-specific assessment (SSA) for the non-NHS research site(s) taking part in this study. The favourable opinion does not therefore apply to any non-NHS site at present. We will write to you again as soon as an SSA application(s) has been reviewed. In the meantime no study procedures should be initiated at non-NHS sites.

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Covering letter on headed paper [Cover Letter]		17 August 2017
Interview schedules or topic guides for participants [Follow up Provisional Interview Schedule with People with Parkinson's]	1	17 August 2017
Interview schedules or topic guides for participants [Follow up Interview Schedule with Caregivers of People with Parkinson's]	1	17 August 2017
Interview schedules or topic guides for participants [Provision outline of follow up telephone calls]	1	17 August 2017
IRAS Application Form [IRAS_Form_25082017]		25 August 2017
IRAS Checklist XML [Checklist_27112017]		27 November 2017
Letter from funder [Confirmation of Funding from NIHR CLAHRC Wessex]		17 August 2017

Letter from sponsor [Letter from Sponsor]		17 August 2017
Non-validated questionnaire [Follow up Questionnaire One. Completion by People with Parkinson's]	1	17 August 2017
Non-validated questionnaire [Follow up Questionnaire Two. Completion by Caregivers of People with Parkinson's]	1	17 August 2017
Non-validated questionnaire [Follow up Questionnaire Three. Feedback Questionnaire]	1	17 August 2017
Other [Authorisation for sign off by Penny Bartlett at Southern Health NHS Foundation Trust]		17 August 2017
Other [Cover letter 2]	1	13 October 2017
Other [Cover Letter. Response to Oxford C REC]		14 November 2017
Other [Participant Information Sheet. Tracked changes]	2	06 November 2017
Other [Participant Information Sheet. Clean Version]	2	06 November 2017
Other [Informed Consent form. Tracked Changes]	2	06 November 2017
Other [Informed Consent form. Clean Version]	2	06 November 2017
Other [Consultee Declaration Form. Tracked Changes]	2	06 November 2017
Other [Consultee Declaration Form. Clean Version]	2	06 November 2017
Other [Baseline Questionnaire One. Tracked Changes]	2	06 November 2017
Other [Baseline Questionnaire One. Clean Version]	2	06 November 2017
Other [Baseline Questionnaire Two. Tracked Changes]	2	06 November 2017
Other [Baseline Questionnaire Two. Clean Version]	2	06 November 2017
Other [Self-management guide. Tracked Changes]	2	06 November 2017
Other [Self-management guide. Clean Version]	2	06 November 2017
Other [Steady Together. Protocol. Tracked Changes.]	3	27 November 2017
Other [Steady Together. Clean Version]	3	27 November 2017
Other [Cover Letter. Response to Oxford C REC. 27.11.2017]		27 November 2017
Referee's report or other scientific critique report [Confirmation of External Scientific and PPI peer review]		09 December 2016
Summary CV for Chief Investigator (CI) [Professor Helen Roberts CV]		17 August 2017
Summary CV for student [Summary CV for Student. Charlotte Owen]		17 August 2017
Summary CV for supervisor (student research) [Professor Helen Roberts CV]		
Summary CV for supervisor (student research) [Dr Emma Stack CV]		
Summary, synopsis or diagram (flowchart) of protocol in non technical language [Summary of Proposed Methods in Non-technical Language]	1	17 August 2017

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Appendix B: Ethical Approvals

Reporting requirements

The attached document “*After ethical review – guidance for researchers*” gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The HRA website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website:

<http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/>

HRA Training

We are pleased to welcome researchers and R&D staff at our training days – see details at

<http://www.hra.nhs.uk/hra-training/>

17/SC/0488

Please quote this number on all correspondence

With the Committee's best wishes for the success of this project.

Yours sincerely



pp. Ms Helen Sivey
REC Manager

Professor Nigel Wellman
Chair

Email: nrescommittee.southcentral-oxfordc@nhs.net

South Central - Oxford C Research Ethics Committee

Attendance at Sub-Committee of the REC meeting on 08 December 2017

Committee Members:

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Mrs Rebekah Howe	Farmer	Yes	
Dr Lee Potiphar	Lecturer in Adult Nursing (Evidence Based Practice)	Yes	
Professor Nigel Wellman (Chair and Meeting Chair)	Professor of Health and Human Sciences	Yes	

Also in attendance:

<i>Name</i>	<i>Position (or reason for attending)</i>
Ms Amy Peters	REC Assistant



Skipton House
80 London Road
London SE1 6LH

Tel: 0207 104 8010
Email: hra.approval@nhs.net

Professor Helen Roberts
Academic Geriatric Medicine, Mailpoint 807
University Hospital Southampton
Southampton
SO16 6YD

11 December 2017

Dear Professor Roberts

Letter of HRA Approval

Study title: Feasibility study of a falls-based self-management guide for people with Parkinson's disease and their informal caregivers
IRAS project ID: 221022
REC reference: 17/SC/0488
Sponsor: Southern Health NHS Foundation Trust

I am pleased to confirm that HRA Approval has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications noted in this letter.

Participation of NHS Organisations in England

The sponsor should now provide a copy of this letter to all participating NHS organisations in England.

Appendix B provides important information for sponsors and participating NHS organisations in England for arranging and confirming capacity and capability. **Please read *Appendix B* carefully**, in particular the following sections:

- *Participating NHS organisations in England* – this clarifies the types of participating organisations in the study and whether or not all organisations will be undertaking the same activities
- *Confirmation of capacity and capability* - this confirms whether or not each type of participating NHS organisation in England is expected to give formal confirmation of capacity and capability. Where formal confirmation is not expected, the section also provides details on the time limit given to participating organisations to opt out of the study, or request additional time, before their participation is assumed.
- *Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria)* - this provides detail on the form of agreement to be used in the study to confirm capacity and capability, where applicable.

Further information on funding, HR processes, and compliance with HRA criteria and standards is also provided.

IRAS project ID	221022
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It is critical that you involve both the research management function (e.g. R&D office) supporting each organisation and the local research team (where there is one) in setting up your study. Contact details and further information about working with the research management function for each organisation can be accessed from the [HRA website](#).

Appendices

The HRA Approval letter contains the following appendices:

- A – List of documents reviewed during HRA assessment
- B – Summary of HRA assessment

After HRA Approval

The document “*After Ethical Review – guidance for sponsors and investigators*”, issued with your REC favourable opinion, gives detailed guidance on reporting expectations for studies, including:

- Registration of research
- Notifying amendments
- Notifying the end of the study

The HRA website also provides guidance on these topics, and is updated in the light of changes in reporting expectations or procedures.

In addition to the guidance in the above, please note the following:

- HRA Approval applies for the duration of your REC favourable opinion, unless otherwise notified in writing by the HRA.
- Substantial amendments should be submitted directly to the Research Ethics Committee, as detailed in the *After Ethical Review* document. Non-substantial amendments should be submitted for review by the HRA using the form provided on the [HRA website](#), and emailed to hra.amendments@nhs.net.
- The HRA will categorise amendments (substantial and non-substantial) and issue confirmation of continued HRA Approval. Further details can be found on the [HRA website](#).

Scope

HRA Approval provides an approval for research involving patients or staff in NHS organisations in England.

If your study involves NHS organisations in other countries in the UK, please contact the relevant national coordinating functions for support and advice. Further information can be found through [IRAS](#).

If there are participating non-NHS organisations, local agreement should be obtained in accordance with the procedures of the local participating non-NHS organisation.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application

IRAS project ID	221022
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procedure. If you wish to make your views known please use the feedback form available on the [HRA website](#).

HRA Training

We are pleased to welcome researchers and research management staff at our training days – see details on the [HRA website](#).

Your IRAS project ID is **221022**. Please quote this on all correspondence.

Yours sincerely

Miss Helen Penistone
Assessor

Email: hra.approval@nhs.net

*Copy to: Dr Charlotte Owen (student)
Ms Penny Bartlett, Southern Health NHS Foundation Trust (sponsor and lead
NHS R&D)*

IRAS project ID	221022
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Appendix A - List of Documents

The final document set assessed and approved by HRA Approval is listed below.

<i>Document</i>	<i>Version</i>	<i>Date</i>
Covering letter on headed paper [Cover Letter]		17 August 2017
Interview schedules or topic guides for participants [Follow up Provisional Interview Schedule with People with Parkinson's]	1	17 August 2017
Interview schedules or topic guides for participants [Follow up Interview Schedule with Caregivers of People with Parkinson's]	1	17 August 2017
Interview schedules or topic guides for participants [Provision outline of follow up telephone calls]	1	17 August 2017
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Non-validated questionnaire [Follow up Questionnaire Two. Completion by Caregivers of People with Parkinson's]	1	17 August 2017
Non-validated questionnaire [Follow up Questionnaire Three. Feedback Questionnaire]	1	17 August 2017
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Other [Informed Consent form. Clean Version]	2	06 November 2017
Other [Consultee Declaration Form. Clean Version]	2	06 November 2017
Other [Baseline Questionnaire One. Clean Version]	2	06 November 2017
Other [Baseline Questionnaire Two. Clean Version]	2	06 November 2017
Other [Self-management guide. Clean Version]	2	06 November 2017
Other [Steady Together. Clean Version]	3	27 November 2017
Other [Cover Letter. Response to Oxford C REC. 27.11.2017]		27 November 2017
Referee's report or other scientific critique report [Confirmation of External Scientific and PPI peer review]		09 December 2016
Summary CV for Chief Investigator (CI) [Professor Helen Roberts CV]		17 August 2017
Summary CV for student [Summary CV for Student. Charlotte Owen]		17 August 2017
Summary CV for supervisor (student research) [Professor Helen Roberts CV]		
Summary CV for supervisor (student research) [Dr Emma Stack CV]		
Summary, synopsis or diagram (flowchart) of protocol in non technical language [Summary of Proposed Methods in Non-technical Language]	1	17 August 2017

Appendix B - Summary of HRA Assessment

This appendix provides assurance to you, the sponsor and the NHS in England that the study, as reviewed for HRA Approval, is compliant with relevant standards. It also provides information and clarification, where appropriate, to participating NHS organisations in England to assist in assessing and arranging capacity and capability.

For information on how the sponsor should be working with participating NHS organisations in England, please refer to the, *participating NHS organisations, capacity and capability and Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria)* sections in this appendix.

The following person is the sponsor contact for the purpose of addressing participating organisation questions relating to the study:

Name: Ms Penny Bartlett

Tel: 02380475373

Email: penny.bartlett@southernhealth.nhs.uk

HRA assessment criteria

Section	HRA Assessment Criteria	Compliant with Standards	Comments
1.1	IRAS application completed correctly	Yes	No comments
2.1	Participant information/consent documents and consent process	Yes	No comments
3.1	Protocol assessment	Yes	No comments
4.1	Allocation of responsibilities and rights are agreed and documented	Yes	This is a single site study taking place in the NHS where the site is also the study sponsor. Therefore, no agreement is expected.
4.2	Insurance/indemnity arrangements assessed	Yes	Where applicable, independent contractors (e.g. General Practitioners) should ensure that the professional indemnity provided by their medical defence organisation covers the

IRAS project ID	221022
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Section	HRA Assessment Criteria	Compliant with Standards	Comments
			activities expected of them for this research study
4.3	Financial arrangements assessed	Yes	Funding to support the study has been granted by NIHR CLAHRC Wessex.
5.1	Compliance with the Data Protection Act and data security issues assessed	Yes	Audio-recordings, which will not include the participant's name, will be securely taken back to the research site, where they will be securely stored, following the interview in the participant's home. The audio recordings of interviews will be transcribed by a member of the research team.
5.2	CTIMPS – Arrangements for compliance with the Clinical Trials Regulations assessed	Not Applicable	No comments
5.3	Compliance with any applicable laws or regulations	Yes	No comments
6.1	NHS Research Ethics Committee favourable opinion received for applicable studies	Yes	No comments
6.2	CTIMPS – Clinical Trials Authorisation (CTA) letter received	Not Applicable	No comments
6.3	Devices – MHRA notice of no objection received	Not Applicable	No comments
6.4	Other regulatory approvals and authorisations received	Not Applicable	No comments

Participating NHS Organisations in England

This provides detail on the types of participating NHS organisations in the study and a statement as to whether the activities at all organisations are the same or different.

This is a single site study. Potential participants will be identified at site and invited to participate. All other activities will take place in the participant's home.

If this study is subsequently extended to other NHS organisation(s) in England, an amendment should be submitted to the HRA, with a Statement of Activities and Schedule of Events for the newly participating NHS organisation(s) in England.

The Chief Investigator or sponsor should share relevant study documents with participating NHS organisations in England in order to put arrangements in place to deliver the study. The documents should be sent to both the local study team, where applicable, and the office providing the research management function at the participating organisation. For NIHR CRN Portfolio studies, the Local LCRN contact should also be copied into this correspondence. For further guidance on working with participating NHS organisations please see the HRA website.

If chief investigators, sponsors or principal investigators are asked to complete site level forms for participating NHS organisations in England which are not provided in IRAS or on the HRA website, the chief investigator, sponsor or principal investigator should notify the HRA immediately at hra.approval@nhs.net. The HRA will work with these organisations to achieve a consistent approach to information provision.

Confirmation of Capacity and Capability

This describes whether formal confirmation of capacity and capability is expected from participating NHS organisations in England.

This is a single site study sponsored by the site. The R&D office will confirm to the CI when the study can start.

Principal Investigator Suitability

This confirms whether the sponsor position on whether a PI, LC or neither should be in place is correct for each type of participating NHS organisation in England and the minimum expectations for education, training and experience that PIs should meet (where applicable).

The Chief Investigator will act as Principal Investigator at site.

GCP training is not a generic training expectation, in line with the [HRA/MHRA statement on training expectations](#).

HR Good Practice Resource Pack Expectations

This confirms the HR Good Practice Resource Pack expectations for the study and the pre-engagement checks that should and should not be undertaken

Where arrangements are not already in place, researchers requiring access to site to assist with recruitment will be expected to obtain a NHS to NHS Letter of Access based on a standard DBS check and occupational health clearance.

IRAS project ID	221022
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Other Information to Aid Study Set-up

This details any other information that may be helpful to sponsors and participating NHS organisations in England to aid study set-up.

The applicant has indicated that they intend to apply for inclusion on the NIHR CRN Portfolio.

B.4 Ethical Approval for Substantial Amendment of the Mixed Methods Feasibility Study of the Intervention (Phase Four)



South Central - Oxford C Research Ethics Committee

Level 3, Block B
Whitefriars Building
Lewins Mead
Bristol
BS1 2NT
Tel: 020 7104 8052

Please note: This is the favourable opinion of the REC only and does not allow the amendment to be implemented at NHS sites in England until the outcome of the HRA assessment has been confirmed.

13 March 2018

Dr Charlotte Owen
Academic Geriatric Medicine, Room CE114B,
University Hospital Southampton, Tremona Road, Southampton
Hampshire
SO16 6YD

Dear Dr Owen

Study title: Feasibility study of a falls-based self-management guide for people with Parkinson's disease and their informal caregivers
REC reference: 17/SC/0488
Amendment number: Substantial amendment 1 05.03.2018
Amendment date: 06 March 2018
IRAS project ID: 221022

The above amendment was reviewed by the Sub-Committee in correspondence.

Ethical opinion

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

Approved documents

The documents reviewed and approved at the meeting were:

Document	Version	Date
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Covering letter on headed paper [Cover Letter. Amendment application. 05.03.2018.docx]		05 March 2018
Letter from sponsor [SHFT sponsor support lett -Substantial Amendment 1.pdf]		05 March 2018
Non-validated questionnaire [Steady Together. Baseline Questionnaire One. Clean Version. V3. 05.03.18.docx]	3	05 March 2018
Non-validated questionnaire [Steady Together. Baseline Questionnaire One. Tracked changes. V3. 05.03.18.docx]	3	05 March 2018
Non-validated questionnaire [Steady Together. Follow up Q1. Clean Version. V3. 05.03.2018.docx]	3	05 March 2018
Non-validated questionnaire [Steady Together. Follow up Q1. Tracked changes. V3. 05.03.2018.docx]	3	05 March 2018
Non-validated questionnaire [Steady Together. Follow up Q3. Clean Version. V3. 05.03.18.docx]	3	05 March 2018
Non-validated questionnaire [Steady Together. Follow up Q3. Tracked changes. V3. 05.03.18.docx]	3	05 March 2018
Notice of Substantial Amendment (non-CTIMP) [AmendmentForm_ReadyForSubmission.pdf]	Substantial amendment 1 05.03.2018	06 March 2018
Participant information sheet (PIS) [Steady Together. PIS. Clean Version. Version 3. 05.03.18.pdf]	3	05 March 2018
Participant information sheet (PIS) [Steady Together. PIS. Tracked Changes. Version 3. 05.03.18.pdf]	3	05 March 2018
Research protocol or project proposal [Steady Together. Protocol. Tracked changes. V4. 05.03.2018..docx]	4	05 March 2018
Research protocol or project proposal [Steady Together. Protocol. Clean Version. V4. 05.03.2018..docx]	4	05 March 2018

Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

Working with NHS Care Organisations

Sponsors should ensure that they notify the R&D office for the relevant NHS care organisation of this amendment in line with the terms detailed in the categorisation email issued by the lead nation for the study.

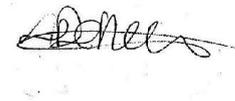
Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

We are pleased to welcome researchers and R & D staff at our Research Ethics Committee members' training days – see details at <http://www.hra.nhs.uk/hra-training/>

17/SC/0488:	Please quote this number on all correspondence
--------------------	---

Yours sincerely
PP



Appendix B: Ethical Approvals

**Professor Nigel Wellman
Chair**

E-mail: nrescommittee.southcentral-oxfordc@nhs.net

Enclosures: List of names and professions of members who took part in the review

*Copy to: Ms Penny Bartlett, Southern Health NHS Foundation Trust
Dr Charlotte Owen*

South Central - Oxford C Research Ethics Committee

Attendance at Sub-Committee of the REC meeting on 16 March 2018

Committee Members:

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Dr Linda Cartwright	Retired Consultant Epidemiologist	Yes	
Professor Nigel Wellman	Professor of Health and Human Sciences	Yes	Meeting Chair

Also in attendance:

<i>Name</i>	<i>Position (or reason for attending)</i>
Miss Lucy Roberts	REC Manager

From: TOTENHOFFER, Ashley (HEALTH RESEARCH AUTHORITY)
To: Roberts H.C.; Owen C.L.
Cc: penny.bartlett@southernhealth.nhs.uk
Subject: RE: IRAS 221022. Confirmation of Amendment Assessment
Date: 20 March 2018 14:06:59

Dear Professor Roberts

Further to the below, I am pleased to confirm **HRA Approval** for the referenced amendment.

You should implement this amendment at NHS organisations in England, in line with the conditions outlined in your categorisation email.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website: <http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/>.

Please contact hra.amendments@nhs.net for any queries relating to the assessment of this amendment.

Kind regards

Ashley

Ashley Totenhofer
Technical Assurance Officer
Health Research Authority

HRA Centre Manchester | 3rd Floor, Barlow House | 4 Minshull Street, Manchester | M1 3DZ
 T. 0207 104 8017
 E. ashley.totenhofer@nhs.net
 W. www.hra.nhs.uk

From: nrescommittee.southcentral-oxford@nhs.net [mailto:nrescommittee.southcentral-oxford@nhs.net]
Sent: 07 March 2018 17:19
To: hcr@soton.ac.uk; c.Lowen@soton.ac.uk
Cc: penny.bartlett@southernhealth.nhs.uk
Subject: IRAS 221022. Amendment confirmation of REC Validation, categorisation and implementation information

Amendment Confirmation of REC Validation, Categorisation and Implementation Information

Dear Professor Roberts,

Thank you for submitting an amendment to your project. Please find attached a copy of the REC validation letter for the submitted amendment.

If you have participating NHS/HSC organisations in any other UK nations we will forward the information to the relevant national coordinating function(s).

Please note that you may only implement changes described in the amendment notice.

What Happens Next?

When available, please forward any other regulatory approvals that are expected for this amendment to hra.amendments@nhs.net. However, you do not need to forward the REC favourable opinion as we will be able to access this through our systems.

Information Specific to Participating NHS Organisations in England

1. You should now share your notice of amendment and, if applicable, amended documents, together with this email, with all participating NHS organisations in England. In doing so, you should include the [NHS R&D Office, LCRN](#) (where applicable) as well as the local research team. A template email to notify participating NHS organisations in England is provided on the [HRA website](#).
2. The participating NHS organisations in England should prepare to implement this amendment.
3. Your amendment will be reviewed by the REC, as per the attached letter. In parallel to this, an assessment against [HRA standards](#) will take place.
4. Once the REC Favourable Opinion is issued, any other regulatory approvals are in place and the HRA assessment has been successfully completed, you will receive an email confirming that your amendment has HRA Approval.
5. You may implement your amendment at all participating NHS organisations in England 35 calendar days from the day on which you provide the organisations with this email and your amended documents (or as soon as the participating NHS organisation confirm that you may implement, if sooner), so long as you have HRA Approval for your amendment by this date. **NHS organisations do not have to confirm they are happy with the amendment.** If HRA Approval is issued subsequent to this date, you may implement following HRA Approval.
6. You may not implement the amendment at any participating NHS organisations in England that requests additional time to assess, until it confirms that it has concluded its assessment.
7. You may not implement at any participating NHS organisation in England that declines to implement the amendment.

Appendix B: Ethical Approvals

IRAS Project ID:	221022
Short Study Title:	Steady Together
Date complete amendment submission received:	07 March 2018
Amendment No./ Sponsor Ref:	Substantial amendment 1 05.03.2018
Amendment Date:	06 March 2018
Amendment Type:	Substantial
Outcome of HRA Assessment	HRA Approval for the amendment is pending. The HRA will separately confirm HRA Approval for the amendment by email.
Implementation date in NHS organisations in England	35 days from date amendment information together with this email, is supplied to participating organisations (provided HRA Approval for the amendment is in place and conditions above are met)
For NHS/HSC R&D Office information	
Amendment Category	A

If you have any questions about the ethical review of this amendment, please do not hesitate to contact me.

If you have any questions relating to the wider HRA approval process, please direct these to hra.approval@nhs.net.

If you have any questions relating this amendment in one of the devolved administrations, please direct these to the relevant [national coordinating function](#).

Additional information on the management of amendments can be found in the [IRAS guidance](#).

Please do not hesitate to contact me if you require further information.

Kind regards

Alison Doherty
REC Assistant
Health Research Authority
 Ground Floor | Skipton House | 80 London Road | London | SE1 6LH
[E. \[hra.amendments@nhs.net\]\(mailto:E.hra.amendments@nhs.net\)](mailto:E.hra.amendments@nhs.net)
[W. \[www.hra.nhs.uk\]\(http://www.hra.nhs.uk\)](http://www.hra.nhs.uk)

Sign up to receive our newsletter [HRA Latest](#).

 This message may contain confidential information. If you are not the intended recipient please inform the sender that you have received the message in error before deleting it. Please do not disclose, copy or distribute information in this e-mail or take any action in relation to its contents. To do so is strictly prohibited and may be unlawful. Thank you for your co-operation.

NHSmail is the secure email and directory service available for all NHS staff in England and Scotland. NHSmail is approved for exchanging patient data and other sensitive information with NHSmail and other accredited email services.

For more information and to find out how you can switch, <https://portal.nhs.net/help/joiningnhsmail>

Appendix C Phase One Appendices

C.1 Phase One: Participant Information Sheet

UNIVERSITY OF
Southampton



STEADY TOGETHER

A study to design a guide to help people with Parkinson's who fall, and those who help to look after them

We Invite you to take part in a study

Before you decide whether or not you would like to take part, we would like you to read this information booklet. This is important for you to understand why the study is being done and what it might involve.

Please read this booklet carefully. Please ask the researchers any questions that you might have.

It is up to you to decide whether or not to take part.

Why have I been invited

You have been invited because you have a diagnosis of Parkinson's and have had at least one fall in the last year, or help to look after somebody with Parkinson's who has fallen.

Summary of the study

The purpose of this study is to design a guide to help people with Parkinson's who fall, and the people who help to care for them at home.

We want to find out the views and experiences of falling in people with Parkinson's, and how it affects people who are close to them.

We would like to invite you to complete a questionnaire to help us to design this guide. You may complete this anonymously.

We will also be interviewing some people with Parkinson's and those close to them. If you would like to take part in these interviews, please provide us with your contact details.

Contents

1. Why are we doing this study?
2. What will I need to do if I take part?
3. What are the possible benefits and disadvantages of taking part?
4. What happens if I don't want to carry on with the study?
5. Will my taking part in the study be kept confidential?
6. What will happen to the results of the research study?
7. Who is organising and funding the research?
8. Who has reviewed the study?
9. What if there is a problem?
10. What do I do now?
11. Contact details of the researchers for further information

How to contact us

If you have any questions about the study, please contact Dr Charlotte Owen at:

University Hospital Southampton
Room CE 114B
Tremona Road, Southampton, SO16 6YD

Tel: 07824 895791

Email: c.l.owen@soton.ac.uk

Alternatively, the research administrator, Angela Dumbleton, can be contacted on:

Tel: 02381 206128

1 Why are we doing this study?

The purpose of this study is to design a guide to help people with Parkinson's, and the people who help to care for them, to self-manage falling.

We want to find out the views and experiences of falling in people with Parkinson's. We also want to know how it affects people who are close to them.

2 What will I need to do if I take part?

If you agree to take part, please complete the two questionnaires and return them in the stamped addressed envelope provided. You can complete these anonymously.

Questionnaire one is to be completed by the person with Parkinson's and a close friend or relative.

Questionnaire two is to be completed by the close friend or relative only.

We will invite some people to participate in an interview, where we will ask questions about your Parkinson's, falling and what concerns you. These interviews will take place at a time convenient to you and at your home address. If you are happy, we will audio-record these interviews, to allow us to concentrate on what you are saying. If you would like to be considered for this stage of the study, please provide us with your contact details at the end of the questionnaire.

3 What are the possible benefits and disadvantages of taking part?

The information you provide will assist us in knowing what information people with Parkinson's, and those who are close to them, would like to know about falls and how to manage them. It will also allow us to find out different ways that you commonly use to find information, which will help us to decide what the guide should look like.

The questionnaire does not ask any personal or sensitive issues. However, please do not answer any questions that you feel uncomfortable with.

4 What happens if I don't want to carry on with the study?

If after choosing to take part in the study you change your mind, you can withdraw at any time without giving a reason, and your usual NHS care will not be affected. However, any information you had given until that point would still be used in the study results.

5 Will my taking part in the study be kept confidential?

Yes, all information about you will be handled in confidence.

All data collected from you will be anonymised. Data will be stored on a password protected computer or locked filing cabinet in a secure office in our research unit and will be accessible only by the research team.

If you participate in the interviews, with your permission, these interviews will be audio-recorded to make an accurate record of what is said. Recordings will be typed up and identifiable data will be removed. The original audio-recordings will be destroyed.

When analysing the results of the study, your data will be used anonymously and will not be attributable to you. Data collected may be used to support research in the future, and your data may be shared anonymously with other researchers.

6 What will happen to the results of the research study?

The results of the research will be published in medical scientific journals, and may be presented at conferences and local meetings. The results may contain quotes from participants, however, these will be anonymised and will not be attributable to any individual. We will send you a summary of the findings if you would like one.

7 Who is organising and funding the research?

The research study is organised and funded by the National Institute for Health Research (NIHR) Collaborations for Leadership in Applied Health Research and Care (CLAHRC) based at the University of Southampton, which is funded by the government.

The lead researcher is Dr Helen Roberts, associate professor in Geriatric Medicine at University Hospital Southampton. The study is being managed by Dr Charlotte Owen, a clinical research fellow in Geriatric Medicine, and supported by Dr Emma Stack and Dr Laura Dennison, researchers at the University of Southampton.

8 Who has reviewed the study?

This study has been reviewed and approved through the Faculty of Medicine Ethics Committee at The University of Southampton; ERGO reference 25364.

9 What if there is a problem?

If there is a problem or you have any concerns, you can contact the researchers on the details provided in section 10 of this information sheet.

If you remained unhappy, you could contact the research governance office at the University of Southampton on:

Tel: 02380 598566 Email: Rgoinfo@soton.ac.uk

10 Contact details of the researchers for further information

If you have any questions about the study please contact the researchers, using the contact details provided below.

Dr Charlotte Owen

University Hospital Southampton

Academic Geriatric Medicine

Room CE114B

Tremona Road

Southampton, SO16 6YD

Tel: 07824 895791

Email: c.l.owen@soton.ac.uk

The research administrator, Angela Dumbleton, can be contacted on:

Tel: 02381 206128

Alternatively, the lead researcher, Dr Helen Roberts, can be contacted at the address above, or on Tel: 023 81204354

11 What do I do now?

If you would like to take part, please complete the questionnaires and return them to us in the stamped addressed envelope provided.

The questionnaires can be completed anonymously. However, should you wish to be involved in the interviews, or in the later review process of the self-management guide, then please provide your contact details.

Thank you for taking time to read this information sheet and considering taking part in this study

C.2 Phase One: PwP Questionnaire

STEADY TOGETHER

PwP Questionnaire

Please answer as many questions as possible: there are no right or wrong answers!

You may complete this questionnaire with a close friend or relative.

- The questions in sections 1-5 are addressed to the person with Parkinson’s
- The questions in sections 6-7 are addressed to both the person with Parkinson’s and those who are close to them.

Section 1: About You (person with Parkinson’s)

- 1 **Please sign below to confirm that you have read the information sheet and understand that completion and return of this questionnaire indicates your consent to use data for research as outlined on the information sheet**

Signature

Date/...../.....

Please circle one answer for each question

- 2 **Are you male or female?**

Male	Female
------	--------

- 3 **What is your date of birth?
(dd/mm/yyyy)**

--

- 4 **Where do you live?**

Own home	Rest home	Nursing home
-------------	-----------	-----------------

5 **Do you live alone?**

Yes	No
-----	----

If no, what is the relationship of the person who lives with you?

Spouse/ Partner	Children of yourself/your partner	Other
--------------------	---	-------

If other, please describe their relationship to you

--

6 **Do you have any difficulty reading a newspaper with glasses?**

No Difficulty	Some Difficulty	Extreme Difficulty
------------------	--------------------	-----------------------

Section 2: About your Parkinson's

1 **Do you have Parkinson's?**

Yes	No
-----	----

2 **When were you diagnosed with Parkinson's?**

If you cannot remember, please guess

--

3 **Do you see a specialist doctor or nurse at the hospital for your Parkinson's?**

Yes	No
-----	----

Section 3: About your memory

1 **Have you been given a diagnosis of cognitive impairment or dementia?**

Cognitive impairment	Dementia	Neither of these
----------------------	----------	------------------

2 **Have you discussed your memory with your family or friends?**

Yes	No
-----	----

Do your family or friends have any concerns about your memory?

--

Is your specialist nurse or doctor aware of these problems?

Yes	No
-----	----

Section 4: Your mobility

1 **Do you use a walking aid?**

Always	Sometimes	No
--------	-----------	----

If so, what walking aid?

Wheelchair	Zimmer Frame	Walking Stick
------------	--------------	---------------

Section 5: Falls

1 **Have you fallen in the last year?**

Yes	No
-----	----

2 **How many times have you fallen in the last year**

Please guess if you are unsure about the exact number of times

--

3 **Have you ever had any difficulty getting up off the floor after a fall?**

Yes	No
-----	----

If yes, what happened?

We would like to know about your 3 most recent falls.

If you have fallen less than 3 times, please tell us about the 1 or 2 falls that you have had

It is fine to write one-word answers, or to write 'can't remember' or 'don't know'.

Fall 1

Where did you fall? (e.g. in a car park),
What were you doing or trying to do? (e.g. climb stairs, turn left)
Was there anybody else with you?
Why do you think you fell? (e.g. froze, feet stuck)
Then what happened? Did you seek any medical attention? (e.g. bruised hip, ambulance called)
Do you think you could prevent it from happening again? If so, how?

Fall 2

Where did you fall? (e.g. in a car park),
What were you doing or trying to do? (e.g. climb stairs, turn left)
Was there anybody else with you?
Why do you think you fell? (e.g. froze, feet stuck)
Then what happened? Did you seek any medical attention? (e.g. bruised hip, ambulance called)
Do you think you could prevent it from happening again? If so, how?

Fall 3

Where did you fall? (e.g. in a car park),
What were you doing or trying to do? (e.g. climb stairs, turn left)
Was there anybody else with you?
Why do you think you fell? (e.g. froze, feet stuck)
Then what happened? Did you seek any medical attention? (e.g. bruised hip, ambulance called)
Do you think you could prevent it from happening again? If so, how?

We are also interested in any *near-misses* you might have had over the last year, when you thought you were about to fall but you did not actually fall.

3 **Have you had near-misses?**

Yes	No
-----	----

If yes, how often do you have near-misses?

Are there any particular situations that usually make you feel unsteady and likely to fall?

Yes	No
-----	----

Please Explain

We are also interested in how concerned you are about falling.

Please tick the box thinking about how you normally feel when you do the activity.

If you do not normally do the activity, please reply how you think you would feel if you were to perform the activity.

	Not at all concerned	Somewhat concerned	Fairly concerned	Very concerned
Getting dressed or undressed				
Taking a bath or shower				
Getting in or out of a chair				
Going up or down stairs				
Reaching for something above your head or on the ground				
Walking up or down a slope				
Going out to a social event				

Section 7: How you access information

We would now like to ask you about how you access information.

Please rate how often you are likely to use the following types of information on a day-to-day basis.

Please circle your answer

	Very Unlikely	Unlikely	Not sure	Likely	Very Likely
Leaflets	1	2	3	4	5
Books	1	2	3	4	5
A computer to access the internet	1	2	3	4	5
A smartphone or a tablet e.g. iPad	1	2	3	4	5
YouTube	1	2	3	4	5
DVDs	1	2	3	4	5

Section 8: Further information

Please let us know who completed this form

Person with Parkinson's	Relative or friend	Both
-------------------------	--------------------	------

Taking part in later stages of the study

There are further stages of our study that you might like to help us with:

- We are going to invite some people to talk to the researchers in more depth about falls.
- Once we have produced our guide we would like to ask people with Parkinson's and their caregivers to provide us with feedback about the guide.

If you would like to be considered for the next stages of our research, please supply your contact details. You can always change your mind at a later date if you decide that you do not want to be involved. The contact details supplied can be those of the person with Parkinson's, or your friend/relative.

Contact details

Name of person with Parkinson's
Name of relative or friend
Telephone number
Email address
How and when is the best way to contact you?

Thank you for completing this questionnaire, please ensure that you have signed next to question one.

Please post the questionnaire back to us alongside questionnaire two using the envelope provided.

C.3 Phase One: Caregiver Questionnaire

STEADY TOGETHER

Questionnaire Two: For completion by a relative or a close friend of a person with Parkinson’s

This form is to be completed by the relative or close friend of the person with Parkinson’s. We are interested to know how you have been affected by having someone close to you affected by Parkinson’s.

- 1 **Please sign below to confirm that you have read the information sheet and understand that completion and return of this questionnaire indicates your consent to use data for research as outlined on the information sheet**

Signature **Date/...../.....**

Please answer as many questions as possible: there are no right or wrong answers!

Please circle the answer that you think most applies to how you feel.

DO YOU FEEL.....

- 2 **That because of the time you spend with your relative/ friend that you don’t have enough time for yourself**

Never	Rarely	Sometimes	Quite Frequently	Nearly always
-------	--------	-----------	------------------	---------------

- 3 **Stressed between caring for your relative/ friend and trying to meet other responsibilities (work/ family)?**

Never	Rarely	Sometimes	Quite Frequently	Nearly always
-------	--------	-----------	------------------	---------------

- 4 **Angry when you are around your relative**

Never	Rarely	Sometimes	Quite Frequently	Nearly always
-------	--------	-----------	------------------	---------------

- 5 **That your relative/ friend currently affects your relationship with family members or friends in a negative way**

Never	Rarely	Sometimes	Quite Frequently	Nearly always
-------	--------	-----------	------------------	---------------

6 **Strained when you are around your relative/ friend?**

Never	Rarely	Sometimes	Quite Frequently	Nearly always
-------	--------	-----------	------------------	---------------

7 **That your health has suffered because of your involvement with your relative/ friend?**

Never	Rarely	Sometimes	Quite Frequently	Nearly always
-------	--------	-----------	------------------	---------------

8 **That you don't have as much privacy as you would like because you are caring for your relative/ friend?**

Never	Rarely	Sometimes	Quite Frequently	Nearly always
-------	--------	-----------	------------------	---------------

9 **That your social life has suffered because you are caring for your relative/ friend?**

Never	Rarely	Sometimes	Quite Frequently	Nearly always
-------	--------	-----------	------------------	---------------

10 **That you have lost control of your life since your relative/ friend's illness?**

Never	Rarely	Sometimes	Quite Frequently	Nearly always
-------	--------	-----------	------------------	---------------

11 **Uncertain about what to do about your relative/ friend?**

Never	Rarely	Sometimes	Quite Frequently	Nearly always
-------	--------	-----------	------------------	---------------

12 **You should be doing more for your relative/ friend?**

Never	Rarely	Sometimes	Quite Frequently	Nearly always
-------	--------	-----------	------------------	---------------

13 **You could do a better job in caring for your relative/ friend?**

Never	Rarely	Sometimes	Quite Frequently	Nearly always
-------	--------	-----------	------------------	---------------

Thank you for completing this questionnaire, please ensure that you have signed next to question one.

Please post the questionnaire back to us alongside questionnaire one using the envelope provided.

C.4 Phase One: Consent Form for PwP and Caregivers**STEADY TOGETHER****Consent form for people with Parkinson's and those close to them**

ERGO reference number: 25364

Chief Investigator: Dr Helen Roberts

Principal Investigator: Dr Charlotte Owen

Thank you for reading the information about our research project. If you would like to take part, please read and sign this form.

PLEASE INITIAL THE BOXES IF YOU AGREE WITH EACH SECTION:

1.	I have read the information sheet version 2 dated 03.03.17 for the above study and have been given a copy to keep. I have been able to ask questions about the study and I understand why the research is being done. I have been informed about any risks or inconveniences involved and the conditions under which the study is to be conducted.	<input type="checkbox"/>
2.	I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason. And if I withdraw from the research study for any reason, data collected up to my withdrawal will be used.	<input type="checkbox"/>
3.	I understand that the audio-recordings will be transcribed into a word document, and that the original audio-recordings will be destroyed once they have been transcribed. I understand that my confidentiality as a participant in this study will remain secure and that the transcript of the interview will not contain my name or identifiable information. I agree for my data to be stored anonymously and that any published quotations or extracts from the research will maintain my confidentiality.	<input type="checkbox"/>
4.	I understand that the data collected may be used to support research in the future, and that my data may be shared anonymously with other researchers	<input type="checkbox"/>
5.	I understand that my participation in this study involves taking part in an interview that will be audio-recorded. I give my permission to the	<input type="checkbox"/>

C.5 Phase One: Consultee Declaration Form

STEADY TOGETHER

Consultee Declaration Form

ERGO reference number: 25364

Chief Investigator: Dr Helen Roberts

Principal Investigator: Dr Charlotte Owen

We feel your relative/friend is unable to decide for himself/herself whether to participate in this research.

To help decide if he/she should join the study, we would like to ask your opinion as to whether or not they would want to be involved. We ask you to consider what you know of their wishes and feelings, and to consider their interests. Please let us know of any advance decisions they may have made about participating in research. These should take precedence.

If you decide your relative/friend would have no objection to taking part, we will ask you to read and sign a Consultee declaration to document your opinion as to how your relative would have chosen to participate in the study. We will then give you a copy to keep. We will keep you fully informed during the study so you can let us know if you have any concerns or you think your relative/friend should be withdrawn.

If you decide that your friend/relative would not wish to take part, it will not affect the standard of care they receive in any way.

If you are unsure about taking the role of a Consultee, you may seek independent advice. We will understand if you do not want to take on this responsibility.

1.	<p>I(NAME OF CONSULTEE) have been consulted about the participation</p> <p>of(NAME OF PARTICIPANT) in this research project. I have read and understand the information sheet version 2 dated 03.03.17 for the above study and have been given a copy to keep. I have been able to ask questions about the study and I understand why the research is being done. I have been informed about any risks or inconveniences involved and the conditions under which the study is to be conducted.</p>	<input type="checkbox"/>
----	--	--------------------------

C.6 Phase one: Interview Schedule (PwP and Caregivers)

STEADY TOGETHER

Interview Schedule (PwP and caregivers)

Introduction

Thank you very much for taking part in this study. My name is Charlotte Owen and I am a research doctor in medicine for older people at the University of Southampton/ my name is Christine Gaulton and I am a student researcher at the University of Southampton. I work with Dr Helen Roberts, associate professor and consultant in Geriatric Medicine at University Hospital Southampton; and Dr's Emma Stack and Laura Dennison, who are researchers at the University of Southampton.

The purpose of this study is to design and introduce a guide to help people with Parkinson's who fall, and the people who help to care for them. We want to find out the views and experiences of falling in people with Parkinson's. We also want to know how falling affects those close to them.

The interview is informal and completely confidential. Only my colleagues and I will listen to anything that is said, and your name will not appear in anything that we write.

With your permission I would like to record this interview with an audio recorder. This is so that I can concentrate on what you are telling me rather than on writing notes. After this interview, I will transfer the information on the tape onto a password protected computer, which will be kept in a secure office in our research department. Anything that you say will be in confidence and will not be attributable to you.

Thank you for completing the questionnaire. This interview is a little bit different. I am really interested to know all about the details of your thoughts and experiences of falling.

To start off I would like to ask a few questions about falls...

1. Tell me about your experience of falling

Probes	Prompts
<p>Tell me about your most recent fall</p> <p>Are all your falls similar or very different to one another?</p>	<p>Can you tell me about any times when you stumble but manage to stop yourself from falling?</p> <p>Can you tell me about the preventable or unpreventable nature of your falls?</p>

2. Can you describe whether your falling has changed how you do your day to day activities?

Probes	Prompts
<p>Can you tell me about...</p> <p>(i) Anything that you now do differently to reduce your risk of falling?</p> <p>(ii) Anything that you have found particularly helpful?</p> <p>(iii) Anything that you have found particularly unhelpful?</p>	

3. How does falling make you feel?

Probes	Prompts
<p>Can you explain about whether these feelings have affected how you perform your day to day activities?</p>	<p>Can you tell me about any concerns that you might have?</p> <p>(i) Anything that you now do differently as a result of these concerns?</p>

I would now like to ask you a few questions about your understanding of falling and of sources of information that are available to help you

4. Can you tell me about which healthcare professionals, if any, you have told about your falls?

We would like to know the professions of those that you have told, not the names of individuals

Probes	Prompts
<p>What role do you think that these professionals might play in helping with falls?</p>	<p>Can you tell me about the role that you think that...</p> <p>(i) Your Parkinson's specialist nurse might play in helping with falls?</p> <p>(ii) Your Parkinson's specialist doctor might play in helping with falls?</p>

5. Where, if anywhere, have you found information that might help you to...

- a. Reduce your risk of falling?
- b. Reduce the risk of injury?
- c. To cope after a fall?

Probes	Prompts
<p>Can you tell me about your experience of these?</p> <p>Can you explain to me whether you find these useful?</p>	<p>Can you explain any support that you might have had through your P (UK) support group for falling?</p> <p>Are you aware of the leaflet available through P (UK)? If so...</p> <p>(i) How do you find this?</p> <p>(ii) How do you find this to read?</p> <p>(iii) How do you find this to navigate?</p> <p>Can you tell me about any other sources that are available such as those on the internet or on YouTube</p>

6. Can you tell me about anything relating to falling that you have learnt ‘along the way’?

Probes	Prompts
Can you explain how this might have altered your (i) Risk of falling? (ii) Risk of injury? Can you explain how this might have altered any concerns that you might have in relation to falling?	

7. Can you tell me about whether you think there is any information that you need that might help you to...

- a. **Reduce your risk of falling?**
- b. **Reduce the risk of injury?**
- c. **To cope after a fall?**

Probes	Prompts
What would be a good or an appropriate way for you to get this information?	

We are going to design a guide to help people with Parkinson’s who fall, and those close to them

8. Can you tell me about what you think should be included in our guide?

Probes	Prompts
Can you explain how you think this information should be provided? Can you explain what you think our guide should look like?	

9. Can you explain any further suggestions that you might have to help us to develop our guide?

Thank you for taking part in this interview

C.7 Phase One: Content Analysis of Falls Data from Questionnaire One

C.7.1 Location of fall

Response	N	Further details re the response (all correspondents)	N	Additional information where applicable (n)
Home environment	114 (77%)	Inside	99 (70%)	Kitchen 12 Bathroom 9 Bedroom 14 Stairs 5 Dining room/lounge/sitting area 20 Hall 8 Not described 23 Other areas 8
		Outside	15 (10%)	Garden 13 Driveway 2
Away from home environment	29 (20%)	Inside	9 (6%)	At a friend's house 2 squash court 1 Church 1 Scout hut (singing group) 1 Squash court 1 Indoor bowls club 1
		Outside	20 (14%)	Car park 6 Footpath 6 Crossing the road 1 Golf course 2 Friends driveway 1
Missing data/ illegible/ response unclear	5 (3.4%)			Missing information/ illegible 3 Response unclear (2 places given in the response) 2

C.7.2 What were you trying to do?

Response	N	Further details re the response where applicable
Walking	36	Rushing 3 Uneven 4 Small space 2 Changing direction 1
Steps	12	Kerb 1 Stairs/step 11
Turning	16	
Open/ close door	3	
Getting dressed	2	
Play golf	1	
Cut grass	2	
Reaching	13	
Moving an object	4	
Unclear	18	
When trying to sit or stand	21	
Gardening	2	
Go through a doorway	8	
Cooking	2	
Washed	1	
Hanging clothes up	3	
Drawing curtains	1	
Making bed	1	
Multitasking	1	
Standing/ sitting still	3	

Total N = 150. Two actions were described as part of the description of two of the falls.

C.7.3 Why do you think you fell?

Response	N
Overreaching	4
freezing	51
Lost balance	24
Trip	17
slip	6
dizzy	3
Leg gave way	7
Doing something stupid/ personal misjudgement	8
Performing an action too quickly	4
Distraction	4
Space too confined	3
'It just happened': participant unable to explain why/ unclear from answer as to why they thought they fell	17
Dyskinesia	2

Total N= 150; Two falls described two descriptions

C.7.4 Then what happened? Did you seek medical attention?Was medical attention sought?

Response	N
Yes	33
No	114
Illegible	1

Was an injury stated within the response?

Response classification	Details of what classifies this response	Number of participants
Yes	described an injury	65
No	actively stated that did not have an injury	17
Not described	no injury described	65
Illegible	illegible	1

Did the participant require help from others?

Response classification	Details of what classifies this response	Number of participants
Yes	Yes, stated that others were called	68
No	Stated OK on their own	5
Not described	Not described any help that they needed	74
illegible	Illegible	1

C.7.5 Do you think you could prevent it from happening again? If so, how?Do you think that you could prevent the fall from happening again?

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Response classification	Details of what classifies this response	Number of participants
Yes	Explicitly stated or implied through the suggestions that they have spoken about	76
No	Explicitly stated or implied through the suggestions that they have spoken about	42
Not clear from the response given	Unclear whether the participant thinks that the fall is preventable/ not	15
Participant unsure if they could prevent it again	Participant not sure whether they could prevent the fall	11
Missing/ illegible response		4

If felt to be preventable, how could you stop it from happening again?

Situation	Number of participants
Question not relevant- fall felt to not be preventable	72
Take more care/ concentrate more/ planning route/ being more aware/ more cautious/ pay more attention	35
Adaptations to the house or to the environment including clutter and equipment	8
Equipment to aid walking or transfers or washing	7
Footwear adaptations	2
Move more slowly/ don't rush	14
No more details	1
Keep things nearby to reduce need to walk	1
Enlist the help of others whilst performing a particular activity	5
Alter activities. Examples given included: avoid doing something risky/ overstretching; develop an awareness of limitations; avoid carrying things; avoid small spaces; never pick things off the floor; avoid walking backwards; avoid doing too many things at once; lift foot higher.	11

Total N=84. During 8 falls the participant felt that the fall could be prevented in 2 of the ways described above.

C.7.6 Have you ever had any difficulty getting up from the floor? If yes, what happened

Response	Number of participants	Further details of the participant's response (where applicable)	Number of participants
Help from others. Where this simply stated 'my wife helped me get up', the response is not categories into physical or non-physical help	27	Stated that this help was from husband/ wife/ friend	17
		Explicitly stated that this was physical help from others	11
		Paramedics provided this physical help	7
		Explicitly stated that this was non-physical help from others e.g. told what to do/ they called an ambulance	2
		Called Helpline	1
Illegible	1		
Fell in an awkward place e.g. wedged or sustained significant injury	9	Unable to get up due to falling in an awkward position e.g. wedged	3
		Sustained significant injury/ LOC	6
Required support of nearby objects	3		
N/A Response states that simply could not get up/ does not describe the difficulties	7		

Total N= 47. 42/61 participants gave a response to this question; 5 participants gave responses within 2 categories.

C.7.7 Are there any particular situations that usually make you feel unsteady and likely to fall?

Response	Number of participants
Freezing	2
When 'off' with their PD	6
Turning	9
Getting dressed/ undressed	2
Walking backwards	3
Getting out of a chair and during transfers	4
Doorways	3
Small spaces (confined/ cluttered spaces)	5
Fatigue (tired/ when have walked a long way)	4
Anxious/ stressed/ thinking of too many things at once/ multitasking	3
Shower	1
Moving too quickly or rushing	5
Going up or down the stairs	7
Changes of floor surface or colour	1
Unfamiliar places	1
Mis-stepping	2
N/A	2
Bending forwards	2
Moving from A to B	3
Confusion and memory loss	1
Everything	1
Lighting	1
Standing still	2
Uneven/ sloping ground	1
Going to the toilet at night	1

Total N=72. Responses received from 52 participants; 16 participants gave more than one response; 12 participants gave two responses, four participants' three responses.

C.8 Coding Manual for Semi-structured Interviews with PwP and their Caregivers

Theme	Subthemes	Contributing data	Data presented elsewhere
Theme 1 “Establishing reasons for falls; attributions and perceptions”	People are driven to try to identify reasons for falling and may encounter uncertainty	PwP and caregivers frequently seek to identify cause of falling	
		Heterogeneous and often multifactorial nature of falling	
		Some PwP preoccupied with their medication	
		Near misses often occur in similar circumstances to falls	Some PwP may be dismissive of near misses discussed within theme 1, subtheme ‘falling may be perceived as unrelenting, unpredictable and unpreventable’. Preventing near misses leading to a fall discussed within theme 3.
		Environmental contributions are often made	Environmental causes often deemed non-modifiable discussed in theme 4.
		Some PwP and caregivers may assign blame on the PwP as to the cause of falling	
		Where there is uncertainty about the cause of falling, PwP and their caregivers may experience frustration	
	Falling may be perceived as unrelenting, unpredictable and unpreventable	Falling may be perceived as constant leading to frustration	Frustration when the PwP initially starts to fall is discussed within theme 2 Caregivers may feel that they are defined by caregivers discussed within theme 4, subtheme ‘loss of caregiver identity’.
		Falling may be perceived as unpredictable, leading to frustration	
		Near misses often associated with concern but a minority are dismissive	
Perceptions surrounding the preventable or unpreventable nature of falling.			
Theme 1 “Establishing reasons for falls; attributions and perceptions” Cont.....	Falling may be perceived as unrelenting, unpredictable and unpreventable Cont.....	Those who have been falling for longer may be more likely to view falling as unpreventable.	
		Interventions to support those who fall may be more effective in those who are earlier in the trajectory of the condition.	

Appendix C: Phase One Appendices

Theme	Subthemes	Contributing data	Data presented elsewhere
Theme 2 “Initial responses, coping and adaptation”	Initial reactions in response to falling	At the onset of falling some PwP and caregivers may experience shock and feel unprepared.	Frustration in association with uncertainty of the cause of falling discussed within theme 1
		Falling can be associated with frustration and embarrassment, which may be more apparent when falling is new to the PwP	
	Development of emotional coping strategies	Range of emotion-focused coping strategies developed by PwP and caregivers in response to falling	
		Social support from within the dyad	Dyads acting as a team front, and self-managing falls discussed within theme 5
		Difficulties in interacting with those outside of the dyad can be met with difficulty	(Social support may be provided from attendance at the Parkinson’s UK group or reading the Parkinson’s magazine, these are discussed within theme 5
		Use of emotional release, though distancing and distraction, and maintaining a sense of calm, and details of which PwP and caregivers are likely to use these strategies	
		Importance of maintaining a sense of ‘calm’ and thinking methodically adopted by many caregivers, which allowed for them to overcome their anxieties.	Methodical actions –as opposed to methodical thinking- discussed within theme 3 as a problem-focused coping strategy
		Caregivers encourage PwP to also remain calm with positive response.	

Theme	Subthemes	Contributing data	Data presented elsewhere
Theme 2 “Initial responses, coping and adaptation” <i>Cont.....</i>	Acceptance and normalisation of falling over time	Adaptation and acceptance of falling as PD progresses and falling becomes more 'commonplace'	
		This can then lead to normalisation of falling	
Theme 3 “Recognising and managing risks surrounding falling”	Adoption of problem-focused coping strategies, which are often self-taught	<u>Behavioural adaptations</u>	
		Self-identification of contributors to fall risk by PwP and caregivers and adaptation of behaviours to overcome these	
		Taking care and being more methodical in their actions to manage the risk of falling, including taking care and not carrying items when walking	Keeping calm and thinking methodically discussed within theme 2 as an emotion-focused coping strategy
		The caregiver plays a key role in making these behavioural adaptations, particularly where the PwP has cognitive impairment or dementia	
		Being aware of and making behavioural adjustment based on patterns of symptoms	
		Prevention and management of freezing episodes, which the caregiver plays a key role in the management of falling	
		Pre-planning journeys to manage fall risk and allowing PwP to continue with the activities that they enjoy	
		Being aware of making adaptations when in particular environments including adaptation to the home to include making wider spaces	Some environments may be deemed unmodifiable leading to avoidance discussed within theme 3, subtheme: adaptations lead to transformation of the lives of PwP How these changes affect the lives of PwP and caregivers discussed within theme 3, subtheme: adaptations lead to the transformation of the lives of PwP and caregivers Concerns about how these adaptations effect PwP and caregivers discussed within theme 4: ongoing concerns
Preventing a near miss from progressing to a fall	How near misses are perceived discussed within theme 1, subtheme 'falling may be perceived as unrelenting, unpredictable and unpreventable'		

Appendix C: Phase One Appendices

Theme	Subthemes	Contributing data	Data presented elsewhere
		PwP who live alone often have the support of others to assist them with falling including neighbours and paid cleaners. These PwP are often keen to maintain their independence.	
		Importance of ongoing physical activity and how this will affect fall risk	Avoidance of physical activity due to falls risk discussed within theme 4 (Adaptation to physiotherapy strategies is discussed within theme 5, subtheme: healthcare provision often insufficient)
		<u>Practical adaptations</u> Practical changes are made to the home, which may be prioritised.	Difficulty with changes to the home discussed within theme 4: ongoing concerns
		Changes needed to the home often change over time	
		Changes may be instigated by caregivers, which can arise through a delay in occupational therapy assessment.	How participants view these delays in assessment discussed within theme 5: healthcare provision
		Mobility aids may allow for independence to be maintained Using mobility aids in different environments to adapt to a particular setting	Difficulties with mobility aids discussed within theme 4: ongoing concerns
		Adaptations lead to transformation of the lives of PwP and caregivers	Adaptation of activities to allow the PwP and the caregiver to spend more time with one another. Details of practical support provided where the PwP lives alone.
	Falling often results in transformation of the lives of PwP and caregivers		
	Adaptation of activities of the PwP to those which the PwP feels confident in performing	Concerns of isolation- raised by PwP and caregivers as a result of changes that have been made are discussed within theme 4 Continued physical activity of the PwP and perceptions surrounding its importance Vs the management of falls risk discussed within theme 4.	

Theme	Subthemes	Contributing data	Data presented elsewhere	
		PwP may avoid particular settings due to the risk of falling where the fall risk is deemed non-modifiable	Avoidance of all physical activity to manage ongoing concerns of falling discussed within theme 4	
		Adaptation of caregiver activities to manage concern of the PwP being alone.	How these changes result in a loss of caregiver identity discussed within theme 4	
Theme 4 “Concerns and worries about consequences”	Despite coping strategies, significant concerns remain	Overarching concerns of injury and that falls be of differing 'degrees' dependant on whether injury occurs		
		Overarching concerns of being unable to get up from the floor, including caregiver concerns about injury and physical strength	Difficulties in relation to asking for external support in helping the PwP up off the floor discussed within theme 5 Wanting more information about how to get the PwP up off the floor discussed within theme 6	
		PwP concerned about being alone in the house		
		Caregivers differences of opinion in whether they can leave the PwP alone		
		Caregivers anxieties of any physical activity that the PwP makes, and how this affects fall risk	Caregivers encouraging ongoing physical activity discussed within theme 3	
		Difficulties with practical changes made within the home	Changes that have been made are discussed within theme 3	
		Difficulties with walking aids: perceptions of how they are viewed and difficulties with their use	Adaptation of walking aids to different environments within theme 3	
	Impact on the relationship between the PwP and the caregiver	Friction within the relationship of the dyad, which may arise from the PwP dependence on the caregiver		
		Frustration when the PwP does not follow the advice of the caregiver or HCPs	Blame of PwP behaviour as a cause of falling discussed within theme 1	
		Caregivers of PwP with cognitive impairment or dementia may have developed patience over time		
		Altered responsibilities within the home between the PwP and the caregivers	How this affects the identity of the caregiver discussed within subtheme: loss of caregiver identity. Constant and unrelenting nature of falling discussed within theme 1	
			Caregivers often defined by their role as a caregiver which	Constant and unrelenting nature of falling discussed

Appendix C: Phase One Appendices

Theme	Subthemes	Contributing data	Data presented elsewhere	
	Loss of pre-caregiver identity	leads to distress. In caregivers of PwP with CI/dementia this distress was not exclusively related to falling.	within theme 1.	
		Loss of pre-caregiver identity and self-preservation		
		Caregivers try to maintain social activity outside of the dyad	How caregivers adapt their activity to manage the risk of falling discussed within theme 3, subtheme 'Adaptations lead to transformation of the lives of PwP and caregivers' How caregivers have ongoing concerns in relation to the PwP being alone discussed within theme 4, subtheme 'Despite coping strategies, significant concerns remain subtheme ongoing concerns'.	
		Caregivers may be frustrated that the PwP does not recognise the changes that PD has had on their life, and perceptions surrounding the transition of spouse/ close friend to caregiver		
		Inability to prevent falling may lead to feelings of inadequacy		
		Support outside of the dyad is often inadequate	Practical (objects) and person (neighbours, friends) support within the caregiver role. However, the primary caregivers maintain overall responsibility	
		Friends and family may not understand the complexities of PD		
		Paid support may not be able to meet caregivers needs	Difficulties with accessing social services discussed within theme 5: healthcare provision subtheme	
	Theme 5 "PwP and Caregivers as case managers" Theme	Parkinson's UK group provides little support for falling	Parkinson's UK support group often provides a source of social support	Social support provided from sources other than Parkinson's UK group are discussed within theme 2
			Parkinson's UK group is often an 'ad hoc' source of advice about falling	
Parkinson's UK group provides services not available within the remit of the NHS				
Social support from Parkinson's UK magazine				

Theme	Subthemes	Contributing data	Data presented elsewhere
	Healthcare provision is often insufficient for successful falls management	Informing HCPs of falling	
		Barriers to informing HCPs of falling including where PwP think falling is unpreventable	Dyads may be more likely to view falling as unpreventable where the PwP has been falling for a longer period discussed within theme 1
		Views surrounding the roles of healthcare professionals in falls management	
		Perceptions of physiotherapy including how physiotherapy exercises may need to be adapted in the setting of CI/ dementia	
		Frustrations with healthcare provision including perceptions of communication between HCPs and long waiting times	Delays in occupational therapy assessment can lead to some PwP and caregivers self-instigating changes within the home, details of these changes discussed within theme 3. How social services may not meet the requirements of PwP and caregivers discussed within theme 4, subtheme: 'Support from outside of the dyad is often inadequate'.
		Barriers to caregivers seeking support from paramedics	
	Good information isn't available or used	The Parkinson's UK leaflet is poorly remembered and not utilised by PwP and caregivers	
		Sense amongst some dyads that they 'collected' information	
		Current information provision may be inadequate and possible barriers to engagement with the current literature	
	Dyads may feel lost and not know where to look for support	Information seeking practices and perceived information requirements.	-
		Dyads may feel that they must 'get on with it' alone, unsure of where they can seek advice or support	Social support from within the dyad as a broad coping mechanism discussed within theme 2. Barriers to PwP and caregivers seeking advice and support discussed within theme 5 subtheme: healthcare provision is often insufficient for successful falls management

Appendix C: Phase One Appendices

Theme	Subthemes	Contributing data	Data presented elsewhere
<p>Theme Six “Views surrounding the content and format of future interventions.”</p>	<p>N/A</p>	<p>Caregivers express a need for information about how to get the PwP off the floor</p>	<p>Caregivers have ongoing concerns about how to get the PwP off the floor discussed within theme 2 Barriers to caregivers seeking external support discussed within theme 5 subtheme: healthcare provision is often inadequate for successful falls management</p>
		<p>PwP and caregivers aware of the multifactorial needs of the population of PwP and caregivers, arising from the heterogeneous nature of PD</p>	
		<p>Dyads perceptions on how much content should be contained within the intervention: ‘short and sweet’</p>	
		<p>Views surrounding language</p>	
		<p>Views surrounding different formats of information and barriers to their use.</p>	
		<p>Views surrounding the use of colour</p>	
		<p>Views surrounding the use of pictures and diagrams</p>	
		<p>Views surrounding font size</p>	

Appendix D Phase Two appendices

D.1 Phase Two: Participant Information Sheet

UNIVERSITY OF
Southampton



STEADY TOGETHER

A study to design a guide to help people with Parkinson's who fall, and those who help to look after them

We Invite you to take part in a study

Before you decide whether or not you would like to take part, we would like you to read this information booklet. This is important for you to understand why the study is being done and what it might involve.

Please read this booklet carefully. Please ask the researchers any questions that you might have.

It is up to you to decide whether or not to take part.

Why have I been invited

You have been invited because you are involved in the provision of healthcare that is provided to people with Parkinson's and their caregivers.

Summary of the study

The purpose of this study is to design a guide to help people with Parkinson's who fall, and the people who help to care for them at home.

We think that your valuable knowledge and expertise will help us to design a guide that is useful to this population.

We would like to invite you to participate in an interview or a small group discussion. If you are interested in taking part please contact us on the details provided.

Contents

1. Why are we doing this study?
2. What will I need to do if I take part?
3. What are the possible benefits and disadvantages of taking part?
4. What happens if I don't want to carry on with the study?
5. Will my taking part in the study be kept confidential?
6. What will happen to the results of the research study?
7. Who is organising and funding the research?
8. Who has reviewed the study?
9. What if there is a problem?
10. Contact details of the researchers for further information
11. What do I do now?

How to contact us

If you have any questions about the study, please contact Dr Charlotte Owen at:

University Hospital Southampton
Room CE 114B
Tremona Road, Southampton, SO16 6YD

Tel: 07824 895791
Email: c.l.owen@soton.ac.uk

Alternatively, the research administrator, Angela Dumbleton, can be contacted on:
Tel: 02381 206128

1 Why are we doing this study?

The purpose of this study is to design a guide to help people with Parkinson's, and the people who help to care for them, to self-manage falling.

We want to find out the views and experiences of falling in people with Parkinson's and their caregivers. We also want to find out the views of health care professionals specialising in the care of people with Parkinson's. A self-management guide that provides information about falling might reduce the concerns that people have about falling and the stress that those who live with them currently experience.

2 What will I need to do if I take part?

If you agree to take part, please contact Dr Charlotte Owen, using the details provided.

We will arrange a time, at your convenience, to ask you some questions either alone, or as part of a small group with some of your colleagues. We will ask you about your previous experience in working with people with Parkinson's disease who fall, and what problems you think need to be addressed to allow for improved self-management of falls. We will also ask you about the sources of information that are currently available for this population, about how accessible they are, and whether you feel that they are utilised.

If you are happy, we will audio-record these interviews, to allow us to concentrate on what you are saying.

3 What are the possible benefits and disadvantages of taking part?

The information you provide will assist us in knowing what information people with Parkinson's, and those who live with them, would like to know about falls and how to manage them. It will also allow us to find out the different ways that this population use to find information, which will help us to decide what the guide should look like.

We will not ask you about any personal or sensitive issues. However, please do not answer any questions that you feel uncomfortable with. All we aim to do is to understand

4 What happens if I don't want to carry on with the study?

If after choosing to take part in the study you change your mind, you can withdraw at any time without giving a reason. However, any information you had given until that point would still be used in the study results.

5 Will my taking part in the study be kept confidential?

Yes, all information about you will be handled in confidence.

All data collected from you will be anonymised. Data will be stored on a password protected computer or locked filing cabinet in a secure office in our research unit and will be accessible only by the research team.

The interview/ group discussion will be audio- recorded to make an accurate record of what is said. Recordings will be typed up and identifiable data will be removed. The original audio-recordings will be destroyed.

When analysing the results of the study, your data will be used anonymously and will not be attributable to you. Data collected may be used to support research in the future, and your data may be shared anonymously with other researchers.

6 What will happen to the results of the research study?

The results of the research will be published in medical scientific journals, and may be presented at conferences and local meetings. Published reports may include quotes from participants, however, these will be anonymised and will not be attributable to any individual. We will send you a summary of the findings if you would like one.

7 Who is organising and funding the research?

The research study is organised and funded by the National Institute for Health Research (NIHR) Collaborations for Leadership in Applied Health Research and Care (CLAHRC) based at the University of Southampton, which is funded by the government.

The lead researcher is Dr Helen Roberts, associate professor in Geriatric Medicine at University Hospital Southampton. The study is being managed by Dr Charlotte Owen, a clinical research fellow in Geriatric Medicine, and supported by Dr Emma Stack and Dr Laura Dennison, researchers at the University of Southampton.

8 Who has reviewed the study?

The study has been approved through the Faculty of Medicine Ethics Committee at The University of Southampton; ERGO reference 25988

9 What if there is a problem?

If there is a problem or you have any concerns, you can contact the researchers on the details provided in section 10 of this information sheet.

If you remained unhappy, you could contact the research governance office at the University of Southampton on:

Tel: 02380 598566

Email: Rgoinfo@soton.ac.uk

10 Contact details of the researchers for further information

If you have any questions about the study please contact the researchers, using the contact details provided below.

Dr Charlotte Owen

University Hospital Southampton

Academic Geriatric Medicine

Room CE114B

Tremona Road

Southampton, SO16 6YD

Tel: 07824 895791

Email: c.l.owen@soton.ac.uk

The research administrator, Angela Dumbleton, can be contacted on:

Tel: 02381 206128

Alternatively, the lead researcher, Dr Helen Roberts, can be contacted at the address above, or on Tel: 023 81204354

11 What do I do now?

If you would like to take part, please contact Dr Charlotte Owen, using the details above.

At your convenience, we will then arrange a time to visit you and to ask some questions about falling and Parkinson's disease. This may be either alone, as an interview, or with a few of your colleagues, as a small group discussion. If you choose to take part we can provide a certificate of participation to thank you for your involvement in the study.

**Thank you for taking time to read this information sheet and considering
taking part in this study**

D.2 Phase Two: Consent Form for Healthcare Professionals**STEADY TOGETHER****Informed Consent form for healthcare professionals**

ERGO reference number: 25988

Chief Investigator: Dr Helen Roberts

Principal Investigator: Dr Charlotte Owen

Thank you for reading the information about our research project. If you would like to take part, please read and sign this form.

PLEASE INITIAL THE BOXES IF YOU AGREE WITH EACH SECTION:

1.	I have read the information sheet version 2 dated 22.05.17 for the above study and have been given a copy to keep. I have been able to ask questions about the study and I understand why the research is being done. I have been informed about any risks or inconveniences involved and the conditions under which the study is to be conducted.	<input type="checkbox"/>
2.	I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason. And if I withdraw from the research study for any reason, data collected up to my withdrawal will be used.	<input type="checkbox"/>
3.	I understand that my participation in this study involves taking part in an interview or focus group which will be audio-recorded. I give my permission to the researcher to conduct the interview and audio-record it with a digital voice recorder.	<input type="checkbox"/>
4.	I understand that the audio-recordings will be transcribed into a word document, and that the original audio-recordings will be destroyed once they have been transcribed. I understand that my confidentiality as a participant in this study will remain secure and that the transcript of the interview will not contain my name or identifiable information. I agree for my data to be stored anonymously and that any published quotations or extracts from the research will maintain my confidentiality.	<input type="checkbox"/>

D.3 Phase Two: Interview Schedule for HCPs

STEADY TOGETHER

Schedule for Semi-structured interviews with HCPs

Introduction

Thank you very much for taking part in this study. My name is Charlotte Owen and I am an academic clinical fellow in medicine for older people at the University of Southampton. I work with Dr Helen Roberts, an associate professor and consultant in Geriatric Medicine at University Hospital Southampton; and Dr's Emma Stack and Laura Dennison, who are researchers at the University of Southampton.

The purpose of this study is to design and introduce a guide to help people with Parkinson's who fall, and the people who help to care for them at home. We want to find out the views and experiences of falling in people with Parkinson's. We also want to know how falling affects those who live with them.

The interview is informal and completely confidential. Only my colleagues and I will listen to anything that is said, and your name will not appear in anything that we write.

With your permission I would like to record this interview with an audio recorder. This is so that I can concentrate on what you are telling me rather than writing notes. After this interview, I will transfer the information on the tape onto a password protected computer, which will be kept in a secure office in our research department. Anything that you say will be anonymised.

I would like to start by asking you a bit about your job and your role in relation to the management of falls in PwP

1. Can you start by telling me about your job title, qualifications and experience?

	Prompts
	Duration in looking after PwP

2. Can you tell me about how and when you become involved in the care of people with Parkinson's who fall?

3. Can you explain your role in relation to the management of falls in PwP?

Probes	Prompts
<p>Can you tell me about how you feel your role meets the needs of PwP who fall and their caregivers?</p> <p>Can you tell me about what happens after you have reviewed a patient?</p> <p>Can you tell me about whether you signpost or refer patients to other professionals?</p>	<p>Do you consider managing the risk of falling as part of your role?</p> <p>Do you consider managing the concerns of falling as part of your role?</p> <p>Do you consider the provision of education about falling as part of your role?</p>

4. Can you tell me about anywhere that PwP and their caregivers might find information about falling?

Probes	Prompts
<p>How do PwP find these?</p> <p>Can you tell me about any feedback you have received from PwP about these?</p> <p>How do you feel these resources meet the needs of PwP and their caregivers?</p>	<p>Are you aware of the P(UK) leaflet about falling? From your experience, how do PwP find this?</p> <p>P(UK) website</p>

I would now like to ask you about your experience of the problems encountered amongst PwP who fall and their caregivers

5. From your experience, what are the most frequently encountered problems amongst PwP who fall?

Probes	Prompts
<p>Can you tell me about any issues that cause the most concern?</p>	<p>How well do you feel that these problems are currently addressed?</p> <p>Are you aware of any coping strategies that PwP and their caregivers have adopted to help to manage these problems?</p>

6. From your experience, how do these problems and experiences differ between those with and without cognitive impairment?

7. From your experience, what are the most frequently encountered problems amongst the caregivers of PwP who fall?

Probes	Prompts
Can you tell me about any issues that cause the most concern in the caregivers of PwP who fall?	How well do you feel that these problems currently addressed? Are you aware of any coping strategies that their caregivers have adopted to help to manage these problems? Can you tell me about their experience of getting PwP off the floor ?

Using the information collected PwP, their caregivers, and healthcare professionals like yourself, we are going to design a guide aiming to help PwP and their caregivers to self-manage falling.

- 8. Can you explain what information you think that patients might need to manage**
- a) Their risk of falling?
 - b) Their risk of injury?
 - c) How to cope after a fall?

Probes	Prompts
	How about information about how to get up of the floor? How about signposting ?

- 9. Can you tell me about any information that might enable PwP to manage their concerns of falling?**

- 10. Can you explain what information you feel that caregivers need in relation to falling in PD?**

Probes	Prompts
	Can you tell me about whether you feel that they need more information about how to get the PwP off the floor after a fall?

- 11. Can you tell me about what you think should be included in our guide?**

12. Can you explain what format you think would be most useful to present this information in?

Probes	Prompts
Can you explain how you think this information should be provided	
Can you explain what you think our guide should look like?	

13. Can you tell me about anything you feel would help us to design this guide but that we have not spoken about?

Thank you for taking part in this interview as part of our research study

D.4 Phase Two: Interview Schedule for Dyads of HCPs

STEADY TOGETHER

Provisional Outline for dyad interviews with Healthcare Professionals

Introduction

Thank you very much for taking part in this study. My name is Charlotte Owen and I am an academic clinical fellow in medicine for older people at the University of Southampton. I work with Dr Helen Roberts, an associate professor and consultant in Geriatric Medicine at University Hospital Southampton; and Dr's Emma Stack and Laura Dennison, who are researchers at the University of Southampton.

The purpose of this study is to design and introduce a guide to help people with Parkinson's who fall, and the people who help to care for them at home. We want to find out the views and experiences of falling in people with Parkinson's. We also want to know how falling affects those who live with them.

This is a discussion to explore the experiences amongst healthcare professionals in relation to this topic. There are no right or wrong answers, it is OK to disagree and I would like to ask you to respect each other's positions. As it is a discussion, I would like to ensure that you are both able to join in and to express your views.

This discussion is completely confidential. Only my colleagues and I will listen to anything that is said, and your name will not appear in anything that we write. To ensure confidentiality and anonymity I am going to ask you, that after we have finished for you to not to talk about what we have spoken about today.

With your permission I would like to record this interview with an audio recorder. This is so that I can concentrate on what you are telling me rather than writing notes. After this interview, I will transfer the information on the tape onto a password protected computer, which will be kept in a secure office in our research department. Anything that you say will be anonymised.

1. Can you both start by telling me about your job title, qualifications and experience?

	Prompts
	Duration in looking after PwP

2. Can you tell me about how and when you become involved in the care of people with Parkinson's who fall?
3. Can you explain your role in relation to the management of falls in PwP?

Probes	Prompts
<p>Can you tell me about how you feel your role meets the needs of PwP who fall and their caregivers?</p> <p>Can you tell me about what happens after you have reviewed a patient?</p> <p>Can you tell me about whether you signpost or refer patients to other professionals?</p>	<p>Do you consider managing the risk of falling as part of your role?</p> <p>Do you consider managing the concerns of falling as part of your role?</p> <p>Do you consider the provision of education about falling as part of your role?</p>

4. Can you tell me about anywhere that PwP and their caregivers might find information about falling?

Probes	Prompts
<p>How do PwP find these?</p> <p>Can you tell me about any feedback you have received from PwP about these?</p> <p>How do you feel these resources meet the needs of PwP and their caregivers?</p>	<p>Are you aware of the P(UK) leaflet about falling? From your experience, how do PwP find this?</p> <p>P(UK) website</p>

I would now like to ask you about your experience of the problems encountered amongst PwP who fall and their caregivers

5. From your experience, what are the most frequently encountered problems amongst PwP who fall?

Probes	Prompts
<p>Can you tell me about any issues that cause the most concern?</p>	<p>How well do you feel that these problems are currently addressed?</p> <p>Are you aware of any coping strategies that PwP and their caregivers have adopted to help to manage these problems?</p>

6. From your experience, how do these problems and experiences differ between those with and without cognitive impairment?

7. From your experience, what are the most frequently encountered problems amongst the caregivers of PwP who fall?

Probes	Prompts
Can you tell me about any issues that cause the most concern in the caregivers of PwP who fall?	How well do you feel that these problems currently addressed? Are you aware of any coping strategies that their caregivers have adopted to help to manage these problems? Can you tell me about their experience of getting PwP off the floor ?

Using the information collected PwP, their caregivers, and healthcare professionals like yourself, we are going to design a guide aiming to help PwP and their caregivers to self-manage falling.

8. Can you explain what information you think that patients might need to manage
- d) Their risk of falling?
 - e) Their risk of injury?
 - f) How to cope after a fall?

Probes	Prompts
	How about information about how to get up of the floor? How about signposting ?

9. Can you tell me about any information that might enable PwP to manage their concerns of falling?

10. Can you explain what information you feel that caregivers need in relation to falling in PD?

Probes	Prompts
	Can you tell me about whether you feel that they need more information about how to get the PwP off the floor after a fall?

11. Can you tell me about what you think should be included in our guide?

12. Can you explain what format you think would be most useful to present this information in?

Probes	Prompts
Can you explain how you think this information should be provided	
Can you explain what you think our guide should look like?	

13. Can you tell me about anything you feel would help us to design this guide but that we have not spoken about?

Thank you for taking part in this interview as part of our research study

D.5 Coding Manual for Data from Semi-structured Interviews with HCPs

Theme	Subtheme	Contributing information	Data presented elsewhere
Theme 1: Causes of falls and their consequences on PwP and their caregivers	Multitude of reasons for falling in PwP	PD specific and non-PD specific causes of falling	
		Effect of Cognitive impairment and dementia on falls risk.	Effect of Cognitive impairment and dementia as a barrier to the implementation of management strategies is discussed within theme 4
		Interaction of PwP with the environment leading to heightened risk	
		PwP and caregivers are not always aware of the multiple causes for falling.	PwP and caregivers are not always aware of the preventable nature of falling' is discussed within theme 5- barriers to accessing HCPs support
	Consequences of falling on PwP and their caregivers	Psychological responses of PwP who fall including shock and fear of falling.	
		Caregiver role in the management of falling	
		Adaptation of caregivers to their new role, and the significant support that they provide to PwP	
		Difficulties that caregivers experience including: <ul style="list-style-type: none"> - Caregivers often struggle getting the PwP off the floor leading to adverse consequences. - Physical and psychological difficulties experienced by caregivers arising from their role in managing falls. - Caregivers may not want to leave the PwP alone, leading to adaptation of caregiver activity and social isolation. - Caregivers are worried about the risk of the PwP falling. This leads to restriction of physical activities of PwP. - Effects of cognitive impairment and dementia on the ability of caregivers to provide support for the PwP. 	How HCPs manage caregiver needs is discussed within theme 3

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Theme	Subtheme	Contributing information	Data presented elsewhere
Theme 2: Healthcare provision	Roles of HCPs and MDT working	How and when falling is monitored and assessed	
		Identification of the needs of PwP and their caregivers	
		MDT working to meet the needs of PwP who fall.	
		Benefits of involving different HCPs from the MDT in the care of PwP	
	Provision of education	Education within the HCPs role	
		Formal education programmes and education during routine clinical care.	
		Educating PwP to self-recognise their symptoms and to problem-solve, leading to a shift of responsibility to the condition to the PwP	
	Signposting to 3 rd sector organisations	3 rd sector signposting: where PwP and their caregivers are signposted to, and what HCPs aim to achieve through these referrals	
Benefits of the Parkinson's UK support group		Social support provided by the Parkinson's UK support group is discussed within theme 5	

Theme	Subtheme	Contributing information	Data presented elsewhere
Theme 3: Personalised Healthcare	Adapting to the heterogeneity of PD	- Comprehensive assessment of PwP by HCPs to identify relevant contributors to falling in each individual.	
		Individualised assessment and management plan instigated by HCPs to include: <ul style="list-style-type: none"> - Adaptation of advice to the day to day variability of PD - Adaptation of assessment based upon the duration that a PwP has been diagnosed. - Adaptation of assessment and advice in the setting of cognitive impairment and dementia 	
	Adapting to personal characteristics	Adaptation to non-PD related variables.	
		Assessment of a PwP within their home environment to identify pertinent individual risk factors	
		Adapting advice dependant on whether the PwP is cautious or a 'risk taker'.	
		Adapting advice so that it is relevant to the individual, and maintenance of patient autonomy.	
		How caregiver needs are identified and managed.	

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Theme	Subtheme	Contributing information	Data presented elsewhere
Theme 4: Limitations of healthcare in meeting patient needs	Barriers to the implementation of management strategies	Some management strategies may be less feasible or acceptable to some PwP/ caregivers: includes views surrounding the acceptability of walking aids and equipment within the home environment.	Data relating to difficulties when respecting personal autonomy and how patient wishes may differ from HCPs views are presented within theme 3 subtheme 'adapting to personal characteristics'
		How the presence of cognitive impairment and dementia effects the implementation of management strategies	
		Some PwP may have difficulties translating HCPs advice into practice.	Data relating to how barriers to management strategies are overcome is presented within theme 4, subtheme: approaches to overcome barriers to the implementation of management strategies
		Barriers to PwP staying physically active.	
		Plethora of information delivered by HCPs can lead to 'Information Overload' in some PwP.	
		Some PwP and caregivers may not engage with the written literature that they have been provided with.	Data relating to problems accessing information, rather than how information is put into practice, or whether it is read, is discussed in theme 5. Data relating to concerns about the future presented within theme 5 subtheme: barriers to accessing healthcare and information about falling
	Approaches to overcome barriers to the implementation of management strategies	Strategies to overcome barriers to implementing management strategies advised by HCPs.	
		Strategies to overcome barriers to engagement with literature that PwP and caregivers are provided with.	

Theme	Subtheme	Contributing information	Data presented elsewhere
Theme 4: <i>(continued from previous page)</i> Limitations of healthcare in meeting patient needs	Healthcare provision often leaves many needs unmet	Adequacy of current healthcare provision.	
		Long waiting times to access physiotherapy, and ways in which HCPs attempt to fill this void	
		Availability of healthcare including waiting times and variations according to patient age or geographical location.	
		Views surrounding the current provision of physiotherapy.	
		Outcomes following signposting- including whether HCPs sought feedback from PwP/ caregivers	
Theme 5: Engagement versus Disengagement of service users with healthcare	Degree of self-management practices	Self-seeking information practices in PwP and their caregivers.	
		Social support, its benefits, and where it is sought from.	
	Barriers to accessing healthcare and information about falling	Delays in accessing healthcare and its adverse consequences for PwP and their caregivers.	Data surrounding whether participants engage with information that they have been provided with by HCPs is presented within theme 4, subtheme: barriers to implementation of management strategies
		PwP may view falling as unpreventable	
		Barriers to calling for paramedic support	
		Barriers to seeking support from services other than the paramedic service	
		Barriers to accessing the Parkinson's UK website	
		Concerns surrounding the progression of PD and how this acts as a barrier to seeking support	

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Theme	Subtheme	Contributing information	Data presented elsewhere
Theme 6: Views surrounding the Content and Format of Future Interventions	N/A	Causes of falling- PD and non-PD specific.	
		Information should be succinct and to the point	
		Information for caregivers should be included within the intervention.	
		The intervention should aim to improve communication between HCPs and PwP and their caregivers.	
		Conflicting views about the content of the intervention and who it should be targeted towards.	
		Individualisation of information and the importance of PwP and their caregivers being able to relate to the content of the intervention	
		Views surrounding how the information should be presented: paper versus online platforms.	
		Views surrounding how the information is presented- clear presentation to increase engagement and the use of pictures.	

Key: PwP= People with Parkinson’s, HCPs= healthcare professionals. MDT= multidisciplinary team. N/A= Not applicable

Appendix E Phase Three Appendices

E.1 Phase Three: Intervention Design Objectives and the Information feeding into these

E.1.1 Intervention Design Objective One: The intervention should provide information about falling, challenge common misperceptions and suggest strategies for the successful self-management of falls

Feeding information into the design objective	Source of Information
For a self-management training programme to be effective, is imperative that PwP and their caregivers are provided with the appropriate knowledge and skills to allow for them to make informed decisions about their care to facilitate a 'Collaborative management approach'.	(40)
For a self-management programme to be effective it must address the beliefs and concerns of the individual and provide vital knowledge about their illness and its available treatment.	(72,82–84)
PwP and caregivers report a paucity of information about falling and may feel unprepared when the PwP starts to fall.	Phase One Phase Two (199)
Some researchers have defined health literacy as an 'asset', which can be developed through education and communication. High health literacy is associated with improved health outcomes.	(87,91,92)
People with LTC have consistently reported that they want to be provided with access to information about their condition, be involved in decision-making processes and to be supported in their confidence to manage their conditions themselves.	(81)
Corbin and Strauss framework dictates that for effective self-management individuals need access to the appropriate information.	(79)
For a self-management programme to be effective it must address the beliefs and concerns of the individual and provide vital knowledge about their illness and its available treatment	(72,82–84).
PwP can fall for a multitude of reasons. Commonly identified difficulties that can lead to unsteadiness or falling include freezing, postural hypotension, multitasking, turning, perceptions of tripping, rushing, small spaces and doorways.	Phase one, phase two (26).
PwP and their caregivers report a variety of different experiences and needs in relation to falling. This can be related to the duration that an individual has been diagnosed with PD.	Phase One, Phase Two
If information is deemed not relevant, it may be left unread. To enhance engagement with the intervention, information must be deemed relevant to each of the participants.	Phase Two
Self-management programmes targeted toward a specific behaviour, as opposed to generalised advice and support, are more likely to lead to success.	(98).
Effectiveness of strategies for the management of falls often change over time.	Phase one
It is important that the experience and knowledge of the participants is acknowledged. Some PwP may collect information. The health literacy of some people may be greater than that of others. This has previously been ignored by HCP.	Phase One, (85)
When an individual perceives that a change is autonomous, it is more likely to be maintained. Competence is satisfied when an individual has confidence in their actions and can control the outcome (self-determination theory).	(93,95)
Self-management interventions seek to address the commonly held concerns that users have to re-frame misperceptions and promote adherence.	(218)
PwP commonly experience fear of falling, which can lead to exacerbation of falls risk and avoidance of particular activities	Phase one, phase two

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Feeding information into the design objective	Source of Information
Most participants, including all therapists, discussed how PwP could feel that falling was unpreventable. These participants felt that those holding this view would be less likely to inform or seek advice from HCP about falling	phase two
Some people may attribute falls to 'tripping', where they might be a preventable cause	Phase One
PwP and their caregivers may normalise falling over time, leading to acceptance.	Phase one
A few participants felt that falling was unpreventable, which may be a barrier to informing HCP. This could be greater amongst those who had been diagnosed for some time	Phase One
Self-efficacy can be improved through 'Re-interpretation of symptoms' to provide an alternative cause. This can allow exploration of different behaviours to self-manage symptoms	(79)
Falling often leads to fear of falling and a decline in confidence and mobility	phase one, phase two, (24,26,31,42)
Some caregivers may try to get the PwP to avoid particular activities to manage caregivers concerns with negative consequences for the PwP and the caregivers	phases one and two)
Decline in physical activity has been associated with increased fear of falling and a decline in muscle mass.	(24,31,198).
The use of distancing strategies is associated with reduced emotional well-being, social functioning and QOL	(16,18,197).
Therapists in phase two had conflicting views as to whether the guide should contain exercises. Some therapists were concerned of the efficacy of generic physiotherapy exercises.	phase two
To remain active, PwP have been able to successfully adapt current activities, or change to those that they feel more confident in performing	Phase One
Reduced engagement of PwP with physical and social activities can lead to feelings of isolation in the PwP and the caregiver	phase one
Environmental contributions to falling may be deemed non-modifiable and may lead to avoidance of particular environments or settings.	phase one, (20,194)
Some PwP can adapt how they perform an activity, or switch to an alternative activity, to modify their falls risk.	Phase One
An individual's home environment may pose additional risks of falling, which can be adapted through modification.	Phase two
Some PwP may be unaware of some non-PD specific risks of falling, such as vision and footwear.	Phase Two
PwP may not be able to access healthcare resources, in particular physiotherapy, in a timely fashion. This may result in PwP and their caregivers not receiving information at the appropriate time, with adverse consequences for the PwP and the caregiver.	Phase One Phase Two
PDNS have previously provided cueing strategies to overcome freezing whilst PwP are awaiting review by a physiotherapist.	Phase two
The inclusion of general physiotherapy exercises within the guide may be unhelpful, as they may not help the particular individual	Phase Two
Barriers identified in relation to caregivers calling 999- included views that it would automatically result in admission to hospital, that the management of falling was not within remit of paramedic service, and the PwP being embarrassed that a fall had occurred.	Phase one, phase two
Some caregivers spoke of keeping calm when trying to help the PwP off the floor and thinking through their actions step by step was helpful. Caregivers reported how physiotherapy classes had helped the PwP to get off the floor.	Phase One
Caregivers play a key role in helping the PwP after a fall, providing verbal and/or physical support.	Phase One
Caregivers may be reluctant to ask for support in helping the PwP up from the floor, they often struggle and can experience injury.	(42,43) Phase One Phase two

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Feeding information into the design objective	Source of Information
Not seeking support after a fall can result in a delay in treatment for the PwP	Phase two
PwP may not inform HCP that a fall has occurred.	Phase One (28)
PwP may not know where they can seek support from in the management of falling. Few HCP reported that PwP had proactively sought information about falling.	Phase Two
PwP and caregivers may be unaware of the role that HCP might play in the management of falls. They may struggle, and not ask for support, and feel lost within the healthcare system. Our qualitative data found PwP and caregivers could instigate large changes without appropriate HCP support.	Phase one
PwP therapy needs often change over time, and they may benefit from later repeat review	Phase Two
P (UK) audit report in 2015 found that 31% of PwP reported requiring, but not receiving, physiotherapy support. Encouraging users to ask for a referral to PT may help to improve this.	(200).
Corbin and Strauss framework states that for individuals to effectively self-manage they need knowledge of what resources provide rather than simply informing them of their presence	(79)
When HCP refer PwP to other HCP they may be unsure of the outcome. Whilst HCP may take the view that 'no news is good news', qualitative data from PwP may suggest that this is not the case	Phase One Phase Two
Qualitative data from Caregivers found that their needs in relation to the management of falling were often left unmet. Qualitative data from HCP identified that HCP often identified these issues thought a reactive rather than a proactive approach. Through enhanced communication between HCP and PwP this may lead to improved CG experiences.	Phase One Phase Two
Some researchers have defined health literacy as an 'asset', which can be developed through education and communication.	(87).
'Living well with Parkinson's' was a self-management programme for PD developed in Christchurch, New Zealand. Providing information of the different services and resources available led to some participants feeling more empowered to cope with PD.	(121).
Caregivers may have a stoical nature and feel that they should manage in situations where help might be available	phase two
The Corbin and Strauss framework states that for effective self-management an individual requires knowledge of the resources that are available, how they can help and how to access them.	(Iorig and Holman).
A pilot study of an information pack for community dwelling PwP and their caregivers, that included signposting to health and social care services, found that the majority of participants found signposting useful.	(119).
Healthcare professionals often signpost PwP and their Caregivers to further sources of support	Phase Two
Need to cover lots of information as to the different causes of falling but keep the guide short as per phase one and to avoid information overload.	Phase one (90)
When too much information is presented it can lead to 'Information overload'. This can result in dis-engagement, anxiety or a feeling of being overwhelmed	(90).
PwP and their Caregivers may be unsure of where they can seek support from	Phase One Phase Two
PwP may find it difficult to interact with those who are less informed about PD	Phase One
Parkinson's UK groups can provide social support for PwP.	Phase one, (15,196)
All HCP in phase two described signposting to 3 rd sector organisations, with the most common being Parkinson's UK. Parkinson's UK support groups can provide social support and subsidised services not available within the remit of the NHS.	Phase 2
Group support has been found to be beneficial in reviews of self-management programmes for other long-term conditions	(98)

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Feeding information into the design objective	Source of Information
Group discussion may lead to improvements in HRQOL.	(139).
Hertfordshire Neurological Services have provided condition specific self-management group programmes, including a group for PwP, since 2002. Participants in the programme enjoyed mutual support in a group comprised of people who were in a similar situation; the most helpful component of the course was listening to the experiences of others.	(117)
Self-efficacy to manage a particular circumstance can be improved through 'Social persuasion'. This can be through encouragement from family, friends and peers to strengthen views that an individual can succeed.	(79)

PwP: People with Parkinson's, CG: Caregivers, HCPs: Healthcare professionals, PD: Parkinson's disease

E.1.2 Intervention Design Objective Two: The intervention should recognise the key role that caregivers play in the management of falls

Feeding information into the design objective	Source
Satisfaction of the three basic psychological needs is associated with improved mental health. One of these is 'relatedness', which is achieved through interaction with, or caring for, others.	(96)
A previous PD education programme for formal caregivers of PwP, led to improvements in both health related QOL and scores on the geriatric depression scale in the PwP.	(55)
Drawing from self-efficacy theory, increasing the falls related self-efficacy of the caregivers may allow for caregivers to feel better equipped to manage falling and lead to improvements in caregiver burden.	(79)
Caregivers of people with Alzheimer's Dementia were positive about the ability of an educational intervention to increase their knowledge, found signposting useful and found that they were more able to seek support from family members	(103)
Falling is associated with high caregiver burden	Phase One, (52)
PwP may not recognise the changes that caregivers have made or the challenges placed upon them	Phase One
Caregivers do not feel integrated in the decision-making process	(43)
If information is deemed not relevant it may be left unread	Phase Two
Caregivers needs are often not addressed or are left unmet	Phase one, (200)
Caregivers may not read the P (UK) leaflet on falling as they feel that it is not directed toward them.	Phase One
Caregivers may be concerned about leaving the PwP alone or of the PwP mobilising due to falls risk, leading to adverse consequences for the PwP and the caregivers	Phase One, Phase Two (24,31,198)
Joint spousal recreational activities linked with reduced avoidance coping strategies and reduced depressive mood in PwP.	(189)
Distancing as a coping strategy may be associated with reduced well-being, social functioning and QOL	(16,18,197)
Self- efficacy to manage a particular circumstance can be improved through 'Social persuasion'. This can be through encouragement from family, friends and peers to strengthen views that an individual can succeed.	(79)
Qualitative data from PwP, caregivers and HCP raised the benefits of social support in helping PwP and their caregivers, which included sharing their experiences of falling.	Phase One, Phase Two

Key: PwP: People with Parkinson's, CG: Caregivers, HCPs: Healthcare professionals, PD: Parkinson's disease

E.1.3 Intervention Design Objective Three: The intervention should be presented in a clear and acceptable format using appropriate language that encourages user autonomy

Feeding information into the design objective	Source
People with LTC have consistently reported that they want to be provided with access to information about their condition, be involved in decision-making processes and to be supported in their confidence to manage their conditions themselves	(81)
Therapists encourage PwP to take control of their diagnosis through teaching them strategies to overcome difficulties that they might encounter in relation to the management of falls.	Phase Two
Improved health outcomes have been found in those who have both high health literacy, and who are also empowered.	(92)
Individuals with high health literacy and low levels of empowerment may be dependent upon healthcare professionals and have low levels of satisfaction.	(91).
The NICE guidelines for the management of PD state that communication with PwP should aim to empower them to participate in decisions about their care	(38)
Patient-centred care is associated with improved treatment compliance, clinical outcomes and reduced cost. To participate in shared decision making PwP need to feel able to influence the decision-making process	(82,206)
Self-efficacy theory states that through improving caregivers / PwP self-perceived thought of how to manage falling, it may improve their ability to do so	(79)
Satisfaction of the basic needs of autonomy, competence and relatedness associated with improved mental health.	(96)
Most self-management programmes are based upon self-efficacy theory	(79)
PwP and caregivers may want different types and amounts of information in relation to the management of falling and PD.	Phase One (43)
People with LTC have consistently reported that they want to be provided with access to information about their condition, be involved in decision-making processes and to be supported in their confidence to manage their conditions themselves.	(81)
SDT predicts that for a particular behaviour to be initiated and maintained, an individual must satisfy their three basic needs and possess intrinsic motivation to change. A systematic review and meta-analysis of health behavioural interventions found support or respect for autonomy, and identification of intrinsic motivators to change, were associated with improved mental and physical health.	(93,95,97)
Increasing the involvement that PwP have in decisions made about their care has led to improvements in overall patient satisfaction	(114)
PwP, caregivers and HCP reported the heterogeneous nature of falling but were keen that the guide remained 'short and sweet'.	Phase one and two.
When too much information is presented, or when it is irrelevant or poorly presented, it can lead to 'Information overload'. This can result in dis-engagement, anxiety or a feeling of being overwhelmed	(90)
PwP and caregivers may report different information requirements in relation to the type and quantity of information that they want to receive.	(43)
Where the target population has varied needs, tailoring the educational intervention to each individual, thereby increasing the amount of knowledge of direct relevance to them,	(149).

Feeding information into the design objective	Source
produces a stronger message and has been shown to be associated with increased chance of long-term behavioural change	
Information provided to people with long term conditions should be individualised to the condition and to the patient. Where information is deemed relevant, users are more likely to be empowered to implement it.	(120)
Most healthcare professions discussed how they tailor their advice to the individual PwP to make it more relevant to them, and therefore more likely to be implemented	Phase two
PwP, caregivers and healthcare professionals discussed how the guide should not contain medical jargon	Phase one, Phase two
Participants may have difficulty accepting their identity as a faller. Through this non-identification, it could place PwP at heightened risk, and may lead to them not informing HCP of falls, or may result in them not adapting their behaviour to manage their falls risk.	Phase one, (27,207,221)
Behavioural change is more likely to be initiated and adopted if it is associated with personally valued outcomes (self-determination theory)	(93)
PwP and their caregivers often tried to attribute a cause for a fall, and could encounter uncertainty, leading to frustration.	Phase One
Amongst PwP and caregivers there was a sense that they should 'manage' falling, which could cause be associated with negative physical outcomes for the PwP and the caregivers. Amongst some participants there was a sense that they wanted greater control over the situation	Phase One
PwP and caregivers could report a decline in physical activity and feelings of social isolation in response to falling, with negative connotations on the relationship between the caregivers and the PwP as a result of the shift in roles arising from falling.	Phase One
Where discussed, PwP, caregivers and HCPs felt that a computerised guide would be non-interactive and would be downloadable.	Phase One Phase Two
Paper based guide would be the most acceptable format. Online interventions may not be accessed by some PwP, which could be related to increased age.	Phase One Phase Two
A study of 'information prescriptions' found PwP most commonly requested information presented in a colour, paper-based format	(120)
In a study of a web-based strength and balance training programme conducted in 2007, where the median age of participants was 77, over a third of participants 'dropped out'. This may suggest that the internet was not an acceptable platform for information delivery for this group	(250).
A meta-analysis of online interventions found that regular computer and internet use amongst the older population remains low when compared to the general population.	(213)
In 2015 32% of those over 65 had never used a computer and only 49% of households with one adult over 65 had internet access	(212)
Older PwP (≥ 75 years) are less willing to use electronic methods of communication	(214)
The P (UK) falls leaflet was often not remembered, and information could often be 'stored away', and did not appear to have been utilised. This was also found in relation to 'information packs' distributed by healthcare professionals	Phase One Phase Two
A study of 'information prescriptions' for PwP found they most commonly wanted information presented in a colour, paper-based format	(120).
When too much information is presented, or when it is irrelevant or poorly presented, it can lead to 'information overload'. This can result in dis-engagement, anxiety or a feeling of being overwhelmed	(90).

Appendix E: Phase Three Appendices

Feeding information into the design objective	Source
Guide should contain colour and picture to guide the reader to relevant sections	Phase One Phase Two
The information should be presented in a clear font. The population may have visual difficulties.	Phase Two
Through completion of a falls diary this could facilitate improved history taking, leading to PwP receiving more appropriate treatment plans, and improved outcomes.	Phase Two
Some healthcare professionals discussed how bringing the guide to clinic could make it more likely to be used	Phase Two

Key: PwP: People with Parkinson's, CG: Caregivers, HCPs: Healthcare professionals, PD: Parkinson's disease

E.1.4 Intervention Design Objective Four: The intervention should motivate the adoption of self-management strategies through using appropriate theory

Feeding information into the design objective	Source
Adoption of emotional focused coping strategies has been linked to depressive mood in PwP, and perceived distress in both PwP and caregivers	(189,191)
The 'Matching hypothesis' proposes that problem-focused coping more likely to be adopted where a situation is deemed modifiable	(193)
In the systematic review of self-management interventions for PwP who fall, four studies measured HRQOL but only one intervention that contained a group discussion and education to problem-solve and develop action plans, led to an improvement	Systematic review, (139).
Greater self-efficacy of managing PD associated symptoms and increased frequency of symptom checking are both independent predictors for better self-management of PD amongst community dwelling PwP	(94)
Increased self-assessment in fallers associated with reduced uncertainty	(221)
Perceived uncertainty as to the cause of falling in caregivers and PwP can lead to caregiver distress	(191)
PwP and their caregivers often tried to attribute a cause for a fall, and could encounter uncertainty, leading to frustration	Phase one
Corbin and Strauss framework states that for effective self-management people must have the ability to problem-solve	(79)
Satisfaction of all three basic psychological needs is associated with improved mental health. Competence is satisfied when an individual has confidence in their actions and can control the outcome.	(96)
Satisfaction of the three basic psychological needs is associated with improved mental health. One of these is 'relatedness', which is achieved through interaction with or caring for others.	(93,95)
In phase one participants often spoke of their positive interactions with people in a similar situation to themselves at the P (UK) support group.	Phase One
A review of meta-analyses of educational programmes for chronic diseases reported that didactic approaches were inferior to those involving social learning and behavioural modification techniques	(72).
Following social learning theory, inclusion of experiences and behavioural modification techniques successfully utilised by other PwP and their caregivers provide a 'model' for observational learning	(222)
Self-efficacy can be improved through 'Modelling', which is achieved through the provision of ways in which the skill can be successfully performed. This may be achieved through shared experiences from peers.	(79)
The three basic needs are autonomy, competence and relatedness. Satisfaction of all three basic psychological needs is associated with improved mental health. When an individual perceives that a change is autonomous, rather than being imposed, it is more likely to be maintained. Competence is satisfied when an individual has confidence in their actions and can control the outcome	(96)
Self-efficacy can be improved through 'Performance mastery', which involves the production of an action plan to execute the targeted skill. Successful completion leads to enhanced self-belief.	(79)
Increasing the involvement that PwP have in decisions made about their care has led to improvements in overall patient satisfaction	(114)
Taking a collaborative approach with patients, which promotes active patient engagement, has been shown to be a cost-effective way of improving quality of care in older patients with chronic conditions	(82).
Previous studies where the intervention has been delivered through a short series of group sessions have shown the concept of 'decay', whereby initial benefits seen declined once the intervention had stopped.	(37,102).

Appendix E: Phase Three Appendices

Feeding information into the design objective	Source
In a qualitative analysis of the Expert Patient Programme, a group-based self-management intervention many participants were positive of the socially cohesive nature of the intervention, which led some participants to feel isolated at programme end.	(85).
An intervention that requires minimal researcher input is more likely to be cost-effective than formal education programmes due to reduced professional- patient contact time, and is also more likely to be replicable on a larger scale to be available to all PwP	(59,72,224).

Key: PwP: People with Parkinson's, HCPs: Healthcare professionals, PD: Parkinson's disease

E.1.5 Intervention Design Objective Five: Suggestions should be described clearly to increase their adoption amongst PwP and caregivers

Feeding information into the design objective	Source
Relaxation amongst caregivers has been linked to reduced caregiver stress	(196)
Caregivers highlighted how keeping calm and taking things step by step was beneficial, in particular when helping the PwP off the floor	Phase One
PwP may plan activities in association with medication timings.	Phase one (21)
PwP may experience intra-individual variation in their PD. They may feel more able to be active on some days more than others.	Phase One Phase Two
All participants in phase two highlighted barriers in relation to the transformation of information and advice into practice.	Phase Two
Some HCP, mainly therapists, discussed the importance of ensuring that the guide contained realistic suggestions, to make it more relatable, and that it was important that the guide acknowledged the limitations placed on an individual because of having PD.	Phase Two

Key: PwP: People with Parkinson's, CG: Caregivers, HCPs: Healthcare professionals, PD: Parkinson's disease

E.2 Phase Three: Prototype of the Paper-based Self-management Guide

UNIVERSITY OF
Southampton



**A guide to help people with Parkinson's who
feel unsteady and those who are close to
them**

Introduction

This guide has been designed to help people with Parkinson's who feel unsteady, as well as those who are close to them. This guide contains information about unsteadiness, falling, and techniques that are frequently recommended by healthcare professionals.

You may have only recently started to feel unsteady, which can make some people feel shocked or unprepared. Or, you may have felt this way for some time, and your life may have changed as a result. The nature of unsteadiness, and the aids and support needed to help you, can vary from person to person, from day to day, and may change over time.

This guide suggests different ways that may help and assist you.

How to use this guide

Parts of this guide will be more relevant to you than to others.

- Step 1: Read section 1.** This contains general information about falls and keeping active
- Step 2: Complete section 2.** This is a diary for you to complete whenever you feel unsteady or have a fall.
- Step 3: Read section 3.** After reading section one and completing section two, read the parts of section 3 that you think might help you.
- Step 4: Complete section 4.** This is your personal action plan. Complete it whenever you think of a way that you would like to address a particular concern that you might have. Once you have tried something, write down how it went.

Contents of the guide

Section 1	What causes falling and what can I do to help?	Page 4
Section 2	Unsteadiness and falls diary	Page 10
Section 3	Common concerns and suggestions	Page 11
Section 4	Personal action plan	Page 25
Section 5	Useful contacts	Page 26

Section 1

What causes falling in Parkinson's?

Parkinson's is characterised by slowness of movement, a feeling of stiffness, shaking and reduced balance. Parkinson's also causes reduced co-ordination of your movements. These symptoms make you more likely to fall.

The symptoms of Parkinson's often vary from person to person, from day to day, and change over time. Symptoms that can lead to increased unsteadiness or falling include:

- **Freezing.** This is where you feel that your feet are 'stuck' to the ground and will not move.
- **Feeling lightheaded when you stand up.**
- **Weakness of your muscles**

Is falling normal?

Falling is common amongst people with Parkinson's, but not all people with Parkinson's fall. You are more likely to fall if you:

- Have fallen before
- Have had Parkinson's for a longer period of time
- Are anxious or fearful of falling
- Have weak muscles
- Have memory problems

What can I do to help?

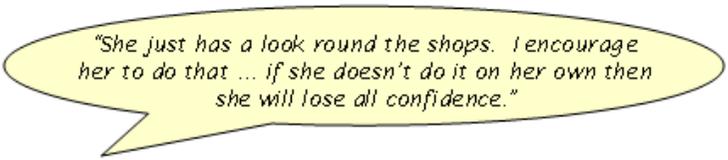
Whilst falling is common, **many falls can be prevented.** It is important to try to keep as active as possible.

The things that can help will depend upon the symptoms that you are experiencing.

- Read this section and complete the diary in **section 2**, then look at the parts of **section 3** that might help you.
- Complete your personal action plan in **section 4** whenever you identify something that might help you.
- Discuss your falls with your doctor and specialist Parkinson's nurse.

Why should I stay active?

For many people, Parkinson's and unsteadiness leads to a change in activities and hobbies. Inactivity can lead to muscle stiffness and weakness, which can increase your risk of falling. Being less active can cause some people to feel frustrated or lonely. Staying active can **help your mental and your physical health.**



"She just has a look round the shops. I encourage her to do that ... if she doesn't do it on her own then she will lose all confidence."

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"She just has a look round the shops. I encourage her to do that ... if she doesn't do it on her own then she will lose all confidence."

How can I stay active?

Things for you to think about and try:

If you can, try limiting the amount of time that you are sitting to half an hour. Sitting for long periods of time can cause you to feel stiff, or unsteady once you get going.

Ask your physiotherapist to recommend some exercises. Doing your exercises regularly can help you to feel less stiff and more steady. If you find walking difficult, seated exercises can be helpful too.

"We've been going to exercises cos they teach you to get up... they definitely help."

Try to continue to do activities where and when you can

Whilst it can be tempting to ask for others to do things for you because they are able to do them faster, this may make your muscles feel stiffer, or more unsteady when you move.

Try making small changes to allow for you to continue with your chosen activity.

- Take things at your own pace, don't feel under pressure to rush
- Finding a place to rest during the activity may allow you to carry on enjoying it.
- A physiotherapist might be able to recommend a mobility aid, which may help you feel more steady
- If you are finding it difficult to walk long distances, enquire about a Blue Badge with your local council, or apply online. You don't need to be able to drive to apply. If you experience difficulties speak with your Parkinson's UK advisor, who may be able to help you.

"We have to plan where there's no stiles, where there's a proper gravel path, like a biking track."

Try to think of activities that you can enjoy with your close/ friends and family.

Through spending time together, and speaking about how Parkinson's has affected you and those around you, it might help to manage any anxieties that you might have.

"I can spend more time with my wife... we go ballroom dancing... we won't let [Parkinson's] stop us doing stuff."

Look to your local Parkinson's (UK) group.

The monthly support groups will enable you to meet with other people like yourself. The group may organise local outings or Tai Chi, and are designed for people with Parkinson's.

"Parkinson's group; we usually try and learn from each other... because everybody's so different."

Discuss any concerns about your walking with your Doctor.

This could be your GP or your Parkinson's specialist doctor. They may be able to make changes to your medication or refer you to a physiotherapist, who could suggest some exercises to help you.

Any suggestions you might like to try? Write them in your action plan and have a go.

How can healthcare professionals help?

The symptoms of Parkinson's change over time. Although you may have had support for falling in the past, the support needed to help you may have now changed.

Healthcare professionals can suggest ways to reduce your risk of falling, and there is also help to support close friends/ relatives of those with Parkinson's.

Paramedics (999) are there to help you in medical emergencies, which includes helping you up from the floor. It is important that you are not lifted up by a close friend/ relative as this could injure both of you. When the paramedics arrive they will assess you and help you up. Calling 999 does not always result in being admitted to hospital.

"Just because someone comes out here to help him it isn't going to mean he has to go to hospital."

Parkinson's specialist doctors and your GP may be able to alter your medications, listen to your worries and anxieties, and can refer you to other professionals who could help you.

Parkinson's specialist nurses are very knowledgeable and can provide support, advice and referral to other professionals who could help.

Occupational therapists can help to support you to live independently through assessing your home and suggesting adjustments that might help you.

"Occupational Therapist is very helpful ... they've arranged to have rails put in and came to give advice when we had the extension built."

Physiotherapists can help in many ways. They can help you to remain active through providing

- Exercises to help with your mobility
- Advice on your posture and walking
- Techniques to overcome episodes of freezing
- Advice on how to get up from the floor
- Advice on mobility aids that might assist you.

"We went to the physiotherapist.... she just knew everything, it was just quite refreshing"

Social services can provide professional care to help you. This could be for a short period whilst your close/ friend or relative is out of the house, or for respite or more regular care. You can contact social services directly through your local council, you do not need a referral from a doctor.

Will the suggestions in this guide help?

All of the suggestions within this guide have been suggested for people who have had Parkinson's for some time. The symptoms of Parkinson's vary from person to person and change over time, meaning that some suggestions are likely to be more relevant to you than others.

- Write down the suggestions that you are going to try in your action plan in [section 4](#).
- If something doesn't work, think about modifying it, particularly if you are feeling tired or unwell, and then try it again.

The suggestions won't do you any harm, but may help for you to feel more in control of your Parkinson's and falling.

Section 2: Unsteadiness and falls diary

Complete this whenever you feel unsteady or fall. Use this log to identify areas in section 3 that might help you.

Try to fill this out whilst the episode is fresh in your mind.

Take this log to your meetings with your doctor/ nurse to help them to understand any problems you are experiencing.

What were you trying to do?	Why do you think you felt unsteady or fell?	What worried you?
<i>E.g. Carrying a cup of tea</i>	<i>Doing too many things at once</i>	<i>Difficulty getting up off the floor</i>

Section 3: Common Concerns and suggestions

Parts of this section are likely to be more relevant to you than others. This section has not been designed for you to read from start to finish.

Read this section after sections one and two. Use sections one and two to help you to identify which parts of this section might help.

Use sections 1, 2 and 3 to help you to write your personal action plan in section 4.

Concern	Page
What to do after a fall	12
Rushing and doing too many things at once	15
Feeling lightheaded	16
Turning, reaching and over balancing	17
Trips and slips	18
Freezing	20
Concerns of close friends and family	22
Falls away from your home	24

What to do after a fall

For the person who falls, falling can be associated with shock, stress and embarrassment. You may also be worried how to get up.

Close friends and relatives may also feel shocked and stressed.

Try not to rush any actions or decisions and to think logically through the options below.

Can you recall any advice from the physiotherapist about how to get up after a fall?

If no, try and get off the floor by following the following steps

1. Roll over onto your front
2. Push your upper body up to get onto your hands and knees
3. Crawl to a sturdy chair (or ask for somebody to bring one close to you)
4. Place your hands onto the seat of the chair
5. Push down with your arms and place one foot on the ground
6. Push down with your arms and place your other foot on the ground
7. Push down with your arms to stand up

Close friends/ relatives: if this does not work, do not lift your close friend/ relative off the floor. Although this might be tempting, you could injure yourself. Make your close friend/ relative comfortable and call 999. The paramedics are there to help you, and helping people in a position like this is part of their job. On arrival they will assess your close friend/ relative and help them up safely.

"The times I've managed to [get] him up, I've made him comfortable on the floor to start with, just until he's sort of got over the initial shock of falling."

Things for you to think about and try:

- **Talk through the fall with a close friend/ relative.** Think about what you were doing at the time of the fall, think about why you might have fallen. Write it in the diary in **section 2**.

"Going through the fall and actually saying, you know, well 'what do we think caused this one. Okay what could we do differently?'"

- **Look at the contents page of this section (section 3) and read information that you think might help you.** Then think about things that you might like to try, and write them in your action plan in section 4.
- **Inform your doctor or nurse that you have had a fall.** They may be able to suggest changes that can help you or refer you to others that can help. Physiotherapists can provide exercises to help you to remain active, and can advise how to get up should you fall again.
- **Consider a pendant alarm or carrying a mobile phone with you at all times.** This will allow you to alert others after a fall. Pendant alarms are worn around the neck or the wrist; when they are pressed a call goes through to another area of the house or to a central call centre. These measures may help the person who is unsteady to feel safe, and may provide your close friend/ relative with reassurance if they are not with you all the time. Pendant alarms are available from many organisations, including Age UK, or ask your GP or specialist nurse.
- **Consider a key safe outside your front door.** If you fall when you are alone and press your pendant alarm, or call 999, this will allow somebody to get to you easily.

Any suggestions you might like to try? Write them in your action plan and have a go.

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- **Consider a key safe outside your front door.** If you fall when you are alone and press your pendant alarm, or call 999, this will allow somebody to get to you easily.

Any suggestions you might like to try? Write them in your action plan and have a go.

Rushing and doing too many things at once

People with Parkinson's often feel unsteady when trying to do more than one thing at once. Through taking your time and concentrating on your movements, this may help for you to feel more steady.

Things for you to think about and try

- **Take your time, try not to rush**

"I try and consciously not rush, and think....if it is the telephone, if it's something important they'll phone me back."

- **Concentrate on what you are doing.** Some people with Parkinson's can feel unsteady when doing more than one thing at once.

Some people find it helpful to stop walking before starting a conversation with somebody.

Some people with Parkinson's find that carrying objects affects their balance. Think about asking somebody else to help you.

"I always carry the drinks up to bed ... there's lots of things that we do now that we wouldn't have thought too much about before."

- **Try planning each journey** that you take, and taking note of your surroundings. Some people find it helpful to plan a route that has places for them to rest.

Any suggestions you might like to try? Write them in your action plan and have a go.

Feeling lightheaded

Parkinson's medication for high blood pressure can cause you to feel lightheaded when you stand up. This is caused by a drop in your blood pressure, called postural hypotension.

This can be particularly noticeable if you have been lying or sitting for some time.

Things for you to think about and try

- **Drink plenty of water.** This is particularly important during spells of hot weather.
- **Try to keep active.** Your symptoms are likely to be worse after long periods of sitting or lying down
- **Try marching on the spot whilst sitting.** If you have been sitting or lying down for some time this may help
- **Take your time when standing up.** If you find that you are lightheaded, wait for your symptoms to pass before you start moving.
- **Discuss your symptoms with your doctor.** They can check your blood pressure and may be able to make changes to your medications to help your symptoms.

"Drink lots of water so you're light-headed....I find if I stand up too quickly I feel really light-headed."

Any suggestions to try? Write them in your action plan and have a go.

Appendix E: Phase three appendices

Falls away from your home

Falling outside of your home can cause some people to feel particularly anxious and vulnerable. This can lead to people with Parkinson's to avoid going outside. This reduction in physical activity can lead your muscles to become weaker, and you to feel more unsteady. This causes your risk of falling to increase.

Things for you to think about and try:

- **If you can, try to continue the activities that you used to enjoy.** This will help for you to feel happier in yourself, and will also help you to feel more steady.
- **Familiarise yourself with your surroundings when you are somewhere new.** Some people with Parkinson's feel that it is helpful knowing where everything is. This can stop you from having to over-reach and losing your balance.

"Be aware of the layout of a room, I'm much more anxious if it's somewhere I don't know.... always make sure I know where the steps are."

- **Apply for a blue badge if you can't walk very far.** Applications are through your local council or online. If you experience difficulties speak with your Parkinson's UK advisor, who may be able to help you.
- **Discuss your concerns with your doctor.** They can refer you to a physiotherapist who may be able to provide you with a walking aid that could help you in particular situations.

Any suggestions you might like to try? Write them in your action plan and have a go.

Turning, reaching and over balancing

Parkinson's can lead to unsteadiness when turning and or reaching for objects.

Things for you to think about and try:

- **Try not to reach too far.** Move closer or ask for somebody to help you.
"Don't go out of your reach... 'cos that's when you can stumble and fall... walk up to it."
- **Take your time when turning.** Try not to pivot, but to walk around in multiple steps.
"I fall if I'm walking along and somebody calls me, and I turn quickly."
- **Discuss your symptoms with your doctor.** They can refer you to a physiotherapist who may be able to offer you some more tips, exercises or equipment to help you to feel more steady.

Any suggestions you might like to try? Write them in your action plan and have a go.

Trips and slips

Many falls are not due to tripping on its own. Try to ask yourself 'would somebody without Parkinson's have fallen in the same situation?' If the answer is 'no', then there may be things that you can do to help for you to feel more steady.

Things for you to think about and try:

- **Take your time.** Some people find that they are more likely to fall when they are rushing. Whilst it can be tempting to try to get something done more quickly, try to take your time and to not push yourself too hard.
- **Concentrate.** Some people find that they are more likely to fall if they think of too many things at once. Try to concentrate on your walking, and think of stopping before talking to somebody at the same time.

"Being very aware of potential obstacles that you might trip over...its concentrating on what you're doing ... if you're with somebody else in deep conversation, takes your mind off being careful where you tread."

- **Walk with nice long strides and focus on your arm swing.** This can help to create a good rhythm and reduce the chance of you tripping.

"When I have a problem... my steps get very short, so I deliberately try to stride out and that helps. You've got to concentrate very hard...but sometimes I just have to stop, and start again."

- **Try humming or counting whilst you walk.** This can also help to create a good rhythm, and may prevent you from freezing.

- **Ensure you have good footwear.** Shoes should have a flat heel and a supportive sole.
- **Ensure spaces are well lit.** Think about leaving lights on at night or installing motion sensor lights outside of your home.

"It was dark, round the side, our son put movement lights up ...if you're in the pitch black, it's not really helping too much."

- **Think about de-cluttering areas of your house where you feel unsteady.**

"Make a wider space for him to walk ... so he's not going to bump into the furniture and stumble."

- **Discuss your symptoms with your doctor.** They can assess your movement and suggest other things that might help you. Physiotherapists can suggest ways to help your balance and posture. An occupational therapists may be able suggest some changes to your home such as grab rails, which may help you to feel more secure, or have discussions with you about equipment that might help.

Any suggestions you might like to try? Write them in your action plan and have a go.

Appendix E: Phase three appendices

Freezing

Freezing is where your feet feel 'stuck' to the floor. This can happen whilst you are walking, or may occur when you try to get going. It can be more noticeable if you feel anxious or when you are trying to think about lots of things at once. It can be worse when your medication is due. Think about when freezing may be more likely to occur for you.

Things for you to think about and try:

- **Plan activities soon after taking your medication.** Freezing may be more common when your medication is due, particularly in crowded places.
- **Where you can, leaving doors wedged open.** Some people find doorways are a trigger.

"[Negotiating] in and out of crowds [is difficult for people with Parkinson's]... quite often people can freeze, just going through a doorway."

- **Try to concentrate on your walking.** Freezing can be worse when you try to think of lots of things at the same time. Some people find it helpful to count as they walk.

"Try not to do two things at once ... just concentrating on where I'm going ... and probably being more careful not to walk when the next dose is due."

- **If you do freeze**
 1. Keep calm, try not to panic. Try not to reach for anything – it could make you more unsteady.
 2. Think carefully what you want to do step-by-step
 3. Put these steps into action
 4. If these suggestions don't help and somebody is nearby, ask for them to bring you a chair to sit on.
- **Sometimes people are able to learn short 'phrases' to get them going again.**

"I say to him 'stop, stand still. Think what you're doing. Long slow stride'. It gets him going again."
- **Discuss your symptoms with your doctor.** They may be able to suggest medication changes or refer you to a physiotherapist who is able to provide tips to prevent and manage freezing episodes, called 'cue' techniques.

Any suggestions you might like to try? Write them in your action plan and have a go.

Concerns of close friends and family

Parkinson's often results in significant changes for the close friends and family of those with Parkinson's.

People who help to look after people with Parkinson's have told us that they sometimes feel that they have to cope with situations for which they feel unequipped.

Some people feel that they are no longer able to enjoy the activities that they used to as they are concerned about their close friend/relative with Parkinson's being on their own.

Things for you to think about and try

- **Discuss your concerns with your close friend/ relative with Parkinson's.** Helping them to understand how you feel may in turn help to manage your worries

"Keeping an open dialogue between my husband and I... being honest and upfront about how it affects us both."

- **Discuss your concerns with other friends and relatives.** They may be able to suggest things that might help you. Parkinson's (UK) organises local groups, and social services may be able to suggest other groups designed for people like you in your local area

"After he was diagnosed, I read more around the subject and going to the support group and meeting other people and discover what works for them."

- **Try to stay active.** It's important that you try to make time for yourself. This may help you to feel more relaxed.
- **Are you worried about leaving close friend/ relative on their own?** Perhaps consider a pendant alarm, or asking social services about any way that they might be able to help, which may help you to feel less worried.
- **Are you finding things too much? Try discussing your concerns with social services.** Options include short and long-term support, or somebody to stay with your close friend/relative for a short period whilst you leave the house. You can self-refer to social services through your local council. This can allow for you to get help quicker; you do not need to wait until you next see the doctor or specialist nurse.

"We have a sitter twice week and I feel happy going out then."

- **Are you concerned about you financial situation and want to know what help you might be entitled to?** Parkinson's UK has local advisors who can assist you with this, as well as anything else related to how Parkinson's is affecting you.
- **Discuss your concerns with your doctor or nurse.** They may be able to provide suggestions for you to try, or to refer you for additional support.

Any suggestions you might like to try? Write them in your action plan and have a go.

Section 5: Useful Contacts

Parkinson's UK

The Parkinson's UK website has many useful resources for both those with Parkinson's and those close to them, including the details of your local Parkinson's (UK) support group and advisor.

www.parkinsons.org.uk email: hello@parkinsons.org.uk

Tel: 0808 800 0303

Pendant alarms

Pendant alarms are available from many sources, including Age UK. Age UK can be contacted on 0800 011 3846

Key Safe

Key safes are available from many sources, for more information contact social services.

Social Services

Social services can be contacted directed through your local council. You can contact them directly, you do not need to wait for a referral from your doctor or nurse.

Blue badge application

Contact your local council to ask for a paper form, or apply online via www.gov.uk/apply-blue-badge.

If you have any difficulties contact your Parkinson's (UK) advisor, who might be able to help

E.3 Phase Three: Provisional Outline for the Support Telephone Calls with PwP and their Caregivers

After the researcher has introduced themselves and has identified who they are talking to, they will ask three questions

- 1 **How are you finding the guide?**
- 2 **Are you experiencing any problems with the guide?**
- 3 **Are there any questions that you want to ask about the guide?**

The researcher will then thank the participant for their time and the telephone call will end.

E.4 Phase Three: Participant Information Sheet

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STEADY TOGETHER

A study to evaluate a guide, which aims to help people with Parkinson's who fall and those who are close to them

We invite you to take part in a study

You have been invited because you have a diagnosis of Parkinson's and have previously fallen, or because you help to look after somebody with Parkinson's who has fallen.

What do I need to do?

Please read the self-management guide and complete the feedback questionnaire, posting it back to us in the pre-paid envelope provided.

Why are we doing this study?

The purpose of this study is to evaluate a self-management guide, which aims to help both people with Parkinson's, and the people who are close to them. A self-management guide that provides information about falling might reduce the concerns that people have about falling.

We would like some honest feedback about the guide that we have produced. The information you provide will assist us in knowing whether our guide could be useful in helping people to self manage falling. Your feedback will help to identify areas where our guide can be improved.

Who is organising and funding the study?

The research study is organised and funded by the National Institute for Health Research (NIHR) Collaborations for Leadership in Applied Health Research and Care (CLAHRC) based at the University of Southampton, which is funded by the government.

The lead researcher is Professor Helen Roberts, Professor of Medicine for Older People at the University of Southampton. The study is being managed by Dr Charlotte Owen, a clinical research fellow in Geriatric Medicine.

How to contact us

If you have any questions about the study, please contact Dr Charlotte Owen at:

University Hospital Southampton, Room CE 114B, Tremona Road, Southampton, SO16 6YD
Tel: 07824 895791
Email: c.l.owen@soton.ac.uk

Alternatively, the research administrator, Angela Dumbleton, can be contacted on:
Tel: 02381 206128

E.5 Phase Three: Feedback Questionnaire



Participant ID				
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STEADY TOGETHER

Feedback questionnaire

For completion by both People with Parkinson's and those close to them

We would like to know how you feel about the guide. Please answer as many questions as possible: there are no right or wrong answers!

We want to hear about your open and honest feedback.

1 Do you think the content is useful?

Please circle your answer

Not at all	Not really	Undecided	Somewhat	Very Much
------------	------------	-----------	----------	-----------

What is the most useful part and why?

What is the least useful part and why?

2 Does the guide increase your knowledge about falling in Parkinson's?

Please circle your answer

Not at all	Not really	Undecided	Somewhat	Very Much
------------	------------	-----------	----------	-----------

Please explain

Participant ID				
----------------	--	--	--	--

3 **Do you think that there is information that that we have missed out and should be included in the guide?**

Please circle your answer

No	Undecided	Yes
----	-----------	-----

Please explain

--

4 **How do you find the way in which the information is presented?**

Please circle your answer

Very Poor	Poor	Not sure	Good	Very Good
-----------	------	----------	------	-----------

Please Explain

--

6 **Do you think the guide would be easy or difficult to use?**

Please circle your answer

Very difficult	Somewhat difficult	Neither difficult or easy	Somewhat easy	Very easy
----------------	--------------------	---------------------------	---------------	-----------

Please Explain

--

Participant ID				
----------------	--	--	--	--

7 **Would you feel confident in applying the information to your daily routine?**

Please circle your answer

Not at all	Not much	Undecided	Somewhat	Very much
------------	----------	-----------	----------	-----------

Please Explain

--

8 **Do you feel that the guide would alter any of the concerns you have about falling?**

Please circle your answer

Not at all	Not really	Undecided	Somewhat	Very Much
------------	------------	-----------	----------	-----------

Please Explain

--

9 **Do you feel that this guide would alter your ability to manage your falls?**

Please Circle your answer

Not at all	Not really	Undecided	Somewhat	Very much
------------	------------	-----------	----------	-----------

Please Explain

--

Participant ID				
----------------	--	--	--	--

10 **Does the guide worry or concern you in any way?**

Please circle your answer

Not at all	Not really	Undecided	Somewhat	Very much
------------	------------	-----------	----------	-----------

Is there anything that we could do to reassure you?

--

11 **How likely is it that you would use the guide?**

Please circle your answer

Very unlikely	Unlikely	Undecided	Likely	Very likely
---------------	----------	-----------	--------	-------------

Please Explain

--

12 **Please let us know who has completed this questionnaire.**

Person with Parkinson's	Relative/ friend	Both
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**Thank you for completing this questionnaire.
Please return it in the prepaid envelope provided.**

E.6 Phase Three: Log of the Suggestions and Changes made to the Self-management Guide in Response to Usability Testing

E.6.1 Changes made to the introduction and contents page

Suggestions from participants	Changes made to the guide
<ul style="list-style-type: none"> • One healthcare professional was unsure of whether the action plan would be completed or referred to. • One PwP, who had not yet fallen, was not sure whether the action plan would be used 	<p>Add the statement ‘this may help you to feel more in control of your symptoms’ to the introduction to rationalise the importance of completing an action plan, and aiming to increase compliance through identified regulators to motivation</p>
<ul style="list-style-type: none"> • The subsection ‘Concerns of Close friends and family’ has been moved from Section three to Section One following the suggestions detailed below to subsequent changes made to the guide. 	<p>The title of Section One has been changed to reflect this modification.</p>

E.6.2 Changes made to sections one and two of the guide

Suggestions from participants	Changes made to the guide
One healthcare professional discussed how they felt that the text within the section 'How Can I Stay Active?' should be re-organised so that it is more coherent for users.	Text within the subsection 'How Can I stay Active?' re-organised so that the suggestions lie within clear categories: <ul style="list-style-type: none"> • Tips for keeping active • Look to your Parkinson's UK Group • Talk to a physiotherapist • Discuss your concerns with a doctor
<ul style="list-style-type: none"> • One healthcare professional discussed how the subsection 'Concerns of close friends and family' did not coherently fit within section three. • One PwP felt that the least useful section was 'concerns of close friends and family'. • The three caregivers who completed the usability questionnaire were unsure or felt that the guide would not alter their concerns of falling. Two of the three caregivers were unsure as to whether they would use the guide. This may suggest that this section needs to be placed more prominently 	<p>Subsection 'Concerns of close friends and family' moved from section three to section one to make the guide flow more coherently.</p> <p>Subsection 'Concerns of close friends/ relatives' edited to add more information about financial support that is available to caregivers. Text edited, and subheadings added to reduce the work count and enhance readability.</p>
Following general feedback relating to the flow of the information within the guide within other subsections, the content and layout of the guide as reviewed.	Quote from a PwP moved to the subsection "How Can Healthcare Professionals Help" from the subsection "How Can I Stay Active?". It was felt to be more relevant in this context.
<ul style="list-style-type: none"> • One healthcare professional was unsure of whether the action plan would be completed or referred to. • One PwP, who had not yet fallen, was not sure whether the action plan would be used. 	Within the subsection 'Will the suggestions in this guide help?' the statement surrounding how the guide might help has been placed in bold to provide a clear rationale for the guide, aiming to enhance its use through targeting identified regulators to motivation.
PwP and healthcare professionals raised that the action plan may not be completed. Although no participants raised that they felt that the falls diary would not be completed, this section has been edited to try and increase compliance with its use.	The text 'Take this log to your meetings with your doctor/ nurse to help them to understand any problems you are experiencing' placed in bold, aiming to provide a clear rationale for use of the guide and enhance its use.

Appendix E: Phase three appendices

E.6.3 Changes made to section three of the guide

Suggestions from participants	Changes made to the guide
Three participants from the usability testing with PwP and their caregivers were unsure as to whether the guide would be easy or difficult to use. One participant felt that they needed to become more familiar with the guide.	The order in which the topics are presented within this section was adjusted to place the more common concerns raised by participants in phases one and two at the front of the section. This aims to increase the perceived relevance of the guide to users. The order of this section is now as follows: <ul style="list-style-type: none"> • What to do after a fall • Freezing • Trips and Slips • Rushing and doing too many things at once • Feeling Lightheaded • Falls away from your home • Turning, reaching and over balancing
Following general feedback relating to the flow of the information within the guide within other subsections, the content and layout of the guide as reviewed.	In the subsection 'What to do after a fall' the text and layout have been edited to reduce the word count without reducing the content to make it more coherent for users of the guide.
One healthcare professional suggested adding information about leaving a blanket, cushion and a flask at a low level in case of a long wait for assistance.	In the subsection 'What to do after a fall' information has been added to suggest that PwP have a blanket, cushion and flask of water at a low level if falls are frequent.
<ul style="list-style-type: none"> • One healthcare felt that clarification was required to explain that freezing did not always respond to changes in medication. • One PwP stated that they would like more information about medication included within the guide. Within phase one of the programme of research, some PwP could appear pre-occupied with medication. 	In the subsection 'Freezing', text has been added to explain that freezing does not always respond to changes in medication.
Following general feedback relating to the flow of the information within the guide within other subsections, the content and layout of the guide as reviewed.	In the subsection 'Freezing', the layout has been changed so that it is more coherent. It is separated into two parts: <ul style="list-style-type: none"> • Tips to overcome freezing • Tips to prevent freezing
On review of the causes of falling discussed by HCP in phase two, HCP often spoke of the importance of vision. On review of the guide, details about this had initially been omitted.	In the subsection 'Trips and slips' information has been added about the importance of ensuring that glasses are clean with an up to date prescription.

Suggestions from participants	Changes made to the guide
<p>Following general feedback relating to the flow of the information within the guide within other subsections, the content and layout of the guide as reviewed</p>	<p>In the subsection 'Falls away from your home' changes made to reduce the amount of text without changing the content, aiming to make the guide more readable</p>
<p>One healthcare professional discussed how the subsection 'Concerns of close friends and family' did not coherently fit within section three. The three caregivers who completed the usability questionnaire were unsure or felt that the guide would not alter their concerns of falling. Two of the three caregivers were unsure as to whether they would use the guide</p>	<p>The subsection 'Concerns of Close friends and family' has been moved to Section One</p>

E.6.4 Changes made to sections four and five of the guide

Suggestions from participants	Changes made to the guide
<ul style="list-style-type: none"> • One healthcare professional was unsure of whether the action plan would be completed or referred to. • One PwP, who had not yet fallen, was not sure whether the action plan would be used. 	<p>The statement ‘This can help you feel more in control of your symptoms’ has been added at the start of this section and placed in bold font. This has been added to place importance on the completion of action plans and to try and increase the use of this section through emphasising identified regulators to motivation.</p>
<ul style="list-style-type: none"> • One PwP felt that the least useful section was ‘concerns of close friends and family’. • The three caregivers who completed the usability questionnaire were unsure or felt that the guide would not alter their concerns of falling. Two of the three caregivers were unsure as to whether they would use the guide. 	<p>Details added about how to go about applying for carers allowance and attendance allowance have been added to this section. Users are informed of these benefits within the subsection ‘Concerns of close friends and Family’.</p>
<p>Following general feedback relating to the flow of the information within the guide within other subsections, the content and layout of the guide as reviewed.</p>	<p>Added that pendant alarms and key safes can be obtained from the local council, in addition to ‘Age UK’ as was originally stated.</p>

E.7 Phase Three: Revised Version of the Self-management Guide

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A guide to help people with Parkinson's who
feel unsteady and those who are close to
them

Introduction

This guide has been designed to help people with Parkinson's who feel unsteady, as well as those who are close to them. This guide contains information about unsteadiness, falling, and techniques that are frequently recommended by healthcare professionals.

You may have only recently started to feel unsteady, which can make some people feel shocked or unprepared. Or, you may have felt this way for some time, and your life may have changed as a result. The nature of unsteadiness, and the aids and support needed to help you, can vary from person to person, from day to day, and may change over time.

This guide suggests different ways that may help and assist you.

How to use this guide

Parts of this guide will be more relevant to you than to others.

- Step 1: Read section 1.** This contains general information about falls and keeping active
- Step 2: Complete section 2.** This is a diary for you to complete whenever you feel unsteady or have a fall.
- Step 3: Read section 3.** After reading section one and completing section two, read the parts of section 3 that you think might help you.
- Step 4: Complete section 4.** This is your personal action plan. Complete it whenever you think of a way that you would like to address a particular concern that you might have. Once you have tried something, write down how it went. **This may help you to feel more in control of your symptoms.**

Contents of the guide

Section 1	What causes falling, common concerns and what can I do to help?	Page 4
Section 2	Unsteadiness and falls diary	Page 12
Section 3	Common concerns and suggestions	Page 13
Section 4	Personal action plan	Page 24
Section 5	Useful contacts	Page 26

Section 1

What causes falling in Parkinson's?

Parkinson's is characterised by slowness of movement, a feeling of stiffness, shaking and reduced balance. Parkinson's also causes reduced co-ordination of your movements. These symptoms make you more likely to fall.

The symptoms of Parkinson's often vary from person to person, from day to day, and change over time. Symptoms that can lead to increased unsteadiness or falling include:

- **Freezing.** This is where you feel that your feet are 'stuck' to the ground and will not move.
- **Feeling lightheaded when you stand up.**
- **Weakness of your muscles**

Is falling normal?

Falling is common amongst people with Parkinson's, but not all people with Parkinson's fall. You are more likely to fall if you:

- Have fallen before
- Have had Parkinson's for a longer period of time
- Are anxious or fearful of falling
- Have weak muscles
- Have memory problems

What can I do to help?

Whilst falling is common, **many falls can be prevented.** It is important to try to keep as active as possible.

The things that can help will depend upon the symptoms that you are experiencing.

- Read this section and complete the diary in **section 2**, then look at the parts of **section 3** that might help you.
- Complete your personal action plan in **section 4** whenever you identify something that might help you.
- Discuss your falls with your doctor and specialist Parkinson's nurse.

Why should I stay active?

For many people, Parkinson's and unsteadiness leads to a change in activities and hobbies. Inactivity can lead to muscle stiffness and weakness, which can increase your risk of falling. Being less active can cause some people to feel frustrated or lonely. Staying active can **help your mental and your physical health.**

"She just has a look round the shops. I encourage her to do that ... if she doesn't do it on her own then she will lose all confidence."

How can I stay active?

Things for you to think about and try:

Tips for keeping active

If you can, try limiting the amount of time that you are sitting to half an hour. Sitting for long periods of time can cause you to feel stiff, or unsteady once you get going.

Try to continue to do activities where and when you can. Whilst it can be tempting to ask for others to do things for you because they are able to do them faster, inactivity may make your muscles feel stiffer, or more unsteady when you move.

Try making small changes to allow for you to continue with your chosen activity.

- Take things at your own pace, don't feel under pressure to rush
- Finding a place to rest during the activity may allow you to carry on enjoying it.
- If you are finding it difficult to walk long distances, enquire about a Blue Badge with your local council, or apply online using the details in **Section 5**. You don't need to be able to drive to apply. If you experience difficulties speak with your Parkinson's UK advisor, who may be able to help you.

"We have to plan where there's no stiles, where there's a proper gravel path, like a biking track."

Try to think of activities that you can enjoy with your close friends and family. Through spending time together, and speaking about how Parkinson's has affected you and those around you, it might help to manage any anxieties that you might have.

"I can spend more time with my wife... we go ballroom dancing... we won't let [Parkinson's] stop us doing stuff."

Look to your local Parkinson's (UK) group.

The monthly support groups will enable you to meet with other people like yourself. The group may organise local outings or Tai Chi designed for people with Parkinson's.

"Parkinson's group; we usually try and learn from each other... because everybody's so different."

Talk to a physiotherapist

Ask your physiotherapist to recommend some exercises. Doing your exercises regularly can help you to feel less stiff and more steady. If you find walking difficult, seated exercises can be helpful too.

A physiotherapist might be able to recommend a mobility aid. This may allow you to continue with the same activities and help you feel more steady

Discuss your concerns with your Doctor

This could be your GP or your Parkinson's specialist doctor. They may be able to make changes to your medication or refer you to a physiotherapist.

Any suggestions you might like to try? Write them in your action plan and have a go.



Concerns of close friends and family

Parkinson's often results in significant changes for the close friends and family of those with Parkinson's.

People who help to look after people with Parkinson's have told us that they sometimes feel that they have to cope with situations for which they feel unequipped.

Some people feel that they are no longer able to enjoy the activities that they used to as they are concerned about their close friend/relative with Parkinson's being on their own.

Things for you to think about and try

- **Try to stay active.** It's important that you try to make time for yourself. This may help you to feel more relaxed.



- **Discuss your concerns with your close friend or relative with Parkinson's.** Helping them to understand how you feel may in turn help to manage your worries
- **Discuss your concerns with other friends and relatives.** They may be able to suggest things that might help you. Parkinson's (UK) organises local groups, and social services may be able to suggest 'carers groups' in your local area

"After he was diagnosed, I read more around the subject. I go to the support group, meet other people and discover what works for them."

Are you worried about leaving your close friend or relative on their own?

- **Consider a pendant alarm.** This will allow for your close friend or relative to alert someone if they were to fall.
- **Consider discussing your concerns with social services.** They can arrange short or long term support. This could just be for short periods whilst you leave the house.

You can self-refer to social services through your local council. This will allow for you to get help quicker; you do not need to wait until you next see the doctor or specialist nurse.

"We have a sitter twice week and I feel happy going out then."

Are you concerned about you financial situation?

- **Your close friend or relative with Parkinson's may be entitled to 'Attendance Allowance' to help with personal support.**
- **As a carer you may be entitled to 'Carer's Allowance'.**
- Attendance Allowance and Carers Allowance are non-means tested. You can apply for these benefits online or on a paper form as outlined in **Section 5** of this guide. Parkinson's UK has local advisors who can assist you with this.
- **Discuss your concerns with your doctor or nurse.** They may be able to provide suggestions for you to try, or to refer you for additional support.

Any suggestions you might like to try? Write them in your action plan and have a go.

How can healthcare professionals help?

The symptoms of Parkinson's change over time. Although you may have had support for falling in the past, the support needed to help you may have now changed.

Healthcare professionals can suggest ways to reduce your risk of falling, and there is also help to support close friends and relatives of those with Parkinson's.

Paramedics (999) are there to help you in medical emergencies, which includes helping you up from the floor. It is important that you are not lifted up by a close friend or relative as this could injure both of you. When the paramedics arrive they will assess you and help you up. Calling 999 does not always result in being admitted to hospital.

"Just because someone comes out here to help him it isn't going to mean he has to go to hospital."

Parkinson's specialist doctors and your GP

may be able to alter your medications, listen to your worries and anxieties, and can refer you to other professionals who could help you.



Parkinson's specialist nurses are very knowledgeable and can provide support, advice and referral to other professionals who could help.

Occupational therapists can help to support you to live independently through assessing your home and suggesting adjustments that might help you.

"Occupational Therapist is very helpful ... they've arranged to have rails put in."

Physiotherapists can help in many ways. They can help you to remain active through providing:

- Exercises to help with your mobility
- Advice on your posture and walking
- Techniques to overcome episodes of freezing
- Advice on how to get up from the floor
- Advice on mobility aids that might assist you.

"We went to the physiotherapist.... she just knew everything, it was just quite refreshing"

"We've been going to exercises cos they teach you to get up...they definitely help."

Social services can advise and provide professional care to help you. This could be for a short period whilst your close friend or relative is out of the house, or for respite or more regular care. You can contact social services directly through your local council, you do not need a referral from a doctor.

Will the suggestions in this guide help?

All of the suggestions within this guide have been suggested for people who have had Parkinson's for some time. The symptoms of Parkinson's vary from person to person and change over time, meaning that some suggestions are likely to be more relevant to you than others.

- Write down the suggestions that you are going to try in your action plan in [section 4](#).
- If something doesn't work, think about modifying it, particularly if you are feeling tired or unwell, and then try it again.

The suggestions won't do you any harm, and may help you to feel more in control of your Parkinson's and falling.

Section 2: Unsteadiness and falls diary

Complete this whenever you feel unsteady or fall. Use this log to identify areas in section 3 that might help you.

Try to fill this out whilst the episode is fresh in your mind.

Take this log to your meetings with your doctor/ nurse to help them to understand any problems you are experiencing.

What were you trying to do?	Why do you think you felt unsteady or fell?	What worried you?
<i>E.g. Carrying a cup of tea</i>	<i>E.g. Doing too many things at once</i>	<i>E.g. Difficulty getting up off the floor</i>

Section 3: Common concerns and suggestions

Parts of this section are likely to be more relevant to you than others. This section has not been designed for you to read from start to finish.

Read this section after sections one and two. Use sections one and two to help you to identify which parts of this section might help.

Use sections 1, 2 and 3 to help you to write your personal action plan in section 4.

Concern	Page
What to do after a fall	14
Freezing	16
Trips and slips	18
Rushing and doing too many things at once	20
Feeling lightheaded	21
Falls away from your home	22
Turning, reaching and over balancing	23

What to do after a fall

For the person who falls, falling can be associated with shock, stress and embarrassment. You may also be worried how to get up.

Close friends and relatives may also feel shocked and stressed.

Try not to rush any actions or decisions and to think logically through the options below.

Can you recall any advice from the physiotherapist about how to get up after a fall?

If no, try and get off the floor by following the following steps

1. Roll over onto your front
2. Push your upper body up to get onto your hands and knees
3. Crawl to a sturdy chair (or ask for somebody to bring one close to you)
4. Place your hands onto the seat of the chair
5. Push down with your arms and place one foot on the ground
6. Push down with your arms and place your other foot on the ground
7. Push down with your arms to stand up

Close friends/ relatives: if this does not work, do not lift your close friend/ relative with Parkinson's off the floor.

- Although this might be tempting, you could injure yourself. Make your close friend/ relative comfortable and call 999.
- The paramedics are there to support people in situations like this. They will assess your close friend/ relative and help them up safely.

Things for you to think about and try:

- **Talk through the fall with a close friend/ relative.** Think about what you were doing at the time of the fall and why you might have fallen. Write it in the diary in **section 2**.

"Going through the fall and actually saying, you know, well 'what do we think caused this one. Okay what could we do differently?'"

- **Look at the contents page of section 3. Only read the information that you think might help you.** Think about things that you might like to try, and write them in your action plan in **section 4**.
- **Consider carrying a pendant alarm or a mobile phone with you at all times.** This will allow you to alert others after a fall. Pendant alarms are worn around the neck or the wrist; when they are pressed a call goes through to another area of the house or to a central call centre. This may help the person who is unsteady to feel safe, and may provide your close friend/ relative with reassurance. Pendant alarms are available from many organisations including your local council and Age UK. 
- **Consider a key safe outside your front door.** If you fall when you are alone and press your pendant alarm, or call 999, this will allow somebody to get to you easily.
- **If falls are frequent, consider having a blanket, cushion and flask of water at a low level.** This can help for you to feel more comfortable in case of a wait for assistance
- **Inform your doctor or nurse that you have had a fall.** They may be able to suggest changes that can help you or refer you to others that can help.

Any suggestions you might like to try? Write them in your action plan and have a go.

Freezing

Freezing is where your feet feel 'stuck' to the floor. This can happen whilst you are walking, turning, or when you try to get going. It can become more noticeable if you feel anxious or when you are trying to think about lots of things at once. It can be worse when your medication is due. Freezing does not always respond to changes in medication.

Things for you to think about and try:

If you freeze....Tips to get you going again

If you do freeze, Keep calm, try not to panic. Try not to reach for anything – it could make you more unsteady.

1. Think carefully what you want to do step-by-step
2. Put these steps into action

If this does not help, there are other strategies that may help to get you going again:

- **Shift most of your weight onto one foot**, then try to get going. This normally happens when you start walking.
- **Marching on the spot, whilst counting '1, 2, 1, 2' or 'left, right, left, right'** can also help you to get going.
- **Sometimes people are able to learn short 'phrases' to get them going again.**

"I say to him 'stop, stand still. Think what you're doing. Long slow stride'. It gets him going again."

General tips to prevent freezing

- **Plan activities soon after taking your medication.** Freezing may be more common when your medication is due.
- **Try to concentrate on your walking.** Freezing can be worse when you try to think of lots of things at the same time. Some people find it helpful to count or hum as they walk. This can help to keep a good rhythm going.
- **Try and stick to wide spaces.** Some people find that crowded or narrow spaces are a trigger.

"Try not to do two things at once ... just concentrating on where I'm going."

Are there any areas within your home where freezing is more likely to occur?

- **Consider de-cluttering these areas or leaving doors wedged open.** Obstacles can make people more likely to freeze.

"Often people can freeze just going through a doorway."

- **Consider putting strips of brightly coloured tape on the floor in these areas.** Place strips in parallel and 2 feet apart. This can help you to keep a good rhythm going, and reduce freezing.
- **Discuss your symptoms with your doctor.** They may be able to suggest medication changes or refer you to a physiotherapist who is able to provide tips to prevent and manage freezing episodes, called 'cueing' techniques.

Any suggestions you might like to try? Write them in your action plan and have a go.

Trips and slips

Many falls are not due to tripping on its own. Try to ask yourself 'would somebody without Parkinson's have fallen in the same situation?' If the answer is 'no', then there may be things that you can do to help you to feel more steady.

Things for you to think about and try:

- **Take your time.** Some people find that they are more likely to fall when they are rushing. Whilst it can be tempting to try to get something done more quickly, try to take your time and don't push yourself too hard.
- **Concentrate.** Some people find that they are more likely to fall if they think of too many things at once. Try to concentrate on your walking, and think of stopping before starting to talk to somebody.

"Being very aware of potential obstacles that you might trip over...its concentrating on what you're doing ... if you're with somebody else in deep conversation, it takes your mind off being careful where you tread."

- **Walk with nice long strides and focus on your arm swing.** This can help to create a good rhythm and reduce the chance of you tripping.

"When I have a problem.... my steps get very short, so I deliberately try to stride out and that helps. You've got to concentrate very hard...but sometimes I just have to stop, and start again."

- **Try humming or counting whilst you walk.** This can also help to create a good rhythm, and may prevent you from freezing.

- **Ensure you have good footwear.** Shoes should have a flat heel and a supportive sole.



- **Make sure that you have clean glasses with an up to date prescription.** Have your eyes tested at least every 2 years.



- **Ensure spaces are well lit.** Think about leaving lights on at night or installing motion sensor lights outside your home.



"It was dark, round the side, our son put movement lights up"

- **Think about de-cluttering areas of your house where you feel unsteady.**

"I made a wider space for him to walk ... so he won't bump into the furniture and stumble."

- **Discuss your symptoms with your doctor.** They can assess your movement and suggest other things that might help you. Physiotherapists can suggest ways to help your balance and posture. Occupational therapists may be able suggest some changes to your home such as grab rails, which may help you to feel more secure, or have discussions with you about equipment that might help.

Any suggestions you might like to try? Write them in your action plan and have a go.

Rushing and doing too many things at once

People with Parkinson's often feel unsteady when trying to do more than one thing at once. Through taking your time and concentrating on your movements, this may help for you to feel more steady.

Things for you to think about and try

- **Take your time, try not to rush**

"I try and consciously not rush....if it is the telephone, if it's something important they'll phone me back."

- **Concentrate on what you are doing.** Some people with Parkinson's can feel unsteady when doing more than one thing at once.

Some people find it helpful to stop walking before starting a conversation with somebody.

Some people with Parkinson's find that carrying objects affects their balance. Think about asking somebody else to help you.

"I always carry the drinks up to bed ... there's lots of things that we do now that we wouldn't have thought too much about before."

- **Try planning each journey** that you take, and taking note of your surroundings. Some people find it helpful to plan a route that has places for them to rest.

Any suggestions you might like to try? Write them in your action plan and have a go.

Feeling lightheaded

Parkinson's medication and medication for high blood pressure can cause you to feel lightheaded when you stand up. This is caused by a drop in your blood pressure, called postural hypotension.

This can be particularly noticeable if you have been lying or sitting for some time.

Things for you to think about and try

- **Drink plenty of water.** This is particularly important during spells of hot weather.



"Drink lots of water so you're not light-headed....I find if I stand up too quickly I feel really light-headed."

- **Try to keep active.** Your symptoms are likely to be worse after long periods of sitting or lying down. Look at the tips suggested on pages 6-7 of this guide.
- **Try marching on the spot whilst sitting.** If you have been sitting or lying down for some time this may help
- **Take your time when standing up.** If you find that you are lightheaded, wait for your symptoms to pass before you start moving.
- **Discuss your symptoms with your doctor.** They can check your blood pressure and may be able to make changes to your medications to help your symptoms.

Any suggestions to try? Write them in your action plan and have a go.

Falls away from your home

Falling outside of your home can cause some people to feel particularly anxious and vulnerable. This can lead some people with Parkinson's to avoid going outside. This reduction in physical activity can lead to your muscles becoming weaker, and make you feel more unsteady. This causes your risk of falling to increase.

Things for you to think about and try:

- **If you can, try to continue the activities that you used to enjoy.** This will help you to feel happier in yourself, and will also help you to feel more steady. Look at the tips suggested on pages 6-7 of this guide.
- **Familiarise yourself with your surroundings when you are somewhere new.** Some people with Parkinson's feel that it is helpful knowing where everything is. This can stop you from having to over-reach, which can cause you to lose your balance.

"Be aware of the layout of a room, I'm much more anxious if it's somewhere I don't know.... I always make sure I know where the steps are."

- **Apply for a Blue Badge if you can't walk very far.** Applications are through your local council or online, using the details in **Section 5**. Your Parkinson's UK advisor may be able to help you.
- **Discuss your concerns with your doctor.** They can refer you to a physiotherapist who may be able to provide you with a walking aid that could help you in particular situations.

Any suggestions you might like to try? Write them in your action plan and have a go.

Turning, reaching and over balancing

Parkinson's can lead to unsteadiness when turning or when reaching for objects.

Things for you to think about and try:

- **Try not to reach too far.** Move closer to the object or ask for somebody to help you.

"Don't go out of your reach... 'cos that's when you can stumble and fall... walk up to it."

- **Take your time when turning.** Try not to turn via pivoting, but to walk around in multiple steps. If you feel that your feet 'stick' to the floor, try reading the section 'freezing' on page 16.

"I fall if I'm walking along and somebody calls me, and I turn quickly."

- **Discuss your symptoms with your doctor.** They can refer you to a physiotherapist who may be able to offer you some more tips, exercises or equipment to help you to feel more steady.

Any suggestions you might like to try? Write them in your action plan and have a go.

Section 5: Useful Contacts

Parkinson's UK

The Parkinson's UK website has many useful resources for both those with Parkinson's and those close to them, including the details of your local Parkinson's (UK) support group and advisor.

www.parkinsons.org.uk email: hello@parkinsons.org.uk

Tel: 0808 800 0303

Pendant alarms

Pendant alarms are available from many sources, including your local council and Age UK. They incur a small cost.

Age UK can be contacted on 0800 707 6369.

Key Safe

Key safes are available from many sources, for more information contact your local council or social services.

Social Services

Social services can be contacted through your local council. You can contact them directly, you do not need to wait for a referral from your doctor or nurse.

Blue Badge applications

Contact your local council to ask for a paper form, or apply online via www.gov.uk/apply-blue-badge.

If you have any difficulties contact your Parkinson's (UK) advisor, who might be able to help.

Attendance Allowance applications

Apply online via www.gov.uk/attendance-allowance, or call 0800 731 0122 to ask for a paper form.

If you have any difficulties contact your Parkinson's (UK) advisor, who might be able to help.

Carers Allowance applications

Apply online via www.gov.uk/carers-allowance, or call 0345 608 4321 to ask for a paper form.

If you have any difficulties contact your Parkinson's (UK) advisor, who might be able to help.

E.8 Phase Three: Revised Outline for Support Telephone Calls

My name is Dr Charlotte Owen. I am calling in relation to the research study 'Steady Together', a study about Parkinson's and falling, as part of which you have received a self-management guide. Can I ask who I am speaking with (*clarify if speaking with the person with Parkinson's or the caregiver and speak with each of them in turn*).

I would like to thank you for taking part in the research study.

- 1 Have you had any falls in the past two weeks/ month/ two months (*delete as appropriate*) since you have had access to the guide?

If yes....

- *Can you tell me about what happened?*
- *Can you tell me about any difficulties getting up off the floor?*
- *Can you tell me about any injury that occurred?*
- *Can you tell me about any support that you have sought from healthcare professional(s)? (Clarify whether this was pre-arranged before the fall occurred).*

- 2 How are you finding the guide?

- Can you tell me about any parts that you find more, or less, useful?
- How have you been finding the unsteadiness/ falls diary and the action plan?
- Do you have any concerns about the guide, or have you had any difficulties using it?

(If difficulties are encountered in relation to using the guide or implementing strategies to overcome unsteadiness/ falling):

- Can you tell me about any solutions that you can think of that you might like to try/ might help?

Provide reassurance for any difficulties raised (where appropriate)

Provide encouragement to use the guide. State: "Using the guide may help you to identify patterns of symptoms, to develop strategies to manage them, or to feel more in control of your symptoms."

- 3 Are there any questions that you want to ask about the guide?

- *Use the framework congratulate/ask/ reassure/ encourage*

The researcher will then thank the participant for their time and the telephone call will end.

Appendix F Phase Four Appendices

F.1 Phase Four: Data Collection Form for Telephone Calls

STEADY TOGETHER

Provisional outline of questioning for Telephone calls with people with Parkinson's and their caregivers

My name is Dr Charlotte Owen. I am calling in relation to the research study 'Steady Together', a study about Parkinson's and falling, as part of which you have received a self-management guide.

Can I ask who I am speaking with (*clarify if speaking with the person with Parkinson's or the caregiver and speak with each of them in turn*).

I would like to thank you for taking part in the research study.

- 1 Have you had any falls in the past two weeks/ month/ two months (*delete as appropriate*) since you have had access to the guide?

If yes....

- *Can you tell me about what happened?*
- *Can you tell me about any difficulties getting up off the floor?*
- *Can you tell me about any injury that occurred?*
- *Can you tell me about any support that you have sought from healthcare professional(s)? (Clarify whether this was pre-arranged before the fall occurred).*

- 2 How are you finding the guide?

- Can you tell me about any parts that you find more, or less, useful?
- How have you been finding the unsteadiness/ falls diary and the action plan?
- Do you have any concerns about the guide, or have you had any difficulties using it?

(If difficulties are encountered in relation to using the guide or implementing strategies to overcome unsteadiness/ falling):

- Can you tell me about any solutions that you can think of that you might like to try/ might help?

Provide reassurance for any difficulties raised (where appropriate)

Provide encouragement to use the guide. State: "Using the guide may help you to identify patterns of symptoms, to develop strategies to manage them, or to feel more in control of your symptoms."

Appendix F: Phase Four Appendices

- 3 Are there any questions that you want to ask about the guide?
 - *Use the framework congratulate/ask/ reassure/ encourage*

The researcher will then thank the participant for their time and the telephone call will end.

F.2 Phase Four: Participant Information Sheet

UNIVERSITY OF
Southampton



STEADY TOGETHER

A study to evaluate a guide, which aims to help people with Parkinson's who fall and those who are close to them

We invite you to take part in a study

Before you decide whether or not you would like to take part, we would like you to read this information booklet. It is important for you to understand why the study is being done and what it might involve.

Please read this booklet carefully and ask the researchers any questions that you might have.

It is up to you to decide whether or not to take part.

Why have I been invited

You have been invited because you have a diagnosis of Parkinson's and have had at least one fall in the last year, or because you help to look after somebody with Parkinson's who has fallen.

Summary of the study

The purpose of this study is to evaluate a guide, which aims to help people with Parkinson's who fall and those who are close to them.

This study will last for three months, during which we would like you to use the guide that we have produced. We will ask you to complete some questionnaires, both before and after using our guide.

We will invite some people to take part in interviews. During these interviews we will ask for feedback about the guide.

Contents

1. Why are we doing this study?
2. What will I need to do if I take part?
3. What are the possible benefits and disadvantages of taking part?
4. What happens if I don't want to carry on with the study?
5. Will my taking part in the study be kept confidential?
6. What will happen to the results of the research study?
7. Who is organising and funding the research?
8. Who has reviewed the study?
9. What if there is a problem?
10. What do I do now?
11. Contact details of the researchers

How to contact us

If you have any questions about the study, please contact Dr Charlotte Owen at:

University Hospital Southampton
Room CE 114B
Tremona Road, Southampton, SO16 6YD
Tel: 07824 895791
Email: c.l.owen@soton.ac.uk

Alternatively, the research administrator, Angela Dumbleton, can be contacted on:
Tel: 02381 206128

1 Why are we doing this study?

The purpose of this study is to evaluate a self-management guide, which aims to help both people with Parkinson's, and the people who are close to them. A self-management guide that provides information about falling might reduce the concerns that people have about falling.

2 What will I need to do if I take part?

1. We will telephone you in 48 hours to ask whether you are interested in taking part in this study and to answer any questions that you might have. If you agree to take part, we will ask for you to complete the consent forms and two questionnaires, posting them back to us in the prepaid envelope provided.
2. We would then like you to use the guide over a period of three months. During this period we will telephone you after two weeks, one month and two months. This will allow us to make sure that we have addressed any concerns that you might have.
3. After three months, we will post three questionnaires to you. Please complete these and return them to us in the pre-paid envelope that we will provide you with.
4. We will invite some people to participate in an interview, where we will ask questions about how you found the guide. These interviews will take place at a time convenient to you and at your home address. If you are happy, we will audio-record these interviews, to allow us to concentrate on what you are saying.

3 What are the possible benefits and disadvantages of taking part?

This guide may improve your knowledge and confidence, to effectively manage falls within your own home. It may help to reduce the concerns of falling that people with Parkinson's, and those who are close to them, currently experience.

The information you provide will assist us in knowing whether our guide is useful in helping people to self manage falling. Your feedback will help to identify areas where our guide can be improved.

We do not anticipate any disadvantages or risks in taking part in the study. However, if you do experience any difficulties then these can be brought forward to the researchers at any time.

4 What happens if I don't want to carry on with the study?

If after choosing to take part in the study you change your mind, you can withdraw at any time without giving a reason, and your usual NHS care will not be affected. However, any data already collected will be used in the analysis of the study.

5 Will my taking part in the study be kept confidential?

Yes, all information about you will be handled in confidence. All data collected from you will be anonymised. Any personal data such as your name or contact details will be retained for no longer than three months after the study has ended. Data will be stored on a password protected computer or locked filing cabinet in a secure office in our research unit and will be accessible only by the research team. There is a possibility that the hospital's Research and Development department may wish to audit the data for monitoring purposes.

If you participate in the interviews, with your permission, these interviews will be audio-recorded to make an accurate record of what is said. Recordings will be typed up and identifiable data will be removed.

When analysing the results of the study, your data will be used anonymously and will not be attributable to you. Data collected may be used to support research in the future, and your data may be shared anonymously with other researchers.

6 What will happen to the results of the research study?

The results of the research will be published in medical scientific journals, and may be presented at conferences and local meetings. The results may contain quotes from participants, however, these quotes will be anonymised and will not be attributable to any individual. We will send you a summary of the findings if you would like one.

7 Who is organising and funding the research?

The research study is organised and funded by the National Institute for Health Research (NIHR) Collaborations for Leadership in Applied Health Research and Care (CLAHRC) based at the University of Southampton, which is funded by the government.

The lead researcher is Professor Helen Roberts, Professor of Medicine for Older People at the University of Southampton. The study is being managed by Dr Charlotte Owen, a clinical research fellow in Geriatric Medicine.

8 Who has reviewed the study?

This study has been reviewed and approved by the Health Research Authority (HRA) through the South Central- Oxford C Research Ethics Committee (REC); REC reference 17/SC/0488; IRAS Project ID 221022 .

9 What if there is a problem?

If there is a problem or you have any concerns, you can contact the researchers on the details provided in section 10 of this information sheet.

If you remain unhappy, you could contact the Research and Development Department at Southern Health NHS Foundation Trust:

Tel: 02380 475373 Email: research@southernhealth.nhs.uk

10 Contact details of the researchers for further information

If you have any questions about the study please contact the researchers, using the contact details provided below.

Dr Charlotte Owen

University Hospital Southampton

Room CE114B

Tremona Road

Southampton, SO16 6YD

Tel: 07824 895791

Email: c.l.owen@soton.ac.uk

Angela Dumbleton, the research administrator, can be contacted on Tel: 02381 206128

Alternatively, the lead researcher, Dr Helen Roberts, can be contacted at the address above, or on Tel: 023 81204354

11 What do I do now?

We will telephone you 48 hours after receiving this information sheet to gauge your ongoing interest in taking part in this study.

If you are interested in taking part we will ask for you to complete the informed consent forms and two questionnaires, and to post them back to us in the prepaid envelope.

Thank you for taking time to read this information sheet and considering taking part in this study

F.3 Phase Four: Informed Consent Form

UNIVERSITY OF
Southampton

Participant ID

STEADY TOGETHER

Informed consent form for people with Parkinson's and their informal caregivers

Study IRAS Reference: 221022
 Chief Investigator: Professor Helen Roberts
 Principal Investigator: Dr Charlotte Owen

Thank you for reading the information about our research project. If you would like to take part, please read and sign this form.

PLEASE INITIAL THE BOXES IF YOU AGREE WITH EACH SECTION:

1.	I have read the information sheet version 2 dated 06.11.17 for the above study and have been given a copy to keep. I have been able to ask questions about the study and I understand why the research is being done. I have been informed about any risks or inconveniences involved and the conditions under which the study is to be conducted.	<input type="checkbox"/>
2.	I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason and without the healthcare I receive or my legal rights being affected. And if I withdraw from the research study for any reason, data collected up to my withdrawal will be used in the analysis of the study.	<input type="checkbox"/>
3.	I understand that my participation in this study may involve taking part in an interview which will be audio-recorded. I give my permission to the researcher to conduct the interview and audio-record it by using a digital voice recorder.	<input type="checkbox"/>
4.	I understand that my confidentiality as a participant in this study will remain secure, and that if I do participate in an interview that the transcript of the interview will not contain my name or identifiable information. I agree for my data to be stored anonymously and that any published quotations or extracts from the research will maintain my confidentiality.	<input type="checkbox"/>
5.	I understand that relevant sections of my medical notes may be looked at by individuals within the research group, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.	<input type="checkbox"/>

Steady Together. Informed Consent form.
 Study IRAS Reference 221022
 Version 2 dated 06.11.17

1

F.4 Phase Four: Consultee Declaration Form



Participant ID (PwP)				
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STEADY TOGETHER

Consultee Declaration form

Study IRAS Reference : 221022
 Chief Investigator: Professor Helen Roberts
 Principal Investigator: Dr Charlotte Owen

We feel your relative/friend is unable to decide for himself/herself whether to participate in this research. To help decide if he/she should join the study, we would like to ask your opinion as to whether or not they would want to be involved. We ask you to consider what you know of their wishes and feelings, and to consider their interests. Please let us know of any advance decisions they may have made about participating in research. These should take precedence.

If you decide your relative/friend would have no objection to taking part, we will ask you to read and sign a Consultee declaration to document your opinion as to how your relative would have chosen to participate in the study. We will then give you a copy to keep. We will keep you fully informed during the study so you can let us know if you have any concerns or you think your relative/friend should be withdrawn.

If you decide that your friend/relative would not wish to take part, it will not affect the standard of care they receive in any way.

If you are unsure about taking the role of a Consultee, you may seek independent advice. We will understand if you do not want to take on this responsibility.

PLEASE INITIAL THE BOXES IF YOU AGREE WITH EACH SECTION:

1.	I(NAME OF CONSULTEE) have been consulted about the participation of(NAME OF PARTICIPANT) in this research project. I have read and understand the information sheet version 2 dated 06.11.17 for the above study and have been given a copy to keep. I have been able to ask questions about the study and I understand why the research is being done. I have been informed about any risks or inconveniences involved and the conditions under which the study is to be conducted.	<input type="checkbox"/>
----	--	--------------------------

2.	I understand that I can request that he/she is withdrawn from the study at any time without giving any reason without the healthcare he/she receives or his/her legal rights affected. I understand that if I request that he/she is withdrawn from the research study for any reason, that data collected up to their withdrawal will be used in the analysis of the study.	<input type="checkbox"/>
3.	In my opinion he/ she would have no objection to completing questionnaires about his/her Parkinson's and falling	<input type="checkbox"/>
4.	In my opinion he/ she would have no objection to participating in the interview that will be audio-recorded with a digital audio-recorder	<input type="checkbox"/>
5.	I understand that the confidentiality of my friend/ relative as a participant in this study will remain secure and that should he/she participate in an interview then the transcript of the interview will not contain their name or identifiable information. I understand that data will be stored anonymously and that any published quotations or extracts from the research will maintain their confidentiality. In my opinion he/she would have no objection to their data being used in this way.	<input type="checkbox"/>
6.	I understand that relevant sections of his/her medical notes may be looked at by individuals within the research group, where it is relevant to his/her taking part in this research. In my opinion he/she would have no objection to these individuals having access to his/her records.	<input type="checkbox"/>
7.	I understand that the data collected may be used to support research in the future, and that his/her data may be shared anonymously with other researchers. In my opinion he/she would have no objection to their data being used in this way	<input type="checkbox"/>
8.	I agree that my relative/ friend would have no objections to participating in this research study.	<input type="checkbox"/>

F.5 Phase Four: Baseline PwP Questionnaire



Participant ID				
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STEADY TOGETHER

Questionnaire One: For completion by the Person with Parkinson's.

Please answer as many questions as possible: there are no right or wrong answers!

Section 1: About You

Please circle one answer for each question

1 **Are you male or female?**

Male	Female
------	--------

2 **What is your age?**

--

3 **What is your employment status?**

Full- time employment	Part-time employment	Retired
Other (please state).....		

4 **Where do you live?**

Own home	Rest home	Nursing home
----------	-----------	-----------------

5 **Do you live alone?**

Yes	No
-----	----

If no, what is the relationship of the person who lives with you?

Spouse/ partner	Children of yourself/ your partner	Other
--------------------	---	-------

If other, please describe their relationship to you

--

1

Participant ID				
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6 **Do you have any difficulty reading a newspaper with glasses?**

No Difficulty	Some Difficulty	Extreme Difficulty
---------------	-----------------	--------------------

Section 2: About your Parkinson's

1 **Do you have Parkinson's?**

Yes	No
-----	----

2 **In what year were you diagnosed with Parkinson's?**

If you cannot remember, please estimate

--

3 **Do you see a specialist doctor or nurse for your Parkinson's?**

Yes	No
-----	----

Section 3: Your memory

1 **Have you been given a diagnosis of cognitive impairment or dementia?**

Cognitive impairment	Dementia	Neither of these
----------------------	----------	------------------

2 **Have you discussed your memory with your family or friends?**

Yes	No
-----	----

If yes, do your family or friends have any concerns about your memory?

--

If yes, Is your specialist nurse or doctor aware of these problems?

Yes	No	N/A
-----	----	-----

Participant ID				
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Section 4: Your mobility

1 **Do you use a walking aid?**

Always	Sometimes	No
--------	-----------	----

If so, what walking aid?
Please circle all that apply

Mobility scooter	Wheelchair	Walking Frame/rollator
Walking Stick	Other.....	

Section 5: Falls

1 **Do you ever feel unsteady?**

Yes	No
-----	----

2 **How often do you usually feel unsteady?**

Daily	Weekly	Monthly
Occasionally	N/A	

3 **Have you ever fallen?**

Yes	No
-----	----

If no, please go to question 9 on the next page

If yes, when did you last fall?
If you cannot remember, please estimate

--

4 **Have you fallen in the last year?**

Yes	No
-----	----

5 **How often do you usually fall?**

Daily	Weekly	Monthly
Occasionally	N/A	

Participant ID				
----------------	--	--	--	--

6 **Have you ever had a fall where you have been admitted to hospital**

Yes	No	N/A
-----	----	-----

If yes, please explain what happened the last time

--

7 **Have you informed your specialist at the hospital about your falls?**

Yes	No
-----	----

8 **Have you informed your Parkinson's Nurse specialist about your falls?**

Yes	No
-----	----

We are also interested in any *near-misses* you might have had over the last year, when you thought you were about to fall but you did not actually fall.

9 **Have you had near-misses?**

Yes	No
-----	----

If yes, How often do you usually have near misses?

Daily	Weekly	Monthly
Occasionally		

Participant ID				
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We are also interested in how concerned you are about falling.

Please tick the box thinking about how you normally feel when you do the activity.

If you do not normally do the activity, please reply how you think you would feel *if* you were to perform the activity.

	Not at all concerned	Somewhat concerned	Fairly concerned	Very concerned
Getting dressed or undressed				
Taking a bath or shower				
Getting in or out of a chair				
Going up or down stairs				
Reaching for something above your head or on the ground				
Walking up or down a slope				
Going out to a social event				

How confident are you that you can keep your falls from interfering with the things that you want to do?

(Please circle the number that corresponds to your current level of confidence)

Not at all confident 1 2 3 4 5 6 7 8 9 10 Totally confident

Section 6: How your Parkinson's affects your life

We would like to know how Parkinson's affects your day-to-day life.

Please **tick the box** that you feel most applies to you.

Due to having Parkinson's disease, how often during the last month have you...

	Never	Occasionally	Sometimes	Often	Always or cannot do at all
1. Had difficulty getting around in public?	<input type="checkbox"/>				
2. Had difficulty dressing yourself?	<input type="checkbox"/>				
3. Felt depressed?	<input type="checkbox"/>				
4. Had problems with your close personal relationships?	<input type="checkbox"/>				
5. Had problems with your concentration, e.g. when reading or watching TV?	<input type="checkbox"/>				
6. Felt unable to communicate with people properly?	<input type="checkbox"/>				
7. Had painful muscle cramps or spasms?	<input type="checkbox"/>				
8. Felt embarrassed in public due to having Parkinson's disease?	<input type="checkbox"/>				

Participant ID				
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Section 7: Further information

Please let us know who completed this form
(Circle the answer)

Person with Parkinson's	Relative/ friend	Both
-------------------------	------------------	------

Thank you for completing this questionnaire

**Please return the questionnaire alongside questionnaire two
and the consent forms in the pre-paid envelope provided**

F.6 Phase Four: Baseline Caregiver Questionnaire



Participant ID				
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STEADY TOGETHER

Questionnaire Two: For Completion by a Relative or a Close Friend of a Person with Parkinson's

For completion by a relative or close friend of the person with Parkinson's

Please answer as many questions as possible: there are no right or wrong answers!

Section 1: About You

1 **Are you male or female?**

Male	Female
------	--------

2 **What is your age?**

--

3 **What is your employment status?**

Full-time employment	Part-time employment	Retired
Other (please state).....		

4 **Do you live with the person with Parkinson's?**

Yes	No
-----	----

5 **What is your relationship to the person with Parkinson's**

Spouse/partner	Child/step-child	Other
----------------	------------------	-------

If other, please describe their relationship to you

--

6 **Do you have any difficulty reading a newspaper with glasses?**

No Difficulty	Some Difficulty	Extreme Difficulty
---------------	-----------------	--------------------

Steady Together. Questionnaire Two: For Completion by a relative or a close friend of a person with Parkinson's.
 Study IRAS reference 221022
 Version 2 dated 06.11.2017

Participant ID				
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Section 2: How Parkinson's has affected you

We are interested to know how you have been affected by having someone close to you affected by Parkinson's.

Please circle the answer that you think most applies to how you feel.

DO YOU FEEL.....

1 That because of the time you spend with your relative/ close friend that you don't have enough time for yourself?

Never	Rarely	Sometimes	Quite Frequently	Nearly always
-------	--------	-----------	------------------	---------------

2 Stressed between caring for your relative/ close friend and trying to meet other responsibilities (work/ family)?

Never	Rarely	Sometimes	Quite Frequently	Nearly always
-------	--------	-----------	------------------	---------------

3 Angry when you are around your relative?

Never	Rarely	Sometimes	Quite Frequently	Nearly always
-------	--------	-----------	------------------	---------------

4 That your relative/ close friend currently affects your relationship with family members or friends in a negative way?

Never	Rarely	Sometimes	Quite Frequently	Nearly always
-------	--------	-----------	------------------	---------------

5 Strained when you are around your relative/ close friend?

Never	Rarely	Sometimes	Quite Frequently	Nearly always
-------	--------	-----------	------------------	---------------

6 That your health has suffered because of your involvement with your relative/ close friend?

Never	Rarely	Sometimes	Quite Frequently	Nearly always
-------	--------	-----------	------------------	---------------

7 That you don't have as much privacy as you would like because you are caring for your relative/ close friend?

Never	Rarely	Sometimes	Quite Frequently	Nearly always
-------	--------	-----------	------------------	---------------

Participant ID				
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8 **That your social life has suffered because you are caring for your relative/ close friend?**

Never	Rarely	Sometimes	Quite Frequently	Nearly always
-------	--------	-----------	------------------	---------------

9 **That you have lost control of your life since your relative/ close friend's illness?**

Never	Rarely	Sometimes	Quite Frequently	Nearly always
-------	--------	-----------	------------------	---------------

10 **Uncertain about what to do about your relative/ close friend?**

Never	Rarely	Sometimes	Quite Frequently	Nearly always
-------	--------	-----------	------------------	---------------

11 **You should be doing more for your relative/ close friend?**

Never	Rarely	Sometimes	Quite Frequently	Nearly always
-------	--------	-----------	------------------	---------------

12 **You could do a better job in caring for your relative/ close friend?**

Never	Rarely	Sometimes	Quite Frequently	Nearly always
-------	--------	-----------	------------------	---------------

Section 3: How Parkinson's and falling affects you

How confident are you that you can keep your close friend/ relative's falling from interfering with the things that you want to do?

(Please circle the number that corresponds to your current level of confidence)

Not at all confident 1 2 3 4 5 6 7 8 9 10 Totally confident

Thank you for completing this questionnaire

Please return the questionnaire alongside questionnaire one and the consent forms in the pre-paid envelope provided.

F.7 Phase Four: Follow up PwP Questionnaire

Participant ID				
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STEADY TOGETHER

Follow up Questionnaire One for Completion by People with Parkinson's

Please answer as many questions as possible: there are no right or wrong answers!

Section 1: Falls

1 **Do you ever feel unsteady?**

Yes	No
-----	----

2 **How often do you feel unsteady?**

Daily	Weekly	Monthly
Occasionally	N/A	

3 **Have you ever fallen?**

Yes	No
-----	----

***If no*, please go to question 7 on the next page**

4 ***If yes*, how many times have you fallen in the last 3 months, since you have had the falls guide**

Please estimate if you are not sure

--

5 **Have you informed your specialist doctor about your falls?**

Yes	No
-----	----

6 **Have you informed your Parkinson's Nurse specialist about your falls?**

Yes	No
-----	----

Participant ID				
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We are also interested in any *near-misses* you might have had over the last 3 months, when you thought you were about to fall but you did not actually fall.

7 Have you had near-misses?

Yes	No
-----	----

If yes, How often have you had near misses?

Daily	Weekly	Monthly
Occasionally		

We are also interested in how concerned you are about falling.

Please **tick the box** thinking about how you normally feel when you do the activity.

If you do not normally do the activity, please reply how you think you would feel *if* you were to perform the activity.

	Not at all concerned	Somewhat concerned	Fairly concerned	Very concerned
Getting dressed or undressed				
Taking a bath or shower				
Getting in or out of a chair				
Going up or down stairs				
Reaching for something above your head or on the ground				
Walking up or down a slope				
Going out to a social event				

--	--	--	--

How confident are you that you can keep your falls from interfering with the things that you want to do?

(Please circle the number that corresponds to your current level of confidence)

Not at all confident 1 2 3 4 5 6 7 8 9 10 Totally confident

Section 2: How your Parkinson's affects your life

We would like to know how Parkinson's affects your day-to-day life.

Please **tick the box** that you feel most applies to you.

Due to having Parkinson's disease, how often during the last month have you...

	Never	Occasionally	Sometimes	Often	Always or cannot do at all
1. Had difficulty getting around in public?	<input type="checkbox"/>				
2. Had difficulty dressing yourself?	<input type="checkbox"/>				
3. Felt depressed?	<input type="checkbox"/>				
4. Had problems with your close personal relationships?	<input type="checkbox"/>				
5. Had problems with your concentration, e.g. when reading or watching TV?	<input type="checkbox"/>				
6. Felt unable to communicate with people properly?	<input type="checkbox"/>				
7. Had painful muscle cramps or spasms?	<input type="checkbox"/>				
8. Felt embarrassed in public due to having Parkinson's disease?	<input type="checkbox"/>				

3



Participant ID				
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Section 3: Further information

Please let us know who completed this form
(Circle the answer)

Person with Parkinson's	Relative/ friend	Both
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Thank you for completing this questionnaire

Please return the questionnaire alongside questionnaires two and three in the pre-paid envelope provided

F.8 Phase Four: Follow up Caregiver Questionnaire

Participant ID				
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STEADY TOGETHER

Follow up Questionnaire Two for Completion by a Relative or Close Friend of a Person with Parkinson's

This form is to be completed by the relative or close friend of the person with Parkinson's. We are interested to know how you have been affected by having someone close to you affected by Parkinson's.

Please answer as many questions as possible: there are no right or wrong answers!

Please **circle the answer** that you think most applies to how you feel.

DO YOU FEEL.....

- 1 **That because of the time you spend with your relative/ close friend that you don't have enough time for yourself?**

Never	Rarely	Sometimes	Quite Frequently	Nearly always
-------	--------	-----------	------------------	---------------

- 2 **Stressed between caring for your relative/ close friend and trying to meet other responsibilities (work/ family)?**

Never	Rarely	Sometimes	Quite Frequently	Nearly always
-------	--------	-----------	------------------	---------------

- 3 **Angry when you are around your relative/ close friend?**

Never	Rarely	Sometimes	Quite Frequently	Nearly always
-------	--------	-----------	------------------	---------------

- 4 **That your relative/ close friend currently affects your relationship with family members or friends in a negative way?**

Never	Rarely	Sometimes	Quite Frequently	Nearly always
-------	--------	-----------	------------------	---------------

- 5 **Strained when you are around your relative/ close friend?**

Never	Rarely	Sometimes	Quite Frequently	Nearly always
-------	--------	-----------	------------------	---------------

- 6 **That your health has suffered because of your involvement with your relative/ close friend?**

Never	Rarely	Sometimes	Quite Frequently	Nearly always
-------	--------	-----------	------------------	---------------

1

Steady Together. Follow-up Questionnaire Two for Completion by a Relative or Close Friend of a Person with Parkinson's.
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Participant ID				
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- 7 **That you don't have as much privacy as you would like because you are caring for your relative/ close friend?**
- | | | | | |
|-------|--------|-----------|------------------|---------------|
| Never | Rarely | Sometimes | Quite Frequently | Nearly always |
|-------|--------|-----------|------------------|---------------|
- 8 **That your social life has suffered because you are caring for your relative/ close friend?**
- | | | | | |
|-------|--------|-----------|------------------|---------------|
| Never | Rarely | Sometimes | Quite Frequently | Nearly always |
|-------|--------|-----------|------------------|---------------|
- 9 **That you have lost control of your life since your relative/ close friend's illness?**
- | | | | | |
|-------|--------|-----------|------------------|---------------|
| Never | Rarely | Sometimes | Quite Frequently | Nearly always |
|-------|--------|-----------|------------------|---------------|
- 10 **Uncertain about what to do about your relative/ close friend?**
- | | | | | |
|-------|--------|-----------|------------------|---------------|
| Never | Rarely | Sometimes | Quite Frequently | Nearly always |
|-------|--------|-----------|------------------|---------------|
- 11 **You should be doing more for your relative/ close friend?**
- | | | | | |
|-------|--------|-----------|------------------|---------------|
| Never | Rarely | Sometimes | Quite Frequently | Nearly always |
|-------|--------|-----------|------------------|---------------|
- 12 **You could do a better job in caring for your relative/ close friend?**
- | | | | | |
|-------|--------|-----------|------------------|---------------|
| Never | Rarely | Sometimes | Quite Frequently | Nearly always |
|-------|--------|-----------|------------------|---------------|

Section 2: How Parkinson's and falling affects you

- 1 **How confident are you that you can keep your close friend/ relative's falling from interfering with the things that you want to do?**

(Please circle the number that corresponds to your current level of confidence)

Not at all confident 1 2 3 4 5 6 7 8 9 10 Totally confident

Thank you for completing this questionnaire.

Please post the questionnaire back to us alongside follow up questionnaires one and three in the prepaid envelope provided

Steady Together. Follow-up Questionnaire Two for Completion by a Relative or Close Friend of a Person with Parkinson's.
Study IRAS reference 221022
Version 2 dated 06.11.2017

F.9 Phase Four: Feedback questionnaire for PwP and Caregivers

Participant ID				
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STEADY TOGETHER

Follow up Questionnaire three: Feedback questionnaire

For completion by both People with Parkinson's and those close to them

We would like to know how you feel about the guide. Please answer as many questions as possible: there are no right or wrong answers!

We want to hear about your open and honest feedback.

1 Did you find the content useful?

Please circle your answer

Not at all	Not really	Undecided	Somewhat	Very Much
------------	------------	-----------	----------	-----------

What was the most useful part and why?

What was the least useful part and why?

2 Did the guide increase your knowledge about unsteadiness and falling in Parkinson's?

Please circle your answer

Not at all	Not really	Undecided	Somewhat	Very Much
------------	------------	-----------	----------	-----------

Please explain

Participant ID				
----------------	--	--	--	--

3 Do you think that there is information that that we have missed out and should be included in the guide?

Please circle your answer

No	Undecided	Yes
----	-----------	-----

Please explain

4 How did you find the way in which the information was presented?

Please circle your answer

Very Poor	Poor	Not sure	Good	Very Good
-----------	------	----------	------	-----------

Please Explain

5 Did you use the guide?

Please Circle your answer

Never	Rarely	Once in a while	Sometimes	Most days
-------	--------	-----------------	-----------	-----------

Please Explain

Participant ID				
----------------	--	--	--	--

6 If you used the guide, who used the guide?

Please Circle your answer

Person with Parkinson's	Friend/ relative	Both	Didn't use the guide
-------------------------	------------------	------	----------------------

Please Explain

7 Did you complete the unsteadiness and falls diary in the guide (section 2)?

Please Circle your answer

Never	Sometimes	Whenever I felt unsteady or I fell
-------	-----------	------------------------------------

Please Explain

8 Did you complete the personal action plan in the guide (section 4)?

Please circle your answer

Never	Rarely	Once in a while	Sometimes	Most days
-------	--------	-----------------	-----------	-----------

Please Explain

Participant ID				
----------------	--	--	--	--

9 Was the guide easy or difficult to use?

Please circle your answer

Very difficult	Somewhat difficult	Neither difficult or easy	Somewhat easy	Very easy
----------------	--------------------	---------------------------	---------------	-----------

Please Explain

10 Did you feel confident in applying the information to your daily routine?

Please circle your answer

Not at all	Not much	Undecided	Somewhat	Very much
------------	----------	-----------	----------	-----------

Please Explain

11 Do you feel that the guide has altered any of the concerns you have about unsteadiness and falling?

Please circle your answer

Not at all	Not really	Undecided	Somewhat	Very Much
------------	------------	-----------	----------	-----------

Please Explain

Participant ID				
----------------	--	--	--	--

12 Do you feel that this guide has altered your ability to manage your unsteadiness and falling?

Please Circle your answer

Not at all	Not really	Undecided	Somewhat	Very much
------------	------------	-----------	----------	-----------

Please Explain

13 Did the guide worry or concern you in any way?

Please circle your answer

Not at all	Not really	Undecided	Somewhat	Very much
------------	------------	-----------	----------	-----------

Is there anything that we could do to reassure you?

14 How likely is it that you would continue to use the guide in future?

Please circle your answer

Very unlikely	Unlikely	Undecided	Likely	Very likely
---------------	----------	-----------	--------	-------------

Please Explain

Participant ID				
----------------	--	--	--	--

15 Did you find the telephone calls useful?

Please circle your answer

Not at all	Not really	Undecided	Somewhat	Very much
------------	------------	-----------	----------	-----------

Please Explain

--

16 Please let us know who has completed this questionnaire.

Person with Parkinson's	Relative/ friend	Both
-------------------------	------------------	------

Thank you for completing this questionnaire.

Please return it alongside questionnaires one and two in the prepaid envelope provided.

F.10 Phase Four: Schedule for Semi-structured Interviews with PwP and Caregivers

Thank you very much for taking part in this study. My name is Charlotte Owen and I am a research doctor in medicine for older people at the University of Southampton. The purpose of this study is to design and introduce a guide to help people with Parkinson's who fall, and the people who help to care for them at home. We would like to find out if the guide that we have produced meets the aims that we have set out to address.

The interview is informal and completely confidential. There are no right or wrong answers; we are interested to hear about your views and experiences. Only my colleagues and I will listen to anything that is said, and your name will not appear in anything that we write.

With your permission I would like to record this interview with an audio recorder. This is so that I can concentrate on what you are telling me rather than writing notes. After this interview, I will transfer the information on the tape onto a password protected computer, which will be kept in a secure office in our research department. Anything that you say will be anonymised.

Thank you for completing the questionnaires. This interview is a little bit different. This is more of a chance for you to tell me in detail, in your own words how you found the booklet we sent/gave you.

1. What do you think about the guide?

Probes and Prompts
Can you tell me about any parts that <ul style="list-style-type: none">- Were Useful- Were relevant for you- You found new or different to things you've read/heard before?- You liked
Can you tell me about any parts that <ul style="list-style-type: none">- Were not useful- Were not relevant for you- Didn't seem new or different to things you've read/heard before- You disliked

2. Can you tell me about whether you used the guide?

Probes and prompts
<p>How often did you use it?</p> <p>Can you tell me about whether it was something that you both used, or one of you used?</p> <p>Can you tell me about what led you to use it?</p> <p>Can you tell me about anything that stopped you from using the guide?</p>

3. Can you tell me about any falls since you have had the guide?

4. Can you tell me about anything that you have learnt whilst using the guide?

Probes and prompts
<p>Do you feel the guide has altered your knowledge of Parkinson’s and falling? Can you give me any examples of this?</p> <p>Have you been able to put any suggestions into practice? Can you give me any examples of this?</p>

5. Can you tell me about any ways, if any, in which the guide has affected your management of falls?

Probes and prompts
<p>Can you describe how, if at all, this has affected your confidence in doing day to day things (e.g. things around the house, getting out and about)?</p>

--

6. Can you describe any ways in which the guide changed your thoughts or feelings about falls?

Probes and prompts
Can you explain any positive changes as a result of the guide?
Can you explain any negative changes as a result of the guide?

7. Can you explain how, if at all, the guide has affected your interaction with healthcare professionals?

Probes and prompts
Can you describe how, if at all, the guide has altered your discussions with healthcare professionals about falling?
Can you tell me about any healthcare professionals that you may have now spoken to about falls as a result of the guide?

8. Can you tell me about anything that concerned or worried you about the guide?

Probes and prompts
Can you describe who, if anybody, you discussed these concerns with?
Is there anything that could reassure you?

9. How likely is it that you will continue to use the guide?

Probes
Can you describe why you might/ might not continue to use the guide?
<u>If would not use:</u> can you describe anything that might lead you to use the guide?

10. Can you tell me about whether you think the guide would be useful for other people with Parkinson’s?

Probes and prompts
Who do you think that the guide would be most useful for?
Who do you think that the guide would be least useful for?

11. Can you tell me about any suggestions that you might have to improve the guide?

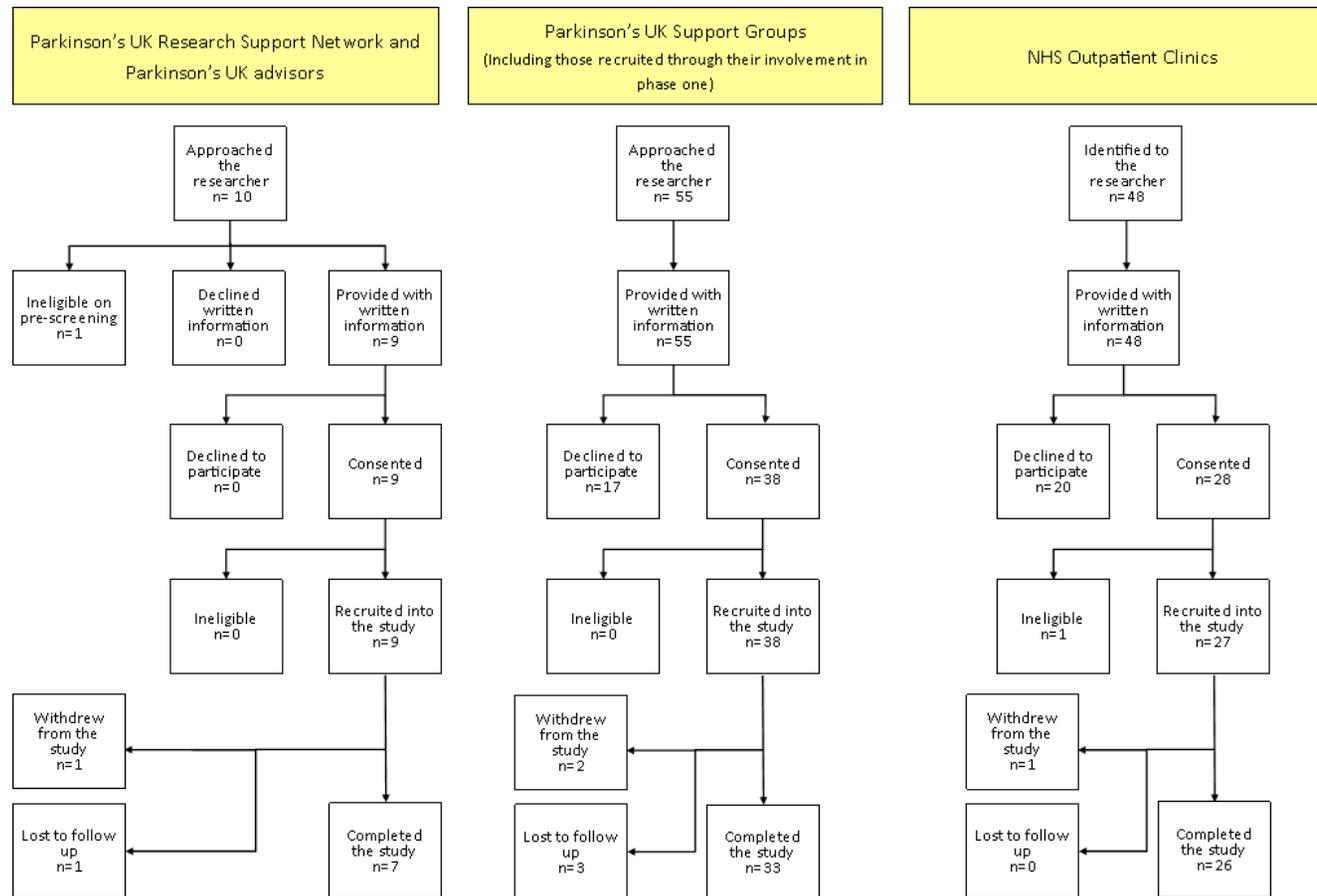
Probes and prompts
Can you tell me about anything that you might include within the guide?
Can you tell me about anything that you might take out of the guide?
Can you tell me how you feel about the length of the guide?
Can you tell me about how you found the guide to read and to navigate?

12. Can you tell me about how you found the telephone calls that you received whilst you had access to the guide?

Probes and prompts
Can you explain how, if at all, the telephone calls affected
<ul style="list-style-type: none">- Your use of the guide?- How you manage falls?

Thank you for taking part in this interview

F.11 Phase Four: Flow Diagram Depicting the Outcome of Participants Approached, Consented and Recruited into the Study



F.12 Feedback about the Guide and the Telephone calls by PwP Baseline Characteristics

Feedback Item	Value	PwP Baseline Characteristics								
		Gender	Recruited from NHS (Y/N)	Recruited alone (Y/N)	CI/ dementia (Y/N)	Age	Years since diagnosis	Baseline FES-I*	PDQ-8-SI*	SI Falls SE question*
Found content Useful (Responses graded 1-5; higher score reflects more useful)	Participants (n)	67	67	67	67	67	65	67	66	66
	Median values (Participants (n))	M=4 (43)	Yes=4 (26)	Yes=4 (14)	Yes=4 (11)	-	-	-	-	-
		F=4 (24)	No=4 (41)	No=4 (53)	No=4 (56)	-	-	-	-	-
	Test Statistic	u= 418.5	u=508.0	u=356.5	u=290.5	rho= 0.18	rho= -0.19	rho= -0.13	rho= -0.23	rho= 0.04
	P Value	0.14	0.71	0.80	0.73	0.14	0.13	0.30	0.06	0.78
Effect size	-0.18	-0.05	-0.03	-0.04	N/A	N/A	N/A	N/A	N/A	
Improved Knowledge (Responses graded 1-5; higher score reflects greater knowledge gained)	Participants (n)	67	67	67	67	67	65	67	66	66
	Median values (Participants (n))	M=4 (43)	Yes=4 (26)	Yes=3.5 (14)	Yes=3 (11)	-	-	-	-	-
		F=4 (24)	No=4 (41)	No=4 (53)	No=4 (56)	-	-	-	-	-
	Test Statistic	u=405	u=392.5	u=299.5	u=253.5	rho=0.06	rho=-0.26	rho=-0.05	rho=-0.24	rho=-0.14
	P Value	0.13	0.06	0.24	0.33	0.65	0.04	0.70	0.05	0.27
Effect size	-0.19	-0.23	-0.14	-0.12	N/A	N/A	N/A	N/A	N/A	
Presentation (Responses graded 1-5; higher score reflects greater perception of presentation)	Participants (n)	66	66	66	66	66	64	66	65	65
	Median values (Participants (n))	M=4 (42)	Yes=4 (25)	Yes=4 (14)	Yes=4 (11)	-	-	-	-	-
		F=4 (24)	No=4 (41)	No=4 (52)	No=4 (55)	-	-	-	-	-
	Test Statistic	u=464	u=473.5	u=339.5	u=296.5	rho=0.22	rho=-0.13	rho=0.10	rho=-0.127	rho=-0.10
	P value	0.51	0.52	0.63	0.90	0.07	0.33	0.42	0.31	0.42
Effect size	-0.08	-0.08	-0.06	-0.02	N/A	N/A	N/A	N/A	N/A	
Use of guide (Responses graded 1-5; higher score reflects greater use)	Participants (n)	66	66	66	66	66	64	66	65	65
	Median values (Participants (n))	M=3 (42)	Yes=4 (25)	Yes=3 (14)	Yes=3 (11)	-	-	-	-	-
		F=4 (24)	No=4 (41)	No=4 (52)	No=4 (55)	-	-	-	-	-
	Test Statistic	u=394.5	u=393.0	u=280.5	u=251	rho=0.01	rho=-0.13	rho=0.15	rho=-0.10	rho=-0.10
	P value	0.11	0.09	0.16	0.34	0.92	0.32	0.25	0.43	0.41
Effect size	-0.19	-0.21	-0.17	-0.17	N/A	N/A	N/A	N/A	N/A	

Feedback Item	Value	PwP Baseline Characteristics								
		Gender	Recruited from NHS (Y/N)	Recruited alone (Y/N)	CI/ dementia (Y/N)	Age	Years since diagnosis	Baseline FES-I*	PDQ-8-SI*	SI Falls SE question*
Complete AP (Responses graded 1-5; higher score reflects greater completion)	Participants (n)	65	65	65	65	65	63	65	64	64
	Median values (Participants (n))	M=3 (41)	Yes=3 (25)	Yes=2 (13)	Yes=2 (11)	-	-	-	-	-
		F=3 (24)	No=2 (40)	No=3 (52)	No=3 (54)	-	-	-	-	-
	Test Statistic	u=427.5	u=376.5	u=181.5	u=222	rho=0.10	rho=-0.10	rho=-0.07	rho=-0.13	rho=0.03
	P value	0.37	0.09	0.01	0.18	0.44	0.43	0.95	0.29	0.84
Effect size (r)	-0.11	-0.21	-0.33	-0.17	N/A	N/A	N/A	N/A	N/A	
Easy/ Difficult to use (Responses graded 1-5; higher score reflects greater ease of use)	Participants (n)	65	65	65	65	65	63	65	64	64
	Median values (Participants (n))	M=4 (41)	Yes=4 (25)	Yes=4 (14)	Yes=3 (11)	-	-	-	-	-
		F=4 (24)	No=4 (40)	No=4 (51)	No=4 (54)	-	-	-	-	-
	Test Statistic	u=468	u=489.0	u=343	u=212	rho=0.16	rho=-0.08	rho=-0.06	rho=-0.15	rho=0.10
	P value	0.73	0.88	0.81	0.12	0.20	0.53	0.65	0.25	0.43
Effect size	-0.04	-0.02	-0.03	-0.20	N/A	N/A	N/A	N/A	N/A	
Confident applying information (Responses graded 1-5; higher score reflects greater confidence)	Participants (n)	63	63	63	63	63	61	63	62	62
	Median values (Participants (n))	M=4 (40)	Yes=4 (25)	Yes=4	Yes=4 (10)	-	-	-	-	-
		F=4 (23)	No=4 (38)	No=4	No=4 (53)	-	-	-	-	-
	Test Statistic	u=360.5	u=396.0	u=275.5	u=236.5	rho=-0.04	rho=-0.07	rho=0.00	rho=-0.11	rho=0.05
	P value	0.13	0.23	0.37	0.57	0.75	0.61	1.00	0.39	0.72
Effect size	-0.19	-0.15	-0.11	-0.07	N/A	N/A	N/A	N/A	N/A	
Altered Concerns of falls (Responses graded 1-5; higher score reflects greater alteration)	Participants (n)	66	66	66	66	66	64	66	65	65
	Median values (Participants (n))	M=3 (42)	Yes=4 (26)	Yes=3	Yes=2 (11)	-	-	-	-	-
		F=2.5 (24)	No=2 (40)	No=2	No=3 (55)	-	-	-	-	-
	Test Statistic	u=480.5	u=341.0	u=346.5	u=207	rho=-0.18	rho=0.02	rho=0.22	rho=0.06	rho=-0.24
	P value	0.74	0.01	0.77	0.09	0.15	0.88	0.07	0.63	0.05
Effect size	-0.04	-0.30	-0.04	-0.21	N/A	N/A	N/A	N/A	N/A	

Appendix F: Phase Four Appendices

Feedback Item	Value	PwP Baseline Characteristics								
		Gender	Recruited from NHS (Y/N)	Recruited alone (Y/N)	CI/ dementia (Y/N)	Age	Years since diagnosis	Baseline FES-I*	PDQ-8-SI*	SI Falls SE question*
Altered ability to manage falls (Responses graded 1-5; higher score reflects greater ability)	Participants (n)	63	63	63	63	63	61	63	62	62
	Median values (Participants (n))	M=3 (40)	Yes=4 (25)	Yes=3	Yes=3 (9)	-	-	-	-	-
		F=4 (23)	No=3.5 (38)	No=4	No=4 (54)	-	-	-	-	-
	Test Statistic	u=344.5	u=407.5	u=265.5	u=167.5	rho=-0.09	rho=-0.11	rho=0.11	rho=-0.11	rho=-0.16
	P value	0.09	0.32	0.29	0.12	0.48	0.39	0.38	0.41	0.20
Effect size	-0.22	-0.13	-0.13	-0.20	N/A	N/A	N/A	N/A	N/A	
Concerns about guide (Responses graded 1-5; higher score reflects greater concerns)	Participants (n)	64	64	64	64	64	62	64	63	63
	Median values (Participants (n))	M=1 (41)	Yes=1 (25)	Yes=1 (13)	Yes=1.5 (10)	-	-	-	-	-
		F=1 (23)	No=1 (39)	No=1 (51)	No=1 (54)	-	-	-	-	-
	Test Statistic	u=427.5	u=448.5	u=319.5	u=230.5	rho=-0.12	rho=-0.14	rho=-0.12	rho=-0.11	rho=0.07
	P value	0.49	0.54	0.82	0.40	0.36	0.28	0.33	0.38	0.59
Effect size	-0.09	-0.08	-0.03	-0.10	N/A	N/A	N/A	N/A	N/A	
Continued use (Responses graded 1-5; higher score reflects more likely to use)	Participants (n)	64	64	64	64	64	62	64	63	63
	Median values (Participants (n))	M=3 (41)	Yes=4 (25)	Yes=4 (13)	Yes=3.5 (10)	-	-	-	-	-
		F=4 (23)	No=4 (39)	No=4 (51)	No=4 (54)	-	-	-	-	-
	Test Statistic	u=373.5	u=466.0	u=326.5	u=222.5	rho=0.05	rho=-0.20	rho=-0.01	rho=-0.22	rho=-0.03
	P value	0.15	0.76	0.93	0.36	0.69	0.11	0.97	0.08	0.80
Effect size	-0.18	-0.04	-0.01	-0.11	N/A	N/A	N/A	N/A	N/A	
Telephone calls useful (Responses graded 1-5; higher score reflects more useful)	Participants (n)	65	65	65	65	65	63	65	64	64
	Median values (Participants (n))	M=4 (42)	Yes=4 (25)	Yes=3 (13)	Yes=4	-	-	-	-	-
		F=4 (23)	No=3 (40)	No=4 (52)	No=4	-	-	-	-	-
	Test Statistic	u=352.5	u=338.0	u=284	u=291.5	rho=0.06	rho=-0.05	rho=0.04	rho=-0.06	rho=-0.12
	P value	0.05	0.02	0.34	0.92	0.66	0.68	0.73	0.65	0.35
Effect size	-0.24	-0.29	-0.12	-0.01	N/A	N/A	N/A	N/A	N/A	

Feedback Item	Value	PwP Baseline Characteristics								
		Gender	Recruited from NHS (Y/N)	Recruited alone (Y/N)	CI/ dementia (Y/N)	Age	Years since diagnosis	Baseline FES-I*	PDQ-8-SI*	SI Falls SE question*
Information missed out of the guide (Binary outcome: no coded as 0; yes coded as 1)	Participants (n)	63	63	63	63	63	61	63	62	62
	Information missing (n/total n) (%)	M=5/23 (23%)	Yes=10/38 (26%)	Yes=4/12 (33%)	Yes=1/11 (9%)	-	-	-	-	-
		F=8/40 (22%)	No=3/25 (12%)	No=9/51 (18%)	No=12/52 (23%)	-	-	-	-	-
	Test Statistic	Fisher's Exact Test	$\chi^2=1.11$	Fisher's Exact Test	Fisher's Exact Test	Exp (B)= 0.91	Exp (B)= 0.99	Exp (B)= 1.01	Exp (B)= 1.03	Exp (B)= 1.02
	95% CI	-	-	-	-	0.83-1.01	0.90-1.09	0.90-1.15	1.00-1.07	0.78-1.33
	P value	1.00	0.29	0.25	0.43	0.08	0.81	0.81	0.07	0.89
	Effect size	0.02	-0.17	-0.15	-0.12	N/A	N/A	N/A	N/A	N/A
Use of the log (Binary outcome: no coded as 0; yes coded as 1)	Participants (n)	66	66	66	66	66	64	66	65	65
	Used the log (n/total n) (%)	M=32/43 (75%)	Yes=22/26 (85%)	Yes=7/13 (54%)	Yes=6/11 (55%)	-	-	-	-	-
		F=20/23 (87%)	No=30/40 (75%)	No=45/53 (85%)	No=46/55 (84%)	-	-	-	-	-
	Test Statistic	Fisher's Exact Test	$\chi^2=0.39$	Fisher's Exact Test	Fisher's Exact Test	Exp (B)= 0.97	Exp (B)= 1.06	Exp (B)= 1.15	Exp (B)= 1.01	Exp (B)= 1.07
	95% CI	-	-	-	-	0.89-1.05	0.95-1.18	0.97-1.28	0.98-1.05	0.83-1.39
	P value	0.35	0.53	0.02	0.05	0.43	0.31	0.12	0.53	0.59
	Effect size	-0.15	0.12	0.30	0.27	N/A	N/A	N/A	N/A	N/A

Abbreviations: CI= Confidence Interval; Exp (B)= Exponentiation of the B coefficient (logistic regression): odds ratio; F=female, FES-I = Short form Falls Efficacy Scale international; M=male; n-number; PDQ-8-SI= Parkinson's disease questionnaire 8 single item; PwP= person with Parkinson's; rho= Spearman's rank correlation; SI falls SE question=single item falls self-efficacy question U= Mann-Whitney U value; χ^2 = chi squared statistic.

*FES-I: higher scores reflect greater fear of falling; PDQ-8-SI: higher scores reflect reduced health-related quality of life; SI falls self-efficacy question: higher scores reflect increased self-efficacy for the management of falls

F.13 Feedback about the Guide and the Telephone Calls by Caregiver Baseline Characteristics

Feedback Item	Value	Caregiver baseline characteristics		
		Age	Baseline ZBI*	SI Falls efficacy*
Found content Useful (Responses graded 1-5; higher score reflects more useful)	Participants (n)	54	53	54
	Test Statistic	rho=0.22	rho=-0.31	rho=0.21
	P Value	0.12	0.03	0.13
Improved Knowledge (Responses graded 1-5; higher score reflects greater knowledge gained)	Participants (n)	54	53	54
	Test Statistic	rho=0.19	rho=-0.22	rho=0.09
	P Value	0.16	0.12	0.52
Presentation (Responses graded 1-5; higher score reflects greater perception of presentation)	Participants (n)	53	52	53
	Test Statistic	rho=0.12	rho=0.01	rho=-0.98
	P value	0.41	0.92	0.49
Use of guide (Responses graded 1-5; higher score reflects greater use)	Participants (n)	53	52	53
	Test Statistic	rho=0.22	rho=-0.16	rho=-0.05
	P value	0.41	0.25	0.74
Complete AP (Responses graded 1-5; higher score reflects greater completion)	Participants (n)	53	52	53
	Test Statistic	rho=0.34	rho=-0.30	rho=0.13
	P value	0.01	0.03	0.35
Easy/ Difficult to use (Responses graded 1-5; higher score reflects greater ease of use)	Participants (n)	52	51	52
	Test Statistic	rho=0.02	rho=-0.21	rho=0.20
	P value	0.90	0.15	0.16
Confident applying information (Responses graded 1-5; higher score reflects greater confidence)	Participants (n)	51	50	51
	Test Statistic	rho=0.26	rho=-0.17	rho=0.16
	P value	0.07	0.24	0.27
Altered Concerns of falls (Responses graded 1-5; higher score reflects greater alteration)	Participants (n)	53	52	53
	Test Statistic	rho=0.19	rho=-0.26	rho=0.23
	P value	0.18	0.06	0.10
Altered ability to manage falls (Responses graded 1-5; higher score reflects greater ability)	Participants (n)	51	51	51
	Test Statistic	rho=0.23	rho=-0.09	rho=0.06
	P value	0.11	0.52	0.69
Concerns about guide (Responses graded 1-5; higher score reflects greater concerns)	Participants (n)	52	52	52
	Test Statistic	rho=-0.02	rho=-0.01	rho=-0.07
	P value	0.87	0.93	0.65
Continued use (Responses graded 1-5; higher score reflects more likely to use)	Participants (n)	52	52	52
	Test Statistic	rho=0.30	rho=-0.34	rho=0.21
	P value	0.03	0.01	0.13
Telephone calls useful (Responses graded 1-5; higher score reflects more useful)	Participants (n)	53	52	53
	Test Statistic	rho=0.26	rho=-0.02	rho=-0.03
	P value	0.06	0.88	0.85

Feedback Item	Value	Caregiver baseline characteristics		
		Age	Baseline ZBI*	SI Falls efficacy*
Information missed out of the guide (Binary outcome: no coded as 0; yes coded as 1)	Participants (n)	51	50	51
	Test Statistic	Exp (B)= 0.98	Exp (B)= 1.01	Exp (B)= 1.06
	95% CI	0.92- 1.05	0.94-1.08	0.84-1.34
	P value	0.52	0.82	0.65
Use of the log (Binary outcome: no coded as 0; yes coded as 1)	Participants (n)	54	53	54
	Test Statistic	Exp (B)= 0.96	Exp (B)= 1.00	Exp (B)= 0.86
	95% CI	0.88-1.06	0.92-1.10	0.61-1.21
	P value	0.42	0.95	0.38

Abbreviations: CI= Confidence Interval; Exp (B)= Exponentiation of the B coefficient (logistic regression); n=number; rho= Spearman’s rank correlation coefficient; SI falls self-efficacy question= single item falls self-efficacy question; U= Mann-Whitney U value; ZBI= Zarit Burden interview short version; χ^2 = chi squared statistic

*ZBI: higher scores reflect greater caregiver burden; SI falls self-efficacy question: higher scores reflect increased self-efficacy for the management of falls

F.14 Feedback about the Guide by PwP Fall-related Symptoms at Baseline and During the Study

Prior Feedback Item	Value	Baseline symptom frequency									Characteristics whilst had the guide	
		Ever fallen (Yes/No)	Fallen in the last year (Yes/No)	Near misses at baseline (Yes/No)	Fall Frequency		Near miss frequency		Unsteady frequency		Fall whilst had access to the guide (Yes/No)	Near misses whilst had the guide (Yes/No)
Found content Useful (Responses graded 1-5; higher score reflects more useful)	Participants (n)	67	67	67	51		59		38		65	66
	Median values (Participants in group (n))	Yes=4 (56)	Yes=4 (53)	Yes=4 (60)	Daily/ weekly	4 (10)	Daily/ weekly	4 (24)	Daily/ weekly	4 (27)	Yes=4 (45)	Yes=4 (59)
		No=4 (11)	No=4 (14)	No=4 (7)	Monthly/ occasionally	4 (41)	Monthly/ occasionally	4 (35)	Monthly/ occasionally	4 (11)	No=4 (20)	No=4 (7)
	Test Statistic	u=247	u=307	u=153	u=192.0		u=348.5		u=142.0		u=388	u=202.5
	P Value	0.24	0.26	0.18	0.72		0.20		0.80		0.32	0.92
	Effect Size	-0.15	-0.14	-0.16	-0.05		-0.17		-0.04		-0.12	-0.01
Improved Knowledge (Responses graded 1-5; higher score reflects greater knowledge gained)	Participants (n)	67	67	67	51		59		38		65	66
	Median values/ Participants citing Yes (n)	Yes=4 (56)	Yes=4 (53)	Yes=4 (60)	Daily/ weekly	3.5 (10)	Daily/ weekly	4 (24)	Daily/ weekly	4 (27)	Y=4 (45)	Y=4 (59)
		No=4 (11)	No=4 (14)	No=4 (7)	Monthly/ occasionally	4 (41)	Monthly/ occasionally	4 (35)	Monthly/ occasionally	4 (11)	N=4 (20)	N=4 (7)
	Test Statistic	u=231	u=302.5	u=103	u=198.5		u=371.0		u=140.0		u=443.5	u=199
	P Value	0.17	0.26	0.02	0.87		0.42		0.77		0.92	0.87
	Effect Size	-0.17	-0.14	-0.28	-0.02		-0.10		-0.05		-0.01	-0.02
Presentation (Responses graded 1-5; higher score reflects greater perception of presentation)	Participants (n)	66	66	66	50		58		38		64	65
	Median values/ Participants citing Yes (n)	Yes=4 (55)	Yes=4 (52)	Yes=4 (59)	Daily/ weekly	4 (10)	Daily/ weekly	4 (24)	Daily/ weekly	4 (27)	Yes=4 (44)	Yes=4 (58)
		No=4 (11)	No=4 (14)	No=4 (7)	Monthly/ occasionally	4 (40)	Monthly/ occasionally	4 (34)	Monthly/ occasionally	4 (11)	No=4 (20)	No=4 (7)
	Test Statistic	u=296.5	u=335.0	u=191.5	u=164.5		u=390.5		u=141.0		u=324.0	u=188.5
	P value	0.90	0.57	0.70	0.29		0.73		0.75		0.04	0.71
	Effect Size	-0.02	-0.07	-0.05	-0.15		-0.05		-0.19		-0.26	-0.05

Appendix F: Phase Four Appendices

Feedback Item	Value	Baseline symptom frequency									Characteristics whilst had the guide	
		Ever fallen (Yes/No)	Fallen in the last year (Yes/No)	Near misses at baseline (Yes/No)	Fall Frequency		Near miss frequency		Unsteady frequency		Fall whilst had access to the guide (Yes/No)	Near misses whilst had the guide (Yes/No)
Use of guide (Responses graded 1-5; higher score reflects greater use)	Participants (n)	66	66	66	50		58		38		64	65
	Median values (Participants in group (n))	Yes=4 (54)	Yes=4 (52)	Yes=4 (59)	Daily/ weekly	3 (10)	Daily/ weekly	4 (24)	Daily/ weekly	4 (27)	Yes=4 (44)	Yes=4 (57)
		No=3 (11)	No=3 (14)	No=4 (7)	Monthly/ occasionally	4 (40)	Monthly/ occasionally	4 (34)	Monthly/ occasionally	4 (11)	No=3 (20)	No=4 (7)
	Test Statistic	u=265	u=319.5	u=182	u=165.0		u=367.0		u=116.5		u=310.5	u=162
	P value	0.49	0.45	0.58	0.35		0.49		0.25		0.04	0.35
	Effect Size	-0.09	-0.09	-0.07	-0.13		-0.09		-0.20		-0.25	-0.11
Complete AP (Responses graded 1-5; higher score reflects greater completion)	Participants (n)	65	65	65	49		57		37		63	64
	Median values/ Participants citing Yes (n)	Yes=2.5 (54)	Yes=3 (51)	Yes=3 (58)	Daily/ weekly	2 (9)	Daily/ weekly	2 (22)	Daily/ weekly	2 (26)	Yes=2.5 (44)	Yes=3 (57)
		No=3 (11)	No=3 (14)	No=3 (7)	Monthly/ occasionally	3 (40)	Monthly/ occasionally	3 (35)	Monthly/ occasionally	2 (11)	No=3 (19)	No=2 (7)
	Test Statistic	u=247	u=336.0	u=176.5	u=141.5		u=364.5		u=107.5		u=372.0	u=176.0
	P value	0.37	0.73	0.56	0.30		0.73		0.22		0.48	0.60
	Effect Size	-0.11	-0.04	-0.07	-0.15		-0.05		-0.26		-0.09	-0.07
Easy/ Difficult to use (Responses graded 1-5; higher score reflects greater ease of use)	Participants (n)	65	65	65	49		57		37		63	64
	Median values/ Participants citing Yes (n)	Yes=4 (54)	Yes=4 (51)	Yes=4 (58)	Daily/ weekly	4 (10)	Daily/ weekly	4 (23)	Daily/ weekly	4 (26)	Yes=4 (43)	Yes=4 (57)
		No=4 (11)	No=4 (14)	No=4 (7)	Monthly/ occasionally	4 (39)	Monthly/ occasionally	4 (34)	Monthly/ occasionally	4 (11)	No=4 (20)	No=4 (7)
	Test Statistic	u=281	u=326.5	u=163.5	u=169.0		u=350.0		u=98.0		u=414.5	u=185.0
	P value	0.77	0.61	0.38	0.50		0.48		0.11		0.81	0.77
	Effect Size	-0.04	-0.06	-0.11	-0.10		-0.09		-0.05		-0.03	-0.04

Appendix F: Phase Four Appendices

Feedback Item	Value	Baseline symptom frequency									Characteristics whilst had the guide	
		Ever fallen (Yes/No)	Fallen in the last year (Yes/No)	Near misses at baseline (Yes/No)	Fall Frequency		Near miss frequency		Unsteady frequency		Fall whilst had access to the guide (Yes/No)	Near misses whilst had the guide (Yes/No)
Confident applying information (Responses graded 1-5; higher score reflects greater confidence)	Participants (n)	63	63	63	49		57		36		61	62
	Median values/ Participants citing Yes (n)	Yes=4 (53)	Yes=4 (50)	Yes=4 (57)	Daily/ weekly	3.5 (10)	Daily/ weekly	4 (23)	Daily/ weekly	4 (25)	Yes=4 (42)	Yes=4 (55)
		No=4.5 (11)	No=4 (13)	No=4 (6)	Monthly/ occasionally	4 (39)	Monthly/ occasionally	4 (34)	Monthly/ occasionally	4 (11)	No=4 (19)	No=4 (7)
	Test Statistic	u=179.5	u=241.0	u=164.5	u=147.0		u=387.5		u=129.0		u=299.0	176
	P value	0.08	0.13	0.87	0.20		0.95		0.75		0.09	0.69
	Effect Size	-0.22	-0.19	-0.02	-0.18		-0.01		-0.27		-0.21	-0.05
Altered Concerns of falls (Responses graded 1-5; higher score reflects greater alteration)	Participants (n)	66	66	66	50		58		37		64	65
	Median values/ Participants citing Yes (n)	Yes=3 (55)	Yes=3 (52)	Yes=3 (59)	Daily/ weekly	3 (10)	Daily/ weekly	3 (3)	Daily/ weekly	3.5 (26)	Yes=3 (44)	Yes=3 (58)
		No=2 (11)	No=2 (14)	No=3 (7)	Monthly/ occasionally	3 (40)	Monthly/ occasionally	2 (35)	Monthly/ occasionally	2 (11)	No=2 (20)	No=2 (7)
	Test Statistic	u=267	u=0.272	u=203.5	u=182.5		u=351.0		u=95.5		u=394.5	u=159.5
	P value	0.52	0.13	0.95	0.66		0.39		0.10		0.49	0.34
	Effect Size	-0.08	-0.19	-0.01	-0.06		-0.11		-0.29		-0.09	-0.12
Altered ability to manage falls (Responses graded 1-5; higher score reflects greater ability)	Participants (n)	63	63	63	49		55		34		61	62
	Median values/ Participants citing Yes (n)	Yes=4 (53)	Yes=4 (51)	Yes=4 (56)	Daily/ weekly	4 (10)	Daily/ weekly	4 (23)	Daily/ weekly	4 (25)	Yes=4 (43)	Yes=4 (55)
		No=4 (10)	No=3 (12)	No=4 (7)	Monthly/ occasionally	4 (39)	Monthly/ occasionally	3 (32)	Monthly/ occasionally	2 (9)	No=3 (18)	No=2 (7)
	Test Statistic	u=261	u=271.0	u=185	u=188.0		u=336.0		u=70.0		u=355.5	u=175.5
	P value	0.94	0.52	0.80	0.86		0.57		0.09		0.60	0.69
	Effect Size	-0.01	-0.09	-0.03	-0.03		-0.08		-0.29		-0.07	-0.05

Appendix F: Phase Four Appendices

Feedback Item	Value	Baseline symptom frequency									Characteristics whilst had the guide	
		Ever fallen (Yes/No)	Fallen in the last year (Yes/No)	Near misses at baseline (Yes/No)	Fall Frequency		Near miss frequency		Unsteady frequency		Fall whilst had access to the guide (Yes/No)	Near misses whilst had the guide (Yes/No)
Concerns about guide (Responses graded 1-5; higher score reflects greater concerns)	Participants (n)	64	64	64	49		56		35		62	63
	Median values/ Participants citing Yes (n)	Yes=1 (54)	Yes=1 (51)	Yes=1 (57)	Daily/ weekly	1 (10)	Daily/ weekly	1 (23)	Daily/ weekly	1 (25)	Yes=1 (44)	Yes=1 (56)
		No=2 (10)	No=2 (13)	No=2 (7)	Monthly/ occasionally	1 (39)	Monthly/ occasionally	1 (33)	Monthly/ occasionally	2 (10)	No=1 (18)	No=1 (7)
	Test Statistic	u=215.5	u=245.0	u=149.5	u=180.5		u=334.0		u=94.0		u=376.5	u=188.0
	P value	0.25	0.10	0.22	0.67		0.38		0.20		0.73	0.85
	Effect Size	-0.14	-0.20	-0.15	-0.06		-0.12		-0.22		-0.04	-0.02
Continued use (Responses graded 1-5; higher score reflects more likely to use)	Participants (n)	64	64	64	49		56		35		62	63
	Median values/ Participants citing Yes (n)	Yes=3.5 (54)	Yes=4 (51)	Yes=4 (57)	Daily/ weekly	3.5 (10)	Daily/ weekly	4 (23)	Daily/ weekly	4 (25)	Yes=4 (44)	Yes=4 (56)
		No=4 (10)	No=4 (13)	No=4 (7)	Monthly/ occasionally	3 (39)	Monthly/ occasionally	4 (33)	Monthly/ occasionally	4 (10)	No=4 (18)	No=3 (7)
	Test Statistic	u=183.5	u=261.5	u=163.5	u=178.5		u=340.0		u=105.0		u=365.0	u=188.0
	P value	0.09	0.22	0.42	0.67		0.49		0.44		0.61	0.85
	Effect Size	-0.21	-0.15	-0.10	-0.06		-0.09		-0.13		-0.06	-0.02
Telephone calls useful (Responses graded 1-5; higher score reflects more useful)	Participants (n)	65	65	65	50		57		37		63	64
	Median values/ Participants citing Yes (n)	Yes=4 (54)	Yes=4 (51)	Yes=4 (58)	Daily/ weekly	3.5 (10)	Daily/ weekly	4 (23)	Daily/ weekly	4 (27)	Yes=4 (43)	Yes=4 (57)
		No=4 (11)	No=4 (14)	No=4 (7)	Monthly/ occasionally	4 (40)	Monthly/ occasionally	3.5 (34)	Monthly/ occasionally	4 (10)	No=3 (20)	No=3 (7)
	Test Statistic	u=288.5	u=336.5	u=181.5	u=183.0		u=339.0		u=125.0		u=320.0	u=173.0
	P value	0.87	0.72	0.62	0.663		0.37		0.71		0.08	0.54
	Effect Size	-0.02	-0.04	-0.06	-0.06		-0.12		-0.06		-0.22	-0.08

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Feedback Item	Value	Baseline symptom frequency							Characteristics whilst had the guide			
		Ever fallen (Yes/No)	Fallen in the last year (Yes/No)	Near misses at baseline (Yes/No)	Fall Frequency		Near miss frequency		Unsteady frequency		Fall whilst had access to the guide (Yes/No)	Near misses whilst had the guide (Yes/No)
Information missed out of the guide (Binary outcome)	Participants (n)	63	63	65	48		55		37		61	62
	Information was missing (n/total n) (%)	Yes=13/52 (25%)	Yes=12/49 (25%)	Yes=13/56 (23%)	Daily/ weekly	2/10 (20%)	Daily/ weekly	8/23 (35%)	Daily/ weekly	4/27 (15%)	Y=10/42 (24%)	Y=13/55 (24%)
		No=0/11 (0%)	No=1/14 (7%)	No=0/7 (0%)	Monthly/ occasionally	9/38 (24%)	Monthly/ occasionally	5/32 (16%)	Monthly/ occasionally	1/10 (10%)	N=3/19 (16%)	N=0/7 (0%)
	Test Statistic	Fisher's Exact Test	Fisher's Exact Test	Fisher's Exact Test	Fisher's Exact Test		$\chi^2=2.72$		Fisher's Exact Test		Fisher's Exact Test	Fisher's Exact Test
	P value	0.10	0.27	0.33	1.00		0.18		1.00		0.74	0.33
	Effect Size	Phi=-0.24	Phi=-0.18	Phi=-0.18	Phi=0.04		Phi=-0.22		-0.06		Phi=-0.09	Phi=-0.18
Use of the log (Binary outcome)	Participants (n)	66	66	66	51		58		37		64	65
	Used the log (n/total n) (%)	Yes=45/55 (82%)	Yes= 44/52 (84.6%)	Yes=48/59 (81%)	Daily/ weekly	8/10 (80%)	Daily/ weekly	21/24 (88%)	Daily/ weekly	22/27 (82%)	Yes=37/44 (84%)	Yes=46/58 (79%)
		No=7/11 (64%)	No=8/14 (57.1%)	No=4/7 (57%)	Monthly/ occasionally	35/41 (85%)	Monthly/ occasionally	26/34 (77%)	Monthly/ occasionally	6/10 (60%)	No=13/20 (65%)	No=5/7 (71%)
	Test Statistic	Fisher's Exact Test	Fisher's Exact Test	Fisher's Exact Test	Fisher's Exact Test		Fisher's Exact Test		Fisher's Exact Test		Fisher's Exact Test	Fisher's Exact Test
	P value	0.23	0.06	0.16	0.65		0.33		0.22		0.11	0.64
Effect Size	Phi=-0.17	Phi=-0.28	Phi=-0.18	Phi=0.06		Phi=-0.14		Phi=-0.22		Phi=-0.21	Phi=-0.06	

F.15 Phase Four: Content Analysis of Open-ended Questions from Feedback Questionnaires

Question 1: Did you find the content useful?

Open ended response feedback from 56 participants; 47 participants provided positive feedback, 31 participants provided negative feedback.

7 participants were unsure of the elements of the guide that were more or less useful.

Most or least useful components relate to information not contained within the guide- 2 participants

What was the most useful part and why?

Aggregated code	Number of participants	Contributing codes	Number of participants
Most useful components relating to information within the guide	29	Freezing information	6
		Section 3	6
		Slips and trips	5
		Promotion of physical activity	4
		Turning and reaching	4
		Information about what to do after a fall including how to get up from the floor	4
		How to contact professionals or services	3
		How to prevent falls	1
		Section 1	3
		Promotion of discussion with healthcare professionals	3
		Light-headedness	1
		Multitasking	1
Non-Parkinson's specific aspects of falls	1		
Increased knowledge of Parkinson's and falling, promotion of reflection and adaptation	13	Reflecting on falls and promoting discussion of issues	5
		Increased understanding of the condition	3
		Feeling more in control	2
		Promotion of adaptation of current activities	2
		The guide provided confirmation that doing all that they can	2
		Knowledge that not alone in experiences	1
Feedback about the log and the action plan, which could promote reflection of events	8	Logging falls which promoted reflection of events	4
		Being able to log concerns and falls,	3
		The Action plan is the most useful component	1
Most useful element related to their personal circumstances	7	Most useful element related to symptoms that they experience, to include those that they feel are not under control	7
The guide provided a useful reminder of information	6	The guide is a useful compilation of information that have previously obtained from various sources	3
		The guide provided a reminder	3
The way that	3	Information is provided in small steps and explained well	2

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information and strategies were explained		The guide is informative and easy to understand	1
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What was the least useful part and why?

Aggregated code	Number of participants	Contributing codes	Number of participants
The guide provides little new information, which may be related to the time from diagnosis.	12	The information within the guide perceived as basic or not new to them.	10
		Comments about duration from diagnosis, and how the information was not new because had been diagnosed for some time	2
Least useful component was the falls diary or the action plan	9	Too little space to write	5
		The action plan as nowhere to hang it up	1
		The falls diary	1
		Too much writing required	1
		Remembering to complete diary	1
Least useful component could relate to a lack of symptoms or concerns in that domain, or difficulties implementing the advice	8	Not relevant to them. Do not get those symptoms or have those concerns	5
		Area where information was difficult to implement (lack of HCP contact, problems arising from dementia, difficulty completing blue badge form)	3
Least useful components relating to information within the guide	6	Decluttering information	1
		Guide missing information relevant to them, but not falls-related	1
		Section 1	1
		Information about freezing	1
		Inactivity leads to falls	1
		Information about healthcare professionals	1
		Information about a blue badge	1
Least useful component relates to what the guide aims to achieve	2	Self-reflection requires concentrating on shortcomings	1
		Re-reading the guide	1
The guide is too long			2
No less useful components			13

Question 2: Did the guide increase your knowledge about unsteadiness and falling in Parkinson's?

Open ended response feedback from 57 participants

Aggregated code	Number of participants	Contributing codes	Number of participants
No increased knowledge- nothing new	19	Other literature or experiences have provided them with this knowledge	12
		Already knew information	7
		- [would be more useful for those starting to fall] - [Information is common sense and little use if PwP has dementia]	1] 1]
Increased knowledge relating to a specific item within the guide	15	Relevant remedies	4
		Tips for freezing	2
		Increased knowledge about freezing or stride length has helped mobility	2
		Increased knowledge as to what to do after a fall	2
		Increased knowledge not to multitask	1
		Increased concentration	1
		Overreaching	1
		Increased knowledge about light-headedness	1
		Try not to rush	1
Increased knowledge attributed to enhanced awareness and focus on symptoms	7	Increased knowledge as enhanced awareness of risk or situations associated with risk	3
		Increased knowledge as increased focus on symptoms	2
		Increased knowledge as reflected	1
		Enhanced awareness not enhanced knowledge	1
Open ended response adds no further information	5	Response does not answer the question	4
Increased knowledge arising from the guide providing clarification and acting as a useful reminder	3	Increased knowledge as provided a reminder of information	1
		Increased knowledge as provided clarification	1
		Increased knowledge useful compilation	1
Outcomes	2	Increased knowledge Feel more able to manage	1
		No increased knowledge as guide does not stop falls	1
		Would be more useful to those new to the world of PD	1
Increased knowledge: Information was helpful or new			5
Increase in knowledge. Previous experiences or knowledge discussed, but not discussed how these experiences effected			5
Undecided. Some Helpful Ideas			2
Increased knowledge. The importance of falling emphasised			2
increased knowledge as showed falling normal for PwP. Not alone			2

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Aggregated code	Number of participants	Contributing codes	Number of participants
Increased knowledge: Step by step breakdown of symptoms into component parts with remedies.			1

Q3 Do you think that there is information that we have missed out and should be included in the guide?

Open ended response feedback from 38 participants

Aggregated code	Number of participants	Contributing codes	Number of participants
Missing information on a specific topic	17 (to include the 9 below)	falls can be due to non-PD related complaints	2
		Guide should be more precise	1
		Information non-specific to PD	2
		information related to medications	2
		info that could help researcher	1
		Interaction with non-PD related complaints	1
		Mobility aids	1
		More details about navigating outside of the home environment	1
Above, plus detailed that relevant to experiences/ their circumstances. Related to previously learnt information or is an ongoing unmet need	9	Advice on posture	2
		Information not specific to falls	2
		Information about getting out of a chair	2
		Additional signposting for support. Non-HCP	1
		importance of resting	1
		More details about freezing	1
Adaptations to the falls diary or the action plan suggested	3	More space to write	2
		More detailed diary	1
No additional information from open ended question	20	No missing information aware of	13
		Response does not answer the question and is not related to feedback about the guide	4
		More useful for those newer to falling in PD	2
		Guide replicates information obtained from elsewhere	1

Question 4: How did you find the way that the information was presented?

Aggregated code	Number of participants	Contributing codes	Number of participants
Feedback about the language used within the guide	21	Positive as clear language and comprehension	11
		Good as easy to understand	9
		Unsure as felt long winded	2
		Good as step by step	1
Feedback about the format and layout of the guide	18	Positive about layout including the use of colour and sections	15
		Positive of size and format	2
		Positive of font	1
		Positive. Comment on some people not liking speech balloons	1
Feedback about the content used within the guide	15	Good as Concise	4
		Found information a bit vague. Wanted more guidance	2
		Positive response. Commented about heterogeneity of target audience or inclusivity of information	2
		Rated as 'good', but felt guide was repetitive at times	1
		Missing information about other aspects of PD aside from falls	1
		Positive about applications for attendance allowance and carers allowance	1
		Positive about information content to include getting up after a fall	1
		Section on freezing helpful as relevant to them	1
		Section for close friends and family interrupts the flow	1
Open ended response provides no additional information	6	No additional information on top of that provided in Likert question	5
		Comment does not relate to additional feedback about the guide	1
Positive of the interactive components within the guide	3	Liked the inclusion of a falls diary and an AP	2
		Positive as thought provoking	1

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Question 5: Did you use the guide?

Open ended response feedback from 49 participants

Aggregated code	Number of participants	Contributing codes	Number of participants
Comments about how often they used it or how they used it	22	Used the guide triggered by a new problem or when needed support	9
		Used the guide: read initially then used less	9
		Did not use. PwP did not engage	1
		Didn't use the guide. Has own strategies	1
		Read daily but may not have always implemented the information	1
		Used the guide because requires daily reminders	1
		Used twice a week	1
		Used the guide: Dipped in and out	1
		Used the guide: Helped to keep a complementary daily diary	1
Guide was perceived to have little new information, or the information was deemed not relevant.	14	Didn't use the guide. Little new information	6
		Didn't use the guide. No falls or deemed not relevant	2
		Didn't use the guide. Would be more useful in the future	2
		Didn't use. Carer wanted more definitive advice	1
		Used but many of PwP not addressed within the guide- non-falls problems	1
		Used the guide but less so because of reduced symptom frequency	1
		Used the Guide. Little new information	1
Practical constraints to using the guide, which could reduce use of the guide	8	Used the guide but less so due to limitations in time or not practical at the time that fell	4
		Didn't use the guide. Time constraints	2
		Reduced use because PwP in care home or in hospital for part of the study	2
Which components of the guide that they used	7	Used the guide. Used the interactive components, which could be perceived as helpful	7
		Used the guide. Signposting information	1
Used the guide because relevant to symptoms			1
Open ended response provides no further information			1

Question 6: If you used the guide, who used the guide?

Open ended response feedback received from 39 participants

Aggregated code	Number of ppt	Contributing codes	Number of ppt
Why used the guide or outcomes obtained from using the guide	15	Used for reference or information sources	3
		Both used. Read together and discussed together	3
		Both used to remedy situations	2
		Both used as a reminder	2
		PwP used to record events and concerns	2
		Both used but nothing new learnt	1
		Caregiver used for tips	1
		PwP but nothing new	1
		PwP used. Information on avoiding falls helpful	1
One party drove the process	11	Caregiver used as PwP had difficulty comprehending information	3
		Both used. Caregiver drove process	2
		Caregiver used as PwP felt not needed or distressed when discussed	2
		Both used but mainly PwP	1
		Both used. Caregiver used to support helping PwP	1
		PwP used but then discussed with the caregiver	1
		PwP used. CG did not have time as works 4 days a week	1
Prompts	3	Both used. Triggered by a new event	2
		Both used when had Telephone calls	1
No additional information from open ended question			7
Both used. Friends also looked at it			1
Both used. Cannot recall the information			1
PwP used but caregiver will use in future			1
Answered PwP used the guide but explanation says CG also used the guide			1

Question 7: Did you complete the unsteadiness and falls diary in the guide (section 2)?

Open ended response feedback received from 47 participants

Aggregated code	Number of participants	Contributing codes	Number of participants
Difficulties using the log within the guide	12	Log not completed at all or just sometimes as symptoms too frequent	3
		Used the log but could forget to complete it or have insufficient time to complete it	3
		Insufficient room within the guide	2
		Completed log but could have difficulty remembering what had occurred	1
		Difficulties writing	1
		Didn't use the log as did not notice it within the guide	1
		Sometimes completed the log. Described themselves as lazy	1
		Didn't complete the log due to lack of time	1
Deemed not relevant or necessary	11	Didn't use the log as no falls	5
		Didn't use the log or reduced use of the log as already problem-solves cause of symptoms	3
		Reduced use of the log as fall-related symptoms infrequent	2
		Already kept a log	1
		Didn't use the guide but would consider future use	1
		Log not completed as not of immediate relevance	1
Why used the log	5	PwP completed the log as a reminder of risks	2
		Used log as an aide memoire for telephone calls	1
		Used log to support discussions with HCPs	1
		Used the log to keep track of symptoms	1
		Used the log to try to identify a pattern or to promote problem-solving	1
How used the log	4	Made own log as insufficient room within the guide	2
		Completed log on iPad due to difficulty writing	1
		Log was completed by the PwP and not the caregiver	1
What using the log led to	3	Used the log but stopped as repetitive and didn't gain anything falls	2
		Completed log but didn't take to doctor as already knows about	1
Open ended response provides no further information	15	No additional info from open ended question	10
		Both completed the log. Unsteady most of the time	2
		response does not provide feedback about the guide	1
		Sometimes completed a log. Completing a log for another study that is participating in	1

Question 8: Did you use the personal action plan in the guide (section 4)

Open ended response feedback received from 33 participants

Aggregated code	Number of participants	Contributing codes	Number of participants
Barriers to using the action plan, which could lead to reduced use or disuse	18	Already knew actions to implement	4
		Didn't complete action plan. Lack of time or forgot about it	3
		Completed action plan but could forget	2
		Cannot recall the action plan	2
		Completed the action plan but reported writing difficulties-	1
		Didn't complete action plan as writing difficulties	1
		Didn't complete. Deemed unnecessary	1
		PwP not engaged	1
		Used the action plan but confusion between log and action plan	1
		Used once in a while: perceived low severity of symptoms	1
		Would have been more useful previously. PwP now lacks comprehensive abilities	1
		Why used/ why would use/ outcomes	11
Action plan used as an aid to communicate with others about difficulties	1		
Action plan used to give focus	1		
Action plan would be more useful in the future	1		
Rarely used but would consider using to aid discussions with healthcare professionals	1		
Used the action plan and found it helpful	1		
Used action plan to document concerns	1		
How participants used the action plan	6	Used in combination with diary	2
		Used the action plan to write some ideas	2
		Completed action plan on iPad due to writing difficulties	1
		Used the action plan in combination with section 3	1
Used in conjunction with diary, felt that would be more useful to correlate with a daily diary as opposed to solely about unsteadiness and falls			1
Has lost the guide			1
No additional information from open ended response	6	Completed it when felt was needed. Used once in a while	1
		No additional information from open ended question	5

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Question 9: was the guide easy or difficult to use?

Open ended response feedback received from 32 participants

Aggregated code	Number of participants	Contributing codes	Number of participants
Layout/ language	21	Rated as easy to use because easy to read and to understand	13
		Rated as easy to use. Positive of layout of the guide and use of sections	9
		Rated as easy to use. Positive of paper format	2
		Rated as easy but felt was too long	1
Difficulties implementing information	2	Neither difficult no easy: could not apply information due to PwP dementia	1
		Rated as easy but difficulties remembering content	1
Barriers to using the guide	6	Rated as easy to use but raised issues with writing in the guide	2
		Rated as difficult as caused frustration between PwP and caregiver	1
		Neither difficult nor easy: difficulty working out what was wanted	1
		Rated as easy but forgot about it	1
		Rated as difficult because not relevant to their situation	1
Content and its effect on them	3	Rated as easy to use as made feel not alone with the symptoms	1
		Positive of ideas within the guide of how to overcome problems	1
		Neither difficult nor easy: feels would be better to separate information for PwP and caregivers to allow more in-depth information for caregivers	1
No additional information from open ended response			6

Question 10: Did you feel confident in applying the information to your daily routine

Open ended response feedback from 29 participants

Aggregated code	Number of participants	Contributing codes	Number of participants
Comments about how the information was not new or relevant to them	11	Confident but not all the information was new to them	4
		Not confident or undecided: information not new	2
		Confident but some information not relevant to them	2
		Not confident: stated action plans do not help (did not use the action plan)	1
		Not confident: do not have a regular routine	1
		Undecided: Did not apply information as would take a crisis to read up on something	1
Rated as confident applying the information and described why	7	Confident as information was useful	2
		Confident as have learnt to slow down and concentrate	2
		Confident arising from enhanced awareness	1
		Confident, tried to change posture	1
		Confident applying some of the suggestions within section 3	1
		Confident in some of the 'basic points' e.g. decluttering as advice is clear	1
		Confident as easy to apply information about freezing strategies	1
Barriers to applying the information	5	Not confident: time constraints to applying information or interventions take priority	2
		Not confident: PwP had difficulty comprehending the information	2
		Somewhat confident: Difficulties remembering strategies	1
No additional information from open ended response	4	Unable to recall if tried implementing information or didn't try implementing	2
		Open ended question provided no additional information	1
Comments about how the information was implemented	2	Confident in combination with physiotherapy. Guide provided confirmation of physiotherapy plan	1
		Describe no difficulties implementing strategy into practice	1
		Neither difficult nor easy. Raised problem with distraction	1
Suggested changes that would enhance their confidence in applying information: Felt confident. But a more detailed diary would have helped			1

Question 11: Do you feel that the guide has altered any of the concerns that you have about unsteadiness and falling?

Open ended response feedback from 36 participants

Aggregated code	Number of participants	Contributing codes	Number of participants
Knowledge and its effect on their concerns	8	No altered concerns as no or little new information	5
		Altered concerns arising from increased awareness of ways to prevent falls	1
		Altered concerns arising from increased knowledge of postural hypotension	1
		Caregiver concerns reduced as more able to support PwP with their symptoms arising from increased knowledge	1
Management of falls and its effect on their concerns	8	Altered concerns as increased focus on falls or more aware when mobilising	3
		Altered concerns through enhanced concentration and taking more care	3
		Altered concerns as have implemented some solutions	1
		Altered concerns through taking strategic steps to the management of falls	1
Enhanced awareness of falling	3	No alteration in concerns, response states that they now have an enhanced awareness of falls	3
Natural history of PD and falling	4	No Altered concerns. Feels these non-modifiable	2
		Altered concerns as realised that they are not alone in their experiences	2
		Altered concerns as guide highlighted falls are preventable	1
Describe ongoing concerns of falls	4	Describe ongoing concerns of falls	3
		Some improvement but concerns remain	1
Report no concerns of falls at present	4	No alteration on concerns: have no concerns related to falls	4
		No concerns of falls: feels guide may help in the future	1
No alteration in concerns as guide not used	1	Concerns not altered as guide not used	1
No additional information from open ended response	6	No additional information from open ended question	5
		Concerns altered but describe non-Steady Together changes	1

Question 12: Do you feel that this guide has altered your ability to manage your unsteadiness and falling?

Open ended response feedback from 33 participants

Aggregated code	Number of participants	Contributing codes	Number of participants
Knowledge of symptoms or focus on falls, and its effect on ability to manage	13	Increased ability to manage arising from heightened awareness of problems/ situation	5
		Increased ability to manage arising from increased knowledge and info within the guide	3
		No altered ability to manage as little new information provided	2
		No increased ability as when PwP has symptoms he does not implement the strategies	1
		No altered ability to manage but enhanced knowledge	1
		No increased ability to manage but enhanced reflection of symptoms	1
		Unsure if altered ability to manage. The guide reminded them of things that had forgotten	1
Describe ability of performing practical skills and how this effects their ability to manage	9	Increased ability through implementing freezing strategies or positive of these	2
		Increased ability to manage arising from increased care, concentration and slowing down	2
		No altered ability as difficulty processing the information and putting it into practice	1
		Increased ability arising through preventative strategies implemented	1
		Increased ability in getting up from the floor	1
Guide deemed not relevant, with most of these participants stating the guide did not alter their ability to manage	8	No altered ability to manage: no perceived difficulties to alter	2
		Increased ability to manage. High frequency of symptoms meant the guide did not make a big difference	1
		No altered ability to manage as has not yet fallen	1
		No altered ability to manage but felt would have been more helpful many years ago	1
		No altered ability to manage as reduced engagement of PwP with the guide	1
		No altered ability to manage as unsure why falls	1
		No altered ability to manage arising from deterioration in cognition	1
Response describes how their perceived increased ability to manage has arisen from, or led to positive outcomes	2	Increased ability to manage arising from enhanced control over symptoms	1
		Increased ability to manage associated with reduced fall frequency	1
No additional information from open ended response			3

Question 13: Did the guide worry or concern you in any way?

Feedback from open ended question from 17 participants

Aggregated code	Number of participants	Contributing codes	Number of participants
Concerns raised within the response	2	Problem solving caused distress	2
No concerns raised within the response	2	No worries but took a while to get motivated to read it	1
		No concerns as already aware of what future could hold	1
No Increased data from open ended response			13

Question 14: How likely is it that you would continue to use the guide in the future?

Feedback from open ended question from 17 participants

Aggregated code	Number of participants	Contributing codes	Number of participants
Guide provided participants with a reminder, and how this effected the likelihood of ongoing use	12	Will continue to use the guide as a reminder	10
		Will dip in and out of the guide or would consider this approach	2
		Unlikely to use the guide, if did would be as a memory jogger	1
		Undecided re ongoing use: would consider referring to the guide as a reminder	1
Response describes how would use or why would use in the future. Ongoing use often driven by positive experiences of using the guide during the study	10	Will continue to use as found it helpful	5
		Likely to use the guide because deems avoidance of falling more important due to osteoporosis	1
		Will continue to use as has an enhanced awareness of falling from the guide	1
		will continue to use as found problem-solving helpful	1
		Will continue to use to promote problem solving and discussion of potential problems	1
		Will continue to use to show to others	1
Unlikely to continue to use the guide as not relevant to them	5	Unlikely to use the guide as other sources of information are available, or the guide provided them with little new information	2
		Unlikely to use the guide as has read the information and learnt from it. Deemed unnecessary to read again	1
		Unlikely to use the guide. No perceived problems at present	1
		Unlikely to use the guide. PwP now going to a nursing home	1
Ongoing use of the guide would be triggered by	6	Would or would consider use if symptoms increased or changed	5
		Unlikely to use the guide, but would consider if deteriorated	1
Response describes difficulties using the guide or a dislike of it, often leading to reduced ongoing use	4	Unlikely to use the guide as it needs more explicit information for the caregiver	1
		Unlikely to use the guide unless it changed format (no further details provided)	1
		Undecided if would continue to use the guide: can forget to document within the guide	1
		Will continue to use the guide: Will try to find time	1
Open ended response adds no further information			4

Question 15: Did you find the telephone calls useful

Open ended response feedback from 34 participants

Aggregated code	Number of participants	Contributing codes	Number of participants
Telephone calls provided a reminder	13	As a reminder to look at the guide	11
		As a reminder, other circumstances during the study limited involvement with the study	1
		As a reminder to implement strategies	1
Telephone calls primarily viewed as a research tool rather than a support tool	9	Telephone calls not useful. Would have liked scheduled Telephone calls so could prepare	3
		Phone calls triggered anxiety or participant found questions difficult	2
		Telephone calls instilled guilt that not using the intervention as designed (direction of guilt not stated unclear if guilt toward the researcher or the PwP)	2
		Caregiver liked Telephone calls through ability to explain why not able to use intervention as designed	1
		PwP liked Telephone calls as felt was helping with research process	1
Telephone calls were helpful and supportive	4	Telephone calls allowed them to feel supported	3
		Telephone calls were helpful	2
		Telephone calls were more helpful at the start	1
		Telephone calls supportive	1
		Undecided: felt not contributing to the research	1
Liked discussion within the telephone calls	4	Telephone calls provided clarification of points did not understand, and an opportunity to ask questions	3
		PwP would have liked to discuss other elements of PD aside from falls	1
No additional information from open ended response	3	No additional information from open ended response	2
		In hospital due to a fall so did not receive all Telephone calls	1
Telephone calls not useful. Management plan of how to manage already discussed within dyad before Telephone calls			1
Unable to recall Telephone calls			1

F.16 Phase Four: Coding Manual for Semi-structured Interviews

Theme	Subthemes	Contributing information	Information presented elsewhere	
<i>Over-arching theme: Engagement with the guide: Enablers and Barriers</i>				
Perceptions of the content of the guide	Topics within the guide and their perceived relevance	Perceptions of the information that was useful, which related to their current symptoms and circumstances	Why quotations are useful discussed within 'conversation starter'	
		Guide provides a useful compilation of information		
		Guide requires expansion with more information		
		Participants may feel that the guide requires more information in areas that are very specific to their needs		
		The guide may benefit from being split into two, with separate information for caregivers and PwP		
	Factors influencing use and non-use of interactive components	May need greater explanation of why some components of the guide could provide benefit	Guilt when had not used elements of the guide, perceiving that they were only for the benefit for the research with no perceived benefit for themselves.	
		Barriers to completion of the falls diary		
		Barriers to completion of the action plan: perceived laziness, writing deemed unnecessary, inability to identify strategies to help		
	How the intervention embeds into current healthcare provision	Discussion of successful support received from other HCPs		
		The guide may be best delivered alongside support from other HCPs going forwards		
		Some participants wanted the option of being able to discuss their difficulties further (although not required during the study)		
	Perceptions about how the information was presented	Perceptions of the paper-based format and suggested changes	Views about the format of delivery: paper versus other possible formats e.g. electronic	
			Information on paper was useful- utilised more than some other mediums of information might be	
Difficulties with a paper format to include not to hand/ misplaced. These situations could be emergencies/ when abroad/ when they had lost the guide.				
Views about the language used within the guide				

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Theme	Subthemes	Contributing information	Information presented elsewhere
		Views surrounding the use of diagrams and colour	
	Perceptions of the layout and suggested changes	Views about the layout of the guide and ease of use	
		Perceptions that the log and the action plan required further development: space to write too small and completing separately	Adaptations that participants made to the log to aid problem-solving, and description of problem-solving and its success/ unsuccessful outcome discussed within 'A facilitator to increase understanding of symptoms'.
		Reading the guide cover to cover so don't miss relevant information versus dipping in and out of the guide	
		The guide could be considered to contain unnecessary repetition in those who read it cover to cover	
		Rearranging the order of the guide to place the log and the action plan next to one another may lead to greater engagement with these components	
Participants' personal and clinical characteristics	Perceived relevance of the guide related to time from PD diagnosis and the presence of CI/ dementia	Amount of information that want about PD relates to the duration that they have been diagnosed	
		Guide may be more useful for those earlier to diagnosis and less suitable if have had the condition for longer	
		Guide may be more useful for those whose symptoms are more frequent than theirs, these PwP may have been diagnosed for longer	
		Those with CI/ dementia may benefit less from the guide	
	Engagement of the guide related to participants perception of falls	A few participants could appear dismissive of their symptoms, or appear to normalise them, which could lead to reduced relevance of the guide and subsequently their engagement	
		Reported previous denial of symptoms; participants discussing how the guide would have been less relevant to them at this time	
		Attribution of symptoms to non-PD and how this effected engagement with the guide	
		Perceiving falls as unpreventable, and its effect on engagement with the guide	
		Discussion of other PD and non-PD related concerns and how these effected engagement with the guide. Includes	

Theme	Subthemes	Contributing information	Information presented elsewhere	
		discussions about medications, fatigue, PD progression and searching for a cure.		
		Some participants perceived that their greatest concern was not falls and how these effected engagement with the guide		
	A drive for a greater understanding of unsteadiness and falls	Motivated to use the guide hoping that it would provide greater understanding of symptoms and how to manage them.		
		Motivated to use the guide hoping that it would provide them with reassurance that they were managing things correctly		
		Comparison of relevance of the guide to each of caregivers and PwP: participants' perceptions. Caregivers may require more comprehensive information.	Guide may benefit from separation into two: different information requirements and flow within the guide.	
		Engagement with other research projects and perceived relevance of the guide		
		Previous employment role or knowledge helping caregiver in their role to support the PwP.		
	Personality traits and communication preferences	An optimistic or analytical mindset may favour engagement with the guide		
		Those who do not favour a problem-solving approach may wish for more explicit advice about how to manage falls		
		Telephone calls triggering anxiety as contact was unscheduled and need to think on feet		
		Difficulties with the lack of non-verbal communication during the telephone calls, which was not specific to the study		
	Existing self-management practices could affect the perceived relevance of the guide		Practical and behavioural strategies to manage falling developed before the study and how this related to perceived relevance of the guide	
			Describing information seeking behaviour before the study and perceived relevance of the guide arising from this	
Problem-solving behaviour displayed prior to the study and perceived relevance of the guide arising from this				

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Theme	Subthemes	Contributing information	Information presented elsewhere
Triggers during the study period: symptoms, prompts and time constraints		New or deteriorating symptoms or concern triggered use of the guide, or would trigger use of the guide in the future	
		HCP review and new symptoms prompted use of the guide	
		Use of the guide to provide a calming influence, reassurance that managing correctly or increased awareness of strategies to manage falls, when in the setting of new symptoms or concerns	
		Telephone calls as an aide memoire to use the guide	Telephone calls triggering reflection on symptoms and prompting initiation of management strategies
		Perceived use of the guide if the intervention did not have telephone calls as a component	
		Difficulties with time to include current or ongoing use, to include time undertaking current caregiving responsibilities	
Being a good participant		Driven to use the guide because said that would take part in the research study	
		Guilt to use the intervention as designed	
		Perception that a reduced frequency of symptoms made them less relevant to the research process	
		Reading up on the guide before the telephone call as unsure what to say	
		Participant would prefer a scheduled telephone call as they felt unprepared for the telephone calls	
<i>Over-arching theme: Impact of the Intervention</i>			
The guide: a source of support and a conversation starter	The guide as a source of social support	Guide allowed for participant to feel that they were not alone. A source of social support	
		Quotations may allow for participants to see how others have overcome difficulties	
	The guide as a facilitator to communication within the dyad	Guide leading to increased caregiver presence or support, or to reminding PwP of strategies to implement	
		Implementation of strategies by other family members	
		One party was often the driving force behind use of elements of the guide or changes to instigate	

Theme	Subthemes	Contributing information	Information presented elsewhere
		One half of the dyad encouraging their spouse to use the guide	
		Guide as a conversation starter to discussions about falls within the dyad and with friends and family	
		Increased awareness of falls and falls-related concerns amongst caregivers arising from discussions within the dyad	
		Guide providing professional backup of viewpoints	
		Enhanced communication between dyads could lead to frustration	
	The guide as a facilitator to communication between the dyad and HCPs	Limited planned contact with HCPs during the study	
		Guide as a facilitator to discussions with HCPs	
		Describing difficulties with communication with HCPs, leading participants to deem signposting to HCPs irrelevant, or that more details were required to navigate the healthcare system	
The guide: effect on knowledge of symptoms and problem-solving practices		Effect of the guide on participant's knowledge of falls in PD	
		Information that was considered new to participants showed considerable variation	
		Participants citing most benefit from the information amongst participants who were diagnosed more recently	
		Those diagnosed with PD for longer may view that the guide contains little or no new information	
		Log or guide as a facilitator to understand or problem solve cause or pattern of symptoms	Uncertainty as to the aims of the log and the action plan presented within views about the intervention
		Views surrounding whether the process of writing helped	
		Adaptations participants made to the log to aid problem-solving	Writing difficulties presented with views about the intervention
		Participants could use the log as a simple record that falls had occurred with no analytical thought processes taking place	
		Difficulties encountered when trying to attribute a cause to symptoms when using the log	
		Deeming writing unnecessary	

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Theme	Subthemes	Contributing information	Information presented elsewhere
Intervention as a facilitator to implement change	Telephone calls as a driver to instigate change	Telephone calls triggering reflection and enhancing focus on the strategies to implement	Difficulties encountered with the telephone calls
		Telephone calls rarely effected participant's management of their symptoms	
	Adopting a more strategic and proactive approach	Management strategies implemented to manage their symptoms. Rarely did participants state that they had made no changes during the study	
		Strategies implemented showed wide variation in line with their heterogeneous personal circumstances	
		Implementation of strategies following a problem-solving approach	
		Implementation of strategies following information read within the guide	
		Guide emphasising why a strategy is important, leading to them making greater effort to implement something that they had already been trying to do	
		Developing a proactive as opposed to a reactive approach	
		Use of the falls diary and completion of the action plan to facilitate the implementation of management strategies	
Effect on Physical and Psychological Outcomes	Effect on fall rate and physical symptoms associated with falls	Fewer falls experienced during the intervention	
		Effect of the guide on symptoms associated with unsteadiness	
		Effect of the guide on the ability to get up from the floor	
		Effect of the guide on views of seeking HCP support when the PwP is unable to get up from the floor on their own	
		Ongoing use of the guide was driven by the benefits obtained from using it. Driven to use the guide as content is beneficial.	
		Ongoing symptoms associated with falls	
	Confidence in managing falls-related symptoms	Effect of the guide on confidence of managing falls	
		Increased confidence could arise from enhanced knowledge of falls management	
		Increased confidence arising from increased ability to manage symptoms	

Theme	Subthemes	Contributing information	Information presented elsewhere
		Increased confidence arising from reassurance that managing falls correctly, versus feeling helpless that doing all that they can	
		Views surrounding the way that falls risk was presented as adaptable	
		Views surrounding control of their symptoms	
	A more positive outlook versus ongoing concerns of falls and their consequences	Effect of the guide on fear of falls, which could relate to their understanding of their symptoms and strategies that they had instigated	
		Ongoing concerns of the PwP being on their own	
		A positive outlook following use of the intervention	
		Guide had a calming influence	
		Effect of the guide on injury concerns	
Difficulties encountered when attempting to implement changes to manage fall risk		Inability to overcome non-modifiable changes in the environment, which could reduce physical activity	
		Those with CI/ dementia are less able to implement changes	
		Difficulties recalling strategies in those without CI/ dementia	
		Failure to accept limitations, leading to non-acknowledgement of fall risk and reduced implementation of fall risk	
		Wanting to maintain current level of independence	
		Difficulties changing behaviour	
		Concerns of how perceived by others	
		Adaptations to management strategies following initial failure	

F.17 Phase Four: Overview of Summary of Findings from the Telephone Calls

Finding	Contributing information	Information presented elsewhere	Data Source
Key finding one: The guide as a facilitator to enhanced focus and understanding of symptoms			
1.1 The guide as a conversation starter	Diary prompting participants of falling or unsteadiness episodes during telephone calls		Reported behaviours by PwP and caregivers
	Diary facilitating interaction with HCPs, which could enhance HCPs management plans		Reported behaviours by PwP and caregivers
	Dyads reflecting together on events that had occurred, which was often facilitated by the log		Subjective researcher interpretation of events from information provided
1.2 Effects of the guide on understanding of symptoms	Guide increasing focus and concentration on falls		Reported behaviours by PwP and caregivers Subjective researcher interpretation of events from information provided
	Problem-solving cause of symptoms, often facilitated by the falls diary		Subjective researcher interpretation of events from information provided
	Pattern of symptoms identified through the log	Log as a facilitator to the identification of management strategies within Key finding 2.2	Reported behaviours by PwP and caregivers
	Using the log as a means of recording that a fall had occurred- no problem-solving element.		Subjective researcher interpretation of events from information provided
	Barriers to using the log as a problem-solving tool and the action plan: already know how to manage falling versus unable to identify strategies to help	Ongoing concerns of uncertainty despite the intervention discussed within Key finding 2.4	Reported perceptions of PwP and caregivers Subjective interpretation of perceptions held by PwP and caregivers from information provided
	Guide as a facilitator to re-visiting events that they might have previously ignored.		Subjective researcher interpretation of events from information provided
	Enhanced understanding of symptoms from reflection on events	Guide as a facilitator to identification of management strategies within Key finding 2.2	Reported beliefs of PwP and caregivers
Key finding Two: Development and implementation of management strategies and their effect on participants' symptoms			

Finding	Contributing information	Information presented elsewhere	Data Source
2.1 Self-management practices developed before the intervention	Unclear whether self-management practices were developed prior to or during the study		Subjective researcher interpretation of events from information provided
	Self-management practices clearly developed prior to the study		Reported behaviours by PwP and caregivers
2.2 Guide as a facilitator to the development and implementation of management strategies	Self-management strategies developed during the intervention		Reported behaviours by PwP and caregivers
	Self-management practices developed in response to an episode of unsteadiness or a fall		Reported behaviours by PwP and caregivers
	Log or action plan as an aide memoire for strategies need to implement or have already implemented		Reported behaviours by PwP and caregivers
2.3 Difficulties could be encountered when implementing management strategies	Attempting strategies within the guide and no help with symptoms or unable to implement them		Reported behaviours by PwP and caregivers
	Difficulties of PwP accepting change in behaviour	Frustration arising from PwP not using the guide, which could arise from denial of risk discussed within key finding 4.1	Reported perceptions of PwP and caregivers
	PwP not following the advice of the caregiver or HCPs in the setting of dementia		Reported behaviours of PwP by caregivers
	Difficulties communicating with HCPs		Reported perceptions of PwP and caregivers
	Adjustment of management strategies when they did not initially work	Adjustment of the log or the action plan to overcome difficulties when using it discussed within key finding 4.1	Reported behaviours by PwP and caregivers
	Self-identification of strategies to manage fall risk (from outside of the guide)		Researcher interpretation of behaviours reported by PwP and caregivers
2.4 Management strategies often resulted in improved PwP symptoms, but concerns frequently remained	Difficulty of the researcher in ascertaining whether change in symptoms arose from the intervention	Difficulty ascertaining whether management strategies were instigated before/ during discussed in Key finding 2.1	Subjective researcher opinion from information provided by PwP and caregivers
	Behavioural changes could be perceived as small.		Reported perceptions of PwP and caregivers
	Participants described improvement in their symptoms arising from management strategies that they had implemented.	Greater understanding and focus on symptoms arising from the guide discussed within key finding 1.2	Reported perceptions of PwP and caregivers of the symptoms that they experienced

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Finding	Contributing information	Information presented elsewhere	Data Source
	Positive outcomes for caregivers to include professional 'back up' for their viewpoints		Reported perceptions of PwP and caregivers
	Ongoing concerns amongst PwP and caregivers relating to unsteadiness and falls: uncertainty of how to manage symptoms, fear of falling		Reported perceptions of PwP and caregivers Subjective interpretation of perceptions held by PwP and caregivers from information provided
Key Finding Three: Engagement with the intervention: Enablers and barriers			
3.1 Variations in engagement across time and user characteristics	Participants' use of the intervention often varied across different time points of the study.	Enablers and Barriers to engagement discussed within key findings 3.2-3.5	Behaviours reported by PwP and caregivers, and then compiled by the researcher for each participant in Excel and analysed longitudinally
	The majority reported use of the guide and engagement with the interactive components of the guide during at least one telephone call	Completing the log and the action plan for the benefit of the researcher- key finding 3.5	Behaviours reported by PwP and caregivers, and then compiled by the researcher for each participant in Excel and analysed longitudinally
	Use of the log was greater than use of the action plan. Use was greatest amongst those with who fell during the duration of the study		Researcher interpretation using information provided by PwP and caregivers, and analysed by the researcher in the context of information provided by PwP and caregivers during the telephone calls
	Use of the guide could be greater amongst PwP than in caregivers.	Participants could be unsure as to who the guide had been targeted toward, which could act as a barrier to engagement amongst caregivers- key finding 3.2 Caregivers could perceive their concerns greater than those of the PwP which could lead to enhanced use in caregivers key finding 3.3 Caregivers could appear frustrated with the reduced use of the guide by the PwP- key finding 4.2	Behaviour comparisons made and reported by PwP and caregivers Behaviour comparisons made by the researcher from information provided surrounding guide use from PwP and caregivers
	Whilst few caregivers used the action plan, use was greater amongst those from within a dyad where the PwP had CI/ dementia.		Behaviours reported by caregivers and analysed in the context of participant characteristics provided in baseline questionnaire one completed by PwP and caregivers.

Finding	Contributing information	Information presented elsewhere	Data Source
	A few participants described having lost the guide.		Activity reported by PwP and caregivers
3.2 The importance of PD duration	Views about the language and the layout of the guide: negative versus positive perceptions.		Reported perceptions of PwP and caregivers
	Views about the information contained within the guide: <ul style="list-style-type: none"> - Positive perceptions to include that the guide acts as a useful reminder or contains new information - Negative perceptions to include that the guide contains little new information and lacks information of relevance to them, which may be more prevalent amongst those who have had PD for a long time 		Reported perceptions of PwP and caregivers
	Participants' doubts that the guide, falls diary, action plan or strategies within the guide will help them and their symptoms (preventing initial engagement).	Difficulties encountered when using the guide presented within key finding 4.1 (preventing ongoing use)	Researcher interpretation of perceptions following information provided by PwP and caregivers
	Participants could be unsure as to who the guide had been targeted toward, which could act as a barrier to engagement amongst caregivers.	Use of the guide could be greater amongst PwP than caregivers key finding 3.1 Caregivers could perceive their concerns greater than those of the PwP which could lead to enhanced use in caregivers key finding 3.3 Caregivers could appear frustrated with the reduced use of the guide by the PwP- key finding 4.2	Researcher interpretation caregiver's perceptions following information provided by caregivers Perceptions reported by caregivers
3.3 Engagement with the intervention and participants' perceptions of falls	How participants perceptions of falling and unsteadiness effect their engagement with the guide: <ul style="list-style-type: none"> - Guide may address their particular concerns, could be driven to engage with the guide following a particular event of falling or unsteadiness, guide can lead to a sense of rapport - Reduced engagement in those who normalise falls, view them as 		Researcher interpretation of PwP and caregivers perceptions and behaviours following information provided by PwP and caregivers Perceptions and behaviours reported by caregivers and PwP Researcher comparisons made between these perceptions (participant and researcher interpretations) and use of the guide (participant and researcher interpretations)

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Finding	Contributing information	Information presented elsewhere	Data Source
	unpreventable or not a concern to them.		
	Caregivers may be driven to use the guide by their concerns of falling or unsteadiness, which may be greater than the PwP.		Caregiver's comparisons of perceptions held by themselves and those of the PwP, linked by the researcher to researcher comparisons made of guide use between PwP and caregiver
	Caregivers may be unaware of falls history, or express concern that use of the guide could dwell on the PwP symptoms and lead to a deterioration in the PwP mood leading to disengagement		Researcher comparisons of falls histories provided by PwP and caregivers. Perceptions reported by caregivers of concerns of guide use.
3.4 Engagement could be limited by participants' general capacity	Parkinson's related circumstances resulting in limitations in general capacity: high frequency of symptoms, fatigue, medical appointments		Circumstances reported by PwP and caregivers, then explicitly stated or implied how this led to reduce use of the guide.
	Non-Parkinson's related circumstances resulting in limitations in general capacity: work commitments, acute illness, holidays, limitations in time		Circumstances reported by PwP and caregivers, then explicitly stated or implied how this led to reduce use of the guide.
3.5 Being a good participant and researcher identification of introjected regulators	Completing the log and the action plan for the benefit of the researcher, perceiving no benefit for themselves		Researcher interpretation of PwP and caregivers perceptions following information provided by them
	Taking part in the study, but perceived low frequency of symptoms, encouragement as per the CARE approach		Researcher interpretation of PwP and caregivers perceptions following information provided by them. Encouragement provided by the researcher as per the CARE approach, and researcher perception of how this might lead to enhanced engagement with the guide.
	Participants were encouraged to use the intervention by the researcher		Encouragement provided by the researcher, and researcher perception of how this might lead to enhanced engagement with the guide.
	Where participants described not using one element of the guide they were provided with		Advice provided by the researcher, and researcher perception of how this might

Finding	Contributing information	Information presented elsewhere	Data Source
	personalised advice as to how that particular element might help		lead to enhanced engagement with the guide.
	Where possible, introjected regulators were identified by the researcher to enhance engagement with the intervention		Advice provided by the researcher, and researcher perception of how this might lead to enhanced engagement with the guide.
Key finding Four: Limitations encountered delivering and implementing the intervention			
	Difficulties with concentration and memory, not limited to those with CI/ dementia		Reported perceptions of PwP and caregivers
	Barriers to completion of the falls diary and the action plan to include problems with writing, forgetting what to do, uncertainty of what to record.	Doubts that the log/ action plan will work discussed within key finding 3.2	Reported perceptions of PwP and caregivers
	Falls diary could be perceived as repetitive and unhelpful leading to cessation	Doubts that the log/ action plan will work discussed within key finding 3.2	Reported perceptions and behaviours of PwP and caregivers
	View that writing action plan down was unnecessary, with details stored in their head, or wanting to try something before writing it down	Doubts that the log/ action plan will work discussed within key finding 3.2	Reported perceptions of PwP and caregivers
	Adaptations made to the falls diary and to the action plan to overcome some of the barriers that they had come across when trying to use them	Adaptions made to management strategies discussed within key finding 2.3	Reported behaviours of PwP and caregivers
	Caregivers could appear frustrated with the reduced use of the guide by the PwP		Researcher interpretation of PwP and caregivers perceptions following information provided by them

F.18 Phase Four: Triangulation Convergence Matrix

Key finding	Questionnaire- quantitative analysis	Questionnaire- content analysis of open-ended questions	Telephone calls	Interviews
1	Deterioration in caregiver burden (not significant)			
2	The majority found the content useful.	Heterogeneity of content that was found more/ less useful, which could relate to their personal circumstances.	Heterogeneity of content reported as useful.	Heterogeneity of information considered useful or new.
3		A few cited the guide as a useful reminder of information, which could lead to increased knowledge.	Guide was a useful reminder and compilation of information. More likely where diagnosed for longer, and if fallen in the last year	Through emphasising why a strategy was important, in some participants, the guide led to enhanced implementation of strategies that they were already aware.
4	Guide less likely to increase knowledge if diagnosed for longer ($p < 0.05$)	Most cited least useful element was that it contained little new information; this could reduce relevance, engagement and knowledge obtained	Some perceived it provided little new information. More common where PD diagnosed longer.	Those diagnosed longer more likely to perceive that the guide contained little new information
5	Majority stated the guide increased their knowledge.			Around half of PwP and caregivers described an increase in their knowledge
6	Less likely to increase knowledge if near misses or lower HRQOL (both $p < 0.05$)			
7	Majority positive of presentation of information and perceived that it was easy to use	Many perceived it clear and easy to understand.	Majority were positive of the layout of the guide. A few without CI/ dementia discussed how reduced concentration and memory led to difficulty using the guide	Most were positive of the format and layout of the guide: easy to read and to navigate. A few felt diagrams would help to illustrate points.
8				Majority positive of paper format. An electronic format would be less acceptable
9			A few had made adaptations to the interactive components	Two PwP described documenting separate to the guide to overcome writing difficulties/ aid problem-solving. Two suggested placing the diary and action plan adjacent to each other would enhance engagement

Key finding	Questionnaire- quantitative analysis	Questionnaire- content analysis of open-ended questions	Telephone calls	Interviews
10		Occasionally discussed that the guide was repetitive; a barrier to its use	A few were positive of the language Vs a few felt guide was too long, needed less text and less repetition	A few who read it cover-cover felt it contained unnecessary repetition; no apparent effect on engagement.
11			Those diagnosed for longer discussed difficulties communicating with HCPs	A few PwP, all with high falls self-efficacy, raised difficulties with communication with HCPs, which could lead them to deem to dislike signposting or feel that it required locality specific information
12	20% felt information had been missed out.	Heterogeneity of information cited missing: related to their unresolved worries or to information obtained elsewhere	A few felt information missing. Heterogeneity of information, often very specific to their circumstances.	Equal numbers felt was comprehensive as felt information missing. Heterogeneity of information cited as missing, which could be very specific to their needs.
13	Majority used the guide; equal split of PwP alone Vs PwP with CG. Few CG used it alone		Use in PwP> CG. A few CG felt it was the PwP responsibility. CG>PwP perceived that the guide provided little new information.	
14				Participants who perceived themselves to have an optimistic or analytical mind-set, were positive of the guide and described enhanced engagement with it.
15		Difficulty of PwP comprehending the information, which could be related to CI/dementia, could lead CG to drive the process of using the guide.	CG could encourage the PwP to use the guide where the PwP was perceived to be in denial.	In the majority, one participant drove guide use. Where this was a CG, most PwP had CI/dementia. CG could encourage PwP to engage with the guide.
16			CG could perceive their concerns to be greater than those of the PwP	CG have different information requirements to PwP; CG information requirements may be perceived to be greater than PwP.
17	With increasing caregiver burden: (i) content less useful, (ii) less likely to use the guide, (iii) less likely to use the action plan (all p<0.05).	Lack of time a barrier to use of the guide and the interactive components, and to implementation of strategies	(i) Around half of participants described limitations in capacity (CG=PwP) leading to reduced use of the guide. PD and non-PD related activities.	Time constraints in some participants (CG>PwP) led to reduced engagement. Most had high CG burden.
18		Perceived relevance of the information to their personal circumstances affected participant's use of it		Some described involvement in previous research/ work as a HCP, which could deem the guide less relevant with fewer changes made

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Key finding	Questionnaire- quantitative analysis	Questionnaire- content analysis of open-ended questions	Telephone calls	Interviews
19			Reduced relevance of the guide due to dementia.	Caregivers of PwP with CI/ dementia may view falls as unpreventable, leading to reduced engagement.
20	More positive of the way information presented if fell during the study (p<0.05)			
21			High symptom frequency a barrier to guide use: too time-consuming Vs if not falls in the last year, could feel the guide more suited to those with a greater frequency of symptoms.	High frequency of symptoms a barrier to completion of the diary Vs a few felt that their perceived low frequency of symptoms made them inferior research participants.
22	More likely to use the guide if fell during the study (p<0.05)	In some, a change in symptoms had triggered use/ would trigger later use.	A few (PwP>caregivers) were prompted to use the guide by symptoms. Use of the interactive components greatest amongst those who fell.	In some, the onset of new symptoms triggered/ would trigger use going forwards.
23	With increasing caregiver burden: (i) content less useful, (ii) less likely to use the guide, (iii) less likely to use the action plan (all p<0.05).		In those attributing falls to non-PD events, use of the interactive components could be reduced. Over-representation of those diagnosed within the last 5 years, and with high caregiver burden.	Those who appeared to normalised falls, could display reduced engagement; over-representation of those with low FES-I scores.
24			Where falls appeared to cause little concern, engagement could be reduced. Over-representation of those with high falls self-efficacy.	The majority of those discussing concerns with other medical issues described reduced engagement with the guide.
25	The majority used the diary (79%). The majority used the action plan (77%)		Two thirds of participants used the interactive components. Diary use> action plan use	
26		Diary as an aide memoire for fall risk, and occasionally as an aide memoire for the telephone calls	Interactive components an aide memoire for strategies.	
27			Diary could facilitate enhanced understanding of symptoms through problem-solving, and identification of patterns	Many (PwP>CG) used the diary to problem-solve the cause of their symptoms; two had used as a simple diary to record falls

Key finding	Questionnaire- quantitative analysis	Questionnaire- content analysis of open-ended questions	Telephone calls	Interviews
28		Most common driver to action plan use was as a medium think about ways of addressing their problems.	Many described an increased focus on falls arising from use of the guide.	(i) Some used the action plan to give greater focus of strategies planning to implement. (ii) Some described adopting a more proactive approach
29	In 69%, the action plan was used 'never', 'rarely' or 'once in a while'	Action plan commonly not completed as already knew the actions to implement.	A few perceived documentation of an action plan unnecessary and could complete one in their head. Barrier to using the diary: already know how to manage falls. 75% of participants had doubts that the suggestions in the guide would work (PETS)	Barriers to completing an action plan: writing unnecessary, self- perceived laziness and inability to identify strategies that might help
30			Could find the diary repetitive and deem it futile	
31		Interactive components could be deemed less useful as too little space to write. Writing difficulties commonly cited as making the guide difficult to use	Some discussed writing difficulties and a lack of space within the guide: a barrier to completion during the study. 13% were uncertain as to how they would do the suggestions, to include difficulties writing (PETS).	The most common difficulty raised with the interactive components was that there was too little space to write: a barrier to use going forward Vs the majority of those using the diary to problem-solve found writing helpful.
32		Use of the interactive components reduced where had doubts they would benefit: more frequent in those diagnosed for longer	Doubts that the interactive component would benefit- more likely if diagnosed for longer and where not fallen in the last year. Diary could be perceived as a research tool only	Those describing reduced engagement with the interactive components could appear confused as to what they aimed to achieve or view them as a research tool.
33	Less likely to use the diary if PwP had CI/ dementia ($p < 0.05$)	(i) Participants could forget to use the interactive components. (ii) CI/dementia could deem the guide less relevant; increased relevance of information led to enhanced use of interactive components.	(i) Participants could forget to document within the guide. (ii) Reduced relevance of the interactive components due to dementia.	The guide could be viewed as less relevant in the setting of CI/ dementia.
34	More likely to use the diary or the action plan if recruited with a caregiver ($p < 0.05$). More likely to use the action plan if caregiver older (both $p < 0.05$).		Majority of caregivers described supporting with falls management. Where CG used the action plan, nearly all from a dyad where the PwP had CI/ dementia.	Nearly all caregivers described providing additional support or reminding the PwP of strategies.
35	Majority were confident in applying the information to their daily routine (75%).	The effect that the guide had on a participant's knowledge effected participant's perceived ability to apply the information.		All who described implementing strategies described difficulties. Non-modifiable changes in the environment were frequently described

Appendix F: Phase Four Appendices

Key finding	Questionnaire- quantitative analysis	Questionnaire- content analysis of open-ended questions	Telephone calls	Interviews
36		CI/ dementia could lead to difficulties comprehending and applying the information	PwP not following advice due to CI/dementia leading to difficulty implementing the information. 13% were uncertain as to how they would do the suggestions (PETS).	Difficulties implementing strategies arising from CI/ dementia raised in all dyads where the PwP had CI/ dementia.
37			Those diagnosed for longer more likely to describe difficulties implementing strategies	Those diagnosed for longer more likely to discuss how strategies within the guide did not work
38			Some PwP had difficulty accepting limitations and changing their behaviour	PwP could experience difficulties in changing their behaviour. Some PwP had concerns of how they were viewed by others: a barrier to change.
39			Few adapted strategies when they did not work	Few adapted strategies when they did not work
40	No change in concerns of falls (FES-I) at 12 weeks compared with baseline. In 41% concerns of unsteadiness and falling were altered.		Ongoing concerns of falls in many dyads: Over-representation of those with CI/dementia, diagnosed in last 5 years, no falls in the last year, high fear of falling	Equal proportions of PwP reported unchanged Vs reduced fear of falling.
41	More likely to alter concerns if lower baseline falls self-efficacy (p<0.05)			Reduced fear of falling arose from enhanced understanding of their symptoms or awareness of fall risk.
42				Some CG discussed ongoing worries of the PwP being alone. Some (CG>PwP) had ongoing concerns of injury. Occasionally, concerns were heightened as now more aware.
43	More likely to alter concerns if recruited through the NHS (p<0.05)	Alteration of concerns of falls commonly cited as secondary to change in knowledge of falls and successful implementation of management strategies		Some recruited from P (UK) groups described pre-existing information seeking behaviour. Those from P(UK) groups could deem the guide less relevant.
44		Alteration of concerns of falls could be cited as secondary to perceived preventable/unpreventable nature of falls.		A few PwP were positive of the presentation of falls risk as adaptable, which led to feeling more in control of symptoms and consequently more positive.

Key finding	Questionnaire- quantitative analysis	Questionnaire- content analysis of open-ended questions	Telephone calls	Interviews
45	The guide led to alteration of 54% of participants' ability to manage falls.		In half, the guide facilitated the development and implementation of strategies (PwP>CG)	Nearly all described strategies to manage falls
46		Heterogeneity of practical skills that were described.	Heterogeneity of management strategies described	Heterogeneity of strategies implemented correlating with their varying circumstances.
47		Alteration in participant's ability to manage falls was commonly perceived to be related to change in knowledge	Identification of symptoms from the diary led to successful management strategies in some, but many uncertain how to manage symptoms	Strategies implemented following problem-solving or in response to information in the guide. Many reported ongoing difficulties to include difficulties attributing a cause to symptoms: over-representation of those diagnosed longer.
48	No change in PwP falls self-efficacy. Improvement in caregiver falls self-efficacy (not significant)	Successful implementation of management strategies could allow participants to perceive greater control over their symptoms.		(i) Many (PwP and CG) had increased confidence of managing falls, commonly arising from increased knowledge and ability to manage symptoms, over-representation of PwP with higher concerns of falls and lower fall frequency. (ii) A few CG, majority with high CG burden, discussed how this arose from the guide reassuring them managing falls correctly.
49	55% would be likely to continue to use the guide in the future.	Most common reasons for ongoing use were (i) as a reminder and (ii) driven by positive experiences from it, to include self-management practices.		Nearly all who used the guide reported likelihood of continued use. Ongoing use driven by the benefits participants reported from it.
50	The guide caused worry or concern in 9% of participants	Reduced likelihood of ongoing use could be attributed to difficulties problem-solving or frustrations frustration within the dyad.	CG occasionally raised concerns: (i) dwelling on PwP symptoms could potentially lead to deterioration in PwP mood, (ii) concerns of nagging PwP	Frustration could arise within the dyad when discussing falls or reminding the PwP of strategies to implement. Analysing events through a diary could be perceived as negative. One CG wanted the guide to provide more specific advice, as opposed to promoting problem-solving.

Appendix F: Phase Four Appendices

Key finding	Questionnaire- quantitative analysis	Questionnaire- content analysis of open-ended questions	Telephone calls	Interviews
51	Participants perceptions of the telephone calls were mixed; 57% found them useful.	Telephone calls most commonly provided a reminder to look at the guide		In the majority, the telephone calls provided an aide memoire to use the guide. In a few CG, they triggered reflection or enhanced focus of the strategies to implement.
52		A few discussed how the telephone calls led them to feel supported.		Some felt that they were no longer alone: arose from support reading the guide or the telephone calls. Dyads where the PwP had high FES-I or reduced HRQOL were over-represented.
53		A few liked how the telephone calls provided an opportunity to clarify points		Some wanted more discussion in the telephone call. Over-representation if (i) diagnosed in the last 5 years, (ii) limited HCP support locally, (iii) lower concerns of falls and (iv) lower caregiver burden
54		(i) A few viewed the telephone calls as a research tool. (ii) Occasionally the telephone calls triggered anxiety in participants.	A few wanted a scheduled telephone call as wanted to prepare/ work commitments/ fatigue. Researcher reflection of difficulties delivering telephone calls: <i>personal advice delivered> introjected regulators, reduced participant recall, fragmented speech, hearing difficulties</i>	(i) A few would prefer scheduled telephone calls arising from feeling unprepared, rather than restrictions on their availability. (ii) A few PwP raised difficulties with telephone calls: lack of non-verbal communication and anxiety with unscheduled contact.
55		Two participants described guilt that they had not used the intervention as designed.	Some appeared guilty when not using the intervention as designed.	(i) Some expressed guilt when had not used certain components (ii) Around half described enhanced engagement as in a research study
56			Guide could provide professional back-up for CG viewpoints	In some (PwP and CG), the guide provided backup for viewpoints, which supported them in discussions with their spouse

Key finding	Questionnaire- quantitative analysis	Questionnaire- content analysis of open-ended questions	Telephone calls	Interviews
57			The guide as a conversation starter: promoting discussion of falls (within the dyad> with HCPs)	(i) In some (CG>PwP) increased discussion about falls -> enhanced awareness of falls and falls-related concerns. (ii) Limited contact with HCPs. Occasionally, heightened confidence to raise issues and seek support from HCPs, the diary could facilitate falls history taking. (iii) A couple were now open to attending a Parkinson's UK support group.
58		Successful implementation of management strategies occasionally led to a reduction in the frequency of their symptoms.	Participants from around 1/3 of dyads described improvement in symptoms; heterogeneity of strategies leading to this improvement. Difficult to ascertain if arose from the intervention.	Some felt fall frequency had reduced, a few PwP with unsteadiness discussed improvement in their symptoms. Improvements attributed to strategies arising from use of the guide.
59	Deterioration in HRQOL (non-significant)			Some PwP (majority with reduced HR-QOL) felt more positive arising from (i) greater perceived control of symptoms, (ii) perceiving falls risk as modifiable, (iii) additional HCP support sought and (iv) the quotations.

Appendix G Discussion Appendices

G.1 Summary of feedback provided by PwP, caregivers in the mixed methods study and possible changes

Feedback relating to the self-management guide

Feedback received from participants in the mixed methods study	Possible Strategy to address this feedback
Considerable heterogeneity of information reported as missing, which often related to their personal circumstances.	<ul style="list-style-type: none"> - Acknowledgment that guide will not contain all info for all ppt - Increased signposting to other resources to include Age (UK), RADAR Keys, more information about attendance allowance, details about the Personal Independence Payment (PIP) for those less than 65 years old.
A few participants in all three qualitative data analyses perceived the guide to be repetitive. In the interviews, these participants described how they had read the guide from cover to cover. This could be associated with reduced engagement with the intervention.	<ul style="list-style-type: none"> - Place text in bold on the introduction page stating that parts of the guide will be more relevant than others. - Amalgamate 'How to use this guide' and the 'Contents' page, with clear explanation of how to use the guide and to only read the parts of section 3 that are relevant to them.
Discussing falls and the changes needed with the PwP had led to friction, and a few others perceived that the problem-solving approach was dwelling on the PwP difficulties.	<ul style="list-style-type: none"> - Write a sentence 'it may help to discuss this with a close friend/ relative on the diary (pg12) - Encourage PwP and caregivers to discuss any concerns with the researcher during the telephone calls through open questioning
In the interviews, a few participants suggested that diagrams would help to illustrate points.	Diagrams about how to get up from the floor
In the interviews, two participants felt that placing the falls diary adjacent to the action plan would enhance user engagement with these components.	<ul style="list-style-type: none"> - Delete the 'what worried you?' column from the diary- has some overlap with the action plan - Clearer signposting to use the diary to try to identify parts of section 3 that might help, and clearer signposting to go on to use the action plan after completing the diary
Additional details for the falls diary- a date column would be useful	Add a date column to the falls diary
Barriers to using the interactive components (i) doubts as to their likely effectiveness, to include perceiving them as a research tool only, (ii) already knowing the actions that they needed to implement, (iii) perceiving the guide repetitive, (iv) limited space to write in the guide, (v) writing difficulties and (vi) perceiving writing to be unnecessary	<ul style="list-style-type: none"> - Add that completing a diary might allow for them to understand their symptoms or to identify ways to help - Provide a clearer rationale on the contents page, and above both the diary and the action plan, as to how these sections might help - State that they could consider asking a close friend/ relative to help them to complete the diary or the action plan if they have difficulty writing - Increase the heights of the rows within the diary and the action plan, consider putting the action plan on a double page spread. These changes would provide more space to write.
Rarely did participants describe adaptations to strategies when they had not been successful.	Add a column to the action plan prompting participants to consider how they might change a strategy where it has not been successful.

Feedback relating to the telephone calls

Feedback received from participants	Possible Strategy to address this feedback
Participants cited difficulties with the telephone calls to include (i) a preference for scheduled calls made, and (ii) difficulties arising from the absence of non-verbal communication.	<ul style="list-style-type: none"> - Consider asking participants whether there is a preferred date and time that they would like to receive the telephone calls - Could consider giving patients the option of opting out of telephone calls if they do not find them helpful/ find that they induce anxiety

G.2 Summary of additional feedback provided by PwP, caregivers and HCPs, and possible changes

Feedback received from participants	Possible strategy to address this feedback
One PDNS felt that there needed to be a stronger emphasis on self-care for postural instability; they described how PwP can focus on medications, and the importance of PwP accepting their limitations should be highlighted.	The guide encourages communication between PwP and caregivers. Already contains a statement that medications may not help symptoms. Do not want to over-emphasise that medications cannot help as this may reduce PwP/caregivers informing HCPs of their falls
Participant suggestions to increase the guide's ease of use included reduced cross-referencing, reduced quantity of text, and clearer explanation of which sections were targeted to specific PwP/ caregivers (rather than designed to be read by all).	<ul style="list-style-type: none"> - Review the guide to ensure that all text is required- remove/ reduce where possible, and aim to reduce cross-referencing where could cause ambiguity - Clearer explanation as to whom sections are targeted toward, with clearer rationale.
Three participants suggested improvements to the language, grammar and punctuation.	Review the guide to ensure that language is clear throughout.
One dyad discussed how some of the quotes used language that was not 'age appropriate' and went so far as to say that it might 'alienate' some users.	<ul style="list-style-type: none"> - Review the quotes included in the guide. Where appropriate, amend to correct the grammar, without changing their meaning. - Particular feedback related to the use of the words 'stuff' and 'biking'. Consider changing these words to 'things' and 'cycling'.
Two PwP raised wanting additional suggestions of how to stay active, to include those relevant to those with earlier PD. One PDNS raised how the guide states 'speak to a physiotherapist', and how PwP may dismiss this advice as they do not currently have access to one.	<ul style="list-style-type: none"> - Modify the guide to include suggestions of how to stay active, with an emphasis on modifying current activities. - Include information about obtaining a RADAR key. - Review the layout of this section to ensure that the suggested resources of information are clear. - Consider moving information about Parkinson's UK support groups to the section 'other sources of support' as more mobile PwP felt that this information, which included information about Tai Chi, was less relevant to them when it was included in the section about keeping active.
It was unclear whether the 'Concerns of close friends and family' section was deemed helpful to PwP and caregivers.	<ul style="list-style-type: none"> - Alter the language within this section to become more understanding of caregivers difficulties - Information about financial support should be moved elsewhere, as this is relevant to both PwP
Two PwP viewed the diary as a 'tick box exercise, rather than an aide to problem-solving.	Clearer rationale as to how the diary might help should be included.
Three participants felt the diary needed additional details; a date would allow for assessment of whether falls were happening in quick succession, and additional details might aid discussion about falls with HCPs.	<ul style="list-style-type: none"> - A date column should be added to the diary - The third column 'what worried you?' should be changed to 'why do you think you felt unsteady or fell', as this statement is probably more likely to help PwP and caregivers to understand their falls and their information needs.
The majority of PwP and caregivers were positive of the 'Personal Action plan'. Suggestions for improvement included (i) removing the word 'personal' from the title as this was deemed irrelevant, and (ii) increased space to write.	<ul style="list-style-type: none"> - The word 'personal' should be removed, with the title called 'Action Plan' - The height of the rows within the action plan should be increased - Distributing the action plan across a two-page spread, would increase the space to write and allow space for PwP and caregivers to document possible modifications of strategies that were not initially successful

<p>Three participants suggested changes to the section providing information about how to get up from the floor. These included (i) a statement that calling 999 does not automatically result in an admission to hospital and (ii) after getting up from the floor, PwP should sit and rest on a chair before getting up and starting to walk.</p>	<ul style="list-style-type: none"> - Add a sentence to state that calling 999 does not automatically result in hospital admission - An 8th instructional step should be added to state to sit on the chair before getting up for a walk - Re-distribute the information providing suggestions to try within 'what to do after a fall'. This would allow space for pictures, to illustrate how participants can get up from the floor and reduce the amount of text on the page- feedback received that the guide could be too text heavy.
<p>In relation to the information about HCPs, a couple of participants discussed how it was unclear whether the word 'doctor' related to a GP or hospital consultant.</p>	<p>Each time the word 'Doctor' is mentioned, this should state 'your GP or your Parkinson's doctor/ nurse'. Whilst some participants discussed how their GP was not able to make changes to their medications, or had reduced knowledge of PD in comparison with their specialist doctor, it is important that PwP and caregivers raise their concerns; where required, these can then be forwarded on to the GP or Parkinson's Dr/ Nurse. Do not want people waiting until next see PD doctor as could be some time and some do not have access to a PDNS. GP can refer/ discuss with PD Dr if concerns cannot wait until next reviewed.</p>
<p>Participants often discussed their positive experiences with occupational therapy and physiotherapy and could suggest expanding on the information provided within the guide. However, these participants did not suggest what information they felt was missing.</p>	<p>There is already lots of signposting in the guide to encourage PwP and caregivers to seek the support of occupational therapists and physiotherapists. Expanding on the information provided, whilst maintaining the relevance of the guide to the majority of users would be difficult due to the heterogeneous nature of PwP and caregivers needs. Physiotherapists who appraised the guide did not feel that more information needed to be included.</p>
<p>One HCP discussed how the freezing section should include advice about turning in an arc rather than on the spot, and another raised how the cueing advice might benefit from the inclusion of a diaphragm.</p>	<ul style="list-style-type: none"> - Information should be added in the freezing section about turning in an arc rather than on the spot. - Including a diagram about how placing strips of tape on the floor to help in areas prone to freezing would not help, as I think this diagram would need to be drawn 'real time' whilst explaining the process.
<p>A couple of participants discussed how they now planned their journeys in response to the section about falls away from the home, and suggested that further emphasis should be placed upon the ways in which PwP might prepare for significant outings, such as calling ahead to identify if there were any specific services available for them.</p>	<p>Details should be added to 'How can I stay active?' section to include planning for journeys ahead, and information about obtaining a RADAR key.</p>
<p>Feedback about the 'useful contacts' section: participants raised that they might like more details about attendance allowance, a space to write their PDNS's number/ other local specific information, information about admiral nurses and possible eligibility for a RADAR key and/or reduced council tax. One PDNS felt that the guide might benefit from the inclusion of a space for the PwP to write a list of their medications to aid interactions with HCPs.</p>	<p>Useful contacts section should be modified to include information about:</p> <ul style="list-style-type: none"> - Personal Independence Payment (PIP) for PwP less than 65 years old. More information about attendance allowance and carers allowance - RADAR keys - Admiral Nurse service for those with dementia, and how to contact them - Age (UK) and how to contact them - A space to document locality and personal specific contacts to include their PDNS and GP

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