

University of Southampton

Faculty of Environmental and Life Sciences

School of Psychology

**Exploring and evaluating the use of digital health interventions for the
management of high blood pressure**

by

Katherine Sarah Morton

**Thesis for the degree of Doctor of Philosophy in Health Psychology Research and
Professional Practice**

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Abstract

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High blood pressure is a prevalent condition affecting more than 1 in 4 adults in the UK. Many patients need several adjustments to their treatment to successfully lower their blood pressure, but healthcare professionals (HCPs) have shown reluctance to increase dose or add new drugs during annual clinic appointments. Barriers to medication change include concerns about patient side effects, doubts about the accuracy of one-off clinic readings, and low confidence that medication changes will successfully reduce blood pressure.

A digital intervention was developed to help improve blood pressure control in Primary Care, prompting HCPs to initiate planned medication changes when patients' home readings were above-target. A separate randomised controlled trial found the intervention to be effective. This thesis aimed to develop understanding of how patients and HCPs perceive self-management digital interventions from the literature, and to explore perceptions and implementation of this digital intervention for high blood pressure in Primary Care.

A qualitative meta-ethnography of 30 primary studies was conducted exploring patients' and HCPs' experiences of self-management digital interventions across different chronic conditions. This indicated that self-monitoring one's own health was a powerful mechanism, and feedback on self-monitored data seemed to influence perceptions of responsibility amongst patients and HCPs, with patient-led systems appearing more feasible to implement in practice. A qualitative process evaluation of patients' experiences of using the digital intervention for high blood pressure suggested that illness and treatment perceptions influenced how beneficial or burdensome the intervention was perceived to be, with implications for evaluating important psychosocial outcomes of using digital interventions such as reassurance, anxiety and guilt. Finally, a mixed methods process evaluation helped understand the extent to which HCPs adhered to target behaviours and possible explanations for this. Suggestions for optimising digital interventions in Primary Care were made, including providing confirmation that patients have received remote support, and 'in the moment' reminders of the rationale and evidence for medication change.

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Research Thesis: Declaration of Authorship

Print name:	Katherine Sarah Morton
Title of thesis:	Exploring and evaluating the use of digital health interventions for the management of high blood pressure

I 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.

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:

Morton, K., Dennison, L., May, C., Murray, E., Little, P., McManus, R.J., & Yardley, L. (2017). Using digital interventions for self-management of chronic physical health conditions: A meta-ethnography review of published studies. *Patient Education & Counseling* 100(4): 616–635.
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Morton, K., Dennison, L., Bradbury, K., Band, R.J., May, C., Raftery, J., Little, P., McManus, R.J., & Yardley, L. (2018). Qualitative process study to explore the perceived burdens and benefits of a digital intervention for self-managing high blood pressure in Primary Care in the UK. *BMJ Open* 2018;8:e020843. doi:10.1136/bmjjopen-2017-020843

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Definitions and Abbreviations

AMUSED	Analysing and Measuring Usage and Engagement Data
BCT	Behaviour Change Technique
BMI	Body Mass Index
BoT	Burden of Treatment
BP	Blood Pressure
CARE	Congratulate, Ask, Reassure, Encourage
CERQUAL	Confidence in the Evidence from Reviews of Qualitative Research
CFIR	Consolidated Framework for Intervention Research
CIHR	Canadian Institute of Health Research
COPD	Chronic Obstructive Pulmonary Disease
COREQ	Consolidated criteria for reporting qualitative studies
DHI	Digital Health Intervention
ENTREQ	Enhancing Transparency in Reporting the synthesis of Qualitative Research
GP	General Practitioner
GRAMMS	Good Reporting of a Mixed Methods Study
HCP	Healthcare Professional
MOSCOW	Must have, Should have, Could have, Would like
MRC	Medical Research Council
NHS	National Health Service
NICE	National Institute for Health and Clinical Excellence
NIHR	National Institute for Health Research
NPT	Normalisation Process Theory
PBA	Person Based Approach

Definitions and Abbreviations

QUARTER	Qualitative Research within Trials: Excellent Reporting
QoF	Quality and Outcomes Framework
QoL	Quality of Life
RCT	Randomised Controlled Trial
SCT	Social Cognitive Theory
SDT	Self Determination Theory
STaRI	Standards for Reporting Implementation Studies
TASMIN	Towards an Integrated Self-monitoring Solution for Hypertension
TIDieR	Template for Intervention Description and Replication
TPB	Theory of Planned Behaviour

Chapter 1 An introduction to the use of digital health interventions for the management of high blood pressure

1.1 Overview

This PhD was completed using the three-paper format, and is nested within a larger programme grant. The programme grant aimed to develop two digital health interventions for self-managing chronic conditions. The PhD thesis aimed to develop understanding of patients' and healthcare professionals' experiences of using digital health interventions for self-managing hypertension. Figure 1 shows how each of the three papers that form this PhD fitted within the overall programme grant.

Chapter 1

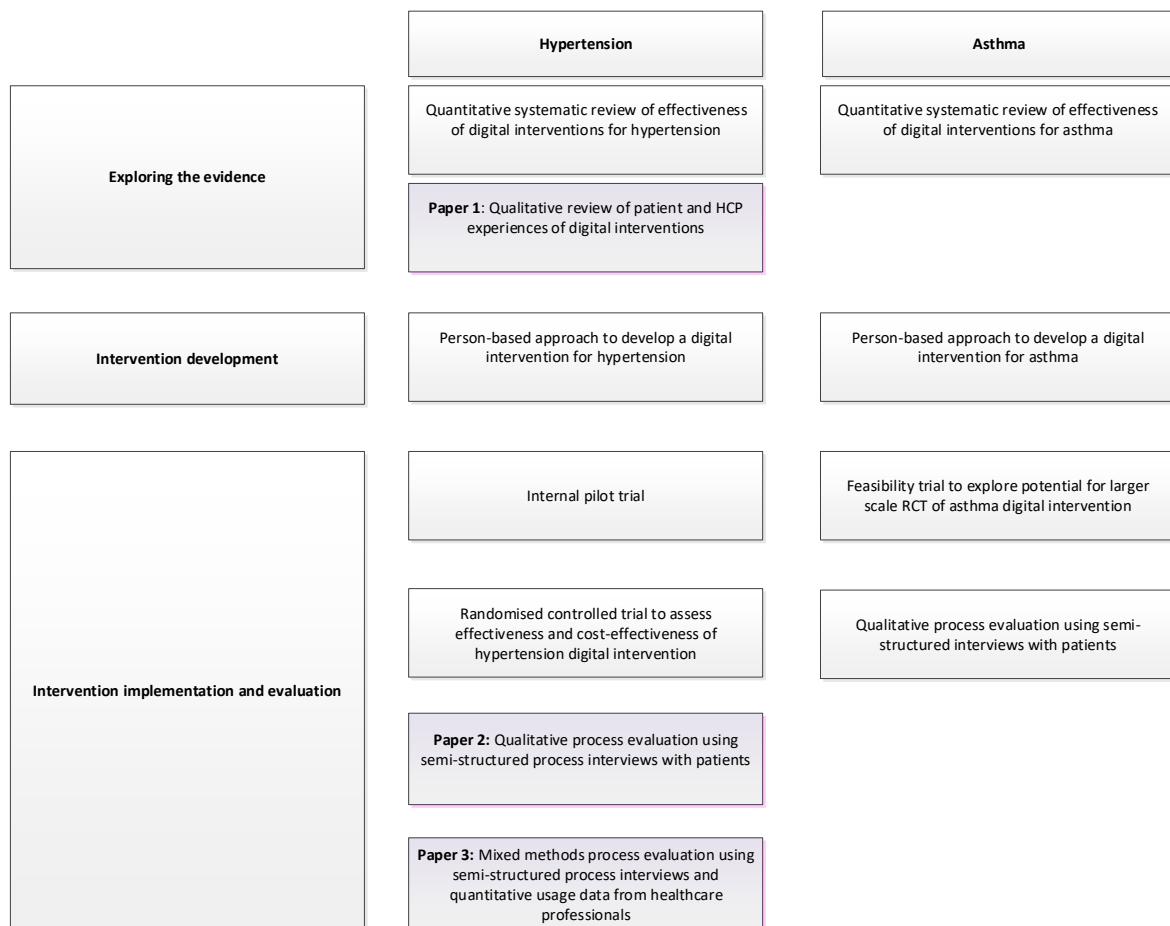


Figure 1 The three papers which formed this PhD thesis and how they fitted within the programme grant

This introduction will aim to provide a detailed background and context to the PhD programme of research, as well as describing the rationale for the decisions made for each piece of research.

The introduction begins by defining digital health interventions, and what is known about possible outcomes of using them. This helps explain the rationale for using these tools to promote self-management behaviours in the context of today's healthcare. The introduction then considers the implications from research and theory in terms of how to design effective digital health interventions, as well as some of the challenges in implementing these interventions, to help place this project in the context of existing knowledge.

The introduction then focuses on hypertension (high blood pressure) as a chronic condition to explain why it is important to improve hypertension self-management, as well as what the evidence has shown to date. Finally, this chapter outlines the development of research questions for each study, discusses the rationale for the methodological approaches adopted, and explains the aims of each paper.

1.2 Digital health interventions: An approach to self-management of chronic conditions

Approximately 15 million people in England suffer from a chronic health condition, defined as a condition without a known cure, e.g. asthma, heart disease or diabetes (Department of Health, 2012a), and this places a huge demand on healthcare systems. Chronic conditions are the reason for 50% of General Practitioner (GP) appointments and they account for 70% of all health and social care costs (Department of Health, 2012a). Currently the average waiting time for a GP appointment in the UK is 13 days (Kaffash).

There is an increasing focus in Primary Care on promoting patient self-management, defined as

“the individual’s ability to manage the symptoms, treatment, physical and psychosocial consequences and lifestyle changes inherent in living with a chronic condition.

Efficacious self-management encompasses ability to monitor one’s condition and to effect the cognitive, behavioral, and emotional responses necessary to maintain a satisfactory quality of life”

(Barlow, Wright, Sheasby, Turner, & Hainsworth, 2002) p. 178.

Self-management is a key goal for the NHS five-year forward plan which recognises that promoting “the knowledge, skills and confidence a person has in managing their own health and care” is important to improve both health outcomes and the experiences of patients living with a chronic condition (NHS England, 2017). A meta-review of the evidence for self-management across 14 chronic conditions concluded that supporting patients to self-manage their health should be integrated as part of standard care (Taylor et al., 2014), making this a highly relevant theme in public health.

Digital interventions have been defined as “Devices and programs using digital technology to foster or support behaviour change” (Michie, Yardley, West, Patrick, & Greaves, 2017), p. 1. Within healthcare, digital interventions have the potential to support people to engage in behaviours such as healthy lifestyles (e.g. physical activity (Schwarzer et al., 2017), diet (Lara et al., 2016), or smoking cessation (Tombor et al., 2016)), adhering to medication (Car, Tan, Huang, Sloot, & Franklin, 2017), and monitoring their own health status (Fairbrother et al., 2014). These are known as Digital Health Interventions (DHIs). DHIs range in complexity from simple digital prompts or reminders to engage in certain behaviours (Varleta et al., 2017), to complex interventions which incorporate multiple interactive components, such as education, self-

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monitoring tools, and remote communication with other patients or healthcare professionals (HCPs) (Murray et al., 2017). In terms of delivery, DHIs include programmes delivered online, via smart phone applications (apps), short message service (SMS or text messages), social media, and even wearable devices which give automated feedback on personal data (such as fitbits).

Telephone support and searching for health information online are generally not regarded as DHIs, as there is no digital component in the first case and no device or programme being delivered in the second, although some broader definitions of DHIs do include these (O'Connor et al., 2016).

DHIs have received a lot of attention from researchers due to several important attributes. Firstly, they can help people to self-manage their chronic condition more effectively in line with the NHS plan for delivering more sustainable care (NHS England, 2017), as well as facilitating more rapid interaction with HCPs when needed without patients needing to leave the house. This could be especially valuable for people who find travel to appointments a source of stress or burden. In addition, DHIs have the potential to reach large populations at low cost and can offer round-the-clock support in real-life settings, which is important given that the vast majority of health and lifestyle behaviours take place outside of healthcare consultations (Bokhour et al., 2012). They also provide discrete support for patients who may find DHIs less stigmatising than seeking face-to-face support (Preziosa, Grassi, Gaggioli, & Riva, 2009). Finally, the increasing ubiquity of technology makes DHIs a potentially highly accessible and convenient mode of support for people, with 90% of adults in the UK having access to the internet (Office for National Statistics, 2018) and 71% owning a smartphone (Ofcom, 2016).

1.3 Possible outcomes of using DHIs

1.3.1 Clinical effectiveness

DHIs have the potential for cost-saving through improving clinical outcomes and reducing use of resources amongst patients living with chronic conditions. However, evidence for their clinical effectiveness is inconsistent. A recent Cochrane review examined the effects of tele-monitoring interventions across a range of physical chronic conditions (Flodgren, Rachas, Farmer, Inzitari, & Shepperd, 2015). Tele-monitoring is a widely researched form of DHI in which patients monitor

their own health status at home, transmit their readings (e.g. blood pressure, weight, or peak flow readings) and receive automated feedback and/or HCP feedback on recommended actions (Kitsiou, Paré, & Jaana, 2015). The review found moderate improvements in glycaemic control and blood pressure in patients using tele-monitoring DHIs, but minimal difference in heart failure outcomes compared with usual care (Flodgren et al., 2015). Systematic reviews of DHIs for Chronic Obstructive Pulmonary Disease (COPD) (McCabe, McCann, & Brady, 2017), HIV (Cooper, Clatworthy, Whetham, & Consortium, 2017), diabetes (Greenwood, Gee, Fatkin, & Peeples, 2017), chronic kidney disease (Jeddi, Nabovati, & Amirazodi, 2017), cognitive impairment (Bateman et al., 2017) and hypertension (McLean et al., 2016) have found evidence of small effects on health behaviours and/or clinical outcomes, although there is large heterogeneity in effect sizes. A clear pattern to explain the discrepancy in findings has not yet been discerned (Salisbury et al., 2015), though evidence has suggested that clinical effectiveness might be influenced by intervention features such as the mode of delivery, design of clinician alerts (Gyllensten, Crundall-Goode, Aarts, & Goode, 2017), or amount of human support (Smith et al., 2017); the use of theory in intervention design (Webb, Joseph, Yardley, & Michie, 2010); patient capabilities; and implementation by the clinical team (May et al., 2014). These factors will be discussed in more detail in sections 1.4 and 1.5 which consider what we know about developing effective DHIs and some of the challenges during implementation.

1.3.2 Quality of life

Evidence has suggested that self-management DHIs may also be capable of fostering improvements in patients' quality of life (QoL), with systematic reviews finding mixed evidence for improved QoL after using DHIs for heart disease, cancer and COPD (Bashi, Karunanithi, Fatehi, Ding, & Walters, 2017; Cruz, Brooks, & Marques, 2014; Seiler, Klaas, Tröster, & Fagundes, 2017). Some DHIs include tools explicitly designed to improve patients' QoL by enhancing abilities to cope with their condition, for example training in mindfulness skills (Kubo et al., 2018), whereas others are designed with a primary focus on clinical outcomes, such as self-monitoring to facilitate early detection of deteriorations, yet can still end up influencing patients' QoL (Jódar-Sánchez et al., 2013). This is possibly a knock-on effect of improved clinical outcomes, although DHIs have also been shown to have positive effects on QoL even when clinical outcomes remain unchanged (Ong et al., 2016) suggesting that they could influence QoL more directly. Amongst cancer survivors, a review of DHIs targeting fatigue found evidence of small to moderate effects on health-related QoL (Seiler et al., 2017), whilst DHIs targeting physical activity and diet behaviours had no impact on QoL (Roberts, Fisher, Smith, Heinrich, & Potts, 2017). This may indicate that

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fatigue is more closely linked with QoL than diet or exercise, but there may be other reasons why some DHIs have a stronger relationship with QoL which systematic reviews are not able to detect when focusing only at a broad level across multiple studies.

A large-scale study including patients with a range of chronic conditions suggested that DHIs might enhance QoL through changing patients' cognitive and emotional representations of their condition (Musekamp, Bengel, Schuler, & Faller, 2016). Improved self-management skills after using an intervention, such as perceived control, confidence to cope with the chronic condition, and understanding of factors influencing health, predicted improvements in QoL 3 months later (Musekamp et al., 2016). This is in line with the extended common sense model which posits that the representations an individual holds about their condition influence how well they cope (Leventhal & Brissette, 2012).

Despite this potential explanation for how DHIs may improve QoL, findings remain mixed and this may be partly due to issues within the research. Varied use of measures might account for some of the discrepancies regarding the benefits to QoL, with a range of generic and disease-specific measures of QoL in use. The lack of adherence to intervention procedures in many studies could also interfere with any potential benefits of self-management interventions to QoL, for example, DHIs promoting physical activity, self-monitoring, and healthy eating often have low adherence to both the DHI and the target health behaviour over time (Aguiar et al., 2017; Guertler, Vandelanotte, Kirwan, & Duncan, 2015; Ryan, Edney, & Maher, 2017) which could detract from any potential benefits to QoL from adhering to these behaviours.

However, it should not be assumed that DHIs would be beneficial for all patients if only they were optimally implemented and the effects measured accurately. There is an argument that DHIs could have a negative impact on patients' QoL. Standardised programmes designed to improve patient adherence for clinical benefits may fail to take account of the patient's lived experience of incorporating dynamic information from all aspects of their life to manage their condition (Kendall, Ehrlich, Sunderland, Muenchberger, & Rushton, 2011). A concept known as 'strategic non-compliance' has emerged within diabetic patient self-management which refers to patients' decisions to *selectively* adhere to clinical best practice in order to achieve a balance between their glucose control and their well-being (Campbell et al., 2003). It has been argued that DHIs offer a 'one size fits all' solution at the cost of ignoring individual patients' needs and dismissing unique management solutions that the patient has developed through living with their condition over time (Lawn, McMillan, & Pulvirenti, 2011), thus favouring clinical outcomes over QoL.

Another potential issue with QoL is that not all patients wish to become more actively involved with their healthcare, and some might feel overwhelmed by taking additional responsibility, or

abandoned if asked to use DHIs at home when they would prefer to see their HCP in person. Studies have found that while some people felt enabled by the insights which tele-monitoring technology provided into their health, others felt that having the equipment in their home was a constant reminder of their sick role, or experienced anxiety about using the self-monitoring equipment or seeing their own readings (Hanley, Fairbrother, Krishan, et al., 2015; Huniche, Dinesen, Nielsen, Grann, & Toft, 2013; Jones et al., 2012; Lupton, 2014a; Middlemass, Vos, & Siriwardena, 2017; Pecina et al., 2011). Engaging in self-management regimens can be impeded by social isolation, fear of negative illness outcomes and competing demands from co-morbidities (May, Cummings, et al., 2016). DHIs can also cause stress or frustration when the technology is erratic or difficult to engage with (Lupton, 2014a). Support from HCPs or carers in learning to use the DHI and maintaining usage might help to reduce the burden of DHIs on patients (Middlemass et al., 2017), but further research is needed on how best to ensure DHIs promote QoL and minimise anxiety for patients with different health conditions.

1.3.3 Burden of treatment

When designing and evaluating DHIs, it is important to optimise their helping potential and minimise any sources of burden for the users. The Burden of Treatment (BoT) theory offers a framework for researching treatment burden. The potential value of this theory in understanding the optimal implementation of DHIs in healthcare will be discussed here.

BoT theory was developed on the basis that while normative expectations of healthcare assume that non-adherence to clinical regimens is the patient's fault for not following instructions, in reality there are many interacting factors which can affect patients' capacity to participate in care (May et al., 2014). BoT theory sees the patient as a co-worker with the HCP, and can help us understand how patients and caregivers respond to the workload of healthcare in a social context (May et al., 2014). BoT theory defines treatment burden as:

"The self-care practices that patients with chronic illness must perform to respond to the requirements of their healthcare providers, as well as the impact that these practices have on patient functioning and well-being."

(Gallacher et al., 2013), p. 1.

This burden can include organising and attending appointments, interacting with HCPs, adhering to medication, and engaging in lifestyle behaviours to control their condition, such as healthy diet,

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physical activity and symptom monitoring. BoT theory states that when the work involved in self-care exceeds a person's capacity, this can lead to non-adherence and poorer health outcomes. Capacity is theorised to be increased by a complex intertwining of social opportunities, such that the stronger social networks a patient has access to (social capital) and the better their skill at interacting with others (social skill), the more resources they will be able to draw on when needed (resilience) which increases their own functional capacity to do the work involved in looking after their health. Capacity is limited by the burden of the condition and patients' own socioeconomic resources. BoT theory highlights the challenges of engaging in healthcare for people lacking a resilient social network and material resources, and draws attention to the limitations created by social inequalities in access to care, including socio-economic status, age, gender and ethnicity (Uphoff, Pickett, Cabieses, Small, & Wright, 2013). BoT theory emphasises that reducing the amount of work HCPs hand over to patients might facilitate better adherence to treatment programmes and improved patient well-being (Mair & May, 2014). On the other hand, more regular HCP support can potentially hinder long-term engagement in self-management behaviours, as found amongst a sample attempting to lose weight, possibly because regular support reduced autonomous motivation (Deci & Ryan, 2011) and created a level of dependence on the HCP for providing external support (Renouf, Bradbury, Yardley, & Little, 2015). Therefore it should not be assumed that giving more responsibility to the patient is necessarily burdensome or counterproductive in terms of health outcomes. Importantly, BoT theory recognises that patient capacity is dynamic and will vary over time according to factors such as availability of social networks and the trajectory of the illness (Gallacher, May, Langhorne, & Mair, 2018), suggesting that HCPs may wish to regularly re-evaluate patients' capacity. A self-report tool has been developed to assess burden of treatment (Eton et al., 2017) although this measure has only recently been validated and evidence for its applicability across multiple conditions and in cases of multimorbidity has not yet been collated.

Evidence supporting the constructs theorised to promote patient capacity was found in a qualitative meta-review of patients' experiences of care for chronic heart failure, chronic kidney disease, and COPD (May, Cummings, et al., 2016). As proposed by BoT theory, patients with better access to health services and stronger social and material support appeared to experience reduced burden in managing their condition. The review also suggested that DHIs to support self-management could increase burden via the demands they placed on patients and caregivers, and only offered temporary benefit (May, Cummings, et al., 2016). However the practical implications of this review are not clear as the details of patients' care experiences and the DHIs used are lost in the high-level interpretations, and no suggestions are made for how DHIs could provide a more lasting impact on self-management and well-being.

Therefore BoT theory appears to be relevant to consider when exploring patients' experiences of using DHIs to self-manage their condition, but explicit support for the constructs theorised to impact on patients' capacity is not forthcoming. It is also worth noting that the BoT theory tends to focus on the more tangible burdens of time and effort but does not consider the emotional burden of living with a chronic condition, such as worry about future health or anxiety about when to seek help, which could also contribute to the patient's overall perceived burden of managing their health (Spurgeon, James, & Sackley, 2013). It is possible that DHIs have the potential to help offset or worsen these aspects of treatment burden, depending on how they are designed.

1.3.4 Summary of DHI potential outcomes

In summary, DHIs may be implemented in order to improve clinical outcomes, to improve patients' QoL, or in some cases both. Despite intentions to improve QoL, for some patients DHIs might risk introducing additional burden instead. Trials of self-management DHIs will often measure a primary clinical outcome and a secondary outcome of health-related QoL, but do not explicitly state how the DHI is anticipated to impact on each of these outcomes. A systematic review of DHIs for cognitive impairment concluded that there is a need for a clearer consensus on which categories of health outcomes to measure in trials of DHIs, to better enable researchers to evaluate their impact (Bateman et al., 2017). Recent recommendations for evaluating DHIs emphasised the importance of selecting appropriate short-term outcomes as well as more definitive clinical outcomes (Murray et al., 2016).

1.4 How to develop effective DHIs?

1.4.1 Using theory to inform DHI development

Many different models of interacting factors have been theorised to promote individual-level behaviour change in health psychology and these are often employed to inform the development of interventions. Such models are used to identify which psychological constructs the DHI needs to target and therefore which behaviour change techniques (BCTs) are appropriate to select (Michie et al., 2013). It is not feasible to cover all models within the scope of this introduction, but this section will discuss some of the most well-known and widely used models of behaviour change in health psychology in terms of their application to developing interventions.

1.4.1.1 Stages of Change model (Prochaska & DiClemente, 1982)

Stage models propose that people progress through distinct stages in terms of behaviour change, and assume that people within each stage will be confronted with certain types of barriers or challenges to engaging with the behaviour change. The Stages of Change model (Prochaska & DiClemente, 1982) posits that people move forwards and backwards in their readiness to change behaviour: between pre-contemplation in which they do not intend to change a given behaviour; contemplating a change; preparing to make small changes; actively performing a new behaviour; and maintaining a new behaviour over time. This theory has been applied to intervention development by tailoring interventions to a certain stage of behaviour change. A meta-analysis found that digital interventions for increasing condom use were more effective if developed using the Stages of Change model (Noar, Black, & Pierce, 2009), which was adopted by three of the 12 interventions as a theoretical framework. However, there is a lack of evidence supporting the existence of these distinct stages and it appears that people's perceptions and thoughts about a behaviour can change rapidly (De Nooijer, Van Assema, De Vet, & Brug, 2005), making the conceptualisation of stages less meaningful as a method of distinguishing target groups for appropriate behaviour change interventions. Indeed the Stages of Change model was heavily criticised for drawing 'arbitrary dividing lines' to define how the stages are distinct, and for actually hindering effective interventions being offered to those who need them due to the arbitrary classification of individuals as 'pre-contemplators' and therefore not ready to receive support to change behaviour (West, 2005). In addition, Stages of Change theory has not tended to be applied to behaviour change for managing long-term health conditions, but rather research has focused on behaviours such as smoking cessation and condom use (Joseph, Daniel, Thind, Benitez, & Pekmezci, 2016).

1.4.1.2 Social Cognitive Theory (Bandura, 1991)

Bandura's Social Cognitive Theory (SCT) provided an underlying basis for several models seeking to predict behaviour change. SCT claims that self-efficacy and outcome expectancies are precursors to behaviour change (Bandura, 1991). Self-efficacy is defined as beliefs about capabilities to perform a behaviour, while outcome expectancies are defined as beliefs about the possible consequences of engaging in a behaviour. SCT is one of the most widely used theories in intervention research (Rolling & Hong, 2016), and mounting evidence suggests that promoting self-efficacy is indeed important for encouraging effective behaviour change (Williams & French, 2011). Bandura proposed four means of increasing self-efficacy: increasing perceived mastery of the behaviour via experiences of success, modelling the behaviour by showing a relevant role model successfully performing the behaviour, positive verbal persuasion, and helping people to

reinterpret physiological anxiety responses to a challenge. A meta-analysis of 27 interventions to promote physical activity found that the most effective means of promoting self-efficacy in terms of behaviour change included planning exactly when and how the behaviour would be performed (termed implementation intentions), providing instruction about how to perform the behaviour, and positive feedback on progress towards behaviour (rather than giving feedback only on actual behaviour change) (Williams & French, 2011). This is line with the mastery approach to increasing self-efficacy, as these techniques focus on increasing the users' perceived success at performing the behaviour. However, effective techniques to promote self-efficacy for physical activity may not be effective for changing behaviour in other contexts and groups, such as self-management of a chronic health condition.

1.4.1.3 Theory of Planned Behaviour (Ajzen, 1985)

Self-efficacy is a key construct in both the Health Action Process Approach model (Schwarzer, Lippke, & Luszczynska, 2011) and the Theory of Planned Behaviour (TPB) (Ajzen, 1985), which have been widely used in intervention research, although their ability to predict behaviour has been criticised. A meta-analysis found that the TPB accounted for less than 20% of variance in self-reported behaviour outcomes, and this was even lower when objective measures of behaviour were used (McEachan, Conner, Taylor, & Lawton, 2011). This suggested that the TPB does not account for many of the important factors which can influence behaviour, and indeed several additional factors have been demonstrated to predict behaviour once the TPB constructs were controlled for, including sociodemographic factors (Snihotta et al., 2013), habit (Gardner, de Bruijn, & Lally, 2011), and physical health (Snihotta et al., 2013). These limitations of the TPB, alongside its lack of utility in developing effective interventions for behaviour change have led some researchers to call for the retirement of the TPB (Snihotta, Presseau, & Araújo-Soares, 2014).

1.4.1.4 Self-determination Theory (Deci & Ryan, 2011)

Social theories of motivation have also been applied in the context of health behaviour change. Self-determination theory (SDT) (Deci & Ryan, 2011) evolved in the context of social learning theory and proposed that behaviour change would be more successful if people are intrinsically motivated, i.e. wanting to change due to an internal drive rather than external pressures. According to SDT, optimal intrinsic motivation is fostered by perceived autonomy (feeling self-directed), competence (feeling competent) and relatedness (feeling supported). Interventions based on SDT seek to promote perceived autonomy around the behaviour change, for example by

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encouraging participants to set their own goals or choose their own schedule for receiving reminders (Dennison, Morrison, Conway, & Yardley, 2013), to help them feel they are acting in line with their own personal choices. Perceived competence might be promoted by positive tailored feedback based on progress towards goals to help promote perceived mastery of the behaviour. Relatedness can be encouraged by helping the person to feel supported and cared for, which may mean that some human support is important alongside the DHI, or that the DHI includes tools to ensure the person feels understood and listened to (Morrison, 2015). The three SDT constructs have been used to inform interventions for behaviour change through guiding the style of support provided by facilitators (Patrick & Williams, 2012). Receiving coaching from SDT-trained facilitators has been found to increase perceived autonomy and competence, and is associated with greater changes in behaviour than receiving non SDT-based coaching (Williams & Deci, 2001) or usual care (Halvari & Halvari, 2006).

1.4.1.5 Dual Process Theories (Strack & Deutsch, 2004)

Many of these theories assume that people are consciously appraising the pros and cons of target behaviours and constructing plans about behaviour change. Sniehotta argued that we need to make room for new theories which incorporate unconscious influences such as implicit attitudes and motivation, and the role of past behaviour (Ouellette & Wood, 1998; Sniehotta et al., 2014). Dual process theories contrast reflective processes (such as conscious thoughts about self-efficacy or risk perceptions outlined in the models above) with impulsive processes which occur sub-consciously based on implicit associations (Strack & Deutsch, 2004). There is a growing body of evidence that implicit cognitions and attitudes, such as attentional bias, can influence behavioural choices (Sheeran, Gollwitzer, & Bargh, 2013). For example, after controlling for factors such as physical activity, stress, and emotional eating, 102 undergraduate students with an attentional bias towards healthy foods in experimental conditions showed a greater reduction in Body Mass Index (BMI) one year later (Calitri, Pothos, Tapper, Brunstrom, & Rogers, 2010), and interventions have been shown to change behaviour by training participants to re-learn attentional bias to threatening or maladaptive stimuli, although this does not always translate from a laboratory experiment setting to the real world (Jones, Hardman, Lawrence, & Field, 2018). Measures have also been developed to capture implicit attitudes through response time experiments, which have shown relationships between implicit attitudes and some health behaviours, particularly alcohol and substance abuse, but effect sizes are varied (Greenwald, Poehlman, Uhlmann, & Banaji, 2009). While stimulus response experiments have shown that short-term behaviours can be changed by re-associating for example, a snack with poor heart health (Hollands, Prestwich, & Marteau, 2011), there is less evidence for how long these shifts in implicit processes last in terms

of maintaining behaviour change, or how such behaviour changes can be implemented in a real-world environment.

1.4.1.6 Theoretical Domains Framework (Michie et al., 2005)

Michie et al. observed that there was overlap between the constructs proposed to predict behaviour change across the different theories, and by synthesising 33 different theories of behaviour they developed the theoretical domains framework which brought together key constructs from across existing models into 14 domains (Michie et al., 2005). This framework does not seek to provide a model to explain behaviour but rather to offer cognitive, social, environmental and affective perspectives through which to better understand behaviour and assist with implementing behaviour change interventions (Atkins et al., 2017). The theoretical domains framework has been used to inform the systematic development of a range of health interventions (Atkins et al., 2017), and a simpler representation has been developed in the form of the behaviour change wheel which represents three central ways of changing behaviour: capability, opportunity and motivation (Michie, Van Stralen, & West, 2011).

Research has attempted to identify how useful behaviour change theory is for developing effective interventions. A systematic review and meta-analysis of 85 studies of physical activity and diet found that DHIs had a larger effect on health behaviour if the intervention development incorporated theory, although there was wide heterogeneity in effect sizes suggesting that the effect of theory on effectiveness of DHIs remains ambiguous (Webb et al., 2010). Another meta-analysis refuted the importance of theory in developing effective interventions (Prestwich et al., 2014), finding only a very weak relationship between the extent to which theory was used in developing the intervention and its effectiveness. These mixed findings are not surprising given the complexities of establishing the role of theory in intervention design. Both meta-analyses used a coding system to evaluate to what extent the primary studies had used theory in the development of their DHIs, which meant that the meta-analysis relied on the authors' descriptions of their methods which could misrepresent the actual use of theory (Lorenzatto, West, Stavri, & Michie, 2012). Furthermore, the latter review found that few studies systematically applied theory throughout intervention development and evaluation, for example by targeting all relevant constructs identified by theory, mapping all the behaviour change techniques to theoretical constructs, or using theory to inform intervention tailoring, making it more difficult to ascertain the value of incorporating theory. Finally, intervention fidelity, i.e. to what extent the designed intervention was implemented during the trial, could also hinder interpretation of these findings as data were not available in either review on how the planned

intervention was delivered in reality. Therefore, while good practice suggests adopting an appropriate theoretical approach to intervention development (Craig et al., 2008), the importance of theory in intervention effectiveness is challenging to determine as so many variables can influence whether a DHI changes behaviour, including the specific context of the behaviour in question, the target population, and how accessible and enjoyable the DHI is to use.

1.4.2 The person-based approach to intervention development

The person-based approach (PBA) complements theory and evidence based intervention design by incorporating the perspectives of the users to try and ensure that a DHI is as acceptable, feasible, persuasive, and as enjoyable to use as possible (Yardley, Morrison, Bradbury, & Muller, 2015). This approach shares some similarities with user-centred design (Vredenberg, Isensee, & Righi, 2001) or participatory design (Schuler & Namioka, 1993), but the person-based approach is focused not only on ensuring the user can adequately interact with the DHI but also on understanding the behaviour change process in detail within each user's specific psychosocial context. The PBA integrates this understanding of the users' beliefs about behaviour with theory and evidence to make decisions about how to optimise behaviour change interventions (Bradbury et al., 2018).

In order to gain this in-depth understanding of users, the PBA proposes that the development phase of a DHI involves several rounds of exploratory qualitative interviews with a wide range of target users (Yardley et al., 2015). The PBA provides a rigorous process for deciding how to modify the intervention based on user feedback (Bradbury, Watts, Arden-Close, Yardley, & Lewith, 2014). The decision-making process draws on the MOSCOW approach for prioritising requirements (which stands for Must have, Should have, Could have, Would like and is widely used in project management) (Clegg & Barker, 1994), and confirming whether changes to the intervention are in line with theory, evidence, and are practical (Bradbury et al., 2018). This process complements the theory and evidence based approaches by helping intervention developers ensure that behaviour change techniques identified by theory are selected and applied in the most optimal way to facilitate behaviour change in a given context.

The PBA also suggests that a set of guiding principles be developed at the planning stage based on existing evidence and primary qualitative research conducted with the relevant population (Yardley et al., 2015). These guiding principles identify specific behavioural issues for a given population and detail how the intervention will seek to address these issues using certain distinctive key features. Guiding principles are designed to be referred back to throughout

intervention development to help ensure that the intervention priorities inform key decisions amongst the research team.

This approach has been successfully applied across a range of interventions for public health and chronic conditions in order to promote uptake, engagement, and effectiveness (Little et al., 2013; Yardley et al., 2010; Yardley et al., 2014). While the focus of the PBA might be on intervention planning and development, it is also a relevant approach to apply at later stages of intervention research to explore usage and outcomes during evaluation, and further identify ways to optimise the intervention.

1.5 Challenges in implementation

Implementation involves the successful roll-out of DHIs into practice, leading to a changed outcome (May et al., 2007). Having focused on different approaches to developing interventions, this section will discuss some of the challenges with implementing DHIs.

1.5.1 Engagement

A significant challenge for researchers is how to create DHIs which promote engagement from the users. Being implemented digitally means that it is very easy to lose users if the DHI is perceived as irrelevant, hard to use, or not sufficiently interesting, as they can easily close down a website or app and not return. Indeed, a cross-sectional survey in the U.S. of mobile phone owners found that approximately half of respondents had stopped using a health app due to losing interest, confusion over how to use it, or burden of self-reporting data at regular intervals (Krebs & Duncan, 2015).

Research has sought to identify factors which can promote engagement with DHIs. A critical interpretative synthesis suggested that incorporating tailored automated feedback in response to self-assessment questions may improve engagement (Morrison, Yardley, Powell, & Michie, 2012). It was found to be important that the feedback was perceived as relevant and consistent with the patient's own representation of their condition, otherwise it was seen as inappropriate and could increase the likelihood of disengagement. This is in line with the elaboration likelihood model which states that tailoring increases the perceived relevance of information for the users, which promotes motivation for engagement with the intervention and target behaviour (Petty & Cacioppo, 1986). More recent research has suggested that tailoring may work by focusing

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attention on personalised material without distracting the user with other less pertinent content (DiClemente, Marinilli, Singh, & Bellino, 2001).

One form of tailoring which has been widely used in DHIs, especially tele-monitoring, is feedback on progress towards goals according to health indicators, such as blood pressure, to motivate users to continue to engage with the intervention and the desired behaviour change. This is in line with self-regulation theory whereby participants are enabled to make informed decisions based on observations rather than habit or fear (Clark, Gong, & Kaciroti, 2014). Qualitative research found that smart phone users perceived tailored feedback in health apps as practical and motivating, although they were concerned about feeling demotivated when the app told them they had not achieved their goals (Peng, Kanthawala, Yuan, & Hussain, 2016). Disengagement when tailored feedback shows that behavioural or health goals were not achieved is a real risk for some intervention users, who find such feedback demoralising and react to it with avoidance rather than strengthened motivation to engage (Kangovi & Asch, 2018). Indeed a large study of diabetic patients found no improvements in glycaemic control when tailored feedback was provided on self-monitoring, and the group receiving enhanced feedback on their progress actually had higher attrition rates than those self-monitoring without feedback (Young et al., 2017). This suggests that the content and style of the feedback needs careful consideration to ensure it does not have the opposite effect in terms of engagement. One way in which feedback could seek to promote motivation rather than disengagement is by helping participants to feel that achieving their goals is within their control (Eberly, Liu, & Terence, 2013). Another means to reduce disengagement when participants are not progressing towards goals is for the feedback itself to promote positive affect by being kind and encouraging, to make the intervention more enjoyable to use despite the challenge of reaching health goals (Morrison, 2015).

In addition to intervention features, patient characteristics can also influence engagement. A recent evaluation of a DHI to improve diabetes self-management found that patients with higher self-efficacy to manage diabetes at the outset, a perception that their diabetes was controllable through maintaining a healthy lifestyle, and low perceived competing priorities had higher engagement with the DHI (Desveaux et al., 2018). Identifying patients who might struggle to engage may enable further support to be provided to these groups when introducing a DHI, as those with lower-self efficacy may be the ones who need the intervention most. Qualitative evidence from diabetic patients who withdrew from a self-management DHI with asynchronous communication with the HCP suggested that additional face-to-face support for patients who struggled to understand the benefit of the intervention, experienced frustrations with the

technology, or experienced competing priorities due to complex lives may promote engagement with self-management DHIs (Lie, Karlsen, Oord, Graue, & Oftedal, 2017). A sense of relatedness with the HCP appeared to be important to promote patient engagement, in line with SDT, and DHIs could consider how to encourage this perception of support without compromising cost-effectiveness or engendering dependence in their users.

Recent research has drawn attention to the difference between promoting maximum engagement with a DHI and promoting sufficient engagement to bring about the desired behaviour change, termed 'effective engagement' (Yardley et al., 2016). This distinction recognises that engaging with a DHI is not equivalent to engaging with the behaviour change, such that some people may only need so much support from the DHI before they successfully change and maintain their behaviour without continuing to use the DHI (Yardley et al., 2016). Therefore disengagement could indicate that the behaviour change is no longer being adhered to, or that the DHI is no longer needed once the new behaviour has been successfully mastered. It is important that researchers are able to distinguish between these two types of disengagement. One issue with the concept of effective engagement with a DHI is that it might be more applicable to behaviours where there is a certain end goal, e.g. smoking cessation, weight loss or adequate hand washing, than other behaviours which are intended to continue over time and actually depend on the DHI to be effectively performed, e.g. self-monitoring health indicators. While it has been acknowledged that effective engagement will need to be defined specifically for each intervention, it may be more relevant for some DHIs than others.

Overall, this section has evaluated both intervention and patient factors which could relate to engagement with a DHI. Implications in terms of possible strategies to promote engagement have been outlined, including tailoring, promoting self-efficacy, and encouraging positive affect. The next section will consider some of the barriers to implementation at the healthcare level.

1.5.2 Implementation in healthcare

Several theories have been developed to identify and explain factors affecting how successfully interventions are implemented in healthcare. These include the Consolidated Framework for Intervention Research (CFIR) (Damschroder et al., 2009) which identifies five domains influencing intervention implementation: The intervention itself (e.g. perceived credibility and adaptability); the inner and outer context of the healthcare setting in which it is being embedded (e.g. extent of wider relationships with other organisations, external policies, leadership engagement); the

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individuals using the intervention (e.g. knowledge and beliefs, perceived identification with the organisation); and the process (specifically, planning, engaging, executing and evaluating).

While the CFIR can help highlight possible factors for researchers to consider during implementation, this thesis draws on another theory which is more focused on the *process* of implementing healthcare interventions in complex systems; Normalisation Process Theory (NPT). NPT includes four mechanisms which are in some ways similar to the planning, engaging, executing and evaluating activities described by the process domain from CFIR (May et al., 2007), but NPT emphasises the importance of understanding behaviour change at a collective or group level in terms of complex social mechanisms (May et al., 2007). While the CFIR provides a useful overview of factors to consider, it does not offer such rich understanding of the implementation of complex interventions in complex settings where people interact and work together to implement a new process. As NPT is used to help interpret the findings in this thesis, this section will now focus on explaining this theory in more detail and considering some of the evidence in order to better understand how DHIs are implemented at an organisational level.

NPT proposes four social mechanisms that influence the likelihood of an intervention being adopted in an existing system, which are described in Table 1. These mechanisms define how a new process is enacted, and they occur in both an individual and a social setting.

Table 1 Definitions of NPT constructs

NPT construct	Definition
Coherence	How people make sense of and understand a new process and the set of tasks they must do, and the value or benefit they attach to this
Cognitive participation	How people collectively engage with driving the new process forward and sustaining it. May involve reorganising themselves and others to perform new practices, and ensuring participants perceive it as part of their role
Collective action	The work that people do to enact the new process and how this is done
Reflexive monitoring	The appraisal that people undertake to evaluate the impact of a new process

NPT has been used to retrospectively understand an implementation process (McEvoy et al., 2014), and a recent study showed this theory can also be effective in prospectively guiding and monitoring implementation of a new procedure in healthcare, with greater normalisation of the intervention (as measured by self-report questionnaires) related to greater compliance and improved health outcomes (Johnson et al., 2017). The value of NPT in understanding implementation has been demonstrated more widely in an overview of systematic reviews, which found that behavioural interventions for HCPs in Primary and Secondary Care seemed to be more successful in changing practice or clinical outcomes when they incorporated more of the NPT constructs (Johnson & May, 2015). Interventions acting on the constructs of collective action and reflexive monitoring (such as those using feedback or reminders to change actions) appeared to be particularly effective compared to those only targeting coherence or early cognitive participation (such as interventions using persuasion). However it is unclear how much this review extends our knowledge as feedback has already been identified as a facilitator of behaviour change in the BCT taxonomy (Guthrie et al., 2016; Michie et al., 2013), so this may simply be allocating NPT terminology to evidence-based behaviour change techniques. It is also worth

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noting that the coders were not blinded to the findings of the systematic reviews when categorising which NPT constructs each intervention incorporated, which could have biased the results. Overall though, it seems that the NPT provides a useful framework of social mechanisms which can influence the successful adoption of interventions in healthcare, and can help researchers consider how to optimise implementation in a complex setting.

In addition to implementation theories, there is a growing recognition of the importance of taking context into account in health intervention research (Craig et al., 2018). A recent in-depth evaluation of context in population research conducted in 2018 by the Canadian Institute of Health Research (CIHR) and National Institute for Health Research (NIHR) developed a comprehensive framework of contextual factors which can interact with the intervention to influence its development, delivery and evaluation (Craig et al., 2018). Twelve contextual dimensions were defined which could interact with the intervention throughout the research process, including cultural, social and economic, political, organisational, and historical (Craig et al., 2018). Not all dimensions were posited to be relevant for all intervention studies or reviews, but using the checklist and the questions posed for how these factors might influence research could help identify which factors might be most relevant in a given situation and ensure greater transparency of this intervention-context relationship. The recency of the CIHR/NIHR report, its comprehensive approach of combining together several existing contextual frameworks, and its explicit focus on developing guidelines for population health intervention research rather than studying implementation processes in general meant that this was deemed a useful approach for conceptualising context in this research thesis, and this was used as well as the NPT to help interpret findings.

1.6 High blood pressure as a chronic health condition

As this PhD thesis was conducted as part of a Programme Grant for Applied Research funded by the National Institute for Health Research (NIHR) (Yardley, 2013), the broader context in which the work was conducted will now be described.

The programme grant aimed to develop and optimise self-management DHIs for implementation in Primary Care for two distinct chronic conditions: uncontrolled hypertension and asthma. It also aimed to assess the effectiveness of the hypertension DHI in a randomised controlled trial (RCT). This thesis focused on the planning and evaluation of the hypertension DHI, known as HOME BP. This section will explain the rationale for developing a self-management DHI for uncontrolled hypertension, and the existing evidence in this area.

High blood pressure (BP) or hypertension is a chronic physical condition with no symptoms, which is a significant risk factor for chronic heart disease, stroke, and chronic kidney disease (NHS, 2016). In most cases, the causes of hypertension are unknown (Collier & Landram, 2012). While the health risks of high BP are cumulative such that every 2mmHg increase in systolic BP increases the risk of death from stroke by 10% (NICE, 2011), the threshold for diagnosis of hypertension in Primary Care in the UK is set at 140/90mmHg (NICE, 2011).

High BP is a prevalent condition, affecting 28% of adults in the UK (NHS Digital, 2016). It places a huge demand on healthcare services, being the most common chronic condition seen in Primary Care consultations (O'Brien et al., 2013) and costing approximately £1 billion in drugs in 2006 (NICE, 2011). However, almost half of patients in England taking antihypertensive medication remain poorly controlled with their BP still exceeding recommended targets (Joffres et al., 2013). Barriers to successful control have been identified at the patient and HCP level. Patient adherence to antihypertensive medication is known to be suboptimal with 45% of hypertensive patients found to be non-adherent to their prescribed medications (Abegaz, Shehab, Gebreyohannes, Bhagavathula, & Elnour, 2017). Factors contributing to poor adherence include intolerance of the side effects of BP medication, a low perceived need for medication (which can be informed by the lack of symptoms), and low health literacy or poor understanding of their condition (Jolles, Padwal, Clark, & Braam, 2013). Furthermore, many people need adjustments to their medication (increased dose or additional drug) to successfully control their BP, but the HCP can be reluctant to make changes to medication. This is known as clinical inertia. Indeed 45% of hypertensive patients with an above-target reading during a consultation did not receive any change to their current medication (Guthrie, Inkster, & Fahey, 2007). Reasons behind clinical inertia can include concern about aggressive management of hypertension leading to adverse side effects for the patient, low confidence in the effectiveness of medication to control patients' BP, uncertainty about the representativeness of clinic BP readings, and doubt about whether adhering to clinical guidelines would improve patient outcomes (Khatib et al., 2014). Achieving successful BP control would appear to involve a complex interaction between these patient and HCP factors.

As well as individual-level barriers, the role of the healthcare system in BP management needs to be acknowledged. Within the NHS, controlling high BP for hypertensive patients is a key target in the Quality and Outcomes Framework (QoF), which encourages HCPs to focus on achieving this goal (NHS England, 2018). However, the target set by these incentives is 150/90 mmHg, which is higher than the clinical threshold of 140/90 mmHg outlined by the NICE guidelines (NICE, 2011), so the extent to which the QoF helps reduce clinical inertia or reinforces reluctance to change

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medication around the 140 mmHg threshold is unknown. Ambiguity over who is responsible for initiating medication change at the GP Practice and shortage of time for appointments can also cause barriers within the healthcare system (Khatib et al., 2014). The need to attend regular clinic appointments (including follow-up appointments to check kidney function when medication is changed) and to pay for each item in medical prescriptions could act as further burdens at the level of the healthcare system for patients engaging in hypertension care.

It has been recognised that self-monitoring BP at home can help to overcome some of these barriers and improve hypertension control, but only when accompanied by interventions to support engagement with strategies to control BP (Tucker et al., 2017). Randomised controlled trials have found that patients monitoring their BP at home and sending the readings to the GP (self-monitoring), or requesting prescriptions for pre-planned changes to antihypertensive medication when readings were above-target (self-management) led to improved systolic BP at 12 months (McManus et al., 2010; McManus et al., 2018). Patients described feeling reassurance from self-monitoring their BP and liked having additional control and insight into their condition, although they weighed up recommendations to change medication against the risk of side effects and to what extent their readings exceeded the threshold (Jones et al., 2012). A qualitative synthesis of patients' perceptions about self-monitoring BP found that on a practical level it helped them to engage in interactive discussions with the HCP and feel more involved in their condition management, although it was important that the GP was perceived to be interested in their home readings otherwise patients felt disempowered (Fletcher, Hinton, et al., 2016). Where there was uncertainty over how to respond to out-of-range BP readings, this could cause anxiety for patients self-monitoring at home (Fletcher, Hinton, et al., 2016). At a more conceptual level, a meta-review of quantitative and qualitative reviews found that self-monitoring BP at home with HCP support could change patients' perceptions about hypertension from a condition caused by stress which manifests as physical symptoms when BP is high, to the more biomedical definition of a symptomless condition (Shahaj et al., 2018). This shift to a more medical view of hypertension helped patients understand the relevance of regular adherence to antihypertensive medication, thus facilitating more effective self-management.

Self-monitoring interventions for BP have often involved significant face-to-face human support, from HCPs or the research team, especially at the outset to train patients to use BP monitors, to understand the meaning of the BP targets and how to initiate a medication change (McManus et al., 2010). This makes the interventions less cost-effective and less feasible to roll out on a wider scale due to the costs and resources needed to provide this face-to-face support. DHIs could offer a more cost-effective means to roll out a wide-scale self-monitoring intervention for high BP. A meta-analysis of interactive DHIs to support patient self-management of high BP found a small

but significant reduction in systolic and diastolic blood pressure (McLean et al., 2016), although only a small number of studies were found suggesting that more research is needed to explore how to optimise a digital self-management intervention for uncontrolled hypertension. A review of existing evidence suggested that DHIs may be less effective at lowering BP when patients self-manage entirely independently without the support of a HCP (Thangada, Garg, Pandey, & Kumar, 2018). This review was unable to determine *how* HCP support facilitated BP control, but possibilities include providing support to interpret readings in a meaningful way, or that additional medication titrations occurred when the HCP was involved. Tailored feedback messages on BP readings appeared to lead to reductions in BP in some studies, suggesting HCP support is not always required (Logan et al., 2012; Park & Kim, 2012).

The Lancet Commission on hypertension management proposed a series of key actions based on the most serious concerns about hypertension on a global scale. These actions included education to promote understanding of BP using new technologies, and home monitoring as a more accurate measure of BP than clinic readings (Olsen et al., 2016). A recent qualitative study explored how HCPs felt about this move towards digital technology and self-management for hypertension, and found that DHIs to support BP self-monitoring were perceived as empowering for patients (Morrissey, Glynn, Casey, Walsh, & Molloy, 2017). Concerns arose about the trustworthiness of DHIs, especially apps, if created by pharmaceutical companies who were perceived to have their own agenda, suggesting that a credible, not-for-profit DHI is needed to ensure HCPs are willing to buy in to the process.

1.7 The HOME BP intervention

The HOME BP intervention was developed as part of the NIHR programme grant (see Figure 1). The intervention development occurred outside the scope of this thesis, but as the first paper informed the intervention planning and the latter two papers evaluated the HOME BP intervention, this section will describe the development process, the intervention components, and theoretical content. The TIDieR checklist was used to ensure thorough reporting of the intervention (Hoffmann et al., 2014).

1.7.1 HOME BP intervention planning and development

1.7.1.1 Intervention planning

HOME BP was developed using evidence, theory, and the person-based approach (Band et al., 2017). During intervention planning, a quantitative systematic review of the evidence for using DHIs to manage high BP was undertaken, identifying seven studies which suggested a small but significant benefit in reducing systolic blood pressure (McLean et al., 2016). The sustainability of this effect over time could not be determined. Many of the DHIs in this review provided considerable face-to-face support for patients but the added value of this support in terms of clinical effectiveness was unclear, and this was an important consideration in HOME BP given the need to create a cost-effective and feasible intervention.

A rapid scoping review of the qualitative literature was also undertaken as part of the intervention planning to explore perceived facilitators and barriers for patients and HCPs engaging with DHIs for self-managing BP (Band et al., 2017). Details about the intervention components from each study were extracted into a table and implications for optimising potential facilitators and minimising potential barriers were identified.

Behavioural analysis was used to map evidence from the literature reviews on to theories describing relevant causal mechanisms for explaining the process of change in HOME BP (Band et al., 2017). The target patient behaviours included engaging with the online components, regularly self-monitoring BP at home for a period of 12 months, adhering to medication change, and to a lesser extent, engaging in healthy lifestyle behaviour changes. Theories of individual behaviour change which informed the intervention included social cognitive theory (Bandura, 1991), the Common Sense Model (Leventhal & Brissette, 2012) and the Necessity-Concerns framework (Horne & Weinman, 2002), while Normalisation Process Theory (NPT) was also used as a theory of organisation-level change to map out the implementation processes for HOME BP intervention (May et al., 2007). These theoretical constructs will be discussed below in relation to managing uncontrolled hypertension.

1.7.1.2 Using theory to understand target intervention behaviours

Possessing sufficient self-efficacy has been found to be important for self-monitoring BP such that when patients felt uncertain how to fit the cuff on their arm or felt they needed reassurance from the HCP to check how to use the monitor, this perceived lack of competence could reduce engagement (Hanley, Fairbrother, Krishan, et al., 2015). One of the most effective ways to increase self-efficacy according to SCT is through personal mastery of the experience, such as practising monitoring BP, as this enables the individual to experience any barriers to engaging

with the behaviour and gain evidence that they can overcome them (Conner & Norman, 2005). Also consistent with SCT, holding the outcome expectancy that taking antihypertensive medications could lead to long-term harm seemed to reduce patients' intention to engage in medication change (Bokhour et al., 2012).

Bandura posited that self-efficacy and outcome expectancies can interact and influence one another (Bandura, 1991). In the context of the HOME BP intervention, if patients perceived that adhering to medication change was worthwhile, they may have perceived that they were more capable of engaging with this behaviour (perceived self-efficacy increased when the outcome was perceived more positively). Similarly, if patients perceived that they were capable of regularly monitoring and making changes to medication, they may have perceived that the outcomes of changing medication were more positive (outcome expectancies were more positive when self-efficacy was higher). This suggested that both constructs were important to promote in order to increase the likelihood of effective behavioural engagement with the intervention.

The behavioural analysis found that the Necessity-Concerns framework (Horne & Weinman, 2002) and the Common Sense Model (Leventhal & Brissette, 2012) provided relevant explanations of patients' engagement with target behaviours, and that these were compatible with SCT in that they offered a more detailed insight into the kind of outcome expectancies hypertensive patients hold about their condition. These models complemented one another, both focusing on understanding the specific patient beliefs about their condition and medication in order to facilitate effective coping behaviours.

The Necessity-Concerns framework proposes that medication adherence behaviours are influenced by the perceived personal need for the medication weighed against concerns about adverse effects of taking the medication (Horne & Weinman, 2002). According to this model, DHIs which take these patient beliefs into account will be more effective. In the context of hypertension, perceiving a benefit of medication has been found to be the strongest predictor of medication adherence (Rajpura & Nayak, 2014). However patients can also hold several concerns about taking medication for high BP, including anxiety about side effects and concerns about the long-term impact of the medication (Jamison, Sutton, Mant, & De Simoni, 2017), suggesting it is important to take both perceived need and concerns into account. The Necessity-Concerns framework has been found to be associated with medication adherence in hypertension (Ross, Walker, & MacLeod, 2004).

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Patients' beliefs about their condition can be further elucidated by the Common Sense or Self-Regulatory model (Leventhal & Brissette, 2012). This model proposes five domains which define a patient's representation of their illness, or the story they have constructed to explain their condition to themselves, and which are theorised to influence their illness management behaviours. These domains include their beliefs about the illness identity (the label to describe the condition and knowledge about its manifestation); cause (beliefs about factors responsible for the condition); consequences (beliefs about the effects of the condition); timeline (beliefs about the nature of the condition over time) and control (beliefs about whether the condition is controllable) (Leventhal & Brissette, 2012). Beliefs held by hypertensive patients about adhering to or changing medication can be understood in terms of these illness representations. A qualitative study exploring hypertensive patients' representations of their condition found that the lack of symptoms of hypertension (part of the illness *identity*, as people often expect symptoms when they are ill) and the perception of high BP as a temporary state caused by stress or activity rather than a chronic condition (*timeline*) can reduce the perceived need for adhering to regular daily medication (Bokhour et al., 2012). Some patients did attribute symptoms to their high BP (e.g. headaches), but perceived these as intermittent and only wished to take antihypertensive medication when the presence of symptoms indicated to them that their BP was raised (Bokhour et al., 2012). Previous experience at the GP Practice of medication not being changed despite above-target clinic readings also reduced the perceived severity of the *consequences* of having high BP, which could minimise the perceived need to change medication when hypertension was poorly controlled. However a quantitative study using the Illness Perceptions Questionnaire (Moss-Morris et al., 2002) found that patients had a high perceived need for antihypertensive medication, perceiving their condition as both long-term and controllable (Ross et al., 2004). Patients held relatively low concerns about the consequences of hypertension which seemed to encourage rather than minimise adherence to medication, possibly due to a lack of emotional response or anxiety about the condition facilitating more adaptive coping.

These studies appear to contradict one another in terms of how hypertensive patients' illness representations influence their self-management behaviours. It is important to note when interpreting these findings that the qualitative study specifically targeted patients with uncontrolled hypertension, and these patients might hold different representations of their condition from the more well-controlled sample who responded to questionnaires. In addition, it may be that in-depth qualitative interviews uncovered more nuanced illness perceptions that were not evident in the illness perception questionnaire. A wide range of illness representations

amongst hypertensive patients is consistent with a recent meta-review of six qualitative reviews exploring patients' experiences of managing the condition (Shahaj et al., 2018).

1.7.1.3 Logic model

The SCT, Necessity-Concerns framework and Common Sense Model were incorporated into a logic model to hypothesise the mechanisms through which the HOME BP intervention was theorised to influence behaviour (Figure 2). The logic model also used the NPT framework to identify how HOME BP would address potential barriers to effective implementation. At the patient level, building motivation for self-monitoring BP was categorised as a means to promote *coherence* of this behaviour, and at the HCP level, email prompts were categorised as promoting *cognitive participation* (May et al., 2007). Behaviour change techniques (Michie et al., 2013) to target these constructs were selected in a process of behavioural analysis combined with a pragmatic approach to determine which BCTs were most feasible to apply in this context using a MOSCOW analysis (Bradbury et al., 2014; Clegg & Barker, 1994). For example, 'inform of health consequences' was used to build patients' motivation to engage in self-monitoring and their *coherence* (NPT) for perceiving this as a valuable behaviour to engage in. This demonstrates how theory and evidence were used to inform intervention planning.

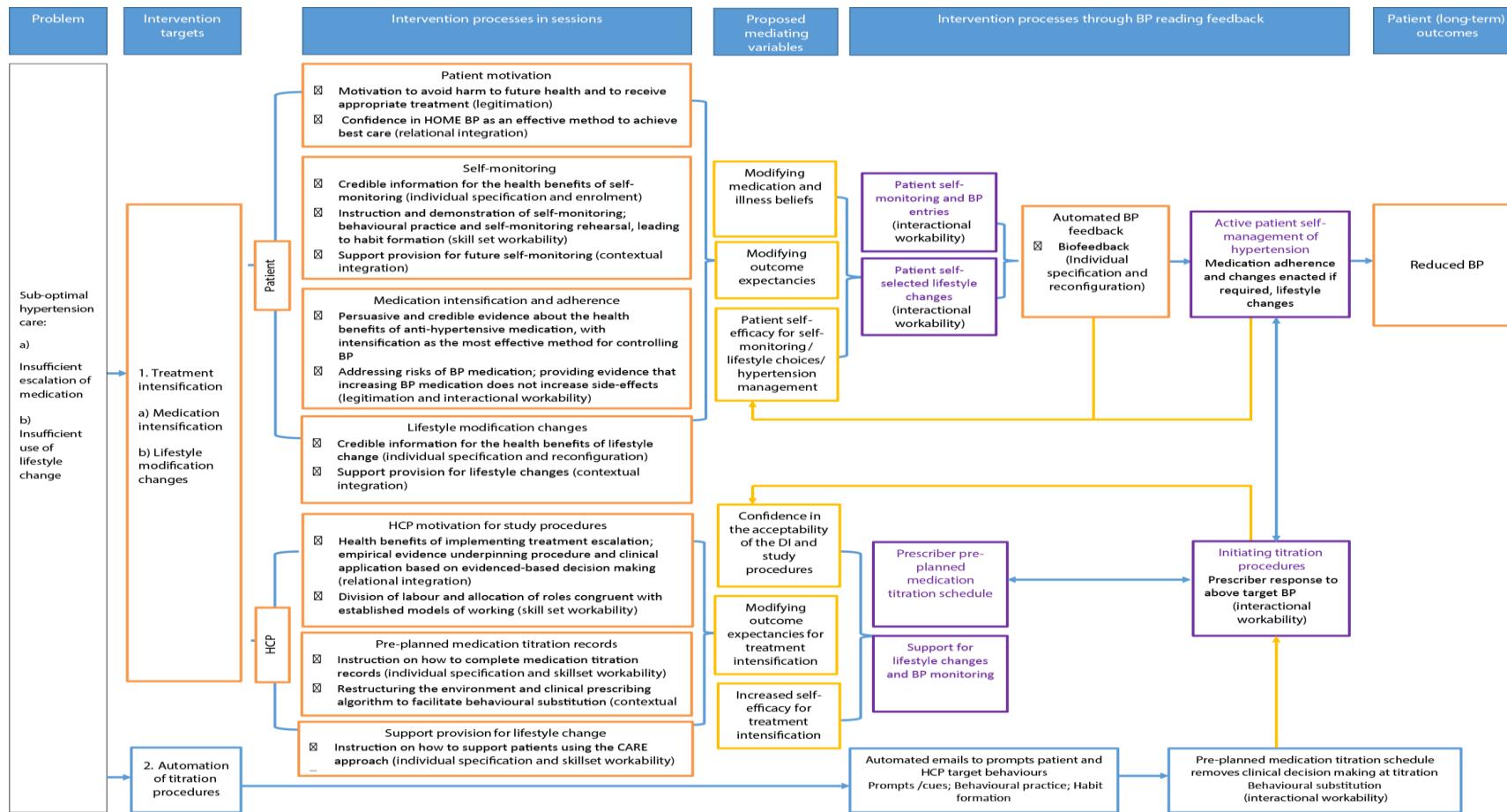


Figure 2 The HOME BP logic model

1.7.1.4 Intervention development using the Person-Based Approach

In addition, the person-based approach was used which involved extensive iterative qualitative research during development to ensure that the intervention materials were as acceptable, feasible, convincing, motivating, meaningful and enjoyable to use as possible (Bradbury et al., 2018). This involved conducting 36 thinkaloud interviews with 12 hypertensive patients (each participant took part in 3 separate interviews focusing on different sessions of the DHI) in an iterative cycle which enabled important modifications to be made to the HOME BP intervention based on the previous round of interviews before seeking further feedback from new participants with the revised version of the intervention. All facilitators and barriers to engaging with the intervention or target behaviours were extracted from the interview transcripts and tabulated, and modifications to overcome participants' concerns were agreed by the research team. The main purpose was to check that the content of the intervention was convincing and persuasive, and to identify any concerns or beliefs held by participants about the target behaviour which the intervention failed to address. For example, some participants believed that their GP already provided them with the best possible care and did not believe they would exhibit clinical inertia, therefore reducing the perceived need for the intervention. Session 1 was re-phrased to explain that the intervention would help GPs to provide the best care by providing more accurate information about the patients' BP to inform their decisions. This appeared to be more acceptable to patients in subsequent interviews as it was more consistent with their beliefs about their GP as competent and caring.

Once no more concerns arose from the thinkaloud interviews, the next phase of the approach involved 11 participants using the HOME BP intervention independently and discussing their experiences retrospectively in semi-structured telephone interviews. This provided the opportunity for patients to experience the intervention and try out the target behaviour (self-monitoring BP and reporting the readings online) in a real life setting. Due to practicalities, it was not possible to try out the other key target behaviour of changing medication when readings were above-target, which was a limitation as ideally all target behaviours would be tried out during this initial phase of intervention development. Nonetheless, this study identified important barriers to engaging with the intervention which could be overcome by appropriate modifications. For example, some participants were not confident in how to use the BP monitor at home and as a result, did not trust the readings to be an accurate indication of their BP. Therefore it was agreed

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that all participants would take a practice week of readings at the start of the intervention, and would have the opportunity to discuss these with their nurse if they were concerned (Bradbury et al., 2018). This was an important modification and was in line with the evidence and theory which suggested that increasing self-efficacy is important for facilitating engagement in self-monitoring.

The third study conducted as part of the person-based approach to developing HOME BP focused on the perceptions of the HCPs. Seven focus groups were conducted with a range of GPs, practice nurses, healthcare assistants and receptionists who had viewed the online practitioner training sessions prior to the focus group (n=55) (Bradbury et al., 2017). As with the thinkaloud patient interviews, these focus groups were conducted in an iterative cycle to enable modifications to be made to the intervention based on previous feedback. Although many HCPs liked the concept of encouraging patients to self-manage and believed that the intervention could save them time, concerns were raised about whether they could trust home readings to inform medication decisions, and potential risks of deciding medication changes in advance. This highlighted important beliefs which the intervention needed to address in the training sessions for HCPs, for example by increasing their confidence in the accuracy of home readings through explaining about the practice week and evidencing successful interventions which have relied on home readings. This was in line with SCT in terms of building self-efficacy in using home readings and increasing outcome expectancies about the benefits of this approach. This qualitative work carried out in the development phase of the programme enabled important modifications to be made to HOME BP to optimise the intervention for both patients and HCPs.

As part of the planning and development process for HOME BP a set of guiding principles were identified, in line with the person-based approach (Yardley et al., 2015) (Appendix A). Based on an in-depth understanding of the target users' context developed from the literature and qualitative research, the team identified key behavioural challenges which the DHI needed to overcome and outlined design features of the intervention to address these. For example, a key design objective of the DHI was to motivate patients and HCPs to titrate medication, and intervention features which were incorporated to achieve this included education about the benefits of medication change and promoting self-efficacy to engage in this behaviour (Band et al., 2017). These guiding principles helped to emphasise the distinctive qualities of the HOME BP intervention and were a key document to refer back to throughout development, especially when making modifications to optimise the intervention during the qualitative interviews with target users as this helped ensure that changes were in line with the guiding principles.

1.7.2 Description of the HOME BP intervention

HOME BP was an online self-management DHI based on the algorithms for self-managing BP found to be successful in TASMINH2 and TASMIN-SR (McManus et al., 2010; McManus et al., 2014). The primary focus of HOME BP was improving BP control in Primary Care through appropriate medication change (also known as medication titration), as medication change is recognised as the most effective method to control high BP (Glynn, Murphy, Smith, Schroeder, & Fahey, 2010). This involves increasing the dose or adding a new drug to a participant's blood pressure medication regime (McManus et al., 2009). Lifestyle change (such as salt and alcohol reduction, and weight loss) can also reduce BP (Svetkey et al., 2005) but adherence to lifestyle change amongst the hypertensive population tends to be low (Tibebu, Mengistu, & Negesa, 2017). Therefore HOME BP prioritised BP self-monitoring and medication change as the key patient behaviours to achieve the primary outcome, but also offered an optional lifestyle support component. The intervention was designed to be implemented with the support of a prescriber (GP or nurse prescriber) and a supporter (nurse or healthcare assistant). Figure 3 shows a flow chart of the HOME BP intervention components.

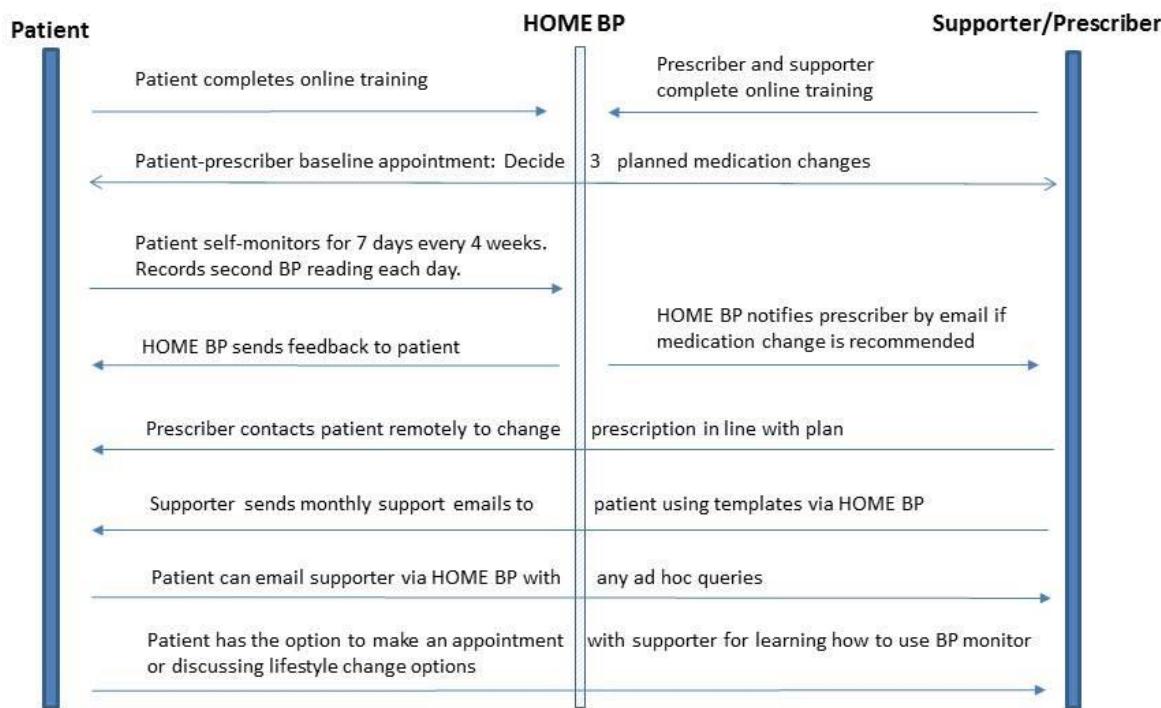


Figure 3 Flow chart of the HOME BP intervention

The prescriber's role was to plan 3 medication changes for each patient at baseline and to initiate medication changes in response to raised average home readings during the trial, ideally without seeing the patient to improve cost-effectiveness. The supporter's role was to provide monthly support to patients to engage with the DHI using pre-written email templates which could be personalised, to respond to ad hoc queries from the patient via email, and to provide optional face-to-face support for using the BP monitor and choosing a lifestyle change.

1.7.3 Training

The prescriber and supporter completed compulsory online training which aimed to explain the effectiveness of BP self-management and the purpose of the HOME BP intervention. The prescriber training included evidence to overcome clinical inertia and improve HCPs' outcome expectancies, for example that increasing antihypertensive medications in a previous trial had not led to more side effects for patients but had improved BP control (McManus et al., 2010), and examples of how to plan medication changes for complex patients with co-morbidities to increase prescribers' self-efficacy. The supporter training included explanations of the email support and a description of the CARE approach (Congratulate, Ask, Reassure, Encourage (Bradbury et al., 2017)) which supporters were encouraged to use during any face-to-face contact with patients during the trial. CARE is based on SDT (Deci & Ryan, 2011) and seeks to promote patient autonomy in behaviour change rather than creating dependence on the supporter. Due to previous evidence that nurses were not confident implementing the CARE approach (Smith et al., 2017), the online training also included examples of how to use each of the CARE components in an appointment to support self-monitoring or lifestyle change, and evidence for its acceptability to patients and HCPs in previous trials.

Patients completed two compulsory online sessions at the start of the 12-month intervention. The first session explained the benefits of self-monitoring BP at home and titrating medication when BP is above target, to improve patients' outcome expectancies. This included an interactive quiz to demonstrate the health benefits of controlling BP, and a question and answer section to address common concerns about self-monitoring BP and changing medication, such as side effects and lack of HCP support. The second session showed patients how to use their monitor, including a video, and explained the rationale for the monitoring schedule. Patients were told that their monitor might be checked against their online readings, to encourage accurate reporting.

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Short stories from other patients who have successfully managed their BP in this way were included to promote self-efficacy.

1.7.4 Blood pressure self-management

Participants monitored their BP at home for 7 days every 4 weeks. This was a similar monitoring schedule to that used in TASMIN4H (McManus et al., 2018) , and was based on NICE best practice guidelines for home monitoring frequency (NICE, 2011). Recommendations for initiating pre-planned medication changes were made after two consecutive months in which the average of 7 readings was raised (>135/85, see Appendix B for BP targets, based on NICE guidance). The patient received instant feedback from HOME BP to let them know if a medication change was recommended, which asked them to wait to hear from their prescriber (see Appendix C), and the prescriber was alerted by email to initiate the next planned medication change (see Appendix D). Prescribers were trained to contact patients by letter in the case of a medication change (a template was provided for the letter, see Appendix E), and patients could pick up their new prescription from the GP Practice or their pharmacy.

1.7.5 Lifestyle

The option to select a healthy lifestyle change became available 9 weeks after randomisation, in order to avoid overwhelming patients with multiple behaviour changes at once (Hyman, Pavlik, Taylor, Goodrick, & Moye, 2007) and to allow time for the key behaviour of self-monitoring BP to become more familiar (Gardner, Lally, & Wardle, 2012).

The optional lifestyle session covered the benefits of five lifestyle changes: increasing physical activity; reducing salt; eating a healthy diet; reducing alcohol; and losing weight (if BMI was over 25). Standalone online interventions were available for each behaviour change, including one-off educational sessions regarding salt, diet and alcohol, an interactive intervention with email prompts for increasing physical activity (Getting Active) and a 24-session intervention shown to be effective in supporting sustainable weight loss through the choice of following a low-carbohydrate or low-calorie plan using self-management techniques such as goal-setting (Little et al., 2016). In addition to the optional session which outlined the five lifestyle change options, there were direct links via the menu section of the HOME BP intervention to each of the lifestyle change interventions. Participants also received six email prompts at various time points during the 12-month trial to highlight the benefits of healthy lifestyle changes, including links to the online programmes.

1.8 Thesis research questions and methodological approaches

This thesis is comprised of three papers:

1. A qualitative meta-synthesis of primary qualitative research on users' experiences of self-management DHIs (intervention planning);
2. A qualitative process study of patients' experiences of using the HOME BP intervention (intervention evaluation);
3. A mixed methods process study of HCPs' experiences of using the HOME BP intervention (intervention evaluation).

This section will describe how the research questions were determined and the rationale for using the methods selected for each study. Some of the outputs were predetermined by the programme grant in which this project is embedded (Yardley, 2013), but decisions about the approach, research questions and methods of analysis were made by the author and will be described below.

1.8.1 Paper 1: Qualitative meta-synthesis

The qualitative meta-synthesis formed part of the intervention planning phase in the grant proposal for this project (Yardley, 2013). Qualitative syntheses are increasingly used in health research in order to develop understanding of patient and/or HCP experiences and to generate new theory to explain relationships or unexpected quantitative findings (Atkins et al., 2008), for example regarding interventions' effectiveness or lack thereof. In the context of this programme grant, the rationale for the synthesis was to complement a quantitative systematic review of the effectiveness of DHIs for managing hypertension by providing an insight into the psychosocial contexts of DHI users and how digital tools are experienced.

The aims of the meta-synthesis were subsequently refined by the author as part of this thesis. Based on scoping searches of the literature it was decided to include the views and experiences of both patients and HCPs as these groups appeared to offer different insights, both of which would be important to understand to inform the development of the hypertension DHI (which would be used by both populations in Primary Care). It was also decided to include qualitative studies across a range of chronic conditions, not only hypertension, as initial searches indicated that experiences of using a self-management DHI were potentially relevant regardless of the specific

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condition in question. This would also enable more studies to be included which was deemed important for gaining sufficiently detailed findings. The final aims are defined in section 1.11.

In terms of the search strategy, some researchers have argued that conducting a systematic, exhaustive search increases the rigour of the review and ensures the findings carry weight in the research community (Toye et al., 2014). However, the decision was made not to conduct an exhaustive search to enable a more focused approach to searching to produce a realistic number of papers for in-depth synthesis and developing understanding, while avoiding an overly inclusive approach which could yield sweeping generalisations (Atkins et al., 2008; Noblit & Hare, 1988; Thomas & Harden, 2008). This decision may have led to some important papers not being included in the synthesis, but it was informed by previous qualitative review search strategies and was in line with the goal of the synthesis to further knowledge rather than to fully review all research to date.

In terms of analysis, the grant proposal planned to use thematic synthesis (Thomas & Harden, 2008) and, if the data allowed, some techniques from meta-ethnography in order to supplement the findings with more theoretical interpretations. Thematic synthesis is an appropriate method for generating practical recommendations, for example identifying barriers and facilitators to intervention effectiveness (Thomas & Harden, 2008). Meta-ethnography meanwhile tends to provide a more interpretive, conceptual level of analysis which is useful for generating theory, as it synthesises the findings of qualitative studies to construct a higher level argument with greater explanatory power than any one study on its own (Campbell et al., 2011). Both methods were used in this qualitative synthesis due to initial uncertainty over whether the data were rich enough for a meta-ethnography, as some of the eligible studies were quite descriptive and shallow in their analysis. Only the meta-ethnography is reported in the paper due to journal restrictions on word limit preventing both methods of analysis from being reported. The meta-ethnography provided richer insights into users' experiences of DHIs which were more appropriate for answering the explorative research question by reinterpreting concepts as opposed to summarising them. The next section describes the meta-ethnography approach in more detail and outlines some of the concerns and limitations of qualitative synthesis.

1.8.1.1 Meta-ethnography methods

The process of conducting a meta-ethnography is described in several research papers (Britten et al., 2002; Campbell et al., 2011; Noblit & Hare, 1988), although some areas of ambiguity remain. The original methods were described in seven steps by Noblit and Hare (Noblit & Hare, 1988). These steps were proposed to be iterative and overlap with one another during the process of conducting the synthesis. After the first step of 'getting started' in which a research question is

determined, the authors proposed the second step of 'deciding what is relevant', which as discussed above does not involve an exhaustive search but rather a more strategic selection of relevant studies to inform the research question. The third and fourth steps involve 'reading the studies' in detail, and 'seeing how the studies are related'. In understanding how studies relate, the authors suggest noting down any similarities or connections in the key ideas or concepts from each and comparing these across all studies to gain an initial impression of the relationships between them. This then develops into the fifth step of 'translation' which involves active re-interpretation of findings by relating the meaning or knowledge from each study to another, and then comparing the interaction between two studies with the meaning derived in all other studies, all the while carefully considering the social and theoretical context in which each primary study was conducted. The authors describe the translation phase as "one case is like another, except that..." (Noblit & Hare, 1988) p. 38. Translations are then compared to one another and synthesised into a higher level understanding (step 6). In this way, meta-ethnography adopts an inductive approach, building understanding from the data upwards rather than from a pre-conceived framework. The final step involves reporting the findings of the meta-ethnography synthesis.

Meta-ethnography was developed to synthesise in-depth ethnographic research, which is defined as "long-term, intensive studies involving observation, interviewing and document review" (Noblit & Hare, 1988) p. 13. However it has since been found to apply well as a method to synthesise qualitative research more widely, including qualitative interview studies (Atkins et al., 2008; Campbell et al., 2003; Pound et al., 2005). Noblit and Hare proposed three types of meta-ethnography depending on whether the studies included are all similar in their findings, whether they refute one another, or whether they build on one another to develop a line of argument. It is only after reading the primary studies in detail that the most appropriate form of synthesis can be established. The meta-ethnography in this thesis developed a line of argument as the studies offered different insights and meaning which when translated into one another generated a new interpretation.

1.8.1.2 Meta-ethnography limitations

The explanations provided by Noblit and Hare for conducting meta-ethnography are not very explicit, particularly in terms of how to go about translating the findings of studies into one another and how to synthesise the translations. Many subsequent meta-ethnographies also do not explicitly describe how they conducted these phases of analysis, or show discrepancies between use of terminology and interpretation of the methods (France et al., 2014). This is not

good research practice as the methods lack transparency for the reader and are difficult for researchers to emulate (Atkins et al., 2008; France et al., 2014). In order to try and overcome this reporting ambiguity in the current thesis, the standard ENTREQ checklist for reporting qualitative meta-synthesis was used (Tong, Flemming, McInnes, Oliver, & Craig, 2012). The criteria for reporting meta-ethnography by France et al. were also useful for promoting transparency as these were developed specifically for this method of synthesis (France et al., 2014).

Another issue identified with published meta-ethnographies is that this method is designed to generate new knowledge, going beyond a simple summary of existing findings, but in some cases it is not clear whether this has been achieved as the findings appear more akin to a thematic synthesis in providing only an aggregation of existing data rather than a fresh interpretation (France et al., 2014). Being aware of this limitation was important for ensuring that this thesis clearly demonstrated how the meta-ethnography provided additional insights into patients' and HCPs' experiences of using DHIs for self-management of chronic conditions.

1.8.1.3 Qualitative synthesis limitations

Synthesising findings across qualitative studies can risk ignoring the unique context in which the primary research was conducted by making inappropriate comparisons between qualitative data collected in different settings and using different qualitative methods (Ring, Ritchie, Mandava, & Jepson, 2011). Despite this, qualitative syntheses are recognised as a useful source of evidence to take into account in health policy decisions and forming clinical guidelines to add to the understanding gleaned from quantitative reviews (Higgins & Green, 2011). The rigorous process of constant comparison and the preservation of context in meta-ethnography can help to ensure that qualitative findings are not generalised beyond their contextual boundaries and the meaning of studies is preserved.

Another area of controversy in qualitative syntheses is the use of quality checklists to appraise primary studies. This is recognised as good practice for quantitative reviews as it enables the researcher either to exclude studies of poor quality, or to take this limitation into account when interpreting the findings of their review (Sanderson, Tatt, & Higgins, 2007). However it has been argued that quality checklists are inappropriate for qualitative research because this applies positivist assumptions about objectivity and validity to a constructivist paradigm in which these constructs are not relevant and could limit creativity (Dixon-Woods, Shaw, Agarwal, & Smith, 2004). There is a lack of agreement over whether to use quality appraisal, and if so, which appraisal checklist is most appropriate to use for qualitative research (Mays & Pope, 2000). Hannes argued that there are some core constructs which indicate quality in research and apply across qualitative and quantitative paradigms, such as ethical conduct, rigorous analysis and

transparent reporting (Hannes, 2011). Evidence suggests that the prevailing tendency amongst researchers is to conduct a quality appraisal, with 72% of syntheses published between 2005 and 2008 doing so (Hannes & Macaitis, 2012), but it seems that a consensus has yet to be reached about how to use the findings of the quality appraisal and where to draw the line in terms of excluding poor quality studies. It has been argued that quality checklists focus overly on methodological criteria rather than conceptual strengths (Toye et al., 2014), although the point stands that if a study was methodologically weak it is important to be aware of this as it could compromise the validity of the findings, however conceptually rich they may be. Therefore for this synthesis it was decided that appraising quality was important both for evaluating the contributing primary studies and for improving the reporting standards of the review, as using a checklist can increase transparency and ensure the reader can evaluate the rigour and trustworthiness of the analysis (France et al., 2014).

1.8.2 Paper 2: Patient qualitative process evaluation

Following the intervention planning and development, the grant proposal specified that the DHI would be assessed in a RCT for clinical effectiveness in terms of BP at 12 months, and cost-effectiveness. A process evaluation of patients' and HCPs' experiences during the trial was planned to explore factors that appeared to influence their adherence to the intervention procedures (Yardley, 2013). The patient qualitative process evaluation formed the second paper of this thesis, while the HCP mixed methods process evaluation formed the third paper. For both the patient and HCP process evaluation, the author decided on the specific research questions, the interview schedules, sampling techniques and methods of analyses, and these decisions are detailed below.

The original aim of paper 2 (the patient process study) defined in the programme grant was to explore patients' experiences of using the HOME BP intervention, but the author further developed this aim to take account of guidelines and best practice from the literature. The Medical Research Council (MRC) have published guidelines for conducting process evaluation which recommend understanding how an intervention is implemented, the mechanisms of impact which influence how it works (or does not work), and whether the findings are likely to apply outside the context and time of the RCT (Moore et al., 2015). These guidelines were used to inform the approach for paper 2, in which understanding how contextual factors might influence users' experience of a DHI was important. Whereas context has previously been regarded as a possible barrier to implementation of interventions and something to try and control for, in 2012

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there was a call for a shift towards more honest reporting of contextual issues in trials, both for improving assessment of internal validity and for considering transferability of the findings (Wells, Williams, Treweek, Coyle, & Taylor, 2012). A review of seven complex RCTs concluded that researchers tend to have an in-depth understanding of the contextual nuances of the trial, but these were not generally reported in the trial write-up (Wells et al., 2012). The 12 dimensions of context identified by the CIHR/NIHR review in 2018 facilitate the careful consideration of context by health intervention researchers (Craig et al., 2018), which is essential both in terms of developing interventions which can be implemented in different contexts, and enabling clear reporting of the intervention-context relationship to better inform decision makers about the transferability of interventions.

Another common pitfall in process research was identified by a large review of process evaluation studies, highlighting that researchers commonly set out to explore users' experiences of an intervention without specifying how these findings will be used in the longer-term (O'Cathain et al., 2014). The MRC guidelines propose that process evaluations should seek to contribute to the development of theory and methodological debate in order to build an accumulation of knowledge. Therefore for papers 2 and 3, the author sought to be explicit about the intended application of the process evaluation to demonstrate the wider impact and value of the study.

Based on these considerations, paper 2 sought to explore the perceived burden and benefits of using a DHI for self-managing blood pressure. This enabled exploration of some of the issues identified earlier in this introduction regarding Burden of Treatment theory and whether using a self-management DHI introduces more benefit or burden for patients, as well as consideration of how best to evaluate participants' experiences of using DHIs. This is in line with the QUARTER recommendations (Qualitative Research with Trials: Excellent Reporting) for conducting qualitative research alongside a trial which state that identifying an explicit research question can help generate more meaningful findings than assuming that patient experiences are interesting in and of themselves (O'Cathain et al., 2014). Therefore at a practical level the study captured data to help inform how the intervention could be optimised for wider implementation, and to enhance understanding of the trial findings (though it should be noted the qualitative research and analysis were conducted before the trial results were known). However, at a more theoretical level, the study sought to understand the findings in terms of their implications for understanding patient burden and evaluating DHIs beyond this single intervention, promoting the transferability of the findings and the potential to challenge existing thinking. This flexibility of qualitative research to evolve and provide useful insights in more ways than originally anticipated is regarded as a strength of this research method (O'Cathain et al., 2014). It was anticipated that broader costs and benefits might be identified by the qualitative research than those captured by the

quantitative process and outcome measures, especially as inductive qualitative research enables the exploration of unanticipated effects which were not recognised from the outset as important.

Perceived burden is a relevant topic to explore as there is growing concern about the potential burden DHIs place on patients to engage in self-management (Lupton, 2014b; May, Cummings, et al., 2016). However, there is also recognition that engaging in self-management DHIs can be beneficial to people and even interesting and enjoyable (Crutzen, Ruiter, & de Vries, 2014; Dunphy, Hamilton, Spasić, & Button, 2017), presenting a strong argument for why we need to better understand how using DHIs influences not only clinical outcomes but also patients' well-being and quality of life. McNamee called for a change in how the use of complex DHIs is evaluated, arguing that we need to adopt a broader approach to capturing relevant outcomes for users (McNamee et al., 2016). This move has been reflected in the field of health economics where a recent report recommended that researchers ought to capture not only the financial costs of an intervention but also the broader effects on a person's life, including their time, the societal costs, and knock-on effects on others (Sanders et al., 2016). BoT theory also adopts a broad view of burden as depending on the person's wider social network and access to healthcare, and seeks to understand how interventions can best minimise burden on people (May et al., 2014). The HOME BP intervention presents an ideal opportunity for enhancing our understanding of the broader impact of using a self-management DHI as it involves several key behaviours which could either be perceived by users as beneficial or as a hassle or stress, including regular self-monitoring, changing medication, and using an online interface. Therefore this process study contributed to the evolving debate over the burden of DHIs, drawing on in-depth qualitative data from a wide range of patients.

1.8.2.1 Decisions about methods for the qualitative process study

Qualitative telephone interviews were deemed appropriate for answering the research question as this method of data collection facilitates the generation of in-depth data regarding experiences, perceptions and beliefs (Farooq & Villiers, 2017). Focus groups were considered to be less appropriate as this could increase the risk of contamination between trial participants sharing their experiences while the trial was still ongoing. Telephone interviews also ensure that participants would be able to take part even if they could not easily leave the house, whereas focus groups might exclude people of poorer health and can risk attracting more confident or educated individuals who may not be as representative of the full sample (Hoddinott, Allan, Avenell, & Britten, 2010).

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The author decided to sample participants from the usual care group in addition to those in the intervention group, in line with recent guidance for conducting qualitative research alongside trials (O'Cathain et al., 2015). This was in order to gain some insight into the burdens and benefits of managing hypertension in usual care without a self-management intervention, as well as to understand the experiences of usual care patients in the trial for practical reasons, e.g. how well had they understood the meaning of being randomised to usual care, and to what extent had their HCPs delivered usual care. It was planned that the usual care interviews would be analysed alongside the intervention group interviews, although some amendments to the interview schedule were required in order to ensure that the questions were appropriate for eliciting this group's experiences of hypertension management. As this study aimed to understand participants' experiences of using a self-management DHI for hypertension, it was anticipated that more participants would be needed from the intervention group supplemented by a small number of usual care participants sufficient to give an insight into their experiences. The wealth of data and range of experiences which emerged from these interviews with the usual care group confirmed that the decision to include these participants was worthwhile.

Opportunistic sampling was used from the relatively small sample of participants in the internal pilot study as it was necessary to ensure that the intervention procedures were feasible in order to progress to the main RCT. During the main trial, it was possible to adopt purposive sampling techniques from the larger sample of participants available, in order to seek a diverse sample in terms of contextual and demographic factors which might influence experiences and implementation of the intervention, such as GP Practice, gender, and age. Both gender and age are known to be related to hypertension perceptions and management, with older patients and female patients more likely to adhere to medication, and older patients having a higher perceived need for medication, lower concern about medication and lower emotional response to hypertension (Ross et al., 2004). Meanwhile GP Practice was an important contextual factor to consider in the purposive sampling. The interview data were analysed in parallel with the data collection which enabled theoretical sampling to be adopted at the later stages of the process study. Here the selection of potential participants was informed by emerging hypotheses, to allow further exploration. For example, the data suggested that patients with poorly controlled blood pressure at the time of interview might hold different perceptions about the intervention from those who were well-controlled, and therefore it was decided to sample more poorly controlled participants to collect additional data about their experiences of HOME BP. In addition, it seemed that people with low engagement with the intervention might have different perspectives from those who were highly engaged, and therefore the final stages of recruitment targeted participants with lower engagement who were harder to recruit for interview. This is in line with

MRC process evaluation guidance which recommends using iterative data collection and analysis to enable emerging themes to be further explored in later interviews (Moore et al., 2015). Achieving diversity in sampling is recognised as one of the key challenges of qualitative research exploring trial implementation, especially in terms of ensuring that different contexts are explored, such as a range of GP Practices, to ensure that findings do not relate to only one specific context (O'Cathain et al., 2015).

Although the BoT theory was of interest in this study, an open interview schedule was used to capture the perspectives and experiences most salient to the users rather than theoretically informed questions based on the BoT theory. This enabled users' experiences to be explored in depth within their specific contexts, and without being constrained by the causal mechanisms which had been theorised to account for their engagement with the intervention, or concepts from the BoT theory. It also enabled any unanticipated consequences of using the intervention to emerge which may not arise when using deductive research techniques which only explore pre-defined concepts. This was in line with the Person-Based Approach of understanding experiences within the users' psychosocial context, rather than using theory to deductively collect and interpret the data. It was then possible to explore how consistent users' context-specific experiences were with the general theoretical mechanisms. Small adjustments were made to the interview schedule following discussion of the early interviews with the research team, for example, adding an open question to ask what happened next after being recommended a medication change when it became apparent that some participants had seen the HCP at this point. Beliefs about changing medication were of particular interest in terms of the research question around the burden of self-management, and it was important to be able to explore this without asking leading questions or questions which might imply judgment.

Inductive thematic analysis was used to analyse the data with some techniques from grounded theory. This was consistent with the Person-Based Approach in terms of being data-driven and seeking to discover unanticipated responses to the intervention rather than being theory-driven. Memoing was used to help explore patterns in the data and record emerging ideas about possible, plausible explanations of processes. Constant comparison helped ensure the codes were consistent with the raw data. The inductive nature of the interview schedule and analysis also enabled new insights about the BoT theory to be generated which would have been more difficult had a pre-defined theoretical coding framework been used.

1.8.3 Paper 3: Mixed methods and epistemology

Paper 3 (the HCP process evaluation) adopted a mixed methods approach to explore HCPs' (in both the 'prescriber' and 'supporter' role) experiences of the intervention. Mixed methods research includes both qualitative and quantitative components either within one study or in a series of studies, to answer the research question (Bishop, 2015). It has been recognised for a while that for certain research questions mixing methods can enrich our understanding further than using qualitative or quantitative methods in isolation, due to their different inherent strengths. The Medical Research Council process evaluation framework recommends the use of considered mixed methods research with clear plans about how the datasets will be integrated (Moore et al., 2015). A report conducted on research in health services and delivery of care proposed that mixed methods are needed in order to understand the complexity of implementing changes to current healthcare systems and to thoroughly explore the value of an intervention as opposed to only the effectiveness (Raine et al., 2016).

The use of mixed methods in health, behavioural and social research has been increasing rapidly (Fàbregues & Molina-Azorín, 2017), and debates around best practice for integrating qualitative and quantitative data and the pitfalls of mixed methods research are ongoing. There may be risks of combining methods if the different underlying assumptions of qualitative and quantitative research are not acknowledged (Yardley & Bishop, 2008). To understand this, it is important to consider ontology and epistemology. Ontology refers to the nature of reality. A positivist ontological position assumes that real concepts exist which we can measure in research, whereas a constructivist position assumes that we construct our world through our own experiences and perceptions and there are no true generalizable concepts across time and culture (Bishop, 2015; Lincoln & Egon, 2000). Epistemology is the study of knowledge or reality. Researchers adopting a positivist stance believe that knowledge is gained by measuring constructs accurately and objectively, and is only limited by our technical skills to capture what is there. Researchers working within a constructivist perspective believe that knowledge is embedded in the historical and cultural context in which it emerged, such that our knowledge of the world is filtered by subjective experiences (Bishop, 2015; Lincoln & Egon, 2000).

These different paradigms influence the methods adopted and the measures employed to explore our research questions. Qualitative research methods are consistent with a constructivist ontology as the emphasis is on understanding a phenomenon in depth within a small sample which is not intended to be generalizable or representative of the wider world (Yardley & Bishop, 2008). Quantitative research methods are generally more in line with a positivist ontology, seeking to explain causal relationships or predict outcomes across circumstances, while the

researcher strives to control for confounding factors and remain independent from this objective discovery of knowledge (Yardley & Bishop, 2008).

Today it is generally acknowledged that the difference between these two research paradigms is not as profound as the apparently opposing ontologies would imply (Yardley & Bishop, 2008). The framework of pragmatism holds that the two research paradigms are not incompatible, as a common goal of all research is the interpretation or analysis of a concept to further enrich or develop our knowledge (Bryman, 2006b; Johnson & Onwuegbuzie, 2004; Morgan, 2013).

Pragmatism encourages an eclectic approach to research and focuses on finding the middle ground between dualisms (Johnson & Onwuegbuzie, 2004). Morgan defined three key beliefs of pragmatism which demonstrate this common sense approach: data analysis is abductive in that findings are generated from the data whilst also drawing on theory and existing knowledge (a middle ground between inductive and deductive approaches); the research process is intersubjective, being neither completely objective nor completely subjective; and the findings may be transferable to other settings to some extent but are neither entirely generalisable nor bound to only one specific context (Morgan, 2007). Pragmatism holds that knowledge of the real world is constructed and influenced by human experience, and refutes the idea of absolute generalisable knowledge. This may be more obviously aligned with a constructivist qualitative epistemology, but while quantitative research is often portrayed as being highly objective, in reality many pragmatic decisions need to be made to understand the meaning behind quantitative findings and these decisions are grounded in the personal experiences and knowledge of the researcher. There is now more of an awareness in quantitative research that the knowledge gained cannot be completely independent of the context in which it was acquired (Yardley & Bishop, 2008).

Some researchers have raised concerns about the abundant use of pragmatism in mixed methods research, believing that this perspective under-represents the importance of philosophical assumptions such that proponents may pick and choose their methods without considering the underpinning epistemologies, making for a less coherent piece of research (Lipscomb, 2008; Maxwell & Mittapalli, 2010). The extent to which mixed methods should be associated with a certain ontology or epistemology is an ongoing discussion point, as while some researchers believe it is important to consider the resolution of paradigms, others feel this limits the creative potential of mixed methods research (Fàbregues & Molina-Azorín, 2017).

Critical realism has emerged more recently as a meta-theory or way of thinking about knowledge in research. Like pragmatism, it is a middle-ground approach which seeks to smooth over the

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differences between positivist and constructivist philosophies, but unlike pragmatism it holds its own ontological assumptions about reality. Researchers from this perspective believe that the concepts being explored do exist in the real world but our knowledge of them is contingent on our cultural context and historical situation, which will change over time (Bhaskar, 2014). Critical realism adopts the positivist ontology that an objective reality does exist, but applies the constructivist epistemology that our knowledge of reality is inevitably influenced by our experiences and perspectives. Reality is seen as highly complex and continually evolving and it is acknowledged that we can only achieve tentative knowledge of it. Specifically, reality is perceived as multi-layered, incorporating the 'empirical domain' which can be experienced directly or indirectly, the 'actual' which exists but may not be observed, and the 'real' which are the filters that influence what we experience.

RCTs have originally been conceptualised from a positivist approach, seeking to establish a cause and effect relationship which can be generalised beyond the trial setting, but a more critical realist approach is often adopted now as this acknowledges that the intervention characteristics do not wholly account for the outcomes in isolation, as multiple factors influence the causal mechanisms resulting in different outcomes for different people (Blackwood, O'Halloran, & Porter, 2010). This approach adopts a middle ground perspective between positivist and constructivist approaches, proposing that it is too simplistic to assume that transferable laws of cause and effect can be discovered, but equally that it is possible to generate some inferences about tendencies or patterns which allow us to make predictions about the combination of mechanisms which are likely to lead to a certain outcome. Critical realism has been adopted as a suitable epistemology for mixed methods research as the definition of reality encourages the exploration of human experiences via a range of methods, recognising that each are best suited to discovering a different layer of reality. All research questions are positioned within these epistemological and methodological frameworks, and understanding these helps to ensure that our rationale for conducting mixed methods research is well thought through (Lipscomb, 2008) and enables researchers to be reflexive about their work (Bishop, 2015).

Paper 3 is consistent with a critical realist approach as data from different research methods were integrated to facilitate understanding of reality through different lenses, enriching our understanding of a phenomenon (Greene, 2007). In the case of the HCPs using this intervention, a critical realist framework enabled the exploration of the relationship between their beliefs and their actual situation (Maxwell & Mittapalli, 2010). The critical realist approach acknowledges the strengths that qualitative and quantitative research can bring, while also emphasising the need to be aware of their limitations (Maxwell & Mittapalli, 2010). A pragmatist stance recommends adopting the most appropriate methods for the research questions. Many researchers perceive

critical realism and pragmatism as entirely compatible and synchronous, as critical realism endorses a very pragmatic approach to methods (Maxwell & Mittapalli, 2010).

Interestingly, while the literature is very focused on the philosophical standpoint of mixed methods research, this issue was not a primary concern for most mixed methods researchers when interviewed about their conceptualisation of this form of research (Fàbregues & Molina-Azorín, 2017). This may indicate that researchers tend to focus on a more pragmatic approach to mixing methods without becoming too concerned about the epistemological assumptions. Indeed this lack of reflexivity amongst researchers about their methodological stance has been criticised, as their inherent assumptions or world view will inform decisions about the type of research undertaken and the research questions explored and therefore it is important to be aware of this (Hesse-Biber, 2012). A stronger awareness of epistemology could help to promote better quality mixed methods research by encouraging an appreciation of the strengths and limitations of each approach and careful consideration of how best to integrate these.

1.8.3.1 Rationale for using mixed methods and research questions

Best practice recommends that the rationale for using a mixed methods design is explicit from the start such that appropriate research questions, study design, methods of analysis and methods of integration can be used in line with the stated rationale. Greene identified five rationales for conducting mixed methods research: triangulation (seeking corroboration between the qualitative and quantitative data); complementarity (seeking to elaborate one set of findings with another); development (seeking to use the findings of one dataset to inform the next phase of research); initiation (seeking to discover new perspectives on constructs being studied); and expansion (seeking to expand the scope of the research by drawing on two sets of findings) (Greene, Caracelli, & Graham, 1989). Bryman expanded on these definitions based on his review of the literature which identified several other reasons for conducting mixed methods research, including completeness (enabling a more holistic account of a phenomenon), and explanation (one dataset is used to explain the other) (Bryman, 2006a).

In the current process evaluation, the rationale for mixing methods was to enhance understanding of how HCPs used the intervention in practice by comparing insights from the qualitative and quantitative datasets. This would be termed 'completeness' using Bryman's categories of rationale for using mixed methods as the study aimed to provide more detailed, holistic understanding of adherence to and implementation of a DHI for managing blood pressure in Primary Care. Some mixed methods researchers believe that integrating qualitative and

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quantitative findings can increase the validity of the research by showing agreement between two separate datasets (Farmer, Robinson, Elliott, & Eyles, 2006), but this assumption was not made for paper 3. The rationale for mixing methods was not to confirm that the findings were 'real' but rather to gain a detailed understanding of how the intervention was delivered and why any adaptations to procedures took place (Moore et al., 2015). Munro (Munro & Bloor, 2010) perceived that qualitative research was limited in the explanations it could provide for quantitative phenomena, regarding it as nuanced and constrained by the context in which it was collected. However while qualitative data cannot provide an absolute account of what occurred during a trial, the value lies in generating possible explanations which can be explored further. Munro's criticism of the scope of qualitative research suggested it was being perceived through a positivist methodological lens, with the aim of finding an underlying 'truth' rather than expanding our knowledge of the diversity of people's experiences through recognising that it is those very nuances that are of most interest, enabling us to understand how the intervention is interpreted by different people in different settings.

The rationale for this mixed methods approach informed the development of research questions. These questions aimed to optimise the individual strengths of the quantitative and qualitative strands of research, and to integrate the findings to enhance understanding. The AMUSED framework for analysing usage data in digital interventions was used to help select meaningful quantitative questions to explore in paper 3 (Miller et al., 2019). This framework provides checklists to clearly categorise all the data captured during a RCT, and consider the key processes of change during the intervention. This informed the development of a post-hoc logic model to show the hypothesised mediators and moderators through which the HOME BP intervention was anticipated to change the HCP target behaviours, based on theory and evidence (Figures 4 and 5). This showed that the online training module for HCPs was expected to change target behaviours via increasing self-efficacy, outcome expectancies and confidence in patients to engage with the intervention behaviours. These variables were captured by questionnaires before and after completing the online training, enabling the relationships with adherence to target behaviours to be tested. The logic model also showed how contextual factors relating to the patient's clinical status were theorised to influence HCPs' adherence to implementing medication change. Meanwhile, the qualitative research question was more open, following the rationale outlined for the patient process evaluation of enabling exploration of unanticipated experiences and contextual factors which could influence engagement with the DHI, and were not necessarily part of the logic model. Finally, a mixed methods research question was developed to specify that the integration of qualitative and quantitative findings aimed to achieve an enriched understanding of the process of implementing a DHI in Primary Care, in line with recommendations for mixed

methods research to have at least one research question which explicitly lays out the objective for the mixed method element of the design (Tashakkori & Creswell, 2007).

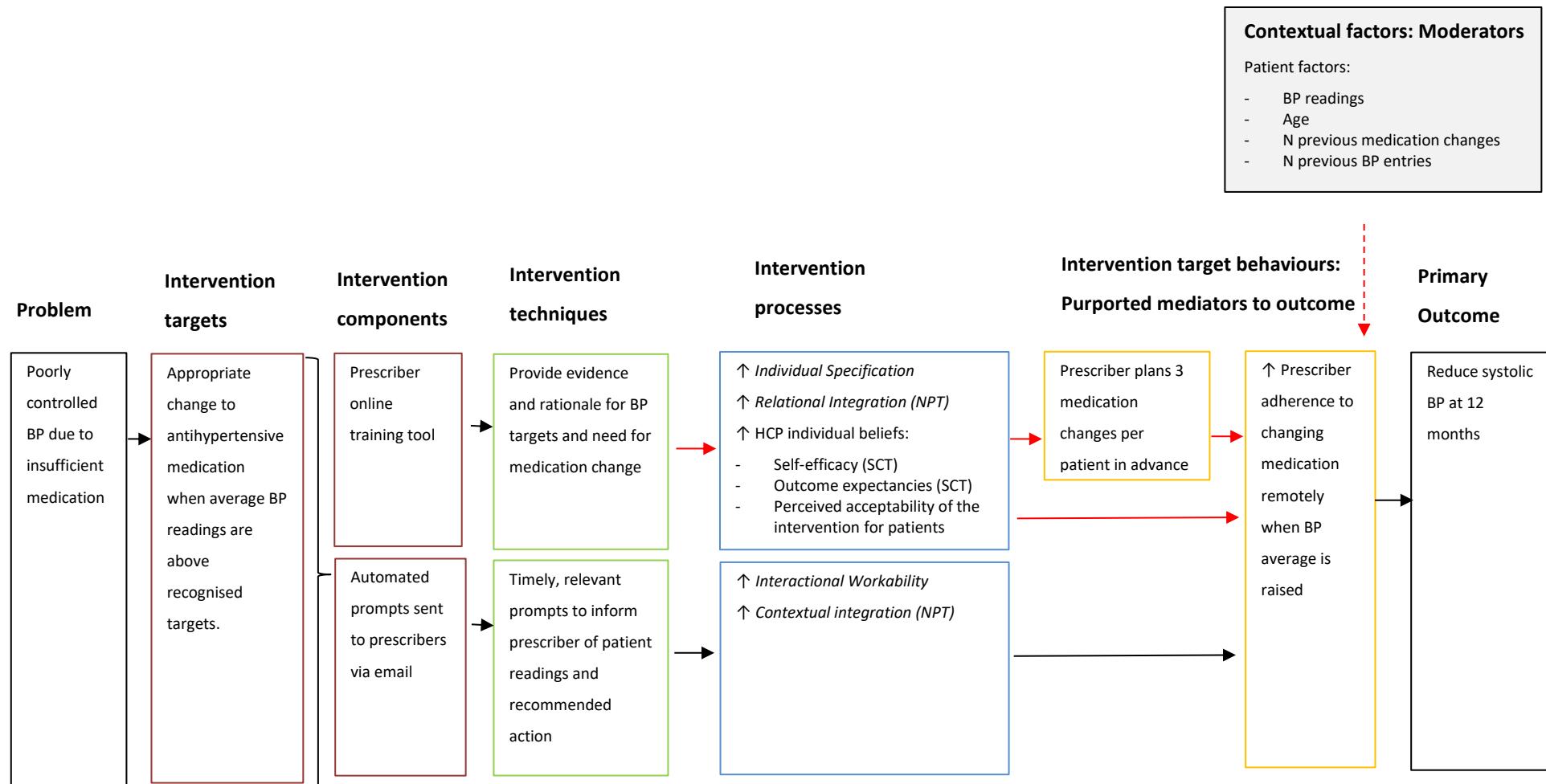


Figure 4 HOME BP Post hoc logic model: Prescribers

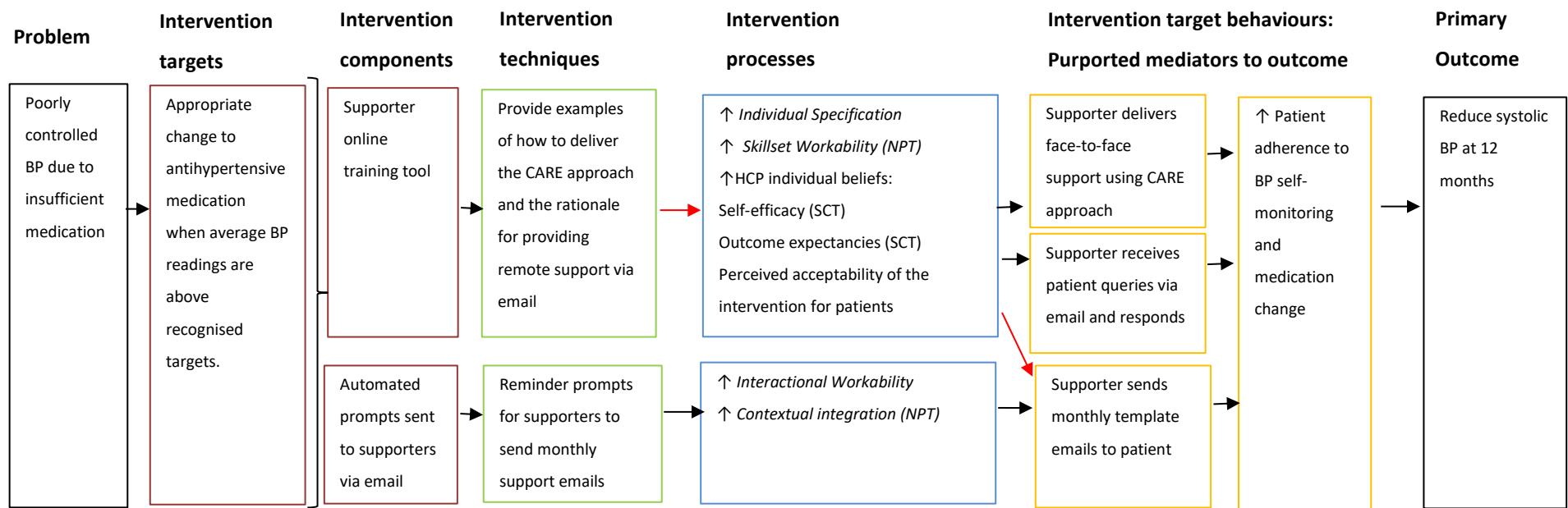


Figure 5 HOME BP Post hoc logic model: Supporters

1.8.3.2 Decisions about how to mix methods

The rationale for mixing methods and the research questions inform whether the quantitative and qualitative research will be carried out in parallel or sequentially, and whether the qualitative or the quantitative element will be treated as dominant during integration or if both are treated equally (Johnson & Onwuegbuzie, 2004). Four potential designs for mixed methods research have been outlined based on these decisions about timing and emphasis, which are shown in Table 2 (Creswell, Plano Clark, Gutmann, & Hanson, 2003).

Table 2 Possible designs for mixed methods studies

	Qualitative emphasis	Quantitative emphasis	Equal emphasis
Sequential timing	Exploratory	Explanatory	N/A
Concurrent timing	Embedded		Triangulation

The HOME BP mixed methods process study adopted a sequential approach in that the qualitative data were analysed independently before the quantitative data, but at integration both were given equal emphasis to answer the research question. Therefore this was closest to a triangulation design, according to the definitions of Plano and Creswell. This was selected because the interviews and adherence data were collected to provide different sources of information about how HCPs implemented the intervention, therefore it made sense to treat both types of data equally. The reason the data were collected sequentially was purely practical, in that the process interviews needed to take place during the trial whereas the adherence data were not available until the end of the trial. It has been suggested that it can be more challenging to preserve the individual assumptions and strengths of qualitative and quantitative research when they are more closely integrated (Bryman, 2007), therefore this was an important risk to be aware of. Conversely, thorough integration of the findings of each component can facilitate more in-depth learning about the topic under study than when the two parts are analysed and reported independently. In this study, the independent collection and analysis of the quantitative and qualitative data sought to preserve the strengths of each approach, while careful integration sought to optimise the mixing of these methods for our learning.

All HCPs in the trial took part in the quantitative strand as these data were collected automatically as part of the intervention. Recruitment of a sub-sample of participants for the qualitative strand was conducted in two parts. Initially all HCPs in the pilot study were invited, driven by a practical need to ensure that the intervention was feasible to be implemented in the main trial and to identify any issues which could prevent effective engagement. Subsequently purposive recruitment of HCPs in the main RCT was used to target those with certain characteristics to ensure a diverse sample, informed by factors such as the number of patients the HCP was supporting to use Home BP, and whether the HCP was adopting a single role of prescriber or supporter, or a dual role of prescriber-supporter.

These recruitment decisions were consistent with the study rationale in that the evaluation sought to understand usage and adherence of the intervention procedures across the sample, and to understand in detail the perspectives and experiences of a sub-sample of the HCPs in the trial. It was not feasible to conduct in-depth interviews with all HCPs in the trial. The need for higher numbers of participants in quantitative studies is a feature of this type of research, and was not perceived to give the findings more weight than the qualitative data, which in turn provides more in-depth insights.

A significant challenge in mixed methods research is achieving thorough integration of the findings. Many papers still report qualitative and quantitative components separately without reaching the full potential of mixed methods to construct an output which is greater than the sum of its parts. Surface-level comparisons have been criticised for being too simplistic in expecting two entirely different methods to replicate or somehow validate one another's findings (Munro & Bloor, 2010). Ideally, the report of a mixed methods approach would provide a fully integrated account of what the findings show (Bryman, 2007). O'Cathain outlined three techniques for mixed methods data integration: triangulation (comparing each finding from the qualitative and quantitative elements after they have been analysed separately), following a thread (following an initial key finding from one dataset in another), and mixed methods matrix (comparing each participant's qualitative and quantitative data at an individual case level before comparing between cases) (O'Cathain, Murphy, & Nicholl, 2010). Informed by the research design and research questions, triangulation was selected as most appropriate for integrating the mixed method findings in the HCP process evaluation. This approach offers a rigorous and systematic process for integrating the data post-analysis, facilitating in-depth reflective accounts of how different sources of data relate to one another. This allows the individual strengths of qualitative

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and quantitative research to be optimised by promoting the separate analysis of each data source prior to integration (Yardley & Bishop, 2008).

Some issues remain in mixed methods research, such as how best to interpret conflicting findings. A risk of poor mixed methods design is that where disparate findings occur, it is assumed that the dominant approach must be correct or that there were issues with the data collection, without exploring the interesting possibilities for why the data tell different stories which could be used to generate new hypotheses (Hesse-Biber, 2012). When discrepancies are fully explored, this can reveal more in-depth understanding of both datasets, and options have been proposed for resolving discrepancies in mixed methods findings (Moffatt, White, Mackintosh, & Howel, 2006), for example, could the theoretical differences between methods account for the discrepancy, were both techniques sufficiently rigorous, could the discrepant findings be due to differences in samples, or was the intervention delivered as expected? This is a strength of mixed method research as it encourages researchers to critique their studies more thoroughly than a mono-method analysis.

O'Cathain's review of published mixed methods studies highlighted several shortfalls common to reporting of mixed methods research, notably lack of transparency about the individual qualitative or quantitative methods used, limited description of the individual analyses and how the findings were integrated, lack of consistency between the results reported and the methods described, limited or no awareness of preserving rigour of the research whilst mixing methods, and poor integration of the qualitative and quantitative findings (O'Cathain, Murphy, & Nicholl, 2008). Using separate checklists to evaluate the qualitative and quantitative components is not generally acceptable as this does not enable reflection on the quality of the integration and interpretation of the data, and conducting high quality qualitative and quantitative research does not necessarily lead to high quality mixed methods research (Collins, Onwuegbuzie, & Johnson, 2012; Fàbregues & Molina-Azorín, 2017). Therefore O'Cathain developed the Good Reporting of a Mixed Methods Study (GRAMMS) guidance for researchers which provided six recommendations to promote comprehensive reporting of mixed methods research (O'Cathain et al., 2008). These included being explicit about the justification for the approach, the design, methods, effective integration, limitations and insights. Indeed, more recent research supported that having a clear rationale for using mixed methods and achieving effective integration of the quantitative and qualitative components appeared to be core principles for conducting good quality mixed methods research (Fàbregues & Molina-Azorín, 2017; Heyvaert, Hannes, Maes, & Onghena, 2013). The GRAMMS guidance was used to promote the quality of this mixed methods study.

Additionally, a checklist developed by Teddlie & Tashakkori was used which focused specifically on evaluating the credibility of the inferences made in mixed methods research, such as whether the inferences are consistent with the findings, and whether they draw sufficiently on both the qualitative and quantitative evidence (Teddlie & Tashakkori, 2009). The use of both these checklists during mixed methods research could promote transparent reporting and reflective awareness of the quality of the inferences made.

1.9 Epistemology

All three studies in this thesis have adopted a critical realist approach, which is described in section 1.8.3. The meta-ethnography method of synthesis is consistent with a critical realist stance as it assumes there are to some extent real concepts which are shared between studies, whilst also emphasising the importance of taking context into account. Meta-ethnography does not seek to generate generalisable conclusions or common findings, but rather to explore and value the differences in relation to their context and to generate explanations of social phenomena. Noblit and Hare state that the meta-ethnography approach sits within the interpretivist or constructivist paradigm as opposed to positivism because it emphasises the importance of understanding that all experiences and perspectives being studied need to be understood within their context (Noblit & Hare, 1988). They also argue that the synthesis process will inevitably be influenced by the world view of the researcher as they construct a narrative about how the studies are related through their eyes and use their experience and knowledge to discern which concepts to focus on. Despite this, meta-ethnography also assumes that there is to some extent a shared reality that can be understood between studies, which is consistent with a critical realist approach.

The qualitative process interviews were analysed using thematic analysis which is a flexible approach that can be used with a range of epistemological stances, and it was suitable for the research question within this study which was exploratory and inductive. The analysis assumed that the data represented the participants' experiences of using the intervention, which were real and meaningful, whilst bearing in mind that these will be influenced by their illness and treatment perceptions and the different contexts in which the intervention was implemented. For example, the time point in the study at which the data were collected was very likely to influence participants' descriptions of their experiences.

The mixed methods study was also consistent with a critical realist approach, as discussed above.

1.10 Author contributions

KM was the lead author and wrote all three papers submitted as part of this thesis. The co-authors were co-applicants on the programme grant and were included to recognise their contribution to the design of the overall project. In addition, LY, LD and KB supervised the analyses of the data in each paper and contributed to the development of themes and interpretation of findings. CM and JR contributed their specialist knowledge to the second paper which informed KM's descriptions of Burden of Treatment theory and health economics. RM is a specialist in hypertension management and designed the algorithm for the BP self-monitoring intervention, and provided clinical insights into some of the findings.

1.11 Aims

The aims of each paper in this thesis are to:

- Paper 1: Develop an in-depth understanding of patients' and HCPs' perceptions of using digital health interventions for self-management from a synthesis of primary qualitative studies.
- Paper 2: Explore participants' personal appraisals of the burdens and benefits of using a digital intervention for self-management of high blood pressure.
- Paper 3: Adopt a mixed methods approach to understand HCPs' experiences of and adherence to supporting patients to self-manage their blood pressure using a digital intervention.

Chapter 2 Using digital interventions for self-management of chronic physical health conditions: A meta-ethnography review of published studies.

This paper was published in Patient Education & Counseling in 2017.

2.1 Abstract

Objectives: To understand the experiences of patients and healthcare professionals (HCPs) using self-management digital interventions (DIs) for chronic physical health conditions.

Methods: A systematic search was conducted in 6 electronic databases. Qualitative studies describing users' experiences of self-management DIs were included, and authors' interpretations were synthesised using meta-ethnography.

Results: 30 papers met the inclusion criteria, covering a range of DIs and chronic conditions, including hypertension, asthma and heart disease. The review found that patients monitoring their health felt reassured by the insight this provided, and perceived they had more meaningful consultations with the HCP. These benefits were elicited by simple tele-monitoring systems as well as multifaceted DIs. Patients appeared to feel more reliant on HCPs if they received regular feedback from the HCP. HCPs focused mainly on their improved clinical control, and some also appreciated patients' increased understanding of their condition.

Conclusions: Patients using self-management DIs tend to feel well cared for and perceive that they adopt a more active role in consultations, whilst HCPs focus on the clinical benefits provided by DIs.

Practice Implications: DIs can simultaneously support patient condition management, and HCPs' control of patient health. Tele-monitoring physiological data can promote complex behaviour change amongst patients.

2.2 Introduction

With the increasing burden of chronic disease on health services, recent health policy has emphasised the central role of patient self-management in future healthcare (Taylor et al., 2014). Digital interventions (DIs) provide a potentially effective means to deliver self-management support to patients via technological media. DIs may use tools such as education or behaviour change support to promote activities which contribute to condition management, for example medication adherence or increasing physical activity. Systematic reviews of the impact of self-management DIs show small benefits to illness outcomes in asthma, diabetes and cardiovascular disease (Morrison et al., 2014; Murray, Burns, See, Lai, & Nazareth, 2005; Pal et al., 2014; Pfaeffli Dale, Dobson, Whittaker, & Maddison, 2015) although the evidence for these programmes remains inconsistent (Black et al., 2011) and our understanding of what makes them more effective is still developing (Salisbury et al., 2015).

A distinction can be made between multifaceted DIs which incorporate several components to support self-management, and standalone tele-monitoring systems in which patients self-monitor health parameters (such as blood pressure) and transmit these data to a healthcare professional (HCP) or automated device to receive feedback on their health status and in some cases, advice on actions to respond to indicators of deteriorating health. Researchers have not always classified standalone tele-monitoring systems as self-management interventions (McLean et al., 2015), but there is evidence that just monitoring one's own health data can prompt changes in behaviour (Salisbury et al., 2015). The recognition of tele-monitoring as a form of self-management is consistent with Schermer (Schermer, 2009) who proposed that tele-monitoring systems mainly facilitate 'compliant self-management', whereby patients adhere to clinical recommendations, but that systems could enhance more 'concordant self-management' whereby patients assimilate their own knowledge of their condition with clinical recommendations to adopt an integrated management regime.

Schermer's distinction between compliance and concordance reflects a wider ambiguity over the goals of self-management in healthcare. It has been argued that DIs favour clinical outcomes over

quality of life, offering a “one size fits all” solution at the cost of ignoring individual needs and dynamic management solutions that the patient has developed (Kendall et al., 2011; Lawn et al., 2011). This conflict in the goals of self-management can present difficulties for HCPs in facilitating the patient to make their own decisions which can contradict clinical recommendations (Smith, 2002).

Recently, many self-management DIs have been developed and a number of studies have used qualitative methods to investigate users’ views, but these papers are distributed across different health conditions and types of DI. The current qualitative synthesis aimed to bring together findings from a diverse range of DIs and conditions to develop a detailed understanding of patient and HCP experiences of using self-management DIs (Morrison et al., 2014)

2.3 Methods

2.3.1 Design

This systematic review adopted a meta-ethnography approach (Noblit & Hare, 1988) to synthesise the findings of qualitative studies, as this inductive method allows an interpretive analysis (Campbell et al., 2011) which fits well with the aim of developing our understanding of how digital self-management is experienced. The ENTREQ checklist (enhancing transparency in reporting the synthesis of qualitative research) was used to ensure systematic reporting of the review (Tong et al., 2012).

2.3.2 Criteria for including studies

Table 3 shows the review inclusion and exclusion criteria. We sought to identify qualitative studies investigating adult patients’ or HCPs’ experiences of using a self-management DI, excluding studies in which participants consider their views on a hypothetical DI. It was important that the primary components of the intervention were delivered digitally, as interventions delivered by telephone or video conference provide real-time interaction which is more akin to a face-to-face consultation. We used a broad definition of self-management to include any behaviour fostering increased responsibility for condition management or increasing confidence, as we held no prior assumptions about which types of intervention might affect patients’ self-management. Initial scoping searches indicated that some studies of standalone tele-monitoring DIs reported relevant reactions in terms

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of patients' self-management behaviours, and thus we wanted to adopt an inclusive approach to defining self-management to incorporate a range of interventions.

Table 3 Inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
Population: Adults with a chronic physical health condition (including any physical health condition requiring long-term management, such as asthma, diabetes, or heart disease), or HCPs involved in their care.	
<p>Intervention: Digital interventions for self-management. Self-management was defined as any behaviour which fosters an increased responsibility for condition management or aims to increase an individual's confidence to become more actively involved in managing the physical and/or emotional impact of their condition, including self-monitoring, medication management, and remote reporting of health parameters to HCPs.</p> <p>Delivered digitally, including via Internet, text messaging, smartphone apps, or tele-monitoring (patient health data monitoring with feedback).</p> <p>User experiences of a DI.</p>	<p>Where the main digital component is live/synchronous, i.e. video conferencing or telephone.</p> <p>Perceptions of a hypothetical DI, e.g. studies that explore whether DIs might be acceptable and/or what features participants might find useful and engaging but which do not involve collecting data on experiences of actually using a DI.</p>
<p>Study type: Qualitative studies.</p> <p>Data collected in semi-structured interviews or focus groups; mixed methods papers were included.</p> <p>Qualitative analysis which summarised and categorised the data and ideally also identified themes or common concepts within the data.</p>	<p>Open-ended questionnaire data, forums.</p> <p>Simple usability assessment.</p>

Qualitative reporting including adequate detail and depth in description of findings to interpret meaning and context.

2.3.3 Systematic search strategy

Systematic literature searches were conducted in August 2016. No date limits were applied to searches as we did not want to exclude potentially relevant studies. Thesaurus terms and abstract key word searches were used across four categories: E-health; intervention; qualitative methods; and chronic illness (see Appendix F). Searches were conducted using CINAHL, Embase, PsycINFO, MEDLINE, Web of Science, and The Cochrane Library. Initial key word search terms were identified by author consensus and in consultation with a specialist librarian. The terms were expanded through referral to a quantitative systematic review of asthma self-management DIs (Morrison et al., 2014), which added several e-health and self-management terms, and a qualitative meta-synthesis of e-health for depression and anxiety (Knowles et al., 2014), which added e-health and qualitative methods terms. The search terms were developed iteratively to ensure a balance between sensitivity and specificity, informed by the results in each database. The references of retrieved articles were searched, and a manual hand search of Journal of Medical Internet Research issues from the last five years was also conducted because early searches indicated that this was a consistently useful source for relevant articles.

The searches aimed to be exhaustive in terms of identifying all relevant papers relating to asthma and hypertension, as the synthesis was conducted in the context of a research programme investigating the integration of DIs into primary care for these conditions. The search terms 'chronic disease/chronic illness' were used in the thesaurus search and Web of Science key word search to identify papers from other chronic physical health conditions to determine whether the findings could be applied more widely (the decision of where to include these search terms was informed by the specificity of the results in each database). This approach is consistent with the literature on conducting searches for a meta-ethnography which advises that it is not necessary to conduct a thoroughly exhaustive search, but rather to select relevant papers which are likely to contribute to the development of new understanding (Campbell et al., 2011; Noblit & Hare, 1988).

2.3.4 Identification of studies

The title and abstract screening and full text screening were completed by the primary author (KM). All of the papers deemed eligible based on title/abstract screening were read in full by KM to decide whether they merited inclusion. 10% of these were also read in full by a second reviewer (LD), plus any papers that the primary author was uncertain about. Discrepancies were resolved through discussion (KM, LD, LY).

2.3.5 Data extraction

The following data were extracted into a database: author, year of publication, country, health condition, aims, DI, participants, target self-management behaviours, HCP involvement, data collection, data analysis, and main findings. The data extraction was performed by KM, and checked by LD.

2.3.6 Analysis and synthesis

The papers were initially grouped by condition and DI design to facilitate cross-comparison between contexts (Atkins et al., 2008; Campbell et al., 2011). First order constructs (quotes from study participants) and second order constructs (study authors' interpretations of their data) were compared within conditions and DI types and across all papers as an iterative process. This helped the authors become highly familiar with the data, and to organise the data coherently for the analysis whilst constantly bearing context in mind. Both the results and discussion sections of papers were included.

To synthesise the translations of the second order constructs, Noblit and Hare's line of argument approach was used whereby similarities and differences were identified between groups of studies to compare findings across conditions and DIs (Noblit & Hare, 1988), in order to gain an advanced understanding of the relationships between the key concepts and develop conceptual third order constructs. The primary author (KM) performed the analysis, facilitated by regular discussion within

the research team. The research team have extensive experience in qualitative methods and synthesis, and include specialists within health psychology, digital interventions, and sociological implementation, as well as clinical expertise in Primary Care and hypertension.

The GRADE-CERQual approach (Lewin et al., 2015) was used to evaluate confidence in the third order constructs developed in the review (Appendix G). This approach encourages transparency in qualitative syntheses by assessing each third order construct on four criteria: methodological limitations of the primary studies contributing to a finding; relevance of the studies in relation to the review question; coherence of the finding itself; and adequacy of the data contributing to a finding (Lewin et al., 2015).

2.3.7 Quality appraisal

The eligible papers were appraised by KM against the well-established multi-dimensional National Institute for Health and Clinical Excellence (NICE) quality appraisal checklist for qualitative studies (National Institute for Health and Clinical Excellence, 2012). This covers domains of quality including theoretical approach, design, data collection, trustworthiness, analysis and ethics. This process enabled us to be transparent about any potential limitations in the primary studies which could affect confidence in the review findings (Tong, Palmer, Craig, & Strippoli, 2014). Papers of low quality were not excluded or given less weight than high quality papers, but the findings were interpreted in the context of possible limitations (Hannes, 2011).

2.4 Results

2.4.1 Searches

The searches identified 120 papers as potentially eligible based on the title and abstract screening. The PRISMA flow-chart (Figure 6) shows that 30 papers met the inclusion criteria, and the most common reason for exclusion after full-text screening was insufficient qualitative analysis.

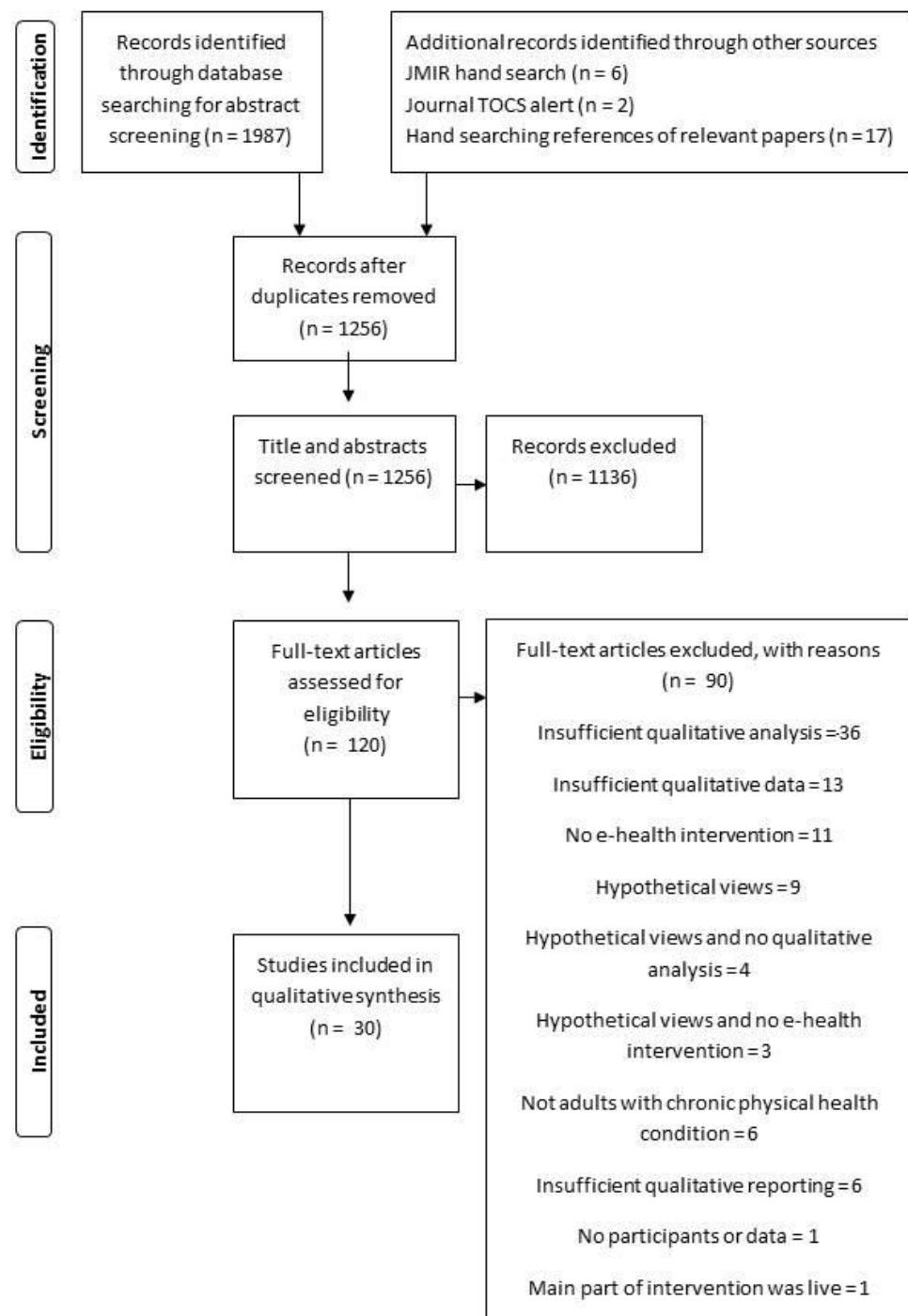


Figure 6 PRISMA 2009 flow diagram

2.4.2 Study characteristics

Table 4 shows the characteristics of the 30 studies included in the review. The health conditions addressed were: hypertension (n=8 papers), diabetes (n=7), chronic obstructive pulmonary disease (COPD, n=7), asthma (n=4), heart disease (n=3) and chronic back pain (n=1). The 30 studies described 25 different DIs; most were designed for use in Primary Care and involved interaction or support from the HCP.

Nine of the DIs were standalone tele-monitoring systems, which could be broken down into four categories: monitoring with a pre-defined algorithm for medication change (n=1); monitoring with automated feedback (n=1); monitoring with HCP feedback (n=2); and monitoring with automated and HCP feedback (n=5). Thirteen were multifaceted DIs with components such as education, behaviour change support, and forums. Two DIs were text-message reminder systems to prompt self-management behaviours, and one provided tailored questions for the patient's next consultation.

Target self-management behaviours included self-monitoring of health readings (e.g. blood pressure, blood glucose), symptoms, or healthy lifestyle habits, engaging in physical activity or healthy diet changes, and adhering to recommended medication changes. Most studies collected data via semi-structured interviews (n=26), though focus groups (n=6) and ethnographic observations (n=2) were also used.

Table 4 Characteristics of eligible studies (total n=30).

Lead author	Year	Country	Health condition	Stated aims	Intervention	Target self-management behaviour	Participants	Design	Main findings
Anhøj (Anhøj & Nielsen, 2004)	2004	Denmark	Asthma	To describe use of the intervention and evaluate users' perceptions.	Multifaceted web-based DI (LinkMedica): Self-monitoring with automated feedback, education and online forum. Data is accessible to HCP.	Self-monitor morning peak flow, doses of rescue medication, and asthma symptoms at night. Follow automated instructions for dose adjustments.	8 adult patients, 2 mothers, 5 GPs	Semi-structured interviews	Patients did not enter their asthma readings daily, and did not respond to the automated feedback. GPs were happy to support patients using the DI but were concerned about the impact on their time and resources.
Burner (Burner, Menchine, Kubicek, Robles, & Arora, 2014)	2014	USA	Diabetes	To uncover those components of the TEXT-MED intervention that participants perceived as most beneficial.	Text-message reminder intervention. Twice daily text messages consisting of educational/ motivational messages, medication reminders, knowledge facts, and healthy living challenges.	Medication adherence, healthy lifestyle behaviours (diet and physical activity), relaxation.	24 Patients	Focus groups	Medication reminders and lifestyle challenges were most popular with patients - cued specific behaviours. Patients would have liked more personalisation of the messages.

Lead author	Year	Country	Health condition	Stated aims	Intervention	Target self-management behaviour	Participants	Design	Main findings
Cottrell (Cottrell, McMillan, & Chambers, 2012)	2012	UK	Hypertension	To investigate experiences of and feedback from intervention patients who used an innovative interactive simple telehealth strategy to monitor and manage their hypertension.	Tele-monitoring: Transmission of home blood pressure readings, automated, personalised feedback messages including advice on medication changes. Healthcare professional reviewed readings weekly, or more frequently if required, and provided advice.	Self-monitor blood pressure, adhere to automated feedback and personalised feedback from HCP on medication changes.	24 Patients	Discussion groups	Patients had a better understanding about hypertension, felt reassured seeing their blood pressure readings and more motivated to adhere to medication, and had feelings of support and companionship from DI.
Dinesen (Dinesen, Huniche, & Toft, 2013)	2013	Denmark	COPD	To describe patients' attitudes towards tele-rehabilitation in the Danish TELEKAT project, in order to better understand patients' behaviour when performing tele-rehabilitation activities in home surroundings.	Multifaceted web-based DI: Monitoring health indicators to receive regular feedback from HCP advising about symptoms, medication, exercises and general questions. Web portal to network with other COPD patients. Provided with training exercises to perform at home.	Self-monitor values such as blood pressure, pulse, weight, oxygen level and lung function, use a step counter, perform home-based exercises and follow advice of HCP.	22 Patients and 26 HCPs	Semi-structured interviews	Patients felt secure knowing that their data were being monitored, and were learning to better manage their condition and how to perform exercises. Seeing their readings motivated patients to try and improve these, unless their readings remained stable over time. HCPs supported patients to become more actively involved in their care.

Lead author	Year	Country	Health condition	Stated aims	Intervention	Target self-management behaviour	Participants	Design	Main findings
Fairbrot-her (Fairbroth er et al., 2014)	2014	Scotland	Chronic heart failure	To understand the views of patients and professionals on the acceptability and perceived usefulness of tele-monitoring in the management of chronic heart failure in the context of day-to-day care provision.	Multifaceted DI: Transmission of symptoms and health data, HCP contacted patient if readings exceeded a threshold. Educational online video to promote self-management.	Self-monitor symptoms, blood pressure readings, weight, oxygen saturation; and self-titrate medication if instructed by HCP.	18 Patients and 5 HCPs	Semi-structured interviews	Patients were monitoring to provide the HCPs with information and placed full trust in their HCP to look after them, though many also found it helpful to see their own data. HCPs were concerned with level of patient dependence and felt patients needed more education to self-manage.
Fairbrot-her (Fairbroth er et al., 2012)	2012	Scotland	COPD	To explore the views of patients and professionals on tele-monitoring for COPD.	Tele-monitoring (Telescot): Transmission of symptoms and health data, HCP contacted patient if readings exceeded a threshold. Patients provided with antibiotics to start if condition worsens.	Self-monitor symptoms and oxygen saturation daily, and self-monitor weight and peak flow weekly. Start medication if symptoms worsen and HCP recommends it.	38 Patients and 32 HCPs	Semi structured interviews	Patients felt they had improved continuity of care, and were reassured by HCP watching over them. HCPs wanted to know the wider context when interpreting patient readings, and were concerned about patients over-treating.

Lead author	Year	Country	Health condition	Stated aims	Intervention	Target self-management behaviour	Participants	Design	Main findings
Fairbrother (Fairbrother et al., 2013)	2013	Scotland	COPD	To explore patient and professional views on self-management in the context of tele-monitoring in chronic obstructive pulmonary disease (COPD).	Tele-monitoring: Same DI as Fairbrother 2012	Self-monitor symptoms, self-monitor oxygen saturation daily, and self-monitor weight and peak flow weekly. Start medication if symptoms worsen and HCP recommends it.	38 Patients and 32 HCPs	Semi-structured interviews	Patients used their data to decide their capacity for physical activity, and whether to adjust treatment or seek professional advice. HCPs felt DI was useful for clinical compliance, and increased communication with patient.
Hallberg (Hallberg, Ranerup, & Kjellgren, 2015)	2015	Sweden	Hypertension	To explore patients' experiences of an interactive mobile phone-based system designed to support the self-management of hypertension.	Multifaceted DI: Transmission of health data, symptoms, medication and lifestyle activities for tailored text message feedback. Programme also provided reminders and shared data with HCP for next consultation.	Self-monitor blood pressure readings, symptoms, side effects, medication adherence, and lifestyle activities. Improve hypertension through changes to physical activity, diet and medication adherence in response to feedback.	49 Patients	Semi-structured face to face or telephone Interviews	Patients were motivated to improve lifestyle and medication adherence when they saw the relationship with their readings. Patients with stable readings over time did not feel this motivation. Patients felt their consultations were more meaningful.

Lead author	Year	Country	Health condition	Stated aims	Intervention	Target self-management behaviour	Participants	Design	Main findings
Hanley (Hanley, Ure, Pagliari, Sheikh, & McKinstry, 2013)	2013	Scotland	Hypertension	To explore the experiences of patients and professionals taking part in an RCT of remote blood pressure monitoring.	Tele-monitoring: Transmission of home blood pressure readings to HCP. DI provided automated feedback on whether patient should contact their HCP. Online record of readings available.	Self-monitor blood pressure, engage in medication changes.	25 Patients, 11 nurses, 9 doctors	Semi-structured Interviews	Patients trusted the average readings as being accurate, and reported having a more meaningful consultation with the HCP due to additional data. HCPs appreciated being able to titrate medication more accurately and rapidly, but were concerned about workload and how to respond to borderline readings.
Hanley (Hanley, Fairbrother, Krishan, et al., 2015)	2015 a	UK	Hypertension in stroke patients	To investigate the likely recruitment rate to a trial, feasibility of using the tele-monitoring service and the experiences and perspectives of those using the tele-monitoring service and those who may not choose to do so.	Tele-monitoring: Same DI as Hanley 2013.	Self-monitor blood pressure, engage in medication changes.	16 patients and 3 nurses	Semi-structured interviews	Patients were not clear on how to respond to their readings, and were unsure if their HCP had seen them. In some cases there was poor communication amongst the healthcare team. Some found monitoring their readings reassuring.

Lead author	Year	Country	Health condition	Stated aims	Intervention	Target self-management behaviour	Participants	Design	Main findings
Hanley (Hanley, Fairbrother, McCloghan, et al., 2015)	2015 b	UK	Diabetes	To explore the experiences of patients and professionals taking part in a RCT of blood glucose, blood pressure(BP) and weight telemonitoring in type 2 diabetes supported by primary care, and identify factors facilitating or hindering the effectiveness of the intervention and those likely to influence its potential translation to routine practice.	Tele-monitoring: Transmission of home blood glucose, blood pressure (BP) and weight readings to the patients' usual HCP. Online record of readings available. Received automated feedback and nurses checked results weekly.	Self-monitor blood glucose, BP and weight, engage in medication changes.	23 patients, 6 nurses and 4 doctors	Semi-structured interviews	Many patients used self-monitoring to support their own self-management. There was some uncertainty in who was responsible for responding to out-of-range readings. HCPs liked being able to change patients' medication more quickly, although some GPs did not use home readings.
Hartmann (Hartmann et al., 2007)	2007	USA	Asthma	To investigate the impact and experience of an interactive patient website and assess	Interactive website to educate asthma patients and provide tailored feedback on questions to ask in their next HCP consultation.	Ask HCP questions in healthcare appointment.	37 Patients	Semi-structured telephone interviews	Patients understood their own role in their care, and perceived a more positive relationship with the HCP.

Lead author	Year	Country	Health condition	Stated aims the impact of such an intervention on the patient-provider relationship.	Intervention	Target self-management behaviour	Participants	Design	Main findings
Hoaas (Hoaas, Andreassen, Lien, Hjalmarseen, & Zanaboni, 2016)	2016	Norway	COPD	The aim of the current study was to explore the patients' perspectives in long-term tele-rehabilitation in COPD. We focused our study on adherence and patients' experiences, aiming to identify factors affecting satisfaction and potential for improvements that might increase adherence.	Multifaceted DI: Tele-rehabilitation with tailored treadmill exercise programme, daily symptom, physiological data and activity monitoring, and weekly feedback sessions with HCP by videoconference.	Physical activity, self-monitoring symptoms, physiological data and activity levels.	10 Patients	Semi-structured focus groups	Patients gained insights into their condition through self-monitoring, and the DI helped them to accept their condition. They increased their confidence to manage their condition, and felt motivated to engage in physical activity where they could see improvements. Motivation waned during and after periods of illness or holiday.

Lead author	Year	Country	Health condition	Stated aims	Intervention	Target self-management behaviour	Participants	Design	Main findings
Jones (Jones et al., 2012)	2012	UK	Hypertension	To explore the views and experiences of those who had undertaken blood pressure self-management.	Tele-monitoring: Home blood pressure monitoring with ability to activate pre-agreed medication changes when readings were high according to algorithm.	Self-monitor blood pressure and self-titration of medication according to pre-planned schedule when readings exceed a threshold.	23 Patients and 6 family members	Semi-structured interviews	Some patients were willing to take responsibility for changes to their medication but others preferred to see the GP, especially those with carers or relatives involved. Patients liked seeing their own readings, and felt motivated to control their condition.
Jones (Jones et al., 2013)	2013	UK	Hypertension	To explore the views of healthcare professionals in primary care participating in a trial of patient self-monitoring with self-titration of antihypertensives	Tele-monitoring: Same DI as Jones 2012.	Self-monitor blood pressure and self-titration of medication according to pre-planned schedule when readings exceed a threshold.	13 GPs, 2 Practice nurses, 1 Healthcare assistant	Semi-structured interviews	GPs were positive about patients engaging in home monitoring of blood pressure, and could see the benefits for patients. They were less confident about patients self-managing their medication, and had concerns about the additional workload at the clinic and the expense of training patients.
Kerr (Kerr et al., 2010)	2010	UK	Heart disease	To explore the effectiveness of a web-based intervention in	Multifaceted web-based DI: Interactive information, behaviour change support, and peer and expert support.	Usage of the web intervention	19 Patients	Interviews	DI usage was relatively low. Patients had a high level of trust in their HCP, and some

Lead author	Year	Country	Health condition	Stated aims decreasing inequalities in access to self-management support in patients with coronary heart disease.	Intervention	Target self-management behaviour	Participants	Design	Main findings
									did not perceive a need to use the DI.
Koopman (Koopman et al., 2014)	2013	US	High blood pressure and type 2 diabetes	To examine the process of implementing home tele-monitoring of blood glucose and blood pressure for patients with diabetes in six primary care practices.	Tele-monitoring: Transmission of blood pressure and blood glucose to nurses, which were assessed twice weekly and data summaries passed on to physicians. HCPs provided feedback to patient by phone.	Self-monitor blood glucose and blood pressure daily, and respond to HCP feedback.	6 nurses, 12 physician s, 93 Patients	Nurses and physicians took part in semi-structured interviews, participants took part in brief telephone exit interviews from which notes were taken.	HCPs appreciated improved clinical care of patients. Physicians preferred data summaries as felt they had insufficient time to review raw data. Nurses were aware of the benefits to patients of increased understanding of their condition.

Lead author	Year	Country	Health condition	Stated aims	Intervention	Target self-management behaviour	Participants	Design	Main findings
Lambert-Kerzner (Lambert-Kerzner et al., 2010)	2010	US	Hypertension	To gather in-depth understanding of the experience of participating in a multifaceted hypertension intervention, with a focus on technology.	Tele-monitoring: Home monitoring of BP reported via an interactive voice recognition system with automated feedback messages. Pharmacist recommended medication changes by phone in response to readings. Option to listen to educational messages.	Self-monitor blood pressure, engage with medication adherence.	146 Patients	Semi-structured interviews	Patients were reassured by seeing their blood pressure readings, and the DI helped them see how their behaviour affected their health readings. They felt they had a more bi-directional relationship with the HCP, and some perceived companionship from the DI.
Langstrup (Langstrup, 2008)	2008	Denmark	Asthma	To explore the reasons why information and communication technologies intended to connect chronic patients with their care provider fail to become a durable part of treatment practices.	Multifaceted web-based DI (LinkMedica): Same DI as Anhoj	Self-monitor morning peak flow, number of doses of rescue medication, and asthma symptoms at night. Follow automated instructions for management. GPs to use decision support tool.	8 GPs, 1 nurse	Ethno-graphic case study, including semi-structured interviews with HCPs and observation of patient.	GPs felt it was a tool for the patient, did not see the value of the decision support tool for them and felt it would be a burden to review the data. Patient only entered her readings for the nurse to see at an appointment, who overrode the DI automated feedback due to contextual factors.

Lead author	Year	Country	Health condition	Stated aims	Intervention	Target self-management behaviour	Participants	Design	Main findings
Leon (Leon, Surender, Bobrow, Muller, & Farmer, 2015)	2015	South Africa	Hypertension	To investigate the wider potential for health interventions delivered via mobile phone by exploring patients' experience of the trial.	Text-message reminder intervention: Weekly tailored text reminders to encourage treatment adherence using goals and planning, and facilitate interaction with healthcare system.	Medication adherence, appointment attendance.	37 Patients	Focus groups and interviews	Personalised messages made some patients feel cared for, and this triggered motivation to engage in self-management. Patients found the reminders for medication adherence useful, particularly those with high levels of stress.
Roblin (Roblin, 2011)	2011	US	T2 Diabetes	To collect preliminary data on usability of mobile Information Communication Technology for self-management of blood glucose (SMBG) adherence and value added of peer support for SMBG adherence.	Tele-monitoring: Transmission of blood glucose readings, automated feedback provided to patient and their selected supporter with advice for action. Texts were sent every 5 days. Supporter is trained in motivational interviewing skills to encourage the patient to self-monitor.	Measure blood glucose regularly and follow feedback advice to improve glycaemic control.	15 Patients	Focus groups	Some diabetes patients reported improved attention to self-monitoring, and increased self-efficacy. Some motivational messages were found to be discouraging.

Lead author	Year	Country	Health condition	Stated aims	Intervention	Target self-management behaviour	Participants	Design	Main findings
Seto (Seto et al., 2012)	2012	Canada	Heart failure	To provide in-depth insight into the effects of tele-monitoring on self-care and clinical management, and to determine the features that enable successful heart failure tele-monitoring.	Tele-monitoring: Transmission of daily weight and blood pressure readings, and self-assessed symptoms via mobile phone to receive automated feedback. Readings stored on hospital repository and physician alerted if readings outside target range, to contact patient with recommendations.	Self-monitor weight, blood pressure and symptoms; modify lifestyle behaviours (e.g., salt and fluid restrictions, diuretic dose, and exercise) in response to automated and HCP feedback.	22 Patients and 5 HCPs	Semi-structured interviews	Increased self-awareness about condition, reassurance someone was watching over them, and motivation for self-care. HCPs liked having alerts for when they needed to contact patients, but were concerned about the burden of responding.

Lead author	Year	Country	Health condition	Stated aims	Intervention	Target self-management behaviour	Participants	Design	Main findings
Tatara (Tatara, Arsand, Skrovseth, & Hartvigsen, 2013)	2013	Norway	Diabetes T2	To contribute toward accumulating knowledge about factors associated with usage and usability of a mobile self-management application over time through a thorough analysis of multiple types of investigation on each participant's engagement.	Multifaceted smart phone DI: Self-monitoring of blood glucose, step counter with feedback, data tracking tool, habit recording of diet, goal setting for diet and PA, and tips for self-management.	Self-monitor blood glucose readings, diet, step-counter; increase physical activity and healthier diet.	12 Patients	Semi-structured interviews	Patients liked seeing trends in their data over time, and were motivated to engage in healthy lifestyle behaviours.

Lead author	Year	Country	Health condition	Stated aims	Intervention	Target self-management behaviour	Participants	Design	Main findings
Ure (Ure et al., 2012)	2012	Scotland	COPD	To explore the perceptions of patients and professionals about the pilot implementation of the COPD tele-monitoring service.	Tele-monitoring: Same DI as Fairbrother 2012	Self-monitor symptoms, self-monitor oxygen saturation daily, and self-monitor weight and peak flow weekly. Start medication if symptoms worsen and HCP recommends it.	20 Patients and 25 HCPs	Interviews, focus group and ethnographic observation	Patients felt benefit of being monitored and having easier access to HCP advice, and most were confident to take action themselves in response to deteriorating symptoms. Clinicians had concerns about over-treatment, increased workload, and uncertainty about how to respond to readings and wanted more clinical information to interpret the readings.

Lead author	Year	Country	Health condition	Stated aims	Intervention	Target self-management behaviour	Participants	Design	Main findings
Urowitz (Urowitz et al., 2012)	2012	Canada	Diabetes	To evaluate the experience of patients and providers using an online diabetes management portal for patients.	Multifaceted web-based DI: Monitoring blood pressure, blood glucose and weight, with HCP feedback, and interactive education and online health record.	Self-monitor blood pressure, blood glucose, and weight, manage diabetes with changes to diet and exercise.	17 Patients	Semi-structured telephone interviews	Patients were reassured that HCP was monitoring their readings, and liked being able to track their own data over time. This was the most well-used feature, education materials were not well-used. Those with stable readings did not perceive such a benefit. HCPs were concerned about the burden of monitoring readings, and did not see the necessity for the DI as felt patients already managed their condition well.

Lead author	Year	Country	Health condition	Stated aims	Intervention	Target self-management behaviour	Participants	Design	Main findings
Van Kruijssen (van Kruijssen et al., 2015)	2015	Netherlands	Asthma and COPD	The aim of this qualitative study was to understand health-care professionals' and subjects' perceptions and behaviors related to self-management diary use.	Multifaceted web-based DI: Self-management online diary to record symptoms and medication, and identify when they are experiencing personally defined health states. DI sends reminders for self-selected personalised actions to manage their health. Patients can ask for advice from HCP via website.	Detect exacerbations and respond by working towards personally defined goals. Regular self-monitoring of symptoms.	12 Patients, 4 HCPs (NB 14 patients who did not use DI are not included)	Semi-structured interviews	Asthma patients used the DI to identify exacerbations, and inform their medication dosage. Some were more confident than others. Both COPD and asthma patients gained increased insight into their condition. HCPs liked improved clinical control of patient's condition, and being able to have more meaningful discussions with patient in consultation.
Voncken-Brewster (Voncken-Brewster et al., 2014)	2014	Netherlands	COPD	To gauge the feasibility of adding a web-based patient self-management support application to yearly COPD consultations with practice nurses.	Multifaceted web-based DI: Website included health risk appraisal with personalised feedback from the nurse, and behaviour change modules on medication adherence, smoking cessation and physical activity.	Behaviour change adherence.	7 Patients	Semi-structured interviews	Some patients liked being reminded to change their behaviour, others did not feel the need. Patients liked personalised messages, nurses would like better integration with e-health record.

Lead author	Year	Country	Health condition	Stated aims	Intervention	Target self-management behaviour	Participants	Design	Main findings
Williams (Williams, Price, Hardinge, Tarassenko, & Farmer, 2014)	2014	UK	COPD	To explore patients' expectations and experiences of using a mobile telehealth-based (mHealth) application and to determine how such a system may impact on their perceived wellbeing and ability to manage their COPD.	Multifaceted tablet computer DI: Self-monitoring pulse oximetry and symptoms daily, nurse reviews data and patient contacts nurse in emergency. Education on smoking cessation, diet, and breathing/ inhaler techniques.	Self-monitor data and symptoms, adhere to treatment, detect exacerbations, know when to contact HCP	19 Patients	Interviews	Patients felt reassured by nurse reviewing their data, and experienced increased self-awareness of condition, feeling encouraged to engage in self-management behaviour in response to symptoms.
Yu (Yu et al., 2014)	2014	Canada	Diabetes	To determine the effect of a web-based patient self-management intervention on psychological (self-efficacy, quality of life, self-care) and clinical (blood pressure, cholesterol, glycaemic control, weight) outcomes.	Multifaceted web-based DI: Self-monitoring blood glucose with automated feedback, goal-setting, and shared forums with peers and experts.	Self-monitor blood glucose, physical activity changes	21 Patients	Qualitative interviews	Patients felt they could not control their condition when seeing variation in health readings over time. Blog was the most well-used feature.

Lead author	Year	Country	Health condition	Stated aims	Intervention	Target self-management behaviour	Participants	Design	Main findings
Zufferey (Caiata Zufferey & Schulz, 2009)	2009	Switzerland	Chronic back pain	To investigate the influences of a self-management website on patients' chronic low back pain self-management attitudes and behaviours.	Multifaceted web-based DI: Educational material, virtual gym, online chat rooms, testimonials.	Website usage, exercises for back pain	18 Patients	Semi-structured interviews	Patients better understood their condition, but found it more useful if they were not already active self-managers and were ready to take on self-management themselves.

2.4.3 Quality appraisal

The quality was high overall with 22 papers rated as high quality, 4 as medium (Caiata Zufferey & Schulz, 2009; Lambert-Kerzner et al., 2010; Ure et al., 2012; van Kruijssen et al., 2015), and 4 as low (Anhøj & Nielsen, 2004; Cottrell et al., 2012; Langstrup, 2008; Roblin, 2011) (Appendix H). The most common criteria which papers failed to meet were reflection on the influence of the researcher, inclusion of ethical details, and justification of decisions about triangulating data. Some of these shortcomings did not necessarily indicate lack of rigour in data collection and interpretation, but may have been due to limited space for reporting (Atkins et al., 2008).

2.4.4 Meta-ethnography analysis

Table 5 shows the key concepts from constant comparison, the first order constructs (primary quotes from the participants in the studies), second order constructs (study authors' interpretations) and third-order constructs, which represent the new understanding derived from the meta-ethnography analysis. Due to the large number of studies in the review, Table 5 is based on a sub-sample of the studies contributing to each third order construct (purposively selected for richness, relevance and diversity of first and second order constructs), but the contribution of all studies is described in the line of argument. As almost half the studies included in the review used standalone tele-monitoring DIs, reactions to self-monitoring data became an important focus of the synthesis.

The CERQual evaluation found moderate confidence in all three third-order constructs, meaning it is likely that these findings are a reasonable representation of patient and HCP experiences of self-management DIs (Lewin et al., 2015).

Table 5 Meta-ethnography synthesis, including key concepts, first-order constructs from study participants' quotes, second-order constructs from study authors' interpretations, and third-order constructs from the meta-ethnography

Key concepts	First order constructs	Second order constructs	Third order constructs
Level of patient/HCP responsibility	Patient: "Normally you go for a visit [...] and they check your blood pressure and just say it's good, but I don't know what would be good or bad, really. Now I know more; that gives me an awareness of how my body works. Yes, now the visit's different for both me and the nurse. Now I had information collected over a longer period of time; before it's only been about when you're there [at the visit]..." (Hallberg et al., 2015). Hypertension.	They (patients) described their participation during the visit as playing a more active role in the conversation and taking more responsibility for discussing their health, compared with previous health-care visits. Moreover, they perceived it as a better and more meaningful consultation as the graphs functioned as a common ground for discussion. (Hallberg et al., 2015). Hypertension	Perceived purpose of the DI: Who is responsible?
	Patient: "If you have a bad reading you're not going to go out and do the gardening or go up and clean the bathroom or something. . . You know that's the day you need to just take it easy" (Fairbrother et al., 2013). COPD.	A number of patients used oxygen saturation measurements to inform decisions about their capacity to undertake domestic activities, such as household chores or taking family excursions. (Fairbrother et al., 2013). COPD.	
	Patient: "It keeps you in the picture... And you know exactly what's going on from day to day..." (Fairbrother et al., 2014). CHF.	Many (patients) found it helpful to know their weight, blood pressure and oxygen saturation score and to have the facility to monitor data trends over time. This was considered beneficial in determining state of health. (Fairbrother et al., 2014). CHF.	
	Patient: "...It tends to eliminate one of the biggest problems of being sick and that's a sense of isolation, because I know that there's regular (ongoing) contact.	The patients also felt more reassured, because they were more connected to their healthcare team and their	Patients across conditions felt that they engaged more with their HCP because the self-management DI had given them a clearer insight into their condition. Patients also indicated that they make their own decisions about their life informed by their use of the DI, demonstrating how the DI facilitated self-management of their condition. HCPs tended to focus on the clinical control afforded to them by DIs, in that they could track patients' progress via their health readings. In a minority of

Key concepts	First order constructs	Second order constructs	Third order constructs
	So, if I'm not feeling well, I know I'm going to be getting a phone call and it seems to me that's worth gold." (Seto et al., 2012). CHF.	clinicians had more information about their condition.(Seto et al., 2012). CHF.	
	Patient: "But I don't know what to do if...I think that if it goes above 15, you have to do it again or something like that... I would let my practice get in touch with me, because I'm not very sure of what it all means". (Hanley, Fairbrother, McCloughan, et al., 2015). Diabetes.	Some patients would wait for the practice nurse to contact them, which many did, others would initiate the communication themselves. (Hanley, Fairbrother, McCloughan, et al., 2015). Diabetes.	studies, HCPs also considered that DIs could help patients to self-manage their condition. If HCPs contacted patients when their readings were high, patients became more reliant on HCP feedback for reassurance, which led to HCPs feeling burdened.
	HCP: "It's a piece of information and a piece of patient learning, which lead to subjects knowing better what their disease is. During a consultation . . . patients can ask different types of questions; they know more, so you can more or less skip the basic questions and move on." (van Kruijssen et al., 2015). Asthma and COPD.	N/A	
	HCP: "I feel that the COPD patients are getting to be more active and motivated to do training at home. I feel like a coach for them." (Dinesen et al., 2013). COPD.	The healthcare professionals viewed themselves as the patients' coaches in the tele-rehabilitation programme. (Dinesen et al., 2013). COPD.	

Key concepts	First order constructs	Second order constructs	Third order constructs
	HCP: "It allows us to look at patients every single day, as opposed to, at the moment, seeing people, maybe every four, six or twelve weeks, dependent on the patient, so you get a much better picture of their daily condition...things get picked up a lot quicker" (Fairbrother et al., 2014). CHF.	Professionals perceived that tele-monitoring facilitated 'closer monitoring' of patients. Tele-monitoring data were attributed as providing a more detailed picture of patient health than usual care, enabling the professional to take pro-active approaches to clinical management. (Fairbrother et al., 2014). CHF.	
	HCP: "Because you can tweak things, adjust medications, rather than having them wait 6 months or 3 months when they come in, and I think you can get a tighter control." (Koopman et al., 2014). Diabetes and hypertension.	Physicians and nurses were able to closely follow patients with whom they had just made treatment adjustments (Koopman et al., 2014). Diabetes and hypertension.	
	HCP: "Some patients take less responsibility in their self-management of the disease as they feel that the health care provider is in constant review of their blood sugars." (Urowitz et al., 2012). Diabetes.	Some providers expressed concern that patients assumed providers were watching their health status on the portal all of the time and might therefore leave problems unreported (Urowitz et al., 2012). Diabetes	
Self-awareness and empowerment	Patient: "The most important thing I've learned is that you should be more physically active.....now you can actually see it on the curve...you get motivated to do something beyond the norm." (Hallberg et al., 2015). Hypertension.	Although they (patients) knew in a general sense that physical activity is good for decreasing high blood pressure, this became more obvious and they gained new knowledge that it really is true. (Hallberg et al., 2015). Hypertension	Perceiving meaning in self-monitored data

Key concepts	First order constructs	Second order constructs	Third order constructs
	Patient: "It's really taught me what the correlation is between salt intake and weight and water retention. An above normal sodium intake will show up immediately the next day as a weight gain and then as you clear that out of your system it goes back." (Seto et al., 2012). CHF.	Patients expressed feeling more in control, confident, and accountable, because they could directly observe the effects of their lifestyle choices on their health and become active participants in their own health. (Seto et al., 2012). CHF.	Self-monitoring symptoms or physiological readings over time tended to be a rewarding process for patients when they could understand a link between their readings and their daily activities, such as medication adherence or healthy lifestyle behaviours.
	Patient: "I get motivated when I see my data on the web portal ... It is a milestone, and I want to improve my values by exercising." (Dinesen et al., 2013). COPD.	Being able to actually see the graphically presented data (blood pressure, pulse, weight, spirometry and saturation) on the web portal or tele-health monitor motivated the patients to continue training and to compete with themselves, especially when the measured values showed improvement over time. (Dinesen et al., 2013). COPD.	Perceiving a link with lifestyle was sufficient to promote engagement with self-management behaviours.
	Patient: "I think it is fine to have 8000 [as a goal], because this I can manage [to walk], but not 10 [ten thousand]. Then I become sad, and think 'oh no, I cannot achieve the pre-set goal'" (Tatara et al., 2013). Diabetes.	Feedback showing progress toward goals was most important for encouraging daily physical activity and good nutrition habits. (Tatara et al., 2013). Diabetes.	Self-management behaviours, but it was important to perceive that readings were meaningful and could be controlled by medication or lifestyle, otherwise self-monitoring became a frustrating or worthless experience.
	Patient: "I could not run faster, but I could increase the duration and walk for a longer time. Then I felt an accomplishment" (Hoaas et al., 2016). COPD.	Participants considered these graphs as motivational factors and learning opportunities.... However, this group of patients cannot increase their physical capacity infinitely. One of the participants, who adhered very well to the study, was able to set new goals when the "upward feeling" was lost. (Hoaas et al., 2016). COPD.	This motivation to change behaviour based on perceived interactions between behaviours and health demonstrates that both multi-faceted self-management DIs

Key concepts	First order constructs	Second order constructs	Third order constructs
	N/A	A 67 year old lady was very happy with using (the intervention) —she said that when she finished using the system she missed the contact and felt that she had 'lost a friend.' (Cottrell et al., 2012). Hypertension.	and standalone tele-monitoring systems can enhance the patient's self-management of their condition.
	N/A	Other patients did not experience the self-management system as very useful, mainly because they had had stable blood pressure or had not perceived any symptoms. (Hallberg et al., 2015). Hypertension	
	Patient: "I don't feel that measuring my values makes a difference for me—They are stable all the time." (Dinesen et al., 2013). COPD.	A small number of patients (5/22) experienced indifference toward the tele-rehabilitation measures. The patients argued that it was because the measured values were stable. These patients reported that they were unable to observe any connection between measured values and physical training over time. (Dinesen et al., 2013). COPD.	
	Patient: "Part of it is, when you see the blood sugar is really high, I already know it's high. I'm not taking the medication. So to log the fact that they are high, ends up making you more frustrated. So why do that?" (Yu et al., 2014). Diabetes	Participants reported feeling frustrated with the uncontrolled nature of their disease, and the collection of self-monitoring information that showed a lack of metabolic control exacerbated this frustration. (Yu et al., 2014). Diabetes.	
Perceptions of medication change	Patient: "There's no way you're going to cheat the machine so it's... it is a good thing like. You cannot kid yourself on with it" (Hanley et al., 2013). Hypertension.	There was consensus between both patients and professionals that the home monitoring system provided a more accurate assessment of BP than surgery measurements and better evidence for action, facilitating	Patients carefully consider recommended medication changes

Key concepts	First order constructs	Second order constructs	Third order constructs
		rapid tailoring of medication.(Hanley et al., 2013). Hypertension.	Making medication changes can be challenging for patients, and this appeared to vary between conditions. Patients with hypertension and COPD were more confident to change their medication, whilst those with CHF tended to be less confident. Those with asthma sometimes did not trust the feedback that their medication needed changing, but this seemed to depend on the format of the DI feedback. Confidence and belief in necessity of medication change were important factors in determining whether a patient adheres to a medication change.
	N/A	Most (patients) perceived that having access to readings and emergency supplies of antibiotics at home gave them confidence to respond to deteriorating symptoms themselves. (Ure et al., 2012). COPD	
	Patient "A couple of times they phoned me telling me that my blood pressure was too high and telling me that they'd be sending me a new prescription through the post which they did. I thought that was bloody wonderful". (Hanley, Fairbrother, McCloughan, et al., 2015). Diabetes and hypertension.	Some GPs were willing to adjust BP medication remotely which was very acceptable to patients. (Hanley, Fairbrother, McCloughan, et al., 2015). Diabetes and hypertension.	
	Patient: "When I've got it bad and it's great to know that you can just take a reading and say; 'well, I do need a doctor or I do need to start these steroids." (Fairbrother et al., 2013). COPD.	Many patients reported using tele-monitoring data to validate their decision to self-medicate and/or to contact healthcare professionals in order to prevent exacerbations and hospitalization. (Fairbrother et al., 2013). COPD.	
	Patient: "Then I get an impression of when there are peaks, when it goes well, how much medication I need. and whether or not I can reduce my medications". (van Kruijssen et al., 2015). Asthma.	N/A	

Key concepts	First order constructs	Second order constructs	Third order constructs
	Patient: "I might have had a low peak flow for a couple of days. But it kept instructing me to increase the dose, and I did not think it was necessary".(Anhøj & Nielsen, 2004) . Asthma	Patients do not readily accept advice from a virtual expert if this advice conflicts with the patient's own previous experience and attitudes. (Anhøj & Nielsen, 2004). Asthma.	
	Patient: "As a result of [tele-monitoring], they increased the quantity of one of the drugs I'm taking... which hasn't made the slightest difference". (Fairbrother et al., 2014). CHF	Reticence was identified among some patients relating to their involvement in self-directed medication during tele-monitoring. Patients held the view that professionals, rather than themselves, held central responsibility for the management of their condition. (Fairbrother et al., 2014). CHF.	
	Patient: " 'There was a couple of times, where it was borderline and the once I did say I didn't want to change ... and I thought well I'd like to see how it pans out before changing". (Jones et al., 2012). Hypertension.	Patients were generally confident about implementing a medication change when their blood pressure was consistently above target levels. However, eight of the 17 patients who had implemented an initial medication change chose not to implement a subsequent change, mostly when their readings were borderline raised. (Jones et al., 2012). Hypertension.	
	N/A	This group of patients received prior instruction from their cardiologist to take extra diuretic medication in this situation, but they still often felt uncertain of making the decision to take the extra medication on their own. (Seto et al., 2012). CHF.	

2.4.5 Line of argument

2.4.5.1 Perceived purpose of the DI: Who is responsible?

Self-management DIs can facilitate HCPs to care for patients, or patients to care for themselves. The studies in this review showed that both goals can be achieved simultaneously. Patients using self-management DIs generally perceive that they are more aware of their condition (Burner et al., 2014; Caiata Zufferey & Schulz, 2009; Cottrell et al., 2012; Dinesen et al., 2013; Fairbrother et al., 2013; Fairbrother et al., 2014; Hanley, Fairbrother, Krishan, et al., 2015; Hanley, Fairbrother, McCoughan, et al., 2015; Hanley et al., 2013; Hoaas et al., 2016; Jones et al., 2012; Leon et al., 2015; Seto et al., 2012; Tatara et al., 2013; Urowitz et al., 2012; van Kruijssen et al., 2015; Voncken-Brewster et al., 2014; Williams et al., 2014), better able to make decisions about their own health (Burner et al., 2014; Dinesen et al., 2013; Fairbrother et al., 2013; Hanley, Fairbrother, McCoughan, et al., 2015; Hoaas et al., 2016; Jones et al., 2012; Lambert-Kerzner et al., 2010; Tatara et al., 2013; Ure et al., 2012; van Kruijssen et al., 2015; Williams et al., 2014) and engage as an equal with the HCP in meaningful discussions (Dinesen et al., 2013; Hallberg et al., 2015; Hanley et al., 2013; Hartmann et al., 2007; Jones et al., 2012; Lambert-Kerzner et al., 2010; van Kruijssen et al., 2015) indicating that the DI facilitated self-management of their condition. Often in the same studies, HCPs focus on the improved clinical control afforded to them by self-management DIs, being able to track patients' physiological data over time to detect exacerbations or change medication (Fairbrother et al., 2013; Fairbrother et al., 2014; Hanley, Fairbrother, McCoughan, et al., 2015; Hanley et al., 2013; Jones et al., 2013; Seto et al., 2012; Ure et al., 2012; Urowitz et al., 2012; van Kruijssen et al., 2015). This shows that these different goals of self-management DIs can operate in tandem, as both patients and HCPs perceive different benefits from the same DIs, and this was apparent across the various health conditions.

However, as well as improving self-management skills in patients, the same DIs can also initiate feelings of reliance on HCPs to manage their health. This reaction was particularly evident when HCPs contacted patients when their home readings were out-of-range. This led patients to feel that they were continually being monitored by their HCP (Dinesen et al., 2013; Fairbrother et al., 2012; Fairbrother et al., 2013; Fairbrother et al., 2014; Hanley, Fairbrother, McCoughan, et al., 2015; Seto et al., 2012; Ure et al., 2012; Urowitz et al., 2012). These patients still interpreted their own readings and used their data to inform decisions (indicating adoption of self-management), but at the same time relied on their HCP to detect when there was a problem. This DI design appeared to be more prevalent in conditions such as COPD and CHF, possibly because of the risk

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of deterioration or severe exacerbations in these conditions, and dependency increased when symptoms became worse. This feeling of 'being monitored' was a positive experience for patients, who felt reduced anxiety about their condition and were reassured by this level of care (Dinesen et al., 2013; Fairbrother et al., 2013; Fairbrother et al., 2014; Hanley, Fairbrother, McCoughan, et al., 2015; Seto et al., 2012; Ure et al., 2012; Urowitz et al., 2012), but HCPs felt burdened by unrealistic patient expectations of continual monitoring and were concerned that this might lessen patients' responsibility to detect exacerbations themselves (Fairbrother et al., 2014; Ure et al., 2012; Urowitz et al., 2012). In one study, COPD patients were responsible for contacting the HCP when their readings were high rather than the other way around, and they still benefited from a feeling of being well cared for just through knowing that the HCP had access to their readings and was using them to inform their care (Williams et al., 2014). Therefore it seems beneficial for patients' peace of mind to know that their home readings are being used by a HCP, but from a practical perspective, not necessarily to rely on HCP feedback for detecting problems. In some studies, patients and HCPs reported feeling uncertain about who was responsible for responding to out-of-range readings (Hanley, Fairbrother, Krishan, et al., 2015; Hanley, Fairbrother, McCoughan, et al., 2015; Koopman et al., 2014; Ure et al., 2012). Careful use of appropriate feedback and ensuring that patients and HCPs have clear instructions about how to respond if a reading is out-of-range might help to prevent over-reliance on HCPs.

While HCPs tended to focus on their own responsibility to clinically control the patient's condition rather than the patient's self-management, in a few studies HCPs reported seeing the benefit for patients of increased self-awareness about their condition when using DIs (Dinesen et al., 2013; Hanley et al., 2013; Jones et al., 2013; Koopman et al., 2014; Langstrup, 2008; Urowitz et al., 2012; van Kruijssen et al., 2015) or wanting to act as the patients' coach to encourage them to self-manage their condition (Anhøj & Nielsen, 2004; Dinesen et al., 2013; Fairbrother et al., 2013). Therefore self-management DIs promoted both patient self-management and HCP clinical control, and patients and HCPs each tended to focus mainly on their own improved control of the condition, although feedback expectations could influence patients' perceived responsibility. HCPs seemed to weigh up the benefit of improved clinical control against the additional time required to process the patients' data and make medical decisions (Anhøj & Nielsen, 2004; Fairbrother et al., 2012; Fairbrother et al., 2013; Fairbrother et al., 2014; Hanley, Fairbrother, McCoughan, et al., 2015; Hanley et al., 2013; Jones et al., 2013; Koopman et al., 2014; Seto et al., 2012; Ure et al., 2012; Urowitz et al., 2012), and in some cases the poor integration of the DI with existing systems was highlighted as an issue for HCPs (Fairbrother et al., 2012; Koopman et al.,

2014; Urowitz et al., 2012). This was more of an issue for physicians/GPs than nurses, and implies that HCPs need an accessible format for reviewing patients' data to minimise additional workload.

2.4.5.2 Perceiving meaning in self-monitored data

The other two third-order constructs identified in the meta-ethnography were focused on specific aspects of patient self-management, and therefore fall under the broader concept of patient responsibility described above. Patients' reactions to self-monitoring their physiological data were complex. Understanding self-monitored physiological or symptom readings in the context of lifestyle behaviours such as medication adherence or physical activity appeared to give patients across conditions a sense of control over their condition and allowed them to assign meaning to their readings (Cottrell et al., 2012; Dinesen et al., 2013; Hallberg et al., 2015; Hanley, Fairbrother, McCoughan, et al., 2015; Lambert-Kerzner et al., 2010; Seto et al., 2012; Tatara et al., 2013; van Kruijssen et al., 2015), which made the self-monitoring process more worthwhile to maintain over time. Perceiving an interaction between lifestyle activities and physiological data not only encouraged patients to continue self-monitoring, but also seemed to motivate them to engage in self-management behaviours in order to see an improvement in their readings, for example, to adhere to medication in order to reduce their blood pressure (Cottrell et al., 2012; Hallberg et al., 2015; Hanley, Fairbrother, Krishan, et al., 2015; Hanley et al., 2013; Jones et al., 2012; Lambert-Kerzner et al., 2010), to better manage their diabetes through physical activity and diet (Hanley, Fairbrother, McCoughan, et al., 2015; Tatara et al., 2013; Urowitz et al., 2012), or to engage in more physical exercise to control their COPD (Dinesen et al., 2013; Hoaas et al., 2016). This motivation to change behaviour based on physiological data was found even amongst patients using standalone tele-monitoring systems with no behaviour change support or educational tools (Cottrell et al., 2012; Hanley, Fairbrother, Krishan, et al., 2015; Hanley, Fairbrother, McCoughan, et al., 2015; Hanley et al., 2013; Jones et al., 2012; Lambert-Kerzner et al., 2010), indicating that just having access to the data was sufficient to trigger behaviour change. Hoaas gives a useful insight into patients' motivation to engage in self-management behaviours over a longer period of time, as this study ran for 2 years (Hoaas et al., 2016). They found that some patients lost motivation to continue engaging in physical activity when they could no longer see an improvement or after a spell of inactivity, but if patients adjusted their goals, e.g. to focus on duration rather than intensity of exercise, this helped to keep them motivated. Diabetic patients felt that feedback showing an improvement towards goals is a key source of motivation to self-manage their condition (Tatara et al., 2013). Therefore, self-monitoring data is motivating to

patients, especially when they can detect an improvement, but careful goal-setting strategies may be needed in cases where improvement is not obvious.

Where diabetic patients had failed to adhere to a behaviour change to control their readings or felt that high readings were out of their control, they found self-monitoring to be a frustrating process (Roblin, 2011; Yu et al., 2014). Those who had stable readings which did not vary over time were less likely to feel a benefit from monitoring and this was the case across health conditions (Dinesen et al., 2013; Hallberg et al., 2015; Urowitz et al., 2012), as readings did not then convey any meaning about their condition.

2.4.5.3 Patients carefully consider recommended medication changes

Self-monitoring could also contribute to patients' engagement with medication change if patients felt confident enough to change their medication based on their readings. Confidence appeared to be high in COPD patients (Dinesen et al., 2013; Fairbrother et al., 2013; Ure et al., 2012) and some hypertensive patients (Hanley, Fairbrother, McCloughan, et al., 2015; Hanley et al., 2013), but lower for CHF patients who were concerned about taking diuretic medication in response to high readings, even when based on prior advice from their HCP (Fairbrother et al., 2014; Seto et al., 2012). It should be noted that age might also be a factor influencing confidence to adjust medication, as CHF patients are on average older than those with COPD.

As well as feeling confident, patients also needed to perceive that a recommended medication change was necessary. For example, hypertensive patients who felt that their readings were borderline were less likely to follow advice to change their medication because they didn't feel their blood pressure was high enough to warrant a change (Jones et al., 2012). Asthma patients could be reluctant to follow automated advice to change medication if this conflicted with their own beliefs about not needing steroid medication regularly (Anhøj & Nielsen, 2004) . However, when using a self-management diary to track symptoms and identify exacerbations, some asthma patients were happy to adjust their medication to control their symptoms (van Kruijssen et al., 2015). Asthma patients in this intervention created personally defined health states and individual treatment plans, and it may be that this personal tailoring helped them to believe in the necessity of medication adjustment when they could see their symptoms were poorly controlled.

Figure 7 shows a visual representation of the third order constructs.

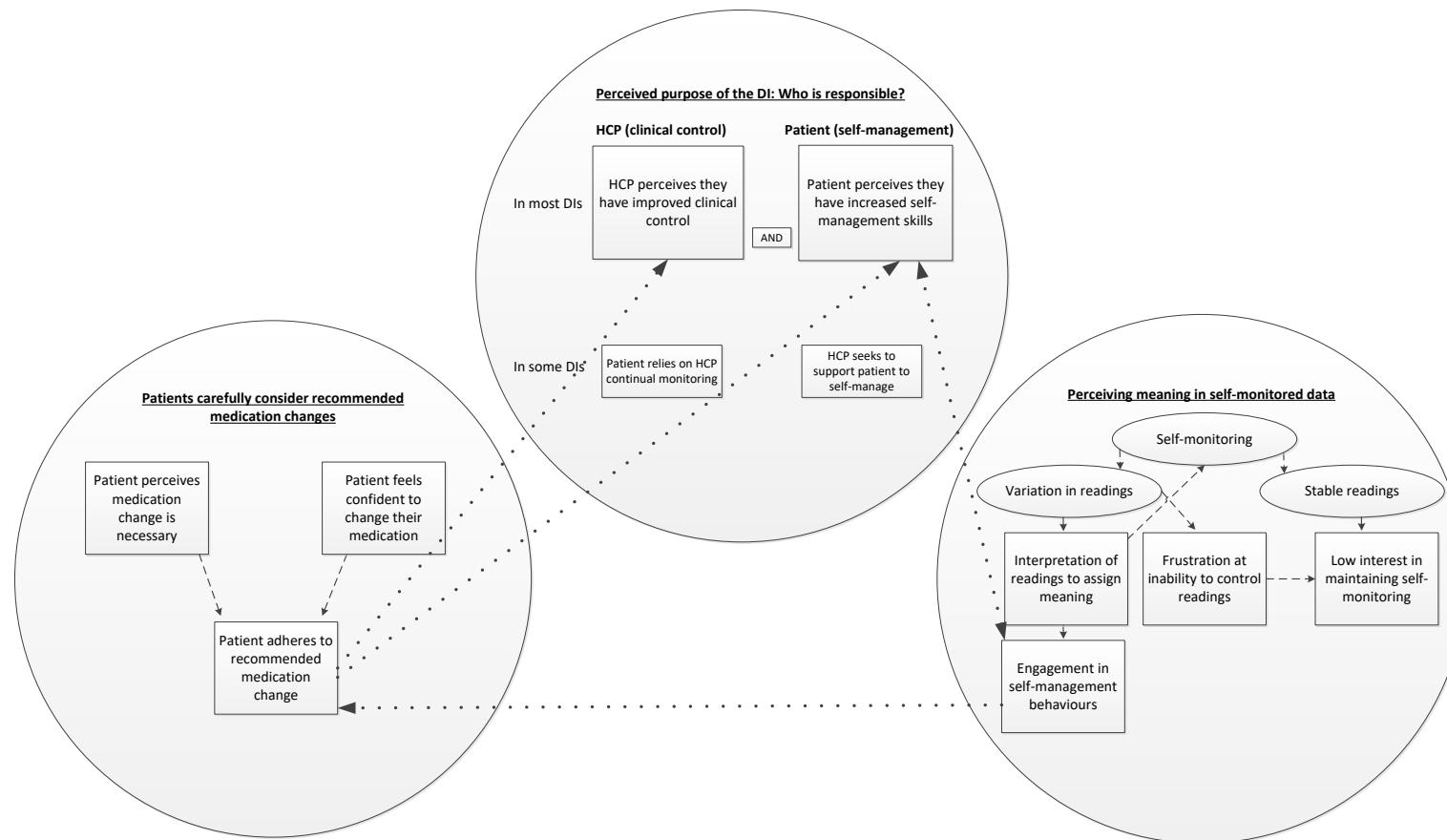


Figure 7 Visual representation of the third order constructs

2.5 Discussion

This review provides an in-depth analysis of patients' and HCPs' experiences of using self-management DIs across common chronic health conditions. Patients and HCPs were found to perceive different benefits of using self-management DIs, showing that the same DI could facilitate both patient self-management and HCP clinical control. Some DIs were designed with an explicit focus on improving clinical control, but even without the tools to encourage self-management, patients tended to feel more involved in their condition management and better informed to make decisions. Appropriate feedback is important for managing patients' expectations about the level of monitoring from their HCP, and for ensuring that both patients and HCPs know who is responsible for responding to out-of-range readings.

2.5.1 Interpretations in the context of current literature

This review extends our understanding of the self-care-dependency continuum referred to in a recent meta-synthesis on tele-health for COPD patients (Brunton, Bower, & Sanders, 2015). The present findings suggest that self-care and dependency are not necessarily incompatible, as both self-management and dependent patient behaviours can be promoted by DIs, although the style of feedback has an important influence on how much responsibility the patient adopts for self-management. Patients in all studies tend to describe increased awareness and improved decision-making skills when using a self-management DI, indicating more engagement in self-management. Receiving HCP feedback on physiological data encouraged patients to feel that they were being monitored and that responsibility remained with the HCP, implying increased dependency. Whereas dependency has been viewed as a negative outcome of self-management DIs (Brunton et al., 2015), it was not a problem from the patient perspective as they felt very well looked after and reassured by the idea that HCPs were monitoring their health status, but it is more problematic for HCPs who are concerned about meeting patients' expectations of continual monitoring. Therefore decisions about how and when patients using self-management DIs will receive feedback are important for optimising their experience of self-management and minimising over-reliance on HCPs.

In terms of evaluating perceived benefits of the DI, patients focused on the positive effects on their understanding and acceptance of their condition, whilst HCPs focused on the clinical benefits DIs offered them for managing the patients' condition. As reported in the synthesis of COPD patients' experiences of tele-health, HCPs were less positive about the use of self-

management DIs than patients (Brunton et al., 2015) and had concerns about the increased workload. This finding is also consistent with a recent synthesis which reported that clinicians can find it challenging to share control of condition management with the patient (Mudge, Kayes, & McPherson, 2015). Explicit guidance for HCPs about how best to deliver support for patients using self-management DIs might help address these concerns.

Patients' motivation to change their behaviour when they have access to their own data is in line with research on visualisation which shows that making health data visible can add meaning to activities which interact with these data (Ruckenstein, 2014). Mamykina's model of sense-making (Mamykina, Smaldone, & Bakken, 2015) describes how patients construct explanations of their health data based on their daily activities, which enables them to make lifestyle decisions in order to improve their health data. The feedback loop between actions and health status is more easily detected in some conditions than others, for example the benefits of adhering to asthma prevention medication are not immediate but accumulate over time (Anhøj & Nielsen, 2004). This highlights the importance of designing digital tools with meaningful feedback systems to help patients review their data and develop a comprehensive understanding of these interactions (Mamykina et al., 2015). The review found that where physiological data remained stable over time, patients were less motivated to engage with self-monitoring, and therefore where self-management behaviours are only likely to have a small impact on physiological data, other forms of encouragement may be needed to encourage patients to stay motivated.

The finding that standalone tele-monitoring DIs without behaviour change support promoted patient self-management supported the concept that tele-monitoring is a complex behaviour change process in itself (Hanley et al., 2013). This is consistent with a review of patient experiences of self-monitoring hypertension (with or without other intervention elements to support self-management) which found positive effects of self-monitoring behaviour on reassurance, patient empowerment and the HCP relationship (Fletcher, Hinton, et al., 2016).

The concerns patients expressed about medication changes in this review can be explained by the extended self-regulatory model (Horne & Weinman, 2002), which incorporates beliefs about *necessity* of treatment and *concerns* about adverse treatment effects into the original self-regulatory model of illness perceptions (Leventhal, Diefenbach, & Leventhal, 1992). Hypertensive patients' non-adherence to recommended medication changes when their readings only slightly exceeded a threshold, and asthma patients' decision not to increase regularity of steroid dose demonstrate the importance of beliefs in the necessity of treatment for adherence. Concerns about adverse effects of treatment were evident in the finding that CHF patients lacked

confidence to change their medication and wanted responsibility to remain with their HCP. This suggests that in order to improve adherence to medication change advice DIs need to convince patients about the necessity of medication changes, and address their concerns about adverse treatment effects. Appropriate, reliable feedback could be essential for this, as differences in tailoring of automated feedback seemed able to influence patients' acceptance of advice about medication changes (Anhøj & Nielsen, 2004; van Kruijssen et al., 2015).

Many of the findings which emerged from our inductive analysis mapped well on to the constructs from Normalisation Process Theory (NPT) (May et al., 2007), which provides a useful framework and standardised terminology for describing how interventions are adopted by HCPs and patients in routine practice (Murray et al., 2010). Patients demonstrated *cognitive participation* by engaging in sense-making of their data, and their experience of a closer and more meaningful relationship with the HCP showed positive *reflexive monitoring* of intervention benefits. The uncertainty of some HCPs in how to respond to patients' readings and the feeling that reviewing patient data was burdensome suggested low *coherence* for HCPs regarding the DI's goals, as well as a lack of confidence in the resources available to them (*collective action*). Implementation into daily practice could be promoted through highlighting the dual benefits of self-management DIs to HCPs to increase *coherence* and *reflexive monitoring*.

2.5.2 Limitations of the current review

This review potentially represents a particularly positive patient perception of self-management DIs as it is based only on patients who volunteered to participate in trials and follow-up qualitative research, which is usually only a small sub-sample of those invited. This potential bias did not appear to be evident in the HCPs' perspectives. The authors are also aware that their own preconceptions could have influenced the analysis of the data. We attempted to limit this by adopting an inductive approach, grounding our themes in the data, and we prioritised transparency by keeping a record of all emerging themes and discussing the analysis regularly to obtain shared viewpoints.

The CERQual evaluation of the review findings indicated moderate confidence in the three third-order constructs generated by the review, meaning that it is likely that these are a reasonable representation of patient and HCP experiences of self-management DIs.

2.6 Conclusion

The evidence from this review of qualitative research suggests that patients using self-management DIs perceived closer contact with HCPs, and felt better cared for. This is in line with previous findings that self-management does not replace professional care but rather enables patients to attain the best healthcare (Taylor et al., 2014). Monitoring their own health data gave patients a greater self-awareness of their condition and they were motivated to engage in lifestyle behaviours to help improve their data, even when using standalone tele-monitoring DIs without explicit behaviour change support. HCPs perceived clinical benefits to self-management DIs, but raised some concerns about the burden of monitoring patient data.

2.7 Practice Implications

The finding that standalone tele-monitoring systems promoted feelings of motivation for condition management suggests that tele-monitoring could be more widely used to promote patient self-management and should not be regarded only as a clinical tool for tailoring treatment. Where physiological data are likely to remain stable over time, patients may need additional forms of encouragement to stay motivated to engage in self-management. Providing explicit guidance to patients and HCPs about responding to home readings might help to manage patient expectations and address HCPs' concerns about the time involved in monitoring patients.

Chapter 3 A qualitative process study to explore the perceived burdens and benefits of a digital intervention for self-managing high blood pressure in Primary Care in the UK.

This paper was published in BMJ Open in 2018.

3.1 Abstract

Objectives: Digital interventions can change patients' experiences of managing their health, either creating additional burden or improving their experience of healthcare. This qualitative study aimed to explore perceived burdens and benefits for patients using a digital self-management intervention for reducing high blood pressure. A secondary aim was to further our understanding of how best to capture burdens and benefits when evaluating health interventions.

Design: Inductive qualitative process study nested in a randomised controlled trial.

Setting: Primary Care in the UK

Participants: 35 participants taking antihypertensive medication and with uncontrolled blood pressure at baseline participated in semi-structured telephone interviews.

Intervention: Digital self-management intervention to support blood pressure self-monitoring and medication change when recommended by the healthcare professional.

Analysis: Data were analysed using inductive thematic analysis with techniques from grounded theory.

Results: Seven themes were developed which reflected perceived burdens and benefits of using the intervention, including worry about health, uncertainty about self-monitoring, and reassurance. The analysis showed how beliefs about their condition and treatment appeared to influence participants' appraisal of the value of the intervention. This suggested that considering illness and treatment perceptions in Burden of Treatment theory could further our understanding of how individuals appraise the personal costs and benefits of self-managing their health.

Conclusions: Patients' appraisal of the burden or benefit of using a complex self-management intervention seemed to be influenced by experiences within the intervention (such as perceived availability of support) and beliefs about their condition and treatment (such as perceived control and risk of side effects). Developing our ability to adequately capture these salient burdens and benefits for patients could help enhance evaluation of self-management interventions in the future. Many participants perceived important benefits from using the intervention, highlighting the need for theory to recognise that engaging in self-management can include positive as well as negative aspects.

3.2 Introduction

The work involved in looking after one's health when living with a chronic condition can include complex tasks such as organising and adhering to treatment regimens, interacting with healthcare professionals (HCPs), regular monitoring of health indicators, and making health-related decisions, all of which can accumulate into a considerable burden (May et al., 2014). Digital self-management interventions are often developed to improve health outcomes, but these interventions could also either increase or minimise the burden of the healthcare process for patients. Developing our understanding of the burdens of self-management can help to better optimise the delivery of healthcare to improve adherence and well-being (Eton et al., 2012; Gallacher, May, Montori, & Mair, 2011; May et al., 2014). Burden of Treatment (BoT) theory provides a mechanism for understanding these experiences in the context of patients' personal capacity to cope, with emphasis on the role of wider healthcare systems and social networks available to the patient (May et al., 2014).

Health economic evaluations also focus on understanding the impact of healthcare on patients, seeking to weigh up the resources used against the health outcomes in order to better inform decision-making. Recent guidelines for economic evaluations in health and medicine recommend adopting a societal perspective such that all relevant outcomes are evaluated, rather than focusing only on formal healthcare costs (Sanders et al., 2016). In particular, personal costs such as time spent in self-care should be included. Consequently, BoT theory and health economic evaluations share an interest in adequately capturing the wider burdens or personal costs of engaging with healthcare. For consistency in terminology in this paper, negative outcomes/personal costs of healthcare will be referred to as 'burdens'.

BoT theory considers patients' time as a resource that is used by the healthcare system, while health economic evaluation counts time as an 'opportunity cost' whereby the patient 'spends' time that could have been spent on something other than healthcare. However, subjective experiences of time spent on digital interventions may be varied and complex. Heterogeneity in the relative value placed on the outcomes of the intervention (Ioannidis & Garber, 2011) may mean that for some participants the time spent engaging with elements of an intervention is not perceived as a burden but rather as a benefit, either because it is interesting, pleasant or meaningful in and of itself or because of the positive outcomes it can lead to. In other words, some people may actually like engaging with healthcare. The value of exploring the personal benefits of intervention participation has not received as much focus as understanding the costs,

such as treatment burden. It has been proposed that the health research guidelines for economic analysis may need to be adjusted for digital health interventions to ensure we can fully capture the heterogeneous costs and benefits arising when complex interventions are implemented in complex systems (McNamee et al., 2016).

To further our understanding of how patients perceive benefits and burdens when using digital health interventions, we carried out a qualitative process study (Moore et al., 2015). The digital HOME BP intervention was developed based on best practice recommendations to help improve hypertension in poorly controlled patients by facilitating self-monitoring of blood pressure (BP) at home and prompting appropriate intensification of medication by HCPs (Band et al., 2016). This intervention could help to minimise the treatment burden of hypertension by providing an online healthcare system in which HCPs have sight of patients' home readings, streamlining the process for finding the most effective medication without the need for attending the GP surgery.

However, HOME BP is a complex, interactive multi-component intervention, which creates potential diversity in the perceived burden and benefits for participants using it. The contexts in which the intervention is embedded may also be diverse, and factors such as individual differences in patients' health status, beliefs about medication and risks of high BP, availability of time and resources, and access to support may influence how the intervention is perceived and valued. The HOME BP intervention was developed using the person-based approach (Yardley et al., 2015) which emphasises the importance of understanding participants' unique perspectives and different situations when developing and implementing digital interventions. Adopting a more granular approach to the evaluation of benefit and burden is consistent with the person-based approach, and with the BoT approach of fully understanding the participants' perspective.

The present study aimed to explore the perceived burden and benefits of using a digital health intervention for self-managing BP using qualitative process interviews with intervention and usual care participants taking part in a randomised controlled trial (RCT). This paper seeks to interpret the implications for optimising the capture of perceived costs and benefits in health economic evaluations and evaluating the burden of treatment.

3.3 Methods

3.3.1 Design

A qualitative process study embedded in the HOME BP trial (Band et al., 2016) was approved by the University of Southampton and NHS Research Ethics committees. The COREQ checklist (Consolidated criteria for reporting qualitative studies) was used to ensure comprehensive reporting of the study (Tong, Sainsbury, & Craig, 2007) (Appendix I).

3.3.2 Intervention

The HOME BP programme supported participants to self-manage their high BP, primarily via home self-monitoring of BP and making changes to dose/drug type when recommended by the HCP. Lifestyle change modules were also available, but optional as the key target behaviours for the intervention were self-monitoring and medication change adherence (Band et al., 2017; Band et al., 2016). Participants using HOME BP were supported by a ‘prescriber’ (GP or nurse prescriber responsible for changing medication) and a ‘supporter’ (nurse or healthcare assistant who supported participants in self-monitoring and choosing lifestyle changes).

Participants were invited to use the online programme by their GP and were randomised to usual care or intervention after completing baseline measures online. Those randomised to the intervention group completed two online training sessions which sought to overcome concerns about variability in readings and changing medication. Participants were encouraged to monitor their BP in the mornings, but the programme allowed flexibility as it was most important that people found a time of day that suited them to monitor their BP. Both intervention and usual care participants were followed up at 6 and 12 months post-randomisation.

Table 6 describes the HOME BP intervention in more detail.

Table 6 HOME BP Intervention Characteristics

Target behaviour	Description
Self-monitoring BP	Participants monitored their BP at home for 7 days every 4 weeks. After 7 days, they entered their BP readings on the HOME BP website and received instant automated feedback using a traffic light system. If BP was very high (red) or

Target behaviour	Description
	very low (blue), they were told to contact their GP surgery. If BP was above target (amber), they were told their prescriber would contact them about a medication change. If BP was on target (green), they were congratulated and asked to monitor their BP again next time.
Medication change	The prescriber planned three potential medication changes with the participant at the start of the study. HOME BP informed prescribers by email when a patient's home BP readings were above-target and they could implement a pre-planned change without needing to see the participant for an appointment.
Optional lifestyle changes	At nine weeks after randomisation, participants had the option of choosing an online session to support lifestyle change to help control their BP, specifically weight management, salt reduction, healthy diet, physical activity, or alcohol reduction. Participants were alerted by email when this became available, and saw an option to view the healthy lifestyles session each time they logged on to HOME BP. The online lifestyle change sessions could be started at any time during the 12-month trial, from nine weeks.

3.3.3 Participants

Patients were eligible to take part in the HOME BP trial if they had uncontrolled hypertension managed in Primary Care (mean BP reading of 140/90 mm Hg or more at baseline taken at the GP surgery using a validated electronic automated sphygmomanometer (BP TRU BPM 200)). In addition, they needed to be prescribed 1-3 antihypertensive medications at baseline, and aged over 18 (full inclusion and exclusion criteria are listed in the protocol (Band et al., 2016)).

Both intervention and usual care participants were invited to take part in interviews as we felt that obtaining an understanding of managing BP in usual care would aid interpretation of the perceived burden and benefits of the intervention. We aimed to speak to participants at a range of time-points during the 12-month trial from 10 weeks onwards as this gave participants the opportunity to become familiar with HOME BP. No new intervention content was introduced after the lifestyles sessions became available at nine weeks.

3.3.4 Recruitment and interview procedure

A sub-sample of RCT participants were invited by email to provide feedback on their experiences of managing their BP (n=78, of 622 patients in the RCT). Informed consent was taken by post or online, depending on participant preference. Recruitment was initially opportunistic, but subsequently a theoretical approach was adopted to target younger participants, low engagers, and those with recent uncontrolled self-monitored BP readings, informed by the concurrent analysis. Recruitment was stopped once the researchers agreed that data saturation had been reached and no new burdens or benefits were arising.

Semi-structured interview schedules were co-developed by experts in health psychology (KM, KB, RB, LY, LD), health economics (JR) and sociology (CM). Open, inductive questions were carefully selected to elicit data about the burden and benefits of BP management perceived as most salient by the participants (see Appendix J for interview schedules). The interviews were conducted by telephone to minimise the burden on participants, except in one case where the participant asked to meet face-to-face due to struggling with hearing on the telephone. The interviews took place between February 2016 and February 2017. Each participant was given a £10 gift voucher to thank them for their time.

All interviews were conducted by KM (MSc, BSc. termed “the researcher”), a female PhD candidate in Health Psychology who was also employed as a research assistant. Each interview was audio-recorded, and the researcher also took notes and completed a self-reflection log afterwards to record any emerging thoughts on the data. Audio-recordings were transcribed verbatim and checked thoroughly by the researcher.

3.3.5 Patient and Public Involvement

Patient and public involvement (PPI) representatives have been involved in the design and conduct of the randomised controlled trial, including decisions about recruitment processes, outcome measures and trial procedures. We also discussed the findings of this qualitative process study with our PPI to facilitate our interpretations of the data. The participants in the study were patients, ensuring we were collecting experiences of burden from the target population, and the results were fed back to the study participants as a newsletter.

3.3.6 Analysis

The analysis was an iterative process led by KM, supported by frequent discussion of emerging themes with LY and LD (who have extensive experience in qualitative research) along with input

regarding health economic and sociological perspectives (JR and CM). Inductive thematic analysis methods were used (Braun & Clarke, 2006; Marks & Yardley, 2004) with techniques from grounded theory such as memoing, constant comparison, and diagramming to enhance our understanding and facilitate the development of higher themes (Charmaz, 2014; Strauss & Corbin, 1997). Data collection and analysis ran concurrently to enable theoretical sampling based on analytic insights. Thorough line-by-line coding was undertaken in NVivo 10 (QSR International Pty Ltd, 2012), and a coding manual was developed which evolved as more data were collected and coded. The emerging codes were constantly checked against the raw data to ensure the analysis was driven by the participants' own language and experiences.

All data relating to burdens and benefits of managing BP were analysed. We also coded factors that appeared to influence perceptions of burdens and benefits to facilitate an in-depth understanding of how participants appraised the intervention's value. A broad and open definition was adopted whereby benefits and burdens were defined as positive and negative outcomes or experiences of engaging in the intervention (Rogers, Stevens, & Boymal, 2009), in order to facilitate a comprehensive representation of all potentially relevant data.

3.4 Results

3.4.1 Participant characteristics

In the intervention group, 28 of 54 invited participants agreed to be interviewed (52%). In the usual care group, 7 of 24 invited participants agreed (29%). Most participants who did not take part chose not to reply, but those who did said they did not have anything to report on the trial (n = 3 in usual care). The participants were from 19 different GP surgeries. Table 7 shows the sociodemographic and intervention details of the sample.

Table 7 Sociodemographic and intervention participant data (n=35)

	Intervention participants	Usual care participants
N	28	7
Median duration of interview (range)	38 (15-67) minutes	28 (22-40) minutes
Median age (range)	70 (41-87) years	67 (52-77) years

	Intervention participants	Usual care participants
Gender	71% female	43% female
Ethnicity		
White	24	6
Black African	1	
Pakistani	1	
Other	2	1
Education levels	9 No formal education	2 No formal education
	8 GCSE or A-level	3 GCSE or A-level
	10 Higher Education	1 Higher Education
	1 Other	1 Other
Median number of weeks into the study at which the interview took place (range)	20 (10-57) weeks	17 (7 to 24) weeks
Poorly controlled BP at the time of the interview	10/28 (36%)	N/A*
Medication change recommended during the study	15/28 (54%)	N/A
Accessed optional healthy lifestyles session	15/28 (54%)	N/A

*As BP self-monitoring was a key component of the intervention, BP readings were available for the intervention group throughout the duration of the study but data about BP from the usual care group were only available at RCT baseline and follow-up points.

3.4.2 Themes

Table 8 presents seven themes exploring perceived burdens and benefits of the HOME BP intervention. One meta-theme also emerged concerning how illness and treatment beliefs about high BP appeared to influence participants' perceptions about the intervention's burdens and

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benefits, and this is discussed in relation to each theme it applies to. Figure 8 shows how illness and treatment perceptions about BP appeared to relate to the sub-themes identified by the thematic analysis.

Where quotes are included, participants are referred to as 'p' followed by a number. Study group (intervention or usual care) is also included to help understand the quotes in context.

Table 8 Themes and sub-themes relating to perceived burdens and benefits of the intervention

Themes	Sub-themes	Exemplar participant quote
Benefit of reassurance from seeing BP readings	Reassurance when BP readings are well-controlled	"I'm so pleased. And my mind is at rest when we go on holidays and all that...I'm alright. I'm alright sort of thing. Yeah, peace of mind" (Intervention p9, well-controlled)
	Reassurance from keeping an eye on BP	"It made me much more aware of what the problem is with the high blood pressure and by monitoring it so regularly, I know exactly where I stand with it" (Intervention p15, well-controlled)
Benefit of motivation for lifestyle change from seeing BP readings	Seeing BP readings motivated lifestyle change	"It is quite interesting to see the effects of what I'm doing on the blood pressure and everything. So, I think that is – it is quite good" (Intervention p18, well-controlled)
Benefit of better health	Perceived health improvements from medication changes	"It helped me to change my medication and then because of change of medication, my blood pressure went down. So definitely there is a benefit" (Intervention p16, well-controlled)

Themes	Sub-themes	Exemplar participant quote
	Intervention can facilitate management of side effects	"That medication didn't work, in that I was on holiday and my ankles swelled up so much – and my feet and my legs, so much so that I couldn't see my toes. So I stopped taking that medication. Was called back to the GP. And I'm now on a medication that works for me and is managing the blood pressure" (Intervention p7, well-controlled)
Burden of worrying about health	Negative emotional responses to seeing high readings	"I was actually quite shocked because it was a—a lot higher" (Intervention p6, poorly controlled)
	Worrying about medication change affecting health	"I don't want to get more medication 'cause I'm already on a high dose and I don't want to increase it because it worries me about my kidneys" (Intervention p24, poorly controlled)
Burden of uncertainty from self-monitoring	Uncertainty about whether readings are representative	"If someone only ever takes it in the morning, and you tend to get those lower readings, are you really getting a true picture of what they're like in the afternoon or the evening?" (Intervention p10, well-controlled)
	Uncertainty about what to do about high or low readings	"I don't know what's going to happen in respect to that [amber feedback]. Whether I'm going to get a call from my GP, or whether he – so I'm a little bit, like, you know, in the air. I don't really know what's going to happen in that respect" (Intervention p22, poorly controlled)

Themes	Sub-themes	Exemplar participant quote
Burden of thinking about making healthy lifestyle changes	Worry or guilt about not engaging with healthy changes	"I have looked at it [online healthy lifestyles session]. I wouldn't say I've looked at it seriously, and I need to" (Intervention p4, poorly controlled)
Burden of the practicalities of adhering to intervention procedures	Burden of fitting self-monitoring into the day	"I like to get up and have a cup of coffee and I'm thinking 'Well, let's get the blood pressure done first because otherwise I can't do that, you know, for a while afterwards.' So, I've found that quite—quite difficult" (Intervention p5, poorly controlled).

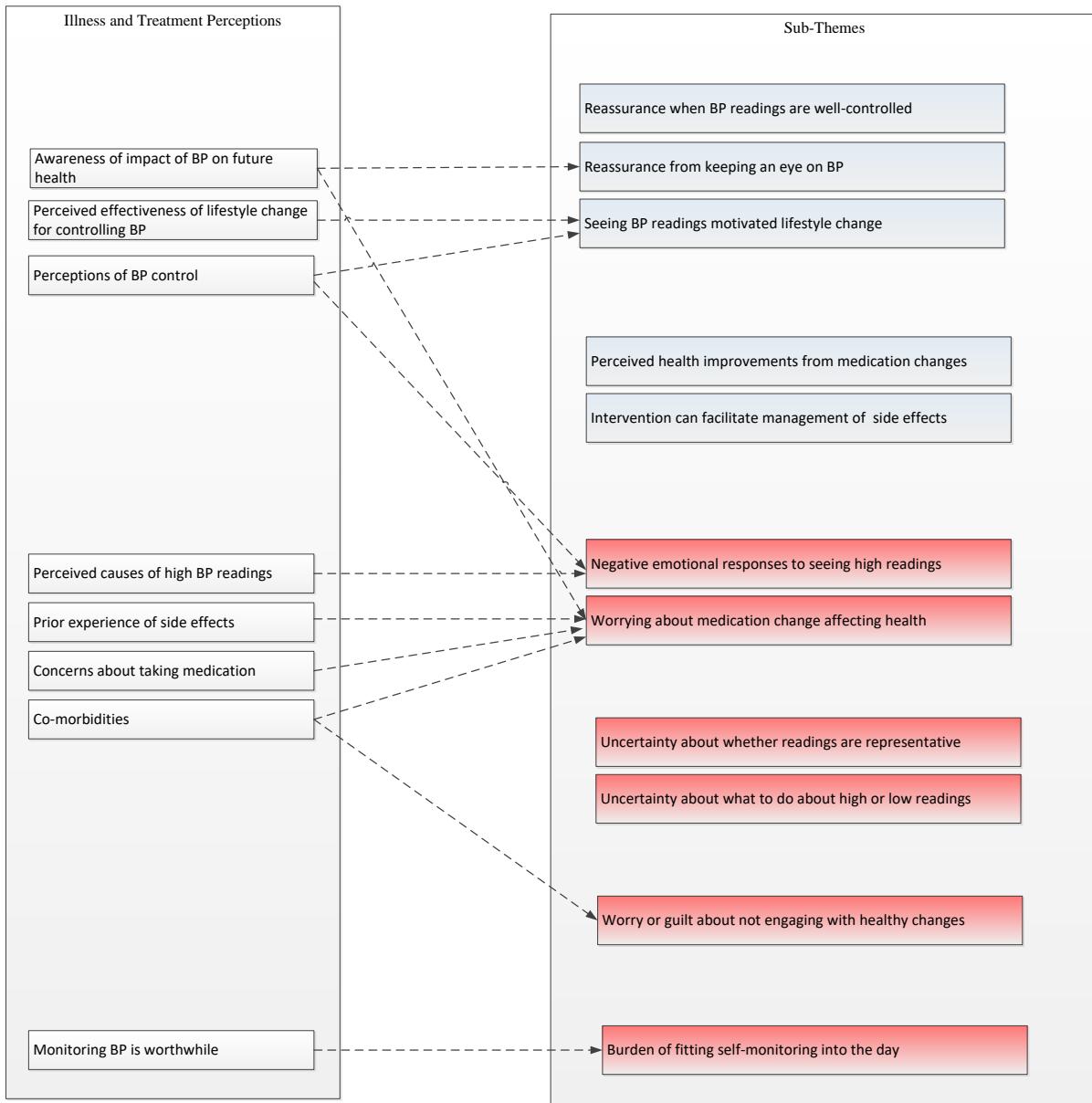


Figure 8 Possible influences of illness and treatment beliefs on perceived burdens and benefits of the intervention

3.4.2.1 Reassurance when BP readings are well-controlled

Seeing well-controlled readings when self-monitoring BP gave participants peace of mind which was widely perceived as a benefit of the intervention. People described feeling relieved that their BP readings were lower than at the GP surgery, and felt this gave them more insight into what their BP was like most of the time.

"What I do like about it is taking the blood pressure here at home, the readings are lower. And I find that quite reassuring that my blood pressure is not always high." (Intervention p11, well-controlled).

Several usual care participants had decided to use their own BP monitors, and this group also described feeling reassurance when seeing their BP was well-controlled.

3.4.2.2 Reassurance from keeping an eye on BP

Most participants liked having an increased focus on their BP through regular monitoring and found it interesting to compare their readings over time. However one participant perceived that taking BP regularly could encourage too much attention on your health, which was a potential burden of the intervention for her (Intervention p28, BP control unknown as did not enter BP readings on HOME BP). This participant had low concern about her BP generally, and was not motivated to engage in self-management.

Even when participants had poorly-controlled readings, many felt a benefit from the intervention as it enabled them to regularly check their BP and detect any problems instantly rather than carrying on unaware.

"I think it's helping me to know where my blood pressure stands because it's a regular thing every month." (Intervention p24, poorly-controlled).

The knowledge that home readings were shared with the prescriber reassured participants as they knew that any problems would not only be detected but also dealt with at the time, making them feel well cared for. This contrasted with the perceived burden of managing BP in usual care where some participants felt concerned that their GP did not change their medication when their home readings were too high, or would have liked more regular contact with their GP surgery to check their BP and medication.

"It would be nice to have it checked, I guess, you know, every three months or whatever. How—however often. I mean, how do they know that everything is working?" (Usual care p4).

This shows that although participants in usual care gained reassurance from seeing low readings when they monitored at home, the lack of interaction with the GP surgery could cause concern when readings were high or when patients did not regularly monitor BP at home of their own accord.

3.4.3 Benefit of motivation for lifestyle change from seeing BP readings

Some participants were motivated to increase their physical activity, engage in stress management activities or healthy eating because they could see this had a positive impact on their BP readings. This helped them feel more in control of their BP.

“By taking the readings regularly and frequently, it gave me more of a feedback straightaway if you like about anything, changes that I did make like a bit of exercise or...practicing relaxation and this sort of thing. So that was quite nice, it was nice to feel that I was more in control of it again.” (Intervention p20, well-controlled).

Other participants felt frustrated after making lifestyle changes in the past which had no effect on their BP. This made them feel that lifestyle was ineffective for controlling BP.

“I’m a completely different person. My diet’s completely different. And my blood pressure remained the same. So I’ve done literally everything you physically possibly can to help yourself, and nothing’s worked.” (Intervention p1, well-controlled).

3.4.4 Benefit of better health

3.4.4.1 Perceived health improvements from medication changes

Many participants felt it was beneficial to change their medication when their readings were too high, and were very pleased when they perceived that a medication change led to lower BP readings because of the positive effect this would have on their health.

“I’ve found that by having the medication changed up at regular intervals my blood pressure’s improved all the time.” (Intervention p15, well-controlled).

A few participants felt that a medication change had not been effective at lowering their BP which could create doubt about their medication’s effectiveness.

“It’s been doubled but it hasn’t seemed to lower my blood pressure at all, in fact, it’s at the same levels as it is sort of now, un-medicated. So I just think – I don’t think it’s the right one. You know, I can take the tablet but, actually, I don’t think it’s doing anything.” (Intervention p26, poorly-controlled).

3.4.4.2 Intervention can facilitate management of side effects

Most participants did not experience any side effects from having their medication changed. Where side effects did occur, participants tended to perceive this as being a cost of taking medication (which was balanced against the benefit of controlling BP), rather than a burden of the intervention itself. They felt that the intervention could help them to be more aware of side effects, to identify alternative medications and to monitor how these affect their health.

“That [side effect] would have happened, you know, no matter what. That would have been an issue but this has actually highlighted it, sort of, more clearly.” (Intervention p5, poorly-controlled).

3.4.5 Burden of worrying about health

3.4.5.1 Negative emotional responses to seeing high readings

A burden of self-monitoring BP for some people was that seeing high readings could cause worry about health. Participants’ beliefs about their BP control appeared to influence their appraisal of high readings. A few participants believed their BP was well-controlled, a belief which was perhaps reinforced by clinical staff approving their readings previously, and had only joined the study to help with research. These participants tended to feel shocked or annoyed when they received above-target feedback from the intervention as this challenged their beliefs.

“At one time, I was told to go on medication, further medication, which I must admit I was not very happy about... When I used to go for a check with the nurse, if I’d have had those particular readings, they wouldn’t have been high.” (Intervention p17, poorly controlled).

Others were confused or frustrated by high BP readings when they could not understand why this might have happened.

“I’m thinking about why my blood pressure has gone up. I can’t think why.” (Intervention p25, poorly controlled).

Meanwhile people who expected to see high readings were less concerned because they had accepted that high readings were likely.

“Just par for the course. It’s what I expect from my blood pressure, really, so, it never worries me.” (Intervention p5, poorly controlled).

Perceptions about the consequences of high BP also influenced how anxious people felt about seeing high readings. Those who felt that high readings held serious implications for their health tended to feel frightened. Some even felt apprehensive *before* self-monitoring in case their readings were out-of-range, as they didn't want to see evidence that their BP was too high or low.

“Before I take my blood pressure, I do get stressed. I wouldn't say I get massively stressed because obviously I'm used to doing it now but ... it's just that apprehension and thinking 'Oh, God, I hope it's not too high today. I wonder really what's going on and how serious this is.'”
(Intervention p26, poorly controlled).

Other people were able to dismiss one-off high readings without feeling anxious as they attributed high readings to less threatening explanations such as feeling stressed, not sitting still for long enough, positioning of the cuff, or held a prior expectation of it being normal for BP to fluctuate. In these cases, the high readings had less negative emotional impact as they were not interpreted as indicating a serious underlying health issue.

3.4.5.2 Worrying about medication change affecting health

Some participants were worried about the effects that changing BP medication could have on their health. Previous experience of side effects, existence of co-morbidities, and concerns about medication dependency or impact on kidneys tended to make participants feel more worried about changing medication.

Perceptions about the health risk of high BP in terms of stroke and cardiovascular disease tended to affect how burdensome participants perceived a medication change to be. Anxiety about future health could override concerns about medication side effects or dependency as the behaviour was evaluated as beneficial in order to bring BP down, although sometimes participants still experienced conflict between the perceived benefit and burden.

“The blood pressure has gone down but now my worries have changed from blood pressure to other things. One is actually depending on medicine whole of my life. And secondly impact of medicine on my body like kidneys.” (Intervention p16, well-controlled).

3.4.6 Burden of uncertainty from self-monitoring

3.4.6.1 Uncertainty about whether readings are representative

Whilst some participants were confident making decisions about when to monitor their BP, others were worried about whether their readings were representative, especially when BP was seen to vary at different times of day or after physical activity or drinking coffee. This could lead to doubt about the meaningfulness of self-monitoring and the recommendations of the intervention.

“I wonder if maybe the time of day I’m doing it, maybe my blood pressure’s always gonna be roughly that. And could it be different during the day, is the sort of thing that does play in my mind a bit.” (Intervention p1, well controlled).

3.4.6.2 Uncertainty about what to do about high or low readings

Uncertainty could also become a burden after seeing an out-of-range BP reading, as the participant had to decide what to do next. This burden was removed when the prescriber provided quick, personalised feedback to the participant, but when they did not receive any contact from their prescriber or felt the prescriber was not available to provide support, this could create a feeling of doubt.

“I suppose I knew there was nothing to worry about but it’s always a bit of a niggle in the back of your mind... even the days she’s [the nurse prescriber] at work I can’t ring her at work because she may be, you know, doing something else.” (Intervention p21, well-controlled).

3.4.7 Burden of thinking about making healthy lifestyle changes

3.4.7.1 Worry or guilt about not engaging with healthy changes

Several participants felt they would like to lose weight, eat more healthily, or do more physical activity but lacked the motivation or self-efficacy to make these changes, especially if they had other co-morbidities. This could create feelings of guilt or worry about their failure to make healthy changes, which was a burden of the intervention for them.

“I understand that, obviously, I need to get my blood pressure down because it is very dangerously high, but I just don’t know what to do about it, you know?... where I feel fatigued and

worn out, I don't feel well enough at the moment to do any exercise." (Intervention p26, poorly controlled).

3.4.8 Burden of the practicalities of adhering to intervention procedures

3.4.8.1 Burden of fitting self-monitoring into the day

Many participants felt that self-monitoring was easy to fit into their day, and some described this as being easier than going to the GP surgery to have their BP taken. Those with busy daily lifestyles tended to find it harder to remember to self-monitor, and a burden for some participants was deciding how best to fit self-monitoring into their routine given the instructions about not drinking coffee or exercising beforehand.

The perceived burden of regular self-monitoring seemed to be mitigated by the perceived benefit of the behaviour, such that those who felt reassurance from seeing low readings or with high motivation to control BP found it less hassle and easier to remember than those who felt anxious about self-monitoring or had only joined the study to help with research.

"There was no big deal. It doesn't take long and it's—it's quite nice to sit down and have a relax during the day." (Intervention p8, well-controlled).

3.5 Discussion

This qualitative study has identified diverse perceived burdens and benefits of using a self-management digital intervention for high BP. In support of the BoT theory (May et al., 2014), the HOME BP intervention appeared to reduce the burden on patients to self-manage their condition by improving access to regular HCP support and facilitating better understanding of their condition, but in some cases there was a burden of worry about health or changing medication. How much benefit a patient perceived from the intervention compared to burden seemed to be influenced by the dynamics of the patient-HCP interaction (described as 'Improving Cooperation' in BoT theory) and the patient's own resources to manage their condition and cope with medication (described as "Capacity").

Another important factor relating to the burden experienced was personal beliefs about BP and treatment. Those who recognised that their BP was too high and did not have concerns about side effects or taking medication appeared to have more positive experiences of the intervention, perceiving self-monitoring as more worthwhile, and feeling less anxious about seeing high readings or changing medication. This is consistent with the necessity-concerns framework (Horne & Weinman, 1999). BoT theory states that people who are better equipped with resources and are more resilient may cope better with the burden imposed by healthcare (Mair & May, 2014), but the importance of an individual's personal conceptualisation of their condition in how burdensome they find self-care is not strongly represented. This beliefs system may be partly encompassed by the "Relational Integration" aspect of BoT theory, which refers to the extent to which patients trust the tasks they do for healthcare, e.g. self-monitoring BP, and feel confident in the outcomes of these tasks, e.g. changing medication. However illness and treatment perceptions (Leventhal et al., 1992) are not explicitly covered by the theory and it may be helpful to consider them as additional factors which might influence the experience of treatment burden.

3.5.1 Implications for measurement of benefit and burden

The present study demonstrates the value of collecting in-depth qualitative data to develop a detailed understanding of the burden of treatment, and to discover perceptions specific to the context in which the intervention was implemented. The important psychosocial outcomes discovered using qualitative research can inform the selection or development of relevant quantitative measures to capture these factors in further evaluation.

Quantitative measures have been developed to appraise the structural aspects of burden of treatment (Eton et al., 2017; Tran et al., 2014), but these are not intended to assess psychosocial factors such as reassurance, anxiety or uncertainty which this study suggests can influence the extent to which using an intervention is experienced subjectively as a burden.

Future research could explore how best to capture the perceived burden or benefit of an intervention. One approach might be to simply ask participants to quantify the net subjective burden or benefit of interventions. However, it could be challenging for participants to weigh complex heterogeneous psychosocial outcomes against one another and decide overall whether an intervention was more burdensome or beneficial. Capturing the extent to which patients experience positive or negative psychosocial outcomes might better assess how beneficial or burdensome the intervention was perceived to be. Although this would not produce a single outcome measure, cost-consequence analysis can be used to inform decision-making when an

intervention has multiple relevant outcomes which cannot be aggregated into one value(NICE, 2014). Coast (Coast, Kinghorn, & Mitchell, 2015) discusses whether a multidimensional approach is more informative for economic analysis or if a single aggregated value is more pragmatic.

Extending the evaluation of outcomes beyond health is in line with the capability approach (Nussbaum & Sen, 1993), which focuses on broader aspects of subjective well-being which are not assessed by generic measures such as the EQ-5D (Brazier, Ratcliffe, Saloman, & Tsuchiya, 2017). Tools used to capture perceived capability (such as the ICECAP (Al-Janabi, Flynn, & Coast, 2012), and ASCOT (Netten et al., 2012)) are gaining support as holistic measures of economic evaluation, but do not assess the more specific psychosocial burdens and benefits of healthcare raised by participants in this study. Process utility emphasises the need to quantitatively measure the value that people attach to healthcare delivery. This approach might be relevant for evaluating how much value people perceive in the process of using digital health interventions and the capability this achieves (Ryan, Kinghorn, Entwistle, & Francis, 2014). It has been argued that process utility measures should also ask about the reasons behind patients' valuations, to better inform the decision-maker (Donaldson & Shackley, 1997). This would help to capture the individual differences found in this study in how people appraise the personal value of a digital intervention, informed by their underlying illness and treatment beliefs.

3.5.2 Strengths and limitations

A strength of the study was that we used relatively open questions formulated by a multi-disciplinary team which enabled us to elicit and explore a wide range of perceived burdens and benefits, some of which were not anticipated at the outset of research. We are aware of the lead researcher's potential influence on the data analysis, which we strived to minimise by transparent memoing of decisions and regular team meetings to discuss the emerging themes. Participants were sent newsletters to describe the findings of the study, but were not invited to provide feedback on the analysis.

We succeeded in speaking to well and poorly controlled hypertensive participants at different points in the intervention, and there was a wide range of demographics in terms of age, education level and gender in the sample. However, the uptake rate from those invited to interviews was not high, particularly in the usual care group. Perhaps unsurprisingly, it was difficult to recruit low engagers in the intervention group, which could have helped reach theoretical saturation. In terms of wider applicability, we are aware that these findings may not be generalisable across

other health conditions, as the lack of symptoms in hypertension and the stepped pathway for changing medication are quite unique features of this condition.

Repeated interviews with the same participants may have offered more insight into the dynamic nature of perceived burdens and benefits over time, although more regular conversations about the target behaviour could have influenced participants' BP management behaviour therefore threatening the RCT conclusions. It has been noted that a key issue with process evaluations of interventions is the tendency for intervention content and impact to change over time (Moore et al., 2015), such that deciding the optimal point to collect evaluation data is challenging.

Some of the burdens and benefits described by patients in this study were also found to a lesser extent in the qualitative development of the HOME BP intervention, such as reassurance from seeing well-controlled readings, and some concerns about side effects and high or variable readings (Bradbury et al., 2018). Others were novel and only arose when participants experienced the full HOME BP intervention during the RCT as opposed to a prototype, for example the perceived health improvements from medication changes. This demonstrates the value of conducting inductive qualitative research to explore users' perspectives at each stage of intervention development and evaluation, in line with the person-based approach (Yardley et al., 2015).

3.6 Conclusions

In the context of this digital intervention, the study shows that participants' appraisal of burdens and benefits appeared to be influenced by both intervention factors, such as BP readings and perceived availability of the healthcare professional, and patient characteristics, such as perceptions of BP control, previous experience of side effects, and co-morbidities. This nuanced evaluation would be lost in a population-level analysis, demonstrating the advantage of a more individualised approach for better understanding participants' perspectives of an intervention and how best to minimise the burden of treatment.

The study develops the recommendations of McNamee et al (McNamee et al., 2016) that complex digital health interventions warrant a wider perspective for measuring health outcomes, and discusses the implications of capturing broader psychosocial outcomes for Burden of Treatment theory and health economic evaluations.

The finding that some participants perceived personal benefits from using the intervention demonstrates that the process of healthcare can, in itself, be positive for some people,

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highlighting the importance of capturing transient short-term benefits to take these into account as well as the burden of self-management.

Chapter 4 Implementing a digital self-management intervention for managing uncontrolled hypertension in Primary Care: A mixed methods process evaluation of healthcare professionals' experiences

4.1 Abstract

Background: A high proportion of hypertensive patients remain above the target threshold for blood pressure, increasing the risk of adverse health outcomes. A digital health intervention (DHI) was developed to facilitate healthcare professionals (HCPs) to support patients remotely as they self-monitor blood pressure at home, and to initiate planned medication changes when home readings were raised. This mixed-methods process evaluation aimed to develop a detailed understanding of how the intervention was implemented in a Primary Care setting, exploring barriers and facilitators to implementation.

Methods: 125 HCPs took part in a randomised controlled trial, including GPs, practice nurses, nurse-prescribers, and healthcare assistants. A sub-sample of 27 HCPs took part in semi-structured qualitative process interviews. Usage data were collected automatically by the DHI and antihypertensive medication changes were recorded from the patients' medical notes. The qualitative data were analysed using thematic analysis and the quantitative data using descriptive statistics and correlations. The two sets of findings were integrated using a triangulation protocol.

Results: Triangulation of the qualitative and quantitative findings suggested that creating a three-step medication plan was well adhered to, but some concerns arose about how to manage updates to the plan for patients who experienced side effects. There was medium adherence to changing medication when readings were raised, with recommendations less likely to be adhered to in the case of borderline readings. Some prescribers felt reluctant to change medication, preferring to recommend lifestyle change or perceiving the change as unnecessary once contextual factors were taken into account. Adherence to delivering remote support was mixed, and HCPs described some uncertainty when they received no response from patients.

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Conclusions: This mixed-methods process evaluation suggested that a self-management DHI for hypertension was relatively feasible to implement in Primary Care, and insights were gained into how interventions could be optimised to overcome barriers to adherence. Future DHIs might consider including an interactive feature to enable confirmation that patients have received remote support, as this appeared to be persuasive for practitioners. Additional support may be beneficial to motivate HCPs to adhere to planned medication changes when patients' readings are only slightly raised.

4.2 Background

The HOME BP digital health intervention (DHI) enabled healthcare professionals (HCPs) to change patients' medication remotely when average home blood pressure (BP) readings were above target (Band et al., 2016). This DHI sought to provide a cost-effective, feasible means to improve Primary Care for uncontrolled hypertension by supporting patients remotely and overcoming clinical inertia, which occurs when patients' medication is not changed despite raised readings during a consultation and is known to contribute to poor BP control (Guthrie et al., 2007). This was the first evaluation of a fully automated DHI which prompted the initiation of pre-planned changes to antihypertensive medication without real-time contact between the patient and HCP. The DHI was developed using a theory, evidence and person-based approach which is described elsewhere (Band et al., 2017).

This process evaluation sought to provide a detailed understanding of how the DHI was implemented in practice and which mechanisms and contextual factors might have influenced adherence, in line with recommendations for intervention research (Fletcher, Jamal, et al., 2016; Moore et al., 2015). The AMUSED framework for analysing usage data in digital interventions was used to guide the systematic selection of meaningful data and research questions (Miller et al., 2019). This informed the development of a revised logic model to represent the mediators and moderators through which the DHI was hypothesised to change HCPs' behaviour, see Figures 4 and 5. The logic model proposed that online training would increase HCPs' self-efficacy beliefs and outcome expectancies in line with Social Cognitive Theory (Bandura, 1991), and promote HCPs' perceived acceptability of the intervention for patients (Sekhon, Cartwright, & Francis, 2017) . In turn, these beliefs were theorised to relate to adherence to the target behaviours. Patient factors (BP readings, age, and n of previous medication changes recommended) were theorised to be key proximal contextual factors likely to influence adherence to changing patients' medication, based on known reasons for clinical inertia in tele-monitoring interventions (Bray et al., 2015; Jones et al., 2013). The logic model used Normalisation Process Theory (NPT (May et al., 2009)) to identify which mechanisms of implementation the intervention techniques were targeting.

The process evaluation adopted a mixed methods approach to enhance understanding by integrating qualitative and quantitative findings. The quantitative analysis sought to establish HCPs' adherence to each of the target behaviours, and test the hypothesised relationships between beliefs, contextual factors and behaviours in the logic model. The qualitative analysis

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sought to explore HCPs' perceptions of implementing the target behaviours in practice to enhance understanding of possible factors influencing these behaviours. The research questions were informed by the logic model:

Quantitative:

- a) To what extent did HCPs adhere to each of the target behaviours?
- b) What factors were related to HCPs' adherence to the target behaviours?
- c) Did online training change HCPs' beliefs about the intervention?

Qualitative:

- d) How did HCPs experience implementing the HOME BP intervention in Primary Care?

Mixed-methods:

- e) How can triangulating the qualitative and quantitative findings facilitate understanding of the process of implementing a self-management DHI in Primary Care?

4.3 Methods

4.3.1 Design

This was a mixed-methods process study nested within a RCT. Randomisation was stratified by Practice, so HCPs had experience of delivering usual care and supporting patients using the DHI. Quantitative DHI usage data and measures of adherence were collected from all HCPs in the trial (n=125). Qualitative interviews were conducted with a sub-sample of HCPs during the trial (n=27).

The design was sequential in that most quantitative data were downloaded and analysed after the qualitative data. However the integration was parallel as the qualitative and quantitative data were analysed separately and then the findings compared to interpret to what extent they converged, diverged or complemented one another (Creswell & Clark, 2007). Both types of data were treated with equal importance, in line with a triangulation design (Creswell et al., 2003).

The study was approved by the University of Southampton and NHS Research Ethics committees (15/SC/0082). The GRAMMS checklist for mixed methods research (O'Cathain et al., 2008) and StaRI checklist for implementation studies (Pinnock et al., 2017) were used to ensure comprehensive reporting.

4.3.2 Intervention and proposed mechanisms of action

HOME BP was an online self-management intervention for reducing uncontrolled hypertension in Primary Care (Band et al., 2016). It was trialled at a time when controlling blood pressure to a threshold below 150/90 mmHg was a target of the national Quality and Outcomes Framework in UK General Practice (NHS England, 2018), and a move towards patient self-management was a priority for chronic conditions (NHS England, 2017). The intervention supported home blood pressure monitoring and appropriate medication change using remote procedures in order to promote cost-effectiveness and feasibility. Patients using the HOME BP intervention were supported by a 'prescriber' (GP or nurse prescriber responsible for changing medication) and a 'supporter' (nurse or healthcare assistant responsible for encouraging the patient to engage with the DHI) at their GP Practice.

Figures 4 and 5 show the post-hoc logic model representing hypothesised mechanisms of action for HCPs. Relationships could only be tested if the intervention process or contextual factors and the target behaviour were captured quantitatively, and these are shown in red. The qualitative interviews explored all aspects of the intervention.

Before patients could be enrolled, prescribers and supporters completed a mandatory online training session of approximately 20-30 minutes which sought to increase adherence to the target intervention behaviours via increasing their self-efficacy, outcome expectancies and perceived acceptability of the intervention to patients. Table 9 describes the HOME BP intervention procedures for HCPs.

Table 9 HOME BP intervention procedures for prescribers and supporters

HCP	Target behaviour	Description
Prescriber	Planning medication changes	At a baseline consultation, prescribers planned three potential consecutive medication changes which they would initiate if the patient's average BP was raised for two consecutive months during the trial.
	Changing medication in response to recommendations	When patients' average BP readings were above-target for two consecutive months, prescribers received an automated email recommending they make the next planned medication change (Appendix D). When patients' had a one-off very high or very low reading, the automated email recommended a clinical review. The patient could email their prescriber via the intervention in the case of raised BP readings or after a recent medication change. Prescribers could reply to patients via email using the HOME BP programme.
	Notifying patient of medication change via remote communication	A template letter was provided for HCPs to send patients, asking them to pick up the prescription.
Supporter	Providing remote support	Supporters were prompted by automated email to send monthly support emails to patients using pre-written templates (Appendix K). These templates were designed to keep patients motivated to continue self-monitoring their BP and engaging in any healthy lifestyle changes (an optional add-on). Supporters could also send ad hoc emails to patients. These could be supporter-initiated (e.g. Congratulating them on well-

HCP	Target behaviour	Description
	Providing in-person support	<p>controlled readings or asking about a new medication), or patient-initiated (e.g. To respond to emails sent from patients via HOME BP).</p> <p>In-person support was designed to be minimal, but patients were offered optional appointments to help learn how to use the BP monitor, and to support them in choosing a healthy lifestyle change.</p> <p>Supporters completed online training at baseline to use the CARE approach (Congratulate, Ask, Reassure, Encourage) (Bradbury et al., 2017) during these optional appointments. The CARE approach was developed to help HCPs provide patient-centred care alongside digital interventions, without the need for specialist skills in behaviour change (Ryan & Deci, 2000; Smith et al., 2017).</p>

4.3.3 Data collection and measures

4.3.3.1 Quantitative

Table 10 shows the data collected for the quantitative process evaluation. Self-report questionnaires were completed at baseline immediately before and after the online training. Number and type of emails sent to and received from patients via the intervention were collected automatically. A review of patients' medical notes at the end of the study extracted medication changes.

Table 10 Quantitative data for the process evaluation

Type of variable	Variable	Data source	Timepoint
Target behaviour	Planned medication changes	Patient medical notes	Post 12-month follow-up
	N of medication change recommendations per prescriber	Objective data automatically recorded by intervention software	Throughout study
	N and dates of medication changes initiated	Patient medical notes	Post 12-month follow-up
	Method for contacting patients re medication change	Patient medical notes	Post 12-month follow-up
	N of support emails sent to patients via HOME BP	Objective data automatically recorded by intervention software	Post 12-month follow-up
Usage of remote support in a DHI setting	N and content of emails received from patients via HOME BP	Objective data automatically recorded by intervention software	Post 12-month follow-up
Individual beliefs theorised to relate	Self-efficacy to implement the intervention procedures	3-item self-report questionnaire (Appendix L)	Pre and post training module at baseline

Type of variable	Variable	Data source	Timepoint
to adherence to target behaviours	Outcome expectancies about the intervention	6-item self-report questionnaire (Appendix L)	Pre and post training module at baseline
	Perceived acceptability of the intervention for patients	3-item self-report questionnaire (Appendix L)	Pre and post training module at baseline
Contextual factors theorised to relate to HCP adherence to medication change	Systolic and diastolic BP readings entered by patient	Objective data automatically recorded by intervention software	Throughout study
	N of BP entries and n of medication change recommendations per patient	Objective data automatically recorded by intervention software	Throughout study
	Patient age	Objective data automatically recorded by intervention software	Baseline
	Patient BP targets: a) Standard (135/85 mmHg) b) Adjusted due to diabetes (135/75mmHg) c) Adjusted due to age (145/85 mmHg if aged over 80 years)	Objective data automatically recorded by intervention software	Baseline

4.3.3.2 Qualitative

The first 25 prescribers and supporters to join the study were invited to an interview, 17 of whom participated. Purposive sampling was subsequently used to target practices with higher numbers of patients in the study and where one HCP acted as prescriber and supporter. Saturation was deemed achieved when the researchers agreed that no new concepts were arising.

Potential participants were contacted by email, and provided informed consent by freepost return or online. Semi-structured interview schedules explored experiences of the intervention procedures (Appendix M). The interviews were conducted by telephone between March 2016 and April 2017, and GP Practices were reimbursed for participants' time.

All interviewers were female researchers in Health Psychology at the University of Southampton with previous experience of interviewing (KM, LP, TC, EH, and JSB). Each interview was audio-recorded, except in two cases where the technology failed and detailed notes were used in the analysis instead. Verbatim transcriptions of the audio-recordings were checked by the interviewer.

The interview transcripts formed the main qualitative data. Emails sent by patients were also analysed to understand how remote support was being used.

4.3.4 Participants

Sixty two prescribers, 58 supporters and 5 prescriber-supporters who performed both roles (n=125) from 70 GP Practices in Southern England took part in the RCT. The sample of HCPs was determined by the number of GP Practices required to recruit 610 patients (Band et al., 2016). Quantitative data were collected from all HCPs, except the baseline questionnaires which were completed by 124/125 (99%).

A sub-sample of 44 HCPs (35%) were invited to participate in qualitative process interviews, and 27 agreed to take part (61% acceptance rate, 22% of overall sample). The sample was comprised of 13 prescribers (GPs), 11 supporters (7 Practice Nurses, 1 Nurse Prescriber, 2 Healthcare Assistants, and 1 deputy Practice Manager) and 3 prescriber-supporters (Nurse Practitioners adopting both roles).

The mean Index of Multiple Deprivation (IMD) for the qualitative and quantitative samples was 7.5 (range 1-10) and 8.0 (range 1-10) respectively (IMD has a range of 1-10 where 1 indicates an area lies within the most deprived 10% in the UK, and 10 indicates the least deprived 10%). The sociodemographic and study details of the qualitative and quantitative samples are included at Appendix N.

4.3.5 Analysis

4.3.5.1 Quantitative

Adherence rates were calculated as follows:

- Mean prescriber adherence to planning medication changes (100% adherence would be three planned changes per patient)
- Mean prescriber adherence to initiating recommended medication changes (n of recommended medication changes initiated within 28 days /total medication changes recommended by the intervention). 28 days was the threshold agreed by two clinicians, which ensured the change was made before further BP readings were submitted by the patient.
- The proportion of medication changes made remotely (email or letter) was calculated.
- Mean supporter adherence to sending monthly support emails to patients

Wilcoxon matched pairs tests were used to compare HCPs' questionnaire scores before and after training, as the data did not meet assumptions for parametric tests. All questionnaire scales were analysed as mean scores as the Cronbach's alpha indicated good internal consistency (>0.8), except for the 3-item scales assessing self-efficacy and perceived acceptability for patients in prescribers which were treated as individual items due to a lower Cronbach's alpha pre-training ($\alpha = 0.67$).

Spearman's correlations assessed the relationships between questionnaire scores after training and adherence to the target behaviours. Contextual factors theorised to influence adherence to medication change were compared between recommendations adhered to and those not adhered to using Mann Whitney U tests for continuous data and chi squared-tests for categorical data.

4.3.5.2 Qualitative

The interview data were analysed using inductive thematic analysis (Braun & Clarke, 2006). The data were coded line-by-line in NVivo 10, and a coding manual was developed in an iterative process. Emerging codes and themes were constantly compared against the raw data to promote transparency and ensure that they remained grounded in the participants' experiences. The analysis was led by KM with frequent discussions about emerging codes and themes with KB and LY. Data collection ran in parallel with data analysis to enable emerging insights to be explored. The inductive findings were subsequently interpreted using NPT, as this was an important mechanism of change in the logic model.

An inductive content analysis was conducted on the emails patients sent to their HCPs, in order to explore how this remote support was used. The categories for coding were developed iteratively from the data. A coding manual was developed with definitions of each category.

4.3.6 Integration

A matrix was used to integrate findings from the quantitative and qualitative analyses. Some themes developed in the inductive thematic analysis were too broad to map directly to the quantitative findings, therefore the triangulation matrix extracted qualitative findings at the level of both themes and sub-themes. Summary statements were written for each key finding (Tonkin-Crine et al., 2016) and triangulated to establish whether they were in agreement, partial agreement (the two findings complemented one another), dissonant (the findings conflicted), or silent (only one data source contributed) (Bergman, 2008; O'Cathain et al., 2010).

4.4 Results

4.4.1 Quantitative adherence rates and factors relating to adherence

Table 11 shows that there was a significant increase in scores on self-efficacy, outcome expectancies and perceived acceptability of the intervention after training for both prescribers and supporters.

Table 11 HCP self-efficacy, outcome expectancies, and perceived acceptability questionnaire scores before and after training

Scale	Individual items where not treated as a scale	Response options	Before training Median (range)	After training Median (range)	Wilcoxon z score	95% CI for mean difference scores
Prescriber self-efficacy (n=67)	a. Create individualised patient medication plans	1-10	9 (1-10)	10 (1-10)	-5.20	0.59 to 1.30
	b. Increase patient medication when BP remains too high		9 (1-10)	10 (1-10)	-3.06	0.13 to 0.68
	c. Integrate the HOME BP programme in to regular care		7 (1-10)	9 (2-10)	-5.95	1.41 to 2.38
Prescriber outcome expectancies mean score (n=67)		1-5	4.00 (3-5)	4.17 (3.33-5.00)	-5.09	0.19 to 0.36
Prescriber perceived acceptability of the	a. Self-monitor their blood pressure at home	1-10	7 (5-10)	8 (5-10)	-4.96	0.62 to 1.30
	b. Enter their blood pressure readings in to HOME BP		7 (1-10)	8 (5-10)	-4.72	0.80 to 1.65

Scale	Individual items where not treated as a scale	Response options	Before training Median (range)	After training Median (range)	Wilcoxon z score	95% CI for mean difference scores
intervention for patients (n=67)	c. Make medication changes to control their blood pressure		6 (1-10)	8 (5-10)	-5.57	1.23 to 2.28
Supporter self-efficacy mean score (n=57)		1-10	7.67 (2.33-10)	9.33 (6.67-10)	-5.55	1.32 to 2.33
Supporter outcome expectancies mean score (n=57)		1-5	4.17 (3-5)	4.5 (3-5)	-4.34	0.16 to 0.38
Supporter perceived acceptability of the intervention for patients mean score (n=57)		1-10	6.67 (1-10)	8.33 (3.67-10)	-4.82	0.88 to 2.00

Adherence rates showed high adherence to planning three medication changes per patient (82%), while the lowest adherence was for contacting patients remotely when a medication change was made (38%). Moderate adherence was found for initiating medication changes when recommended within the trial (53%) and sending monthly support emails to patients (56%), see Appendix O.

Spearman's correlations between questionnaire measures post-training and adherence to intervention behaviours showed that self-efficacy was significantly correlated with prescribers' adherence to initiating recommended medication change within the trial ($r = 0.27, p < .05$), but none of the other correlations were significant (Appendix O).

In terms of the contextual factors theorised to influence medication change adherence in the logic model, a small to medium effect was found for mean systolic BP reading, where recommendations based on higher systolic BP readings were more likely to be adhered to ($d = 0.41$), see Appendix O. Mann Whitney U tests showed that recommendations were less likely to be adhered to for later months of BP readings (accounted for 7% of the variance), and when a higher number of recommendations for medication change had already been made for that patient (8% of the variance). The logic model was also supported in that prescribers who adhered to planning medication changes were more likely to adhere to recommendations to change medication ($r = .29, p < .05$).

The mean number of emails received by each supporter was 1.2 per patient (range 0-5.3), and for prescribers was 0.7 per patient (range 0-6). Sixty one percent of patients used the DHI to email their HCP, and each patient sent a mean of 2 emails (range = 0-21) over 12 months.

4.4.2 Qualitative thematic analysis

The inductive thematic analysis developed four themes, shown in Table 12 (for an excerpt from the coding manual see Appendix P). These were subsequently mapped on to NPT constructs to help interpret the findings in terms of implementation theory (May et al., 2009). The qualitative findings are discussed alongside the quantitative findings as a mixed-methods interpretation.

Table 12 Themes developed from the inductive thematic analysis, mapped on to NPT constructs

Theme	Sub-theme	Definitions	NPT Construct	
Supporting patients to manage their own blood pressure	Planning medication changes	How prescribers adapted the medication planning to facilitate implementation	Collective Action (Contextual Integration)	
		Perceptions of the benefits and issues with using this approach to BP management	Reflexive Monitoring (Individual appraisal)	
	Using remote communication to manage BP	Prescribers' perceptions of implementing medication change remotely	Collective Action (Relational Integration, Interactional Workability)	
		Supporters' experiences of supporting patients via email	Collective Action (Relational Integration)	
		Prescribers' and supporters' experiences of receiving emails from patients	Collective Action (Interactional workability)	
	Delivering additional support to patients at the Practice	Perceptions about using the CARE approach to support patients	Coherence (Individual Specification) Collective Action (Skillset Workability)	
		Perceptions about patients seeking additional contact during the study	Collective Action (Interactional Workability)	
Reluctance to change medication		Barriers to adhering to recommended medication changes	Collective Action (Relational Integration)	
Ease or burden of implementing HOME BP		Perceptions about how well the DHI fits with current roles	Coherence (Individual Specification)	
		How task setup was organised with colleagues	Cognitive Participation (Enrolment, Activation)	
Belief in the concept of HOME BP		Perceptions about how the DHI fitted with organisational goals or patient outcomes	Coherence (Internalisation)	

4.4.3 Integration via triangulation

Table 13 shows the outcomes of triangulating the key findings from the quantitative and qualitative analyses. Each outcome from the triangulation process will be discussed below.

Table 13 Triangulation outcomes from integrating quantitative and qualitative data.

Quantitative data finding	Qualitative data finding	Triangulation outcome
Adherence to planning three medication changes was high (82%). Social cognitive beliefs and perceived acceptability of the intervention were not associated with adherence to planning medication change.	While some prescribers perceived planning medication facilitated more comprehensive care, others described issues with planning in advance, including patient anxiety and additional effort when the plan needed revising.	Dissonance
Adherence to initiating medication changes was moderate (53%). Pre-planning medication changes, self-efficacy beliefs and contextual patient factors such as average BP reading and n of previous recommendations were related to adherence to initiating medication change.	Some prescribers believed that changing medication in response to recommendations was straightforward, but some reasons were discussed for not changing medication, including preferring to suggest lifestyle changes or concerns about the lack of contextual information.	Agreement
Adherence to remotely changing medication was fairly low (38%).	Prescribers described preferring real-time contact at the time of a medication change in order to ensure patients have understood, and to avoid the hassle of sending a letter.	Agreement
Adherence to sending patient support emails was moderate (56%). Social cognitive beliefs and perceived acceptability of the intervention were not	Perceptions about supporting patients by email were mixed. Positive feedback from patients about the emails seemed to promote the perceived value of email support for supporters.	Agreement

Quantitative data finding	Qualitative data finding	Triangulation outcome
associated with adherence to sending patient support emails.		
The number of emails received from patients was low (1.2 emails per patient for supporters, and 0.7 emails per patient for prescribers).	Prescribers and supporters felt happy with receiving emails from patients and perceived this enabled them to provide better care, though one divergent case found it a burden.	Partial agreement (Complementary findings)
No quantitative adherence data were collected on using the CARE approach.	Supporters described a very low uptake to appointments by patients, so many had no experience of using CARE in practice. Hypothetical concerns included how to congratulate when patients' progress was limited, and how to avoid giving advice when the patient expected it.	Silence
No quantitative data were collected on setting up and integrating the DHI in normal practice.	Most HCPs considered that the programme was easy to integrate and described flexible approaches to organising the work.	Silence
Prescribers and supporters' reported positive outcome expectancies and high confidence in intervention acceptability.	HCPs perceived the DHI as a more accurate way of managing BP and as being in line with the direction of Primary Care.	Partial agreement (Complementary findings)

4.4.3.1 Prescriber adherence to planning three medication changes

Adherence to planning three medication changes for each intervention patient at baseline was high. However, the qualitative interviews suggested an awareness that these plans sometimes do not work in practice, which implied dissonance between the findings.

Some prescribers found it difficult to plan three options for patients already taking multiple medications or with a history of side effects, while others felt concerned about planning medication escalation in case subsequent side effects or comorbidities rendered the plan inappropriate. These prescribers still described following the protocol for planning medication changes, but would have preferred to decide medication changes when needed.

“normally you get patients back after the first change of medication and see how they’re getting on with side effects, and whether they’re willing to carry on... And that was lacking in this study.” (Prescriber 10).

In terms of evaluating the effects of planning medication changes, some perceived the plan facilitated medication change later on and encouraged a more comprehensive approach to patients’ care.

“things that we should be doing anyway, which is, you know, that very sort of conscious sort of reviewing their medications properly and considering them as a patient with other conditions, rather than just quickly saying “Your BP’s fine” and giving them their repeat prescription.” (Prescriber 7).

However, those who had needed to revise a medication plan after the patient experienced side effects on the first step felt concerned about patient anxiety, or irritated by the additional work.

“You’ve got a plan and now that’s changing and now do I have to make another three-point plan? And that’s really irritating and now I’ve gone off—I’ve gone off piste.” (Prescriber 1).

These concerns showed how prescribers were appraising this new way of working to consider how it affected them and their patients (*Reflexive Monitoring*).

4.4.3.2 Prescriber adherence to initiating recommended medication changes

Prescribers’ adherence to changing patients’ medication within 28 days of a recommendation was medium. This was in agreement with the qualitative analysis, which showed prescribers felt that changing medication when prompted was often straightforward but some significant challenges remained.

Some prescribers felt the process was facilitated by a perception that the patient was expecting the change, as the intervention notified patients that their prescriber would make the next

change in their plan. Home monitoring was perceived as more accurate for making decisions than clinic readings, although a healthcare assistant suggested that the home monitors would need calibrating during the study because “Machines go wrong. We all know that” (supporter 4), and a prescriber-supporter preferred to check patients’ BP readings in the clinic to confirm whether they were too high. This prescriber-supporter showed general clinical inertia, only adhering to 4/24 recommended changes throughout the trial (17%). As well as her low confidence in home readings, she preferred to suggest lifestyle change rather than intensifying medication. Another prescriber believed the BP targets were too strict and did not take contextual factors into account, such as illness, and the quantitative data indicated he adhered to 0/2 medication change recommendations.

Other prescribers believed in the necessity of medication change. One felt that the notifications to change medication needed to be more directive, and a prescriber-supporter described how she overcame reluctance from her patients to change medication.

“I think there's a lot of them make excuses, so “I drink a lot of caffeine” and this kind of thing... And I just say to them “Well, it's been a couple of months now and it's high and I think we just need to start new medication.” (Prescriber-supporter 2).

These findings suggested differences in *Relational Integration* as some prescribers were not confident in the value and rationale for changing medication using this new system.

4.4.3.3 Prescriber adherence to remotely changing medication

Adherence to contacting patients remotely to notify them about a change to their medication was fairly low, with telephone or face-to-face contact being more common. This was in line with mixed opinions about remote medication change in the process interviews.

Some prescribers felt changing medication remotely was efficient.

“It's easy, it's quite nice because, you know, you don't need to contact the patient, you just do the prescription, print off that letter, and that's quite nice, I like that.” (Prescriber 13).

However, others found it a hassle to amend the template letter, or disliked having no record that it had been received, and so preferred to phone the patient. There were also concerns about whether the patient would understand and accept the medication change.

"The patients maybe would sooner speak to a healthcare professional before starting that medication. Because they might have forgotten what was just said earlier. Yeah. Go through the side effects of everything." (Prescriber 8).

Several prescribers described how 'anxious' patients initiated phone or face-to-face contact for reassurance about their BP readings, changing medication or experiencing side effects.

"The patient is quite worried. She's generally quite a worried person. So I think that's probably why she came in". (Prescriber 11)

This suggested that issues in remotely changing medication occurred both in terms of *Interactional Workability* with the logistics of implementing this process in practice, but also in terms of *Relational Integration* with low confidence that this was an appropriate method to contact the patient.

4.4.3.4 Supporter adherence to sending patient support emails

The quantitative analysis indicated medium adherence to sending monthly support emails, which was in agreement with the qualitative interviews which suggested a wide range of perceptions about using email to support patients.

Supporters liked being provided with templates as this saved them time, and in some practices the task was shared between staff or delegated to a member of the administrative team. Having designated time appeared to help supporters manage this task. However, it seemed that perceiving the process as straightforward was not sufficient to ensure high adherence. This supporter had low adherence (27%), despite describing the process as easy.

"I've just used your templates and that was fine. It's quite easy to follow... I haven't had any replies to my – I didn't have any replies to my supportive emails." (Supporter 1).

The template emails were not designed to initiate spontaneous updates but many patients chose to reply to their supporters to let them know how they were getting on. Two supporters with very high adherence rates (sending 95% and 118% of emails respectively, as some supporters sent additional ad hoc emails to patients) both described how their patients liked receiving the support emails. Where supporters did not hear anything from their patients, they could feel out of the loop or frustrated that they were not more directly involved with patients' BP management.

"I've had nothing back, and nobody has asked to see me face to face.... ...I suppose that really is a slight frustration, that you're not getting much feedback from them. But I suppose, I would think that they feel because they're in touch with the GP, they don't really need to respond to me." (Supporter 11).

A minority of supporters felt that face-to-face support was more personal and easier for addressing issues, such as raised BP. Two of these supporters still used the email system to some extent (20% and 42% adherence rates respectively), but the other chose to see all her patients in person and did not send any patient emails.

Here the normalisation issue appeared to be *Relational Integration*, as while the templates were easy to send, some supporters had low confidence about the value of the emails to patients.

4.4.3.5 Emails received from patients

The average number of emails sent per patient was low, suggesting that HCPs were not exposed to high levels of burden from patient emails. This complemented the qualitative analysis, as most prescribers were happy with the level of email contact from their patients, although there was one divergent case who felt this created too much work.

Supporters tended to feel reassured that patients could email queries so they could offer personal support. Sometimes supporters discussed how they provided patients with their work email address to facilitate this, rather than using the online tool for contact (which suggests that some supporters received more emails than were counted via the intervention and available for quantitative analysis).

However, one prescriber raised concerns about both the number of emails he received and the complexity of content.

"they email readings plus a whole narrative of what's going on in their life....it's the moment you start adding a way for a patient to get hold of you by email, then you're going to get flurries of emails." (Prescriber 13).

This prescriber had more patients in the intervention group than most (n=10), but had only received four emails from patients at the time of his interview. It's possible that this comment may be more indicative of a concern about how many emails he *might* need to deal with than

burden actually experienced. This relates to *Interactional Workability* in terms of the feasibility of the workload involved in receiving patient emails.

Content analysis of patient emails generated 19 codes representing reasons for emailing the HCP (see Appendix Q for coding table and frequency counts). The most common emails were about the logistics of taking home readings, for example, letting the supporter know about delays. Another common reason was to hypothesise about factors influencing BP readings, including illness, temperature, travel, coffee, stress and changes in other medication. Patients also emailed to let the HCP know about side effects from BP medication, and concerns about changing medication.

4.4.3.6 Using the CARE approach

It was not possible to collect quantitative data on adherence to the CARE approach, so this section describes only the qualitative findings. Most supporters said they had no experience of using CARE in the optional support appointments due to a low uptake rate by patients, and therefore their perceptions were mainly hypothetical. When prompted about CARE, supporters tended to concentrate on the *Congratulation* and *Encouragement* aspects of CARE, which were generally perceived to be in line with what they already do, but did not discuss their perceptions of *Asking* or *Reassuring* patients.

While some supporters described congratulation as a normal part of their role, a couple described feeling reluctant to congratulate participants if their progress was limited, either because this could feel insincere or because they felt the patient had not made enough progress to warrant praise.

“It feels fake to congratulate. If there is not enough steps. Or if somebody says, “Oh I lost weight, half kilo.” Well, well done, but not excellent.” (Supporter 7).

Some concerns arose about not giving advice during an appointment if a patient expected this, with one supporter feeling unsure how much ‘intervening’ she was allowed to do (Supporter 11). It may be that the infrequency of contact contributed to supporters’ low confidence or confusion in implementing CARE.

This suggested that the barriers to normalising the CARE approach in practice concerned both *Individual Specification* in how the supporter perceived CARE fitted with their role, and *Skillset Workability* in whether the supporter felt they had the necessary skills to deliver CARE.

4.4.3.7 General ease of implementing the DHI

Most HCPs considered that the DHI was straightforward to implement and fitted well with normal practice. The organisation of work between the prescriber and supporter was flexible, such that in some practices they worked very closely together and even shared some tasks, while in other practices they worked more independently. This demonstrated intervention plasticity (May, Johnson, & Finch, 2016) which seems to facilitate *Cognitive Participation* in a new process. There were no quantitative data to triangulate this finding against.

4.4.3.8 Beliefs and confidence in the DHI outcomes

HCPs' questionnaire scores demonstrated high perceived acceptability of the intervention and positive outcome expectancies (Appendix O). This complemented the qualitative interviews which showed that HCPs believed in the concept of the DHI as a means for improving management of BP in Primary Care, feeling confident that it was a more effective system and that it would empower patients. This is categorised as complementarity as although the insights gained from the qualitative and quantitative findings were slightly different, together these findings implied that HCPs perceived the DHI to be useful and effective.

4.5 Discussion

This mixed-methods process evaluation triangulated qualitative and quantitative findings to develop an in-depth understanding of the process of implementing a self-management DHI in Primary Care. This discussion will consider the implications of these findings in terms of the feasibility of adhering to the target behaviours in practice.

While creating a three-step medication plan for patients appeared acceptable based on the high adherence rates, some doubts emerged about the benefit of deciding changes in advance and inefficiency or patient anxiety when the plan needed changing. This suggested that the procedure may have some feasibility issues for prescribers, especially when working with patients with more complex needs or anxious patients. Emphasising the flexibility to change the three-step medication plan when needed might help increase feasibility, for example by reminding HCPs in

the automated prompts that the action plan can be updated whenever needed, and encouraging them to reassure patients that trying a few different medications is common when working towards controlling hypertension, to try and minimise anxiety.

The rate of 53% adherence to medication change when average BP was above-target is comparable to a previous BP tele-monitoring trial in which medication changes were patient-initiated (55%) (Bray et al., 2015), and exceeds a US tele-monitoring trial in which physicians initiated 41% of recommended changes (Crowley et al., 2011). Estimates of adherence rates in normal practice vary considerably from medication change occurring in 13% to 55% of consultations when BP was above-target (Guthrie et al., 2007; Okonofua et al., 2006) but these rates are not recent and were calculated using different thresholds. Comparison with usual care indicated that the current intervention was successful in increasing the number of medication changes and led to significant reductions in systolic BP, suggesting that this adherence rate was high enough to be effective (McManus et al., Under review) but could potentially be improved.

Borderline readings were identified as a barrier to medication change in the quantitative analysis, which is consistent with previous research (Jones et al., 2013; Mant et al., 2016), while the qualitative analysis suggested some prescribers held a more general reluctance to increase medication due to a wariness over lack of context or a preference for recommending lifestyle change. Mapping the findings to NPT suggested that barriers related more to accepting the recommendations as appropriate and credible (*Relational Integration*), than in interacting with the DHI or fitting with existing workflow (*Interactional Workability*). Changing HCPs' beliefs about BP thresholds and patient outcomes may be an effective if challenging means to overcome reluctance to change medication. The baseline training did appear to increase self-efficacy and outcome expectancies, but these findings suggested that some doubts remained about planning and changing medication. Reinforcing the evidence for the BP threshold in the automated email alerts might be useful as an 'in the moment' cue to action (Michie et al., 2013), especially in the case of borderline readings. In some cases the decision not to change medication may be entirely appropriate, therefore tailoring additional behaviour change support for those prescribers with lower self-efficacy at baseline may be important. However, self-efficacy items evaluating 'choice behaviours' which are not challenging to perform (such as deciding to initiate a medication change) may be more indicative of inclination than perceived capacity (Kirsch, 1982). Therefore any additional support may need to focus more on increasing motivation to change medication than self-efficacy, perhaps targeting the beliefs raised in the process interviews about low perceived necessity. There may also be a need for a contextual change in perceived acceptable thresholds for BP. The legislative strategies for incentivising BP control at the time of this intervention used a threshold of 150/90 mmHg (NHS England, 2018), a discrepancy which could

contribute to reluctance to change medication when BP readings were in the vicinity of 135-140 mmHg.

There is growing interest in using email consultations in Primary Care in order to reduce HCP workload and improve access for patients (Department of Health, 2012b), but implementation remains low with only 8% of almost 900 HCPs in the UK reporting using email regularly to communicate with patients in Primary Care (Brant et al., 2016). The current process evaluation showed that HCPs were concerned that patients might not receive clinical information if sent remotely, or doubted the value of email support if no response was received, suggesting that the lack of feedback from patients can be disconcerting. This may be a normal part of adjusting to a more remote care system (Atherton et al., 2018). A more interactive system which enables the patient to acknowledge receipt of remote support might help provide the reassurance that HCPs were missing. As with medication change, the main barrier to remote support was perceiving email as unsuitable or ineffective to communicate with patients (*Relational Integration*) despite finding the process straightforward and manageable (*Interactional Workability*). Contextual changes in organisational services could facilitate engagement with remote support, normalising the use of email where appropriate.

The wider evidence suggests that HCPs are concerned that patients might inundate them with emails if given the opportunity to send queries (Atherton et al., 2018). However, most HCPs in this study seemed to appreciate receiving patient emails and while over half of patients sent at least one email via the DHI, demonstrating capacity and access, most sent very few emails during the 12-month trial. This DHI used a guided system offering patients the opportunity to login online and email queries about their BP, which may have reduced the risk of unmanageable quantities of emails. Therefore the context in which email consultations are offered may be important in terms of the workload it creates.

4.5.1 Strengths and limitations

The mixed methods approach was a strength of this process evaluation. The rigour and coherence of the interpretations were supported by their consistency with the literature, theory and with each other (Tashakkori & Teddlie, 2008). Additional methods, such as recordings of consultations to explore how HCPs and patients interact when planning or changing medication, or surveys to explore beliefs about medication change and contextual variations between sites might further enhance understanding of the barriers to these key behaviours.

The apparent increase in questionnaire scores after completing the online training should be interpreted with caution, as it is possible that a desire to demonstrate competence after completing the training drove the rise in scores rather than a genuine change in beliefs.

4.6 Conclusions

A fully automated DHI for adjusting medication to improve uncontrolled hypertension appeared to be relatively feasible for HCPs to implement in Primary Care. In-depth exploration of beliefs and adherence to target behaviours during implementation helped identify how the DHI might be optimised.

It was suggested that timely reminders of the rationale for engaging with a target behaviour may help promote adherence to DHIs, especially in cases where adherence is less likely either due to contextual factors or HCP beliefs. Email communication with patients appeared to be implemented more readily when feedback from patients led to it being evaluated as worthwhile, suggesting that rather than being a burden, responses from patients were important for reinforcing engagement with remote support. Future DHIs might want to consider including an interactive component enabling patients to acknowledge receipt of remote support, or even send a short response, as this appeared to be persuasive to practitioners.

Chapter 5 General Discussion

This chapter takes the opportunity to further explore the findings and implications from the three pieces of research conducted as part of this thesis. A detailed discussion of findings was not possible within each paper due to the strict word limit, therefore this chapter provides additional insights and implications which could not be discussed fully in the papers themselves.

Each section discusses what has been discovered in terms of the aim for that piece of research, followed by consideration of the strengths and limitations. The chapter finishes by considering the overall implications for theory, clinical practice and research.

5.1 Paper 1 Aim: To develop an in-depth understanding of patients' and HCPs' perceptions of using digital health interventions for self-management from a synthesis of primary qualitative studies.

The meta-ethnography review (paper 1) synthesised the findings of 30 qualitative studies exploring the experiences of patients and healthcare professionals (HCPs) using Digital Health Interventions (DHIs) for self-management, including simple tele-monitoring interventions and more complex multifaceted tools. A line of argument was developed with a key over-riding third-order construct concerning perceptions of responsibility. This achieved the aim by providing a higher-level understanding of how HCPs and patients perceive the purpose of DHIs, and how the DHI design seemed to influence their perceptions. This will be discussed with reference to Normalisation Process Theory (NPT) to help relate the findings to commonly identifiable constructs and consider the wider implications for DHI design and implementation (May et al., 2009).

The findings concerning perceptions of responsibility showed that patients and HCPs each tended to focus on their own responsibilities, with patients describing how DHIs could change their perceptions of self-managing their condition, and HCPs' focusing on how DHIs could improve their clinical control. It appeared that DHIs could facilitate both outcomes simultaneously. This evaluation of the value of DHIs is part of the *Reflexive Monitoring* process according to NPT, in which people appraise how a new process affects them and decide how useful this is. In a small

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number of studies, HCPs were not only focused on their clinical management, but also perceived it as part of their role to support patients using the DHI and to encourage patient self-management. Meanwhile other HCPs felt confused about the purpose of the DHI or how to respond to data sent via tele-monitoring. In line with the *Coherence* construct from NPT (May et al., 2009), this implied that the explanation and introduction of the purpose of a DHI in clinical practice, how this complements or enhances existing care systems, and exactly what the HCP's role involves may be important for promoting successful adoption of DHIs.

A risk in some studies was ambiguity over who was responsible for responding to self-monitored data, which created a burden of uncertainty for patients and HCPs. This was an issue of *Coherence* according to NPT, as the participants lacked clarity over what their role involved. Therefore clear and timely feedback on self-monitored data could be important for minimising burden and ensuring DHI users understand the implications of the outputs from the DHI. Another issue in terms of responsibilities was patients relying on HCPs to continuously monitor the data they sent via DHIs. While patients felt well cared for when they relied on HCPs to detect and respond to problematic readings, this created concern for HCPs about unrealistic expectations, increased workload and patients becoming more dependent. This was an issue with *Cognitive Participation*, as ongoing surveillance of data was not perceived to be part of their role, as well as *Collective Action* in terms of the feasibility of the workload. This finding suggested that designating responsibility for action to the patient might help create a more sustainable model of patient care. In line with this, a programme of tele-monitoring research spanning five years shifted the responsibility for action from being HCP-led (which involved ongoing surveillance of data), to being patient-led with HCPs only reviewing the patients' data at pre-specified intervals or at patients' request (Hanley, Pinnock, Paterson, & McKinstry, 2018) in order to improve feasibility.

The meta-ethnography also developed two subsidiary third-order constructs relating to how patients perceived meaning in self-monitored data, and their perceptions of changing medication when using a DHI. These constructs also emerged in the HOME BP process evaluation, and therefore will be discussed further within the discussion about papers 2 and 3.

5.1.1 Strengths and limitations

A strength of the review was the thorough quality appraisal of all primary studies using the NICE checklist for qualitative research (National Institute for Health and Clinical Excellence, 2012). While

this was good practice to enable any limitations of primary research to be taken into account, it was only of limited use as the scoring system was relatively insensitive, and papers with lower quality scores often contributed very valuable insights. Indeed the researchers who developed the meta-ethnography approach suggested that quality appraisal was not necessary as a paper's quality and richness would be indicated by the level of contribution to the synthesis (Noblit & Hare, 1988). Nonetheless, the application of this checklist ensured that the quality of primary studies was given systematic consideration. One of the most important indications of quality was the inclusion of participant quotes in the primary papers, which enhanced the line of argument by providing insight into individuals' experiences in their own words, sometimes yielding novel insights, instead of relying only on the authors' interpretations which were influenced by their own research question as well as their background and perspectives. Although only a small selection of participant quotes were available to the reviewer, as chosen by the primary studies' authors in order to support their argument, the reviewer found that at times the quotes included had a different interpretation or were not interpreted at all in the primary study, and therefore these were very valuable to the development of understanding in the meta-ethnography.

Another strength was the inclusion of the CERQual evaluation which maximised transparency by reporting which studies related to each interpretation (Lewin et al., 2015). The CERQual evaluation also highlighted some important limitations of the review. Exploring the relevance of primary studies underlined the low representation of asthma studies in the review, which may mean these findings do not translate well to an asthma context. Indeed, research has suggested that there are a wide range of unique factors contributing to beliefs about asthma medication, including social stigma and embarrassment (Lycett et al., 2018), which could influence how self-management DHIs are perceived by this population and would not be well represented by this review. In addition, subtle differences in the aims of the primary studies might be a limitation of the review. Whilst all studies explored users' experiences of DHIs, some had more specific agendas such as assessing feasibility, optimising the intervention, or understanding the impact of the DHI on well-being. These more focused research questions were likely to influence how the study was conducted, what data were collected and how the researchers analysed their data, meaning that although the meta-ethnography had a broad research question about understanding users' experiences, the data informing the synthesis may at times have been collected with a different research agenda in mind. Despite this diversity of aims and approaches, the reviewers were successful in identifying key concepts for comparison between studies and the development of a clear line of argument suggested that it was possible to combine findings from very different studies to develop new knowledge.

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A final strength of the meta-ethnography process was that the third-order constructs were developed while considering how the context in which interventions were delivered could have interacted with participants' experiences. This was important when combining findings across such a diverse range of conditions and DHIs, as contextual factors inevitably varied considerably between studies, and interpreting each study's findings within the context they were collected helped develop a more nuanced understanding. Recent recommendations for reviews of intervention research have emphasised the importance of taking context into account (Craig et al., 2018), and the following paragraph considers to what extent various contextual dimensions were considered in this meta-ethnography, using an established framework (Craig et al., 2018).

The review included a table to report basic contextual details such as the health condition (*epidemiological context*) and country (*geographical context*) for each study, which can help readers interpret the findings and assess whether they might be relevant in other situations (Burford, Lewin, Welch, Rehfuss, & Waters, 2013). However, this did not include details about the participants' sociodemographic status as most primary studies did not report factors such as ethnicity, level of education, health literacy, or cognitive impairment (*social context*), meaning that it was difficult to consider whether the findings were transferable across socioeconomic groups. It appeared that unless it was a specified target of the intervention to support a hard-to-reach group (Burner et al., 2014), these important details were omitted. Furthermore, the primary studies were conducted in very different healthcare organisational settings across a range of countries (*organisational context*), and these different service demands, policies and approaches to chronic condition management might have influenced users' perspectives, but again this was not reported in detail in the primary papers. Even had the information been captured, it might be challenging in a large-scale synthesis to determine to what extent the findings can be applied across different populations. This review included data from 30 studies with diverse participant groups from multiple countries, but without knowing the denominator it is difficult to know whether sufficient reach has been achieved (Guagliano, 2018).

Overall, this review helped to bring together the experiences of patients and HCPs using DHIs and contributed to the cumulative knowledge on how to optimise DHIs for implementation. While the CERQual evaluation helped readers to consider credibility of the third-order constructs, further explicit discussion of applicability and transferability of the findings might have been useful for policy makers. Indeed a possible disadvantage of meta-ethnography compared with thematic synthesis is that findings can be less tangible and practical to apply, as they tend to identify more theoretical concepts than concrete barriers and facilitators to improving healthcare (Toye et al.,

2014). The application of NPT to interpreting the implications of the findings for DHIs helped overcome this limitation to some extent and generated suggestions for how DHIs could be optimised, such as providing clear explanations of a DHI's purpose; giving informative self-monitoring feedback for patients and HCPs which explicitly states a recommended action; and using patient-led systems for initiating action where appropriate.

5.2 Paper 2 Aim: To explore participants' personal appraisals of the burdens and benefits of using a digital intervention for self-management of high blood pressure.

The qualitative process study provided an in-depth insight into the perceived benefits and burdens of using a self-management DHI for hypertension. While there were some consistencies with the meta-ethnography, there were also novel insights regarding how patients' beliefs appeared to influence whether they felt anxious or confident about changing medication, or guilty or empowered from seeing how their blood pressure (BP) was related to their lifestyle. This helped further develop understanding of how DHIs could be optimised going forwards. This section explores the perceived benefits and burdens from the thematic analysis in relation to current literature, which could not be discussed in paper 2 due to the word count. The section aims to improve understanding of how patients perceive the value of DHIs and the implications for DHI design. In two cases, the benefits and burdens appeared to be two ends of a spectrum and so are discussed together.

5.2.1 Benefit: Reassurance from seeing BP readings

A key benefit for some patients using HOME BP was seeing well-controlled readings every month, and the feelings of reassurance this created seemed to motivate them to continue. This is in line with a recent review of theoretical concepts associated with maintenance of behaviour change which found that perceiving an immediate positive outcome from initiating a new behaviour helped motivate people to continue performing that behaviour over time, for example enjoyment of the behaviour itself, or as in this case, positive affect resulting from the behaviour (reassurance) (Kwasnicka, Dombrowski, White, & Sniehotta, 2016). Interestingly, paper 1 found

that seeing continuously well-controlled BP or blood glucose readings tended to reduce perceived need to use the DHI (Hallberg et al., 2015; Urowitz et al., 2012), and other studies have found that participants with better health perceived fewer benefits from using a DHI than those with poorly-controlled health (McCreadie & Tinker, 2005; Sanders et al., 2012). However, in HOME BP this did not appear to be the case, as patients with well-controlled BP appeared to have high motivation to continue engaging over time. It may be that the combination of relatively low effort in terms of frequency (seven days of home monitoring per month, which could be reduced to seven days every three months once readings were consistently well-controlled) and the positive feedback messages regarding well-controlled BP helped promote the benefit of reassurance that can result from self-monitoring, making ongoing engagement appealing even when readings were consistently well-controlled. However, it is unknown to what extent people would continue to perceive self-monitoring as beneficial in the longer-term, outside the setting of a 12-month trial.

5.2.2 Benefit: Seeing BP readings motivated lifestyle change / Burden: Worry or guilt about not engaging with healthy changes

In line with the findings of paper 1, having access to one's own health data seemed a powerful mechanism which could motivate patients to change their self-management behaviours, and this was described as a benefit by some patients. Self-monitoring improved understanding of their condition by showing how changes in BP were related to behaviours such as medication adherence, diet and physical activity.

However, it seemed that this insight from self-monitoring BP was only perceived as beneficial by patients who felt motivated to act on it. Meanwhile some patients felt guilty for not engaging with healthy lifestyle behaviours after seeing raised BP readings. A desire to avoid such guilt is a recognised barrier to participating in DHI research in the first place (Dasgupta et al., 2013; Fukuoka, Kamitani, Bonnet, & Lindgren, 2011) and may reflect a wider societal issue of the morality of self-monitoring and health. There is a growing discourse in the public health arena that patients need to take more responsibility for their health and live healthy lives to avoid chronic disease (Department of Health and Social Care, 2018), and concerns have been raised about the implied responsibility to act after seeing data indicating poor control (Andersen & Whyte, 2014; Lupton, 2014b). Even though the HOME BP intervention reinforced to patients that the best way to control BP was through medication change, some patients still felt guilty or negligent for not increasing their physical activity or eating more healthily to control their BP, especially as the DHI offered optional modules to support these behaviour changes.

People generally want to view themselves as responsible patients (Svendsen, 2005), and DHIs could try to minimise the blame that can be introduced when people are given insight into poor health control. Self Determination Theory might be helpful for ensuring that people feel they have an autonomous choice in changing their behaviour rather than feeling pressured to do it by society or the DHI (autonomy), that the behaviour change support offered is suitable for the target population (competence), and that positive support is available (relatedness) (Teixeira, Carraça, Markland, Silva, & Ryan, 2012). Interestingly some patients felt that lifestyle changes were futile as past experience had led them to believe that leading a healthy lifestyle did not reduce their BP, potentially offsetting this burden of guilt for not engaging.

5.2.3 Benefit: Better health/Burden: Worrying about health

Those who perceived raised BP readings as dangerous, or held concerns about changing medication seemed to perceive self-monitoring as more burdensome due to the anxiety around what would happen if readings were raised. Meanwhile patients who were happy to change their medication and perceived this as a priority in order to improve their health tended to see self-monitoring and changing medication as beneficial. These perceptions seemed to be partly influenced by whether a recent medication change had been effective at lowering their BP, with those who had seen their BP come down perceiving a benefit of improved health, while those who had not seen a reduction in BP after a medication change felt more anxious and doubtful about the DHI.

Hypertensive patients often need to try a few changes to their treatment, including different combinations of medications, and/or increased doses, in order to achieve BP control (Webster et al., 2018). This raises a potential problem as if those with the highest need for continual engagement in order to control their condition perceive it as being more burdensome due to the negative experience of seeing poorly controlled readings, they may be less likely to engage over time.

Recent research has suggested that interventions need to promote positive attribution of undesirable health data and encourage perceptions of control in order to avoid disengagement (Kangovi & Asch, 2018). Perceived controllability of one's condition is a similar if not identical concept to a patient's self-efficacy to control their health (Bandura, 1991), implying that DHIs need to find ways to promote patients' self-efficacy to control their health rather than compromise it. HOME BP sought to increase patients' self-efficacy and outcome expectancies about self-monitoring and changing medication through carefully constructed baseline training. However, it is challenging for a DHI to *maintain* positive beliefs if a patient's BP readings are

consistently raised despite engaging with medication change. Careful tailoring of feedback messages in the event of continually raised readings despite medication changes may help increase self-efficacy in the moment, in addition to the training at the start. The high credibility and trust that patients appeared to have in their prescriber suggested that some patients might benefit from the offer of a HCP consultation if readings were continually raised, to manage their expectations and increase self-efficacy that BP control is attainable for them even if it takes a little time and a few attempts at finding the right combination of medication.

5.2.4 Burden: Uncertainty from self-monitoring

In HOME BP, patients received clear feedback when their average BP reading was raised that their HCP would contact them in the next seven days about their next medication change. However, some patients did not hear from their HCP or were not sure if they were supposed to act, and this uncertainty appeared to be a burden of using DHIs for self-monitoring health status. Paper 1 showed that clear and appropriate feedback on self-monitored data can reduce patient and HCP burden, but this process evaluation further suggested that clear feedback did not offset patients' concerns if the HCP did not contact them soon enough, or if patients were feeling anxious about their readings but had not been given a way forward other than to wait. This supported the suggestion that patient-led systems may facilitate implementation of DHIs. While this arguably creates a burden on the patient by asking them to take action and contact their HCP, a recent review of telehealth interventions for cancer survivors found that patients still appeared to find self-initiated support beneficial (Cox et al., 2017). By putting the onus on the patient to contact their HCP rather than the other way round, this could help avoid patients feeling uncertain about their health while they wait to hear if their medication will be changed. However, if the HCP is unavailable, this can also be stressful for patients. A challenge for DHIs in Primary Care is how best to balance HCPs' workload in terms of realistic time frames for contacting a patient against patients' anxiety if they need to wait a while to hear about what to do next.

5.2.5 Burden: Practicalities of adhering to intervention procedures

Finally, some patients perceived HOME BP to be burdensome due to the hassle of fitting self-monitoring in to their day and avoiding activities beforehand which could influence their readings (such as drinking coffee), or due to the need to remember to do it. Interestingly these perceptions seemed more prevalent amongst poorly controlled patients. It may be that the perceived burden

of a DHI in terms of time and effort is partly offset by the instant benefits gained; such that those who were rewarded with the reassurance of knowing their BP was fine tended to feel that self-monitoring was easy to do, whereas those who saw raised readings were more likely to perceive it to be a chore. Alternatively, there may be a third factor influencing both perceived burden of the DHI and BP control, such as interest in health.

The finding that some patients perceived it a hassle to self-monitor suggested that ensuring DHIs are as easy as possible to embed in daily lives and perhaps offering optional reminders to prompt engagement might help to minimise the burden of incorporating DHI activities into busy lives. Burden of Treatment theory describes this kind of burden as the work involved in engaging with healthcare, and suggests that increasing patients' resilience and social networks can help offset the burden (May et al., 2014), but in this case there was little evidence to suggest that existing social support was helpful to patients, or that having more social support would have made it easier.

5.2.6 Strengths and limitations

A strength of this process evaluation was the inclusion of interviews with usual care participants. This helped to understand the burdens and benefits arising within the intervention group through providing an insight into experiences of managing BP without a DHI and some of the issues which can arise in usual care – especially in terms of worry that BP is not being checked, and lack of communication about home readings. A limitation of the usual care interviews was that the participants had been exposed to the invitation and recruitment materials which emphasised the importance of home monitoring, as well as answering questionnaires about their hypertension and self-management, which could have changed their perceptions about their current care. Indeed, one usual care participant described in her interview a perception that she had not been eligible for a BP monitor from the study so had decided to purchase her own. This meant that the interviews with usual care participants may not represent the benefits and burdens of normal practice, a recognised issue with 'usual care' groups in RCTs (Smelt, van der Weele, Blom, Gussekloo, & Assendelft, 2010). However, these interviews still provided a useful contrast to the intervention group's perceptions of managing BP.

Another strength was the open interview schedule which was designed to ask questions that would elicit detailed responses about patients' experiences of the DHI, and led to very rich data. Starting with open questions about experiences enabled participants to raise whatever was most important to them about the DHI, rather than being led by questions of particular interest to the

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interviewer. However, it is also important to consider that benefits and burdens may only have been raised because patients were asked about them in an interview context, as the interview schedule inevitably shapes the data (Hammersley & Gomm, 2011). How much of a benefit or burden these factors were and the extent to which they influenced behaviour could not be established from this process evaluation.

A limitation of this study was that participants' perceptions of benefits and burdens were only captured at one point in time, whereas repeated interviews over time might have helped understand how perceptions of benefit or burden change while using a DHI, and provided more insight into how they could relate to behaviour. For example, one participant was thrilled that her BP was well-controlled after a recent change in medication, but had she been interviewed at an earlier point when her BP was poorly controlled and she was experiencing side effects from her medication, her evaluation of the burden of the DHI might have been very different. Whilst comparison between participants enabled some insights to be gleaned into how BP control might influence perceptions of the DHI, a longitudinal qualitative design could have facilitated more in-depth exploration of the extent to which perceived benefits and burdens change according to contextual details. On the other hand, a risk of conducting repeated interviews during an RCT is that asking participants to reflect on their experiences can influence the behaviour of interest (Spangenberg, Karelklaas, Devezer, & Sprott, 2016; Wood et al., 2016), in this case engagement with BP self-monitoring and medication change. Indeed even with one-off interviews there was evidence that these changed participants' behaviour in some cases, for example, an intervention group patient with low levels of engagement deliberately completed all the optional lifestyle sessions shortly before the interview in order to be able to discuss it.

Another potential limitation of the study was the methods used to determine when to cease recruiting participants for process interviews. The concept of saturation was employed, such that recruitment stopped when no new insights were emerging from the ongoing analysis. It was decided that saturation was reached after 28 interviews with intervention group patients, but had a 29th interview been conducted this could have revealed entirely novel insights, and this is a limitation of saturation (Saunders et al., 2018). Some researchers have suggested saturation should be seen more as an incremental, ongoing process of determining when sufficient data have been gathered, rather than a single point at which a complete picture is achieved (Dey, 1999). Information power has been proposed as an alternative approach to saturation for deciding sample size in qualitative research, in an effort to improve robustness (Malterud,

Siersma, & Guassora, 2016). This approach suggests that decisions about sample size can be informed by five factors: the purpose of the research, the relevance of participants to the research question, whether the research is informed by existing theory or is exploring a new concept, practical decisions about the quality of the data, and how the data will be analysed. The authors argued that information power is more robust than the concept of saturation, which is widely used across qualitative research but was originally developed specifically for grounded theory analysis and referred to *theoretical* saturation, i.e. when additional data did not add to the new theory which had been developed (Charmaz, 2014). Retrospectively applying the concept of information power to the HOME BP process evaluation suggested that the aim of the study was fairly broad, which would imply a large sample size was needed. The sample was specifically relevant to the research question as all were participants in the HOME BP intervention, and they appeared diverse in their experiences of the intervention. The quality of the data was high in that the dialogue was rich and detailed. The sample of 28 participants was also appropriate for thematic analysis, and the analysis was not informed by existing theory suggesting a large sample size would be appropriate. Overall, it appeared that using information power to determine sample size rather than saturation would not have substantially changed the sampling strategy, but using this approach may have offered another perspective for informing when to cease recruitment.

In terms of the data analysis process, the researcher was aware of how their own perceptions and agenda might influence their interpretation of the data. Having already conducted a meta-ethnography of patients' experiences of using DHIs, there was an existing awareness of some of the common perceptions around DHIs which might have influenced the development of themes. The researcher sought to minimise potential bias by engaging in ongoing discussions with the supervisory team, ensuring the themes were grounded in the data using constant comparison, and exploring deviant cases which did not fit the rest of the data to help develop more elaborate understanding of how benefits and burdens were perceived. Despite this, in qualitative research the researcher will inevitably shape the findings and it is important to be aware of this limitation when considering the findings.

Some qualitative researchers have cited the lack of generalisability of their findings beyond their particular study as a limitation (O'Cathain et al., 2014). However it has been proposed that it is not within the scope or aims of qualitative research to generate universally applicable truths or recruit statistically representative samples, as might be the goal of quantitative research, and therefore it is misleading and demeaning to qualitative research to describe this as a limitation (Smith, 2018). Instead it is important to consider how transferable the findings are to other contexts, as this helps policy makers and researchers make decisions about the relevance of the

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research findings for their local setting. This is partly an assessment to be made by the reader, but there are considerations which the researcher can undertake in order to reflect on the potential transferability of their findings and encourage their readers to do the same (Smith, 2018).

Factors to consider when evaluating transferability of these findings included the characteristics of the sample who took part in the study, how they were recruited, and why. Participants in this study had volunteered to take part in a trial and subsequently agreed to participate in qualitative interviews, suggesting they may already be more motivated to self-manage their condition than the wider hypertensive community. It has been recognised that only a small percentage of people with a health condition take part in clinical research (Kanarek, Kanarek, Olatoye, & Carducci, 2012) and this can create disparity, often with under-representation from minority populations, which limits the potential to understand how interventions work and for whom (Stronks, Wieringa, & Hardon, 2013).

Within the sample of participants in this study, it might be possible to qualitatively explore whether there appeared to be any patterns in experiences of the DHI amongst sub-groups which could inform further research (Stronks et al., 2013), but it is not possible to explore this variation amongst sub-groups who were not represented in the first place. This sample of n=28 participants were 70% female, whereas in the general population hypertension has a higher prevalence among men than women at a younger age, and has equal prevalence in men and women aged 65-74 years (Public Health England, 2017). There was also a relatively low representation of ethnic diversity (86% of participants were white, and only 1 participant was Black African), whilst prevalence rates show people from Black Caribbean and Black African ethnic groups have a higher risk of hypertension (Public Health England, 2017). Researchers have called for more informed exploration of diversity in clinical research, with study design informed by evidence-based hypotheses about the potential way that heterogeneity in the sample might influence the outcomes, in order to focus on the diversity issues which are known to be important (Stronks et al., 2013).

It was also beyond the scope of this study to evaluate the perceived benefits and burdens of DHIs amongst those who declined to participate. Previous research has shown that some of the perceived burdens which have deterred COPD, heart failure and diabetic patients from taking part in tele-monitoring trials were the same as those found in this study, such as not wanting to feel anxious or guilty about lifestyle choices when seeing poorly controlled readings, but other concerns raised were different, such as anxieties about lack of competence to use technology, not wanting to feel dependent or 'sick', not feeling ill enough to need it, and feeling satisfied with

existing methods of care (Sanders et al., 2012). It is important to understand barriers to participation in the first place as well as engagement once in a trial, in order to improve recruitment of a diverse range of participants to DHI research and ensure that the interventions which are developed are appropriate and appealing for everyone (Subramanian, Hopp, Lowery, Woodbridge, & Smith, 2004).

Overall, there were some known limitations in the diversity of this sample, and likely further limitations in other characteristics that were not captured. In addition, the trial setting and methods of recruitment may limit how transferable the findings are to other contexts. While this may seem quite negative, it is also worthwhile considering analytical generalisability, or the extent to which the concepts found to be important by the qualitative research were consistent with wider theory and literature (Smith, 2018). In this case, many of the benefits and burdens described by participants resonated with research conducted in different contexts, suggesting that there is evidence of some analytical generalisability. This implies that the findings make sense in other contexts as well as the present one under study.

One approach which has been used to explore transferability of findings is to ask a larger group of people from the population of interest how they feel: do the findings make sense, and do they seem to represent their experiences (Smith & Caddick, 2015)? If so, this could provide some evidence that the findings may be relevant beyond the immediate context of the trial. In this case, it might have been interesting to see if other participants in the trial who did not participate in qualitative interviews were willing to comment on the burdens and benefits found from this study, to further explore transferability.

Overall, this process evaluation suggested that in the context of hypertension, DHIs could seek to minimise burden and promote benefit by helping participants to perceive their readings as meaningful and BP control as achievable, managing concerns about medication, providing very clear actions following a raised reading, and offering patients additional support when BP readings were continuously raised.

5.3 Paper 3 Aim: To adopt a mixed methods approach to understand HCPs' experiences of and adherence to supporting patients to self-manage their blood pressure using a digital intervention.

The HCP mixed methods process evaluation explored how HCPs experienced and adhered to the HOME BP DHI. This paper suggested that planning medication changes in advance was well adhered to but several concerns were raised about the value of this system in practice. Adherence to changing medication was only medium and some prescribers described key concerns which seemed to inform clinical inertia. The paper also revealed interesting insights into using email to communicate with patients using a DHI, suggesting that this may be a feasible system going forwards but lack of feedback from patients could be a barrier to implementation.

This section will explore the implications of the findings in terms of the workload of using DHIs in practice, how DHIs might increase adherence to changing antihypertensive medication, and the feasibility of using remote communication with patients in a DHI in Primary Care. These insights expand on those discussed within the limited word count of paper 3.

5.3.1 Workload of DHIs

The findings from paper 1 regarding HCPs' concerns about increased burden created by DHIs in Primary Care were not generally found in paper 3, with HCPs seeming to perceive that the workload involved in the HOME BP intervention was acceptable. The online training provided for patients minimised the burden on HCPs in setting patients up in the study, which has been reported as an issue with tele-monitoring previously (Eccher, Botteri, Ortolani, Forti, & Piras, 2014) and may have helped make this DHI more feasible for integration into Primary Care. In addition, the feedback systems for HOME BP put the onus on the patient to act in the case of out-of-range readings, and provided HCPs with a recommendation for action in the case of a raised average reading, addressing the concern held by some HCPs of being held constantly accountable for monitoring patients' health status.

In terms of understanding the workload involved in DHIs, an extended normalisation process theory (ENPT) was recently developed which introduced the concepts of *Intervention Plasticity*; to what extent an intervention can be adapted to fit a new context, and *Context Elasticity*; to what extent a context can be changed to accommodate intervention processes (May, Johnson, et al., 2016). Paper 3 supported the importance of intervention plasticity in terms of how efficiently a DHI is implemented in practice. In most Practices, the prescriber took responsibility for medication change and the supporter took responsibility for supporting patients via email, but in some cases the prescriber adopted both roles, or the supporter dealt with all incoming information, organising the planned medication changes and simply sending the prescription to the prescriber to approve. Both these alternative systems appeared to work well according to the qualitative data and quantitative measures of adherence, and demonstrated the importance of the intervention being flexible enough to adapt to different ways of working (May, Johnson, et al., 2016). There was also evidence of context elasticity in the extent to which current ways of working could be modified to incorporate the new intervention procedures. Some HCPs had dedicated time to send patient emails whereas for others this was an additional task that had to be fitted into their already busy day. Therefore it seemed from this study that intervention plasticity and context elasticity were relevant factors which could influence how easily a DHI was implemented in different settings, supporting the value of these theoretical concepts as part of NPT.

5.3.2 **Changing medication**

This study also explored HCPs' perceptions of changing medication when patients' readings were above-target, the core behaviour through which the intervention was theorised to reduce BP. The quantitative findings showed that adherence was medium and fairly consistent with previous tele-monitoring studies for titrating antihypertensive medication (Bray et al., 2015; Schwartz et al., 2018), but the qualitative data found some prescribers described low perceived necessity for changing patients' medication and triangulation showed these prescribers had very low levels of adherence.

The Necessity-Concerns framework was relevant for explaining perceptions of medication change across all three pieces of research in this thesis, proposing that treatment perceptions are influenced by a balance between perceived necessity for medication and concerns about adverse outcomes (Horne & Weinman, 2002). Reasons for low perceived necessity described by HCPs in paper 3 included readings being too close to the target to warrant a change, and a concern that contextual factors such as illness or stress could have led to temporarily raised readings. This is consistent with doubts raised by HCPs using another tele-monitoring intervention to intensify

blood pressure treatment (Jones et al., 2013) as well as some of the concerns raised in a face-to-face hypertension intervention (Mant et al., 2016). Reasons for clinical inertia in more traditional clinic-based BP management did not arise, including doubts about the accuracy of BP readings, lack of confidence that increasing medication will reduce BP, concerns about side effects for the patient, and perceiving insufficient consultation time to manage hypertension (Khatib et al., 2014). This suggested that the DHI may have overcome some of the issues which can lead to clinical inertia, but for some prescribers there were additional barriers to address.

The qualitative findings suggested that some prescribers were resistant to changing medication throughout the trial, which was supported by the wide range of individual adherence rates (0-100%) found in the quantitative analysis. For some prescribers, it appeared that the online training was not sufficient to change beliefs about the importance of medication change, and more intense training to increase motivation to change medication and increase confidence in how to approach medication change with their patients might be beneficial, although this needs to be weighed against cost and feasibility. In addition, the quantitative data suggested that there was a tail-off in adherence to recommendations later on in the trial, when prescribers might have already tried a medication change for a patient which had been ineffective. As the qualitative interviews were mostly conducted in the first six months, the rationale for this increase in clinical inertia later on could not be fully explored qualitatively. Additional behaviour change techniques might be needed when several medication change recommendations were made for the same patient, such as guidance on how to discuss this with the patient. Borderline readings were a barrier to medication change in both the qualitative and quantitative findings, suggesting that tailoring prescribers' automated emails when average BP was close to the threshold might help reinforce the validity of the BP target and increase perceived need for change.

5.3.3 Remote communication

The option for patients to send queries or information about their BP readings to their HCP via the DHI seemed feasible and well-liked by both patients and HCPs. HCPs considered the amount of information patients sent to be manageable, except for a divergent case who was concerned about patients overusing the system. This is consistent with a study across several European countries which found that patients did not tend to inundate their HCPs with emails once this option was available (Newhouse, Lupiáñez-Villanueva, Codagnone, & Atherton, 2015). Some HOME BP supporters even wanted to hear more from their patients as they felt out of the loop, while others gave patients their email address so they could email directly rather than via the

intervention, suggesting that they wanted to hear from patients remotely. It is likely that the way in which the DHI provides access to email the HCP and the context in which this is framed for patients (in this case, specifically for queries relating to the DHI) might influence the balance between increasing patient access without creating unreasonable demand for HCPs (Atherton et al., 2018).

While receiving emails from patients was viewed quite positively by HCPs, using email to support patients in their self-management had a more mixed reception. Supporters felt ambiguity over whether remote patient support was consistent with their role or useful for patients, and this was supported by evidence that HCPs believed they could deliver better support in face-to-face consultations, and that these were more in line with their role (Hanna, May, & Fairhurst, 2011; Segar, Rogers, Salisbury, & Thomas, 2013; Smith et al., 2017). A few supporters described receiving positive feedback from their patients in response to their support emails, and one described how the email system had benefitted their care by enabling them to look up the most appropriate information to answer patient queries. Therefore it seemed that supporters' confidence that patients' needs were being met was an important factor in how acceptable they perceived email support to be.

There is growing interest amongst policy-makers in the potential for alternatives to face-to-face consultations in healthcare, both to increase access for patients and save time for HCPs (Department of Health, 2012b), but more evidence is needed on how this works in practice and in which contexts it is most acceptable and appropriate. In line with a recent detailed review of remote support in Primary Care, HOME BP supporters perceived real-time contact was important for more complex discussions (Atherton et al., 2018). There was also a perception in HOME BP that more anxious patients needed additional support to reassure them, which ties in with the findings from the review that remote consultations were more appropriate for 'sensible patients' (Atherton et al., 2018). This suggested that some HCPs make assumptions about patients' needs or suitability for remote support. The recent in-depth review found low usage of alternatives to face-to-face consultations by HCPs (Atherton et al., 2018), and evidence has found that HCPs prefer using telephone to email to contact their patients (Rutland, Marie, & Rutland, 2004). Against this backdrop, the finding from paper 3 that medications were intensified by letter or email in one third of cases in HOME BP may be more encouraging than it first appeared, suggesting there is potential for this remote medication titration system to be adopted in practice in some contexts, but that flexibility is important. The real-time baseline appointment to create the three-step plan was intended to lay the groundwork for subsequent contacts to be remote, and this may have increased the feasibility of remote medication change in this study.

5.3.4 Strengths and limitations

The mixed methods approach was a strength of this study as it facilitated the development of a holistic understanding of HCPs' experiences when using a DHI to manage hypertension.

Triangulating quantitative usage data indicating adherence against in-depth qualitative data exploring contextual influences and beliefs about behaviour change enabled key behavioural challenges to be viewed from different perspectives. The triangulation approach also allowed individual HCPs' adherence to target behaviours to be compared against their perceptions from the qualitative interviews, which was valuable in understanding how their beliefs appeared to inform their behaviour.

A challenge of triangulation was identifying which were the key findings of the qualitative and quantitative analysis in order to enable comparison. For the quantitative analysis, this was a clearer process as the key findings were extracted at the level of each discrete analysis or piece of data. The qualitative data were analysed inductively using thematic analysis which meant that each theme did not necessarily map to each quantitative finding. Therefore the extraction of some key qualitative findings was performed at the more specific level of subthemes and codes, extracting each finding which was relevant to the quantitative data to enable comparison. An alternative approach might be to adopt a more deductive approach to analysing the qualitative data, coding only data which related to the quantitative findings, but this would potentially prevent other insights being generated and is not in line with the principles of triangulation which enables two datasets analysed entirely independently to be subsequently integrated. The category of 'silence' was important for ensuring that one dataset could contribute a relevant finding, even if this was not found in the other dataset. The category 'partial agreement' was also important for cases where the two sets of findings complemented one another by offering different but compatible perspectives on an aspect of the intervention, although the label 'partial agreement' was felt to be slightly misleading in implying more contradiction than complementarity.

Another strength of the study was the use of the StaRI checklist, recommended specifically for implementation studies (Pinnock et al., 2017), which ensured transparent reporting of important issues such as contextual factors and rationale for the sample size which might have otherwise been missed. The GRAMMS checklist was also used to ensure the rationale, design, methods, integration, limitations and insights gained from the mixed methods design were transparently described (O'Cathain et al., 2008). However, the GRAMMS checklist did not provide a structure for evaluating the quality of the insights themselves. For this purpose, the concept of 'interpretive

'rigour' was useful (Tashakkori & Teddlie, 2008). This list of criteria helps researchers assess the credibility of their interpretations of the data integration, for example, whether the interpretations are consistent with each other, with theory, and with existing knowledge, and whether each interpretation draws sufficiently on both the qualitative and quantitative data. Checking the consistency of these outcomes with the existing evidence confirmed that they were in line with what we know about adherence to changing medication and implementing remote interactions with patients in Primary Care. In addition, the interpretations were consistent with one another and with the qualitative and quantitative data which contributed to them.

Overall, this mixed methods process evaluation helped establish which behaviours were most feasible for HCPs to implement in practice and why this might be. Concerns about planning medication change, initiating changes in response to raised readings, and supporting patients via email were interpreted with reference to the wider literature to help generate recommendations for optimising DHIs going forwards. These recommendations included online training for patients to reduce the workload on HCPs, careful use of feedback on patients' self-monitored data to minimise burden, a tool to facilitate confirmation that patients have received and understood information sent via email, and tailored support with explicit guidance on how to discuss medication changes with patients to address concerns about changing antihypertensive medication.

5.4 Theoretical implications

This section discusses the theoretical implications of this research thesis, including expanding the application of the Necessity-Concerns framework (Horne & Weinman, 2002), suggesting additional factors to take into account alongside the Burden of Treatment (BoT) theory (May et al., 2014), and considering the application of Normalisation Process Theory (NPT) going forwards (May et al., 2009).

This thesis suggested that the Necessity-Concerns framework can provide a useful explanation of *changing* medication as well as adhering to it (Horne & Weinman, 2002). Most hypertensive patients report high perceived necessity for taking their medication (93%, (Maguire, Hughes, & McElnay, 2008)) but perceived necessity for *changing* medication when BP was above-target seemed to be lower. Reasons for low perceived necessity amongst patients in this research included that the BP target was too low, that BP was adequately controlled as it was (this seemed more likely amongst older patients or those with co-morbidities), and that two weeks of readings over consecutive months did not give sufficient evidence that a change was needed. Meanwhile *concerns* appeared to centre around side effects, long-term dependency, damage to kidneys (a concern which seemed to arise due to the need to test kidney function when taking certain medications), and a general antipathy to increasing pharmaceutical drugs, which is consistent with evidence of a broader underlying concern amongst patients that drugs tend to have damaging effects and are over-prescribed by GPs (Horne et al., 2013; Horne, Parham, Driscoll, & Robinson, 2008). These concerns about changing their medication were fairly consistent with the concerns which influence patients' adherence to *taking* medication, but the rationale informing perceived necessity to change medication appeared somewhat different from perceiving the medication as necessary to take in the first place.

Mapping these findings on to the Necessity-Concerns framework suggested that this model could help conceptualise beliefs about changing medication, enhancing understanding of how to optimise this behaviour. Exploring whether perceived necessity and concerns assessed by the Beliefs about Medications Questionnaire (Horne, Weinman, & Hankins, 1999) are associated with patients' adherence to medication change might be a useful next step to explore this further. As perceived necessity and concerns also seemed to inform HCPs' decisions about whether to adhere to medication change, it may be useful to develop a measure to capture these beliefs amongst HCPs which can be correlated with adherence behaviour and help identify individuals who might be particularly prone to clinical inertia and need additional support when implementing a DHI.

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Paper 2 supported the BoT theory (May et al., 2014) in highlighting how the work involved in self-managing health can have dispersed burdens in someone's life. However, paper 2 also showed the importance of capturing the wider *benefits*, as for some patients these benefits appeared very influential in their evaluation of the DHI's worth and their willingness to use it. BoT theory and health economics evaluations view all time spent on healthcare as a burden or cost, but if engaging in healthcare is perceived as beneficial by some patients, this suggests that we might need to conceptualise outcomes of DHIs differently.

In addition, the process evaluation drew attention to more subjective aspects of health and well-being such as reassurance or anxiety, which are not accounted for by BoT theory where the focus is on the balance between tangible demands placed on the patient and their resilience and resources to manage this. Mapping the findings of the inductive analysis on to BoT theory did not help to understand patients' experiences of using a DHI, as important emotional burdens such as anxiety were amalgamated into broad social constructs, and benefits such as reassurance were not recognised at all. Therefore in this case, BoT theory did not help to achieve the aim of understanding perceived burdens and benefits of using a self-management DHI. This finding suggested that subjective benefits and burden may be important factors to take into account *in addition* to existing theory, as they seem to influence how much value patients place on DHIs and ultimately how willing they might be to use them. These outcomes are not currently measured by generic quality of life instruments such as the EQ5D, nor the Patient Experience with Treatment and Self-management questionnaire which focuses on more structural burdens such as side effects, attending appointments, and monitoring health (Eton et al., 2017), suggesting there may be a gap in current theory and measures regarding how to evaluate these more subjective responses to DHIs.

Finally, this thesis found support for all four social mechanisms identified by NPT as shaping the implementation of interventions. This was despite papers 2 and 3, as well as the preponderance of studies in paper 1, focusing mainly on the introduction of novel DHIs during trials rather than long-term implementation. This supports the concept that all four NPT mechanisms were relevant even at the relatively early stages of implementation when a DHI was being introduced to healthcare, rather than viewing the four mechanisms as a sequential process whereby *Coherence* is the first stage of implementation and over time this leads into *Cognitive Participation* and so on, (Alharbi, Carlström, Ekman, & Olsson, 2014; Blickem et al., 2014) or that *Coherence* needs to be achieved before any other normalisation process can occur (Finch, 2008). This thesis suggested that the social mechanisms were more dynamic than this and that *Collective Action* (the actual

work involved in enacting the tasks) did not depend on users having sufficient *Coherence* regarding the purpose of the intervention. This implies that when considering these theoretical constructs either prospectively in the design of an intervention or retrospectively in the evaluation of an implementation process, it is important to evaluate all four mechanisms throughout the intervention and be aware of how these might interact (Hooker, Small, Humphreys, Hegarty, & Taft, 2015).

5.5 Implications for clinical practice

The findings of this thesis suggested that a self-management DHI for hypertension was feasible to implement in practice, and the RCT (conducted outside the scope of this thesis) showed it was effective and cost-effective at lowering BP (McManus et al., Under review), despite the use of real time contact with HCPs in some cases. Given that many hypertensive patients remain poorly controlled in the UK (Joffres et al., 2013), this suggests that a self-management DHI may be a useful tool to lower BP and improve health outcomes. From the patients' perspective, self-monitoring BP at home for seven days a month was acceptable and compared with normal care this offered reassurance that they and their HCP could keep a regular eye on their readings. Having a purpose-built system for sharing home readings with the HCP was an important benefit over current practice, as many patients already monitored their readings at home but the DHI helped make the recording and sharing of readings more systematic, as well as providing feedback to aid decision-making about readings. Collating seven readings per month into one email notification with a clear recommended action for the HCP also created a manageable system for Primary Care. Encouragingly, patients seemed happy to self-monitor their BP after completing two sessions of core online training and the uptake to optional support appointments with a HCP was low, suggesting that online training was an effective way to train patients in the intervention procedures. Therefore DHIs might find it helpful to include carefully developed training for patients to promote cost-effectiveness and minimise input from HCPs. Considering how to feedback self-monitored data to HCPs most effectively also appeared important for DHIs.

Some elements of the DHI were potentially less feasible to implement in practice. Providing remote support for patients worked well for some HCPs but others still preferred to have real-time contact with patients. It seemed that a lack of communication received back from patients could be disconcerting, making HCPs doubtful whether their advice had been received, understood or valued when sent by email. Incoming emails from patients were acceptable to manage in practice for most HCPs and were not over-used by patients, suggesting that providing the option for patients to send additional information to their HCP within a DHI could be a feasible and helpful support tool. Going forwards this suggests that incorporating a quick 'chat' tool in DHIs through which patients can easily acknowledge receipt of clinical advice could be reassuring for HCPs and potentially promote engagement with remote support in clinical practice. This would need to be weighed against the burden on HCPs of increasing volume of emails, and the most feasible way for this to be integrated into existing systems would need consideration.

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The research implied that the DHI could be further optimised to facilitate implementation in clinical practice. To overcome patients' and HCPs' reluctance to change medication in response to raised readings, HCPs could be trained to discuss with the patient the likelihood of medication changes with more explicit reference to the fact that several attempts at finding the right combination of medication may be needed. This could help manage patients' expectancies about changing medication and normalise this process for them, as well as reassuring the HCP that the patient is ready to change their medication when needed. This discussion could also give the patient the opportunity to raise any concerns about changing medication or the BP target being appropriate for them, which could alleviate anxiety caused by these beliefs when self-monitoring at home. In addition, the process evaluation suggested that some patients appreciated receiving monthly support emails and liked being able to reply to their supporter to update them on how they were getting on. Supporters found this useful for reinforcing the value of their emails, which supports the suggestion above that a function within the DHI which facilitated two-way interactions by email might be beneficial.

5.6 Implications for research

This thesis has suggested several implications for further research. Conducting more than one process interview with the same participant over time could help further understand how experiences of the DHI interacted with perceptions of benefit and burden, and times when additional support might be beneficial. This would also enable exploration of benefit and burden at the very early stages of implementing a new DHI, as most of the current interviews were conducted several months into the trial when patients were already familiar with the procedures.

This research also held implications for evaluating benefit and burden during DHI research. The patient process evaluation suggested that intervention research needs to focus not only on the medical and behavioural aspects of self-management, but also the emotional consequences which to date have been less of a priority (Elissen et al., 2013). Further research might seek to develop a questionnaire measure to capture emotional benefits and burdens of using DHIs, which can complement the current treatment burden questionnaires that focus only on structural burden (e.g. attending appointments, taking medication) (Eton et al., 2017). This would enable intervention evaluations to assess how these perceptions about benefit or burden might relate to engagement with the intervention, and health outcomes. This has implications for policy decision-makers as if the outcomes which are important and relevant to patients in DHIs are not evaluated, this risks interventions being introduced that may have negative psychosocial impact for patients, which could ultimately compromise engagement.

It would also be useful to conduct further research to better understand the phenomenon of changing medication in response to raised readings. Ethnographic observations of HCP consultations with patients about medication changes during the study might help enhance understanding of reasons for clinical inertia and how to overcome this. Having established that perceived necessity and concerns seemed to influence decision-making about medication change, it would also be interesting to explore whether other factors known to influence medication adherence also inform perceptions of *changing* medication, such as social support (Anderson, Ory, Cohen, & McBride, 2000), pill burden (Mathes, Jaschinski, & Pieper, 2014) and the patient-doctor relationship (Benson & Britten, 2002; Zolnierek & DiMatteo, 2009).

5.7 Conclusions

The NHS 10-year plan released in January 2019 highlighted remote blood pressure management with digital access for patients and HCPs as a priority for the NHS going forwards (NHS, 2019). This PhD thesis adds to our understanding of some of the important considerations in implementing a successful digital health intervention for this highly prevalent condition.

The systematic review and process evaluations conducted within this thesis provided evidence that a digital health intervention for self-management of high blood pressure was acceptable and feasible for patients and healthcare professionals (HCPs) to use in practice. Self-monitoring appeared to be a powerful mechanism for patients which could induce feelings of reassurance or anxiety, and the feedback messages from the intervention were important for supporting patients and promoting appropriate behaviours in response to self-monitoring.

The beliefs which appeared to influence patients' acceptance and HCPs' adherence to medication change were consistent with the Necessity-Concerns framework. While this theoretical framework was developed to account for adherence to taking medication, the constructs of perceived necessity and concerns seemed to be relevant in the context of *changing* medication too. It may be that additional rationale in the notifications for HCPs and guided discussions between the HCP and patient about blood pressure targets and normalising medication change could help to overcome some of the barriers to changing medication. Further research could explore how best to overcome doubts about the need to change medication and the perceived adverse outcomes of changing medication, in order to help increase the effectiveness of DHIs for uncontrolled hypertension. Another priority identified for future research was to explore methods for capturing the perceived burdens and benefits of engaging with DHIs for patients, especially the emotional consequences such as anxiety and reassurance which are not currently captured by burden of treatment questionnaires.

5.8 Personal development

Completing this PhD has enabled me to develop my research skills in planning and designing research studies, conducting literature reviews, and in different methods of data analysis, including thematic synthesis, meta-ethnography, thematic analysis, and mixed methods integration techniques, and understand the appropriate application and limitations of each of these. I have also developed my specialist knowledge of the current evidence and theory in the area of self-management DHIs.

In terms of broader, transferable skills, I have advanced my project management skills for planning stages of a project and managing my time to prioritise tasks and achieve deadlines. I have developed advanced writing skills for communicating key messages from a project and writing for publication, having already published two of my papers. Alongside this, I have developed my critical thinking for interpreting the implications of research and increased my awareness of the wider policy implications of conducting public health research, and the issues associated with implementation and dissemination.

My experience in working on the HOME BP project led to me being asked to join a multi-disciplinary team to plan and develop a DHI for stroke patients. The skills I had acquired in behaviour change and the person-based approach enabled me to lead the development of the intervention content, which has been a rewarding and challenging opportunity.

Overall I feel my self-confidence as a researcher has increased and I have improved capabilities to adopt responsibility for planning and managing research going forwards.

Appendix A HOME BP Guiding principles

Intervention design objectives	Key features
To motivate patients and practice staff to undertake medication titration	<ul style="list-style-type: none"> • Education for patients and staff about benefits of titration and study procedures (e.g. quizzes to promote knowledge; evidence of need and efficacy) • Elements to promote patient and staff self-efficacy and autonomy for undertaking titration (e.g. skill building; emphasising health professional oversight) • Addressing concerns of patients and staff about medication side effects (e.g. encouraging realistic expectations about side effects; providing methods to seek advice on side effects), and of staff about patients' acceptance of medication titration.
To facilitate implementation of medication titration by patients and practice staff	<ul style="list-style-type: none"> • Carefully designed automation of practice-patient interaction to make implementation of titration procedures as easy and well-controlled as possible • In-built procedures to manage patient or staff concerns or objections to titration
Easy and low cost to implement the protocol	<ul style="list-style-type: none"> • Limiting the study co-ordinator role • Online training • No passwords for healthcare practitioner log on- to ensure easy access to procedures, training and documentation • Prioritising medication titration as the key behaviour in reducing hypertension

Appendix A

- | | |
|--|---|
| | <ul style="list-style-type: none">• Providing optional (and flexible) support at the most crucial time points |
|--|---|

Appendix B BP targets, based on NICE guidance

Systolic (SYS)	Diastolic (DIA)	What does this mean ?
180 or more	110 or more	<p>Red Reading: BP is too high</p> <p>Your feedback will be red if 1 or more of your readings during monitoring were red.</p> <p>You should contact your GP surgery within 48 hours (if you haven't already).</p>
135 - 179	85 - 109	<p>Amber Reading: BP is above target.</p> <p>Amber readings are based on the average of either your SYS or DIA BP (or both) being too high.</p> <p>If you get two sets of amber readings in a row, this is strong evidence that your BP has stayed too high for too long and you need to make a medication change. At this point your GP and nurse will be informed and will contact you to tell you what to do next.</p>
101 - 134	84 or less	<p>Green Reading: Target blood pressure.</p> <p>Green readings are based on the average of both your SYS and DIA BP being in this range.</p> <p>No changes are required to medication as your BP is currently well managed.</p>
100 or less	N/A	<p>Blue Reading: BP is too low</p> <p>Your feedback will be blue if 1 or more of your readings during monitoring were blue.</p> <p>You should contact your GP surgery within 48 hours (if you haven't already).</p>

Appendix C Patient feedback for a raised average

Your BP readings this week mean that you are in the amber zone. This means that your BP is still too high as your average readings are above the target for home bp readings for you of 135/85.

As it has stayed high for both weeks you measured it, this is very strong evidence that you need to make a medication change.

HOME BP has now emailed your HOME BP GP and nurse. Your HOME BP GP will give you a new prescription either by:

1. Posting you a new prescription to your home address over the next few days (this may take up to a week to arrive).
2. In some cases your GP surgery may phone you to ask you to pick up your new prescription from the surgery.
3. If your surgery normally uses electronic prescriptions they may email you to let you know that your prescription has been sent to your chosen pharmacy.

If you don't hear from your GP surgery about this in the next 10 days then please contact your surgery. You do not need an appointment with your GP or nurse, as they will give you the medication that they chose for you (during your appointment at the start of the study).

Do not worry – this change is not at all urgent so you can carry on taking your medication until your new prescription is ready. It usually takes 1 week - 10 days for your Practice to issue the new prescription and post the letter to you. If you do not hear within this time, please contact the doctor on the card you were given at the start of the study, or if you have lost the card - just ask the Practice who is the GP for the HOME BP study.

From the HOME BP team

Appendix D Automated email prompts received by HCPs to change patients' medication

Email sent to prescriber following two consecutive months of raised average readings:

Email subject line: Prescriber ACTION REQUIRED - HOME BP patient requires a medication change

Dear HOME BP Prescriber,

Your patient <insert username> has had BP readings that have remained above target for two consecutive months and is now required to make a medication change. They have been informed of this. Remember that the study protocol is for medication changes to go ahead without seeing the patient, unless there are unusual clinical circumstances that mean you need to see them. Specifically this email will provide you with the home BP data in order to facilitate titration without increasing workload in clinic. Most patients are happy to start or adjust a new medication change without seeing their GP.

Their readings last time they monitored were: <insert readings > The patient's new readings from the last week are: <insert new readings>.

Remember that the target thresholds for the study are based on the NICE guidelines for home BP readings: 135/85 for patients under 80 without diabetes, 135/75 for patients with diabetes, and 145/85 for patients over 80 without diabetes. The medication titration procedure is outlined below:

- 1- Print the prescription for the next medication change (you previously saved a list of future planned medication changes in the patient's notes).
- 2- Next complete the 'Patient medication letter' which your practice manager has saved on your computer system – you can also access a copy of this letter in HOME BP, just click the following link and go to the Forms area of the menu <insert link>.
- 3- Now post the prescription and patient medication letter to your patient, or alternatively leave these with the reception staff and ask reception to call the patient to collect their prescription and letter.
- 4- Save the letter to the patient notes, or use any other method that you wish to indicate in the notes that you have implemented the medication change.

For further information about the titration procedures or any other study information just click on the link <insert link >

Appendix D

If this link doesn't work for any reason, then you can open a new web page and copy and paste the link into the web-address bar at the top of your new web page. If you have any problems then you can also contact the study team (details below).

Thanks again for your help with this study.

From the HOME BP Team

Appendix E Template letter for changing patients' medication

Dear (insert patient's name),

Your blood pressure has stayed above target for too long and so you need to make a medication change to bring your blood pressure down, which is important to prevent health problems.

(Address any patient comments which were included in the email if appropriate)

I have looked at your blood pressure readings and recommend making the following change to your medication:

DRUG NAME	DOSE	INSTRUCTIONS

Additional instructions or comments (if any):

Blood test needed: **Yes/No**

If yes then specify the test(s), and any necessary instructions (e.g. timing of test):

Appendix E

When it is next time for you to monitor your BP, you will hopefully notice your blood pressure has reduced. If you have any problems with this medication, then just email your nurse through the HOME BP programme and we can arrange a suitable alternative for you.

With very kind regards,

Insert prescriber's name here

Appendix F Search terms for thesaurus and key word searches

Table F-1. Search terms for thesaurus searches by database

Database	Thesaurus terms
CINAHL	Self care
	Asthma, Hypertension (exploded), chronic disease
	Online systems, online services, internet, world wide web, computer systems, therapy computer assisted
Medline	Self-care
	Asthma, Hypertension, Blood pressure, Chronic disease
	Internet, online systems, computers, computer systems
Psycinfo	Self -care skills, self management, self monitoring

	Asthma, hypertension, essential hypertension, blood pressure, diastolic pressure, systolic pressure, chronic illness
	Internet, communication systems, information systems, computer applications, computer mediated communication, online therapy, telecommunications media, telemedicine, websites, computer assisted therapy, computer mediated communication, computer programming
Embase	Self care, self help, self medication
	Asthma, hypertension, elevated blood pressure, chronic disease
	Internet, online system, computer program, computer, computer assisted drug therapy, computer system, computer assisted therapy

Table F-2. Search terms for Ebscohost key word searches (PSYCinfo, Medline and CINAHL)

Source	E-health terms	Intervention terms	Qualitative methods terms	Chronic illness terms
Author consensus	Internet Online Digital Web E-health Telemonit*	Intervention Programme	Qualitative Interview Focus group Experience View Perspective Feedback Ethnograph* Thematic	Asthma Hypertens* Blood Pressure

Appendix F

			Theme	
			Mixed methods	
			Usability	
			Thinkaloud	
			Think aloud	
Morrison review terms	Computer*	Self-management		
	Technolog*	Self management		
	Telecommunication*	health education		
	Multimedia	Self care		
	PC	Self-care		
	Website	Self-monit*		
	WWW	Self monit*		

	Cellular Phone Cell phone Mobile Smartphone Smart phone Electronic Ehealth Mhealth M-health			
Knowles review terms	Telemedicine Text messag* Email		Open-ended Semi-structured	

Appendix F

	Telehealth		
	Teletherap*		

Table F-3. Search terms for Web of Science key word search

Source	E-health terms	Intervention terms	Qualitative methods terms	Chronic illness terms	Self-management
Author consensus	Internet	Intervention	Qualitative	Asthma	Self-management
	Online	Programme	Interview	Hypertens*	Self management
	Digital		Focus group	Blood Pressure	
	Web		Experience	Chronic illness	
	E-health		View	Chronic disease	
	Computer		Perspective		
			Feedback		
			Ethnograph*		
			Thematic		

			Theme		
			Mixed methods		

Appendix G CERQual evaluation of confidence in the third-order constructs

Table G-1. CERQual evaluation of confidence in the third-order constructs

CERQual categories	Studies contributing to the construct	Methodological limitations	Relevance	Coherence	Adequacy of data	Overall CERQual assessment of confidence	Explanation of decision
		Problem in design of primary studies that contribute to this concept.	The extent to which the body of evidence from the primary studies supporting a review finding is applicable to the context (perspective or population, phenomenon of interest, setting) specified in the review question.	The extent to which the review finding is well grounded in data from the contributing primary studies and provides a convincing explanation for the patterns found in these data.	An overall determination of the degree of richness and quantity of data supporting a review finding.		
Perceived purpose of the DI: Who is responsible?	Fairbrother (Fairbrother et al., 2014), van Kruijssen (van Kruijssen et al., 2015), Seto (Seto et	Minor concerns about methodological limitations:	High relevance to review question:	Minor concerns about the coherence of this finding.	No concerns about adequacy of data.	Moderate confidence*	Many of the studies in the review contributed to

<p>al., 2012), Zufferey (Caiata Zufferey & Schulz, 2009), Dinesen (Dinesen et al., 2013), Voncken Brewster (Voncken-Brewster et al., 2014), Williams (Williams et al., 2014), Fairbrother (Fairbrother et al., 2013), Hoaas (Hoaas et al., 2016), Burner (Burner et al., 2014), Urowitz (Urowitz et al., 2012), Tatara (Tatara et al., 2013), Hanley (Hanley, Fairbrother, McCloughan, et al., 2015), Cottrell (Cottrell et al., 2012), Hanley (Hanley et al., 2013), Hanley (Hanley, Fairbrother, Krishan, et al., 2015), Jones 2012, Leon (Leon et al., 2015), Lambert Kerzner (Lambert-Kerzner et al., 2010), Ure (Ure et al., 2012), Hartmann</p>	<p>20 of the studies contributing to this review finding met all or most of the NICE checklist criteria, 4 studies met some of the criteria and where they had not been met this was unlikely to affect the conclusions, and 3 studies had low quality meeting only a few of the criteria and this was likely to have affected the conclusions.</p>	<p>Studies concern patient population with chronic illness and a range of self-management DIs within the inclusion criteria.</p>	<p>The evidence from the studies provided a coherent argument and where there were exceptions, this seemed to be accounted for by DI design. However, more evidence would be useful to help account for why HCPs sometimes focus more on patient self-management.</p>	<p>There were rich data to support the finding across many studies.</p>	<p>this finding, and the pattern of results was consistent. Where there were discrepancies in the findings, these could be accounted for by the DI design.</p>
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	(Hartmann et al., 2007), Hallberg (Hallberg et al., 2015), Koopman (Koopman et al., 2014), Jones (Jones et al., 2013), Langstrup (Langstrup, 2008), Anhøj (Anhøj & Nielsen, 2004), Fairbrother (Fairbrother et al., 2012)						
Perceiving meaning in self-monitored data	Jones (Jones et al., 2012), Hallberg (Hallberg et al., 2015), Hanley (Hanley et al., 2013), Lambert-Kerzner (Lambert-Kerzner et al., 2010), Cottrell (Cottrell et al., 2012), Seto (Seto et al., 2012), Dinesen (Dinesen et al., 2013), Urowitz (Urowitz et al., 2012), Tatara (Tatara et al., 2013), Yu (Yu et al., 2014), Van Kruijssen (van Kruijssen et al., 2015), Hanley (Hanley, Fairbrother, Fairbrother et al., 2012)	Minor concerns about methodological limitations: 11 studies contributing to this finding met all or most of the checklist criteria, 2 studies met some of the criteria and where they had not been met this was unlikely to affect the	No concerns about relevance: All studies used a relevant self-management DI for a chronic health condition, and were relevant to the review.	Minor concerns about coherence: Studies are mainly consistent that having access to digital data promotes self-awareness and motivation to manage condition.	No concerns about adequacy of data: The studies contributing to this finding were rich and varied.	Moderate confidence*	This finding was reported across a range of rich studies, mainly of high quality. There were minor concerns about coherence in that two studies showed patients were not motivated to self-manage by self-monitoring, and our ability to account for

	McCloughan, et al., 2015), Williams (Williams et al., 2014), Roblin (Roblin, 2011), Hanley (Hanley, Fairbrother, Krishan, et al., 2015)	conclusions, and 2 studies had low quality meeting only a few of the criteria and this was likely to have affected the conclusions. Importantly though, one of the two studies which was a disconfirmatory case for this construct had low quality due to poorly explained data analysis and shallow results, limiting our confidence to account for the discrepancy (Roblin, 2011).		Yu (Yu et al., 2014) and Roblin (Roblin, 2011) refuted this finding, which was explained in terms of patients not feeling motivated to self-manage when they perceive their condition was not controllable, but more data would be needed to explore more fully whether this accounts for the discrepancy.			this was limited, especially as one of these studies was of low methodological quality. Further research would be needed to confirm or refute the explanation we have proposed.
Patients carefully consider recommended	Jones (Jones et al., 2012), Seto (Seto et al., 2012), Fairbrother (Fairbrother et al., 2013), Fairbrother (Fairbrother et al., 2014),	Minor concerns about methodological limitations:	Minor concerns about relevance:	Minor concerns about coherence:	Moderate concerns about the adequacy of data:	Moderate confidence*	The finding concerning medication change perceptions in

medication changes	Hanley (Hanley et al., 2013), Dinesen (Dinesen et al., 2013), Ure (Ure et al., 2012), Anhøj (Anhøj & Nielsen, 2004), Van Kruijssen (van Kruijssen et al., 2015), Hanley (Hanley, Fairbrother, McCloughan, et al., 2015)	7 studies contributing to this finding met all or most of checklist criteria, 2 studies met some of the criteria and where they had not been met this was unlikely to affect the conclusions, and 1 study had low quality meeting only a few of the criteria and this was likely to have affected the conclusions.	Studies from a range of conditions and DI formats contributed to this finding. The level of HCP involvement and type of feedback provided to patients was not fully reported in some papers, giving rise to some uncertainty when interpreting the findings, and causing minor concerns about uncertain relevance.	Evidence was consistent across studies, and where a discrepancy occurred in asthma patients' perceived necessity to change medication, this could be accounted for by different DI formats (Anhøj & Nielsen, 2004; van Kruijssen et al., 2015) .	Although some studies discussed perceptions about medication change in detail (Hanley et al., 2013; Jones et al., 2012) others did not provide rich data around this topic because it was not the focus of their research (Dinesen et al., 2013; Fairbrother et al., 2013) and therefore there is only	different health conditions appeared to be relatively consistent, giving rise to a coherent and relevant finding. However, further evidence from studies focusing on medication change would be useful to explore this further, and additional data may change or add to this finding.
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				relatively thin data to support the finding.		
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*Definitions of levels of confidence from the CERQual evaluation (Lewin et al., 2015):

High confidence: It is highly likely that the review finding is a reasonable representation of the phenomenon of interest

Moderate confidence: It is likely that the review finding is a reasonable representation of the phenomenon of interest

Low confidence: It is possible that the review finding is a reasonable representation of the phenomenon of interest

Very low confidence: It is not clear whether the review finding is a reasonable representation of the phenomenon of interest

Appendix H Quality appraisal of studies using the NICE checklist for qualitative studies

Table H-1. Quality appraisal of studies using the NICE checklist for qualitative studies.

	Theoretical approach		Study design	Data collection	Trustworthiness			Analysis					Conclusions	Ethics	Relevance	Overall assessment
Checklist Item*	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P
Anhøj (Anhøj & Nielsen, 2004)	1	2	1	2	3	2	1	3	1	2	1	1	2	2	1	-
Burner (Burner et al., 2014)	1	1	1	1	2	1	1	1	2	1	1	1	1	2	1	++
Cottrell (Cottrell et al., 2012)	1	1	3	1	3	3	1	3	3	3	1	1	1	2	1	-
Dinesen (Dinesen et al., 2013)	1	1	1	1	3	1	1	1	1	1	1	1	2	1	1	++
Fairbrother (Fairbrother et al., 2012)	1	1	1	1	1	1	1	1	2	1	1	1	1	2	1	++

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Fairbrother (Fairbrother et al., 2013)	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	++
Fairbrother (Fairbrother et al., 2014)	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	++
Hallberg (Hallberg et al., 2015)	1	1	1	1	3	1	1	1	1	2	1	1	1	1	1	1	++
Hanley (Hanley et al., 2013)	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	++
Hanley (Hanley, Fairbrother, Krishan, et al., 2015)	1	1	1	1	1	1	1	1	1	1	1	1	2	1	1	1	++
Hanley (Hanley, Fairbrother, McCloughan, et al., 2015)	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	++
Hartmann (Hartmann et al., 2007)	1	1	1	1	3	1	2	1	1	1	1	1	1	1	1	1	++
Hoaas (Hoaas et al., 2016)	2	1	1	2	1	1	1	1	1	1	1	1	1	1	1	1	++

Jones (Jones et al., 2012)	1	1	1	1	3	1	1	3	1	1	1	1	1	1	1	1	++
Jones (Jones et al., 2013)	1	1	1	1	3	2	2	1	1	2	1	1	1	1	1	1	++
Kerr (Kerr et al., 2010)	1	1	1	1	3	1	1	1	1	1	1	1	1	1	1	1	++
Koopman (Koopman et al., 2014)	1	1	1	2	3	1	1	1	1	1	1	1	1	1	2	1	++
Lambert-Kerzner (Lambert-Kerzner et al., 2010)	1	1	1	1	2	3	1	3	3	1	3	1	3	2	1	1	+
Langstrup (Langstrup, 2008)	1	1	1	2	3	3	2	3	1	3	3	1	1	2	1	1	-
Leon (Leon et al., 2015)	1	1	1	1	2	1	1	1	1	1	1	1	1	1	1	1	++
Roblin (Roblin, 2011)	2	1	3	1	3	1	2	3	3	3	2	1	2	1	2	1	-
Seto (Seto et al., 2012)	1	1	1	1	3	2	1	2	1	1	1	1	1	2	1	1	++

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Tatara (Tatara et al., 2013)	1	1	1	2	1	1	1	2	1	2	1	1	1	2	1	++
Ure (Ure et al., 2012)	2	1	1	1	3	1	1	2	1	1	2	1	2	2	1	+
Urowitz (Urowitz et al., 2012)	1	1	1	2	3	1	1	1	1	1	1	1	1	2	1	++
Vn Kruijssen (van Kruijssen et al., 2015)	1	1	1	1	3	1	2	2	3	2	2	1	1	1	1	+
Voncken Brewster (Voncken-Brewster et al., 2014)	1	1	1	1	3	1	1	1	2	2	1	1	1	1	1	++
Williams (Williams et al., 2014)	1	1	1	1	1	1	1	1	1	1	1	1	1	2	1	++
Yu (Yu et al., 2014)	2	1	1	1	2	1	1	1	1	1	1	1	1	1	1	++
Zufferey (Caiata Zufferey & Schulz, 2009)	2	2	1	1	3	1	2	2	2	2	2	1	1	2	1	+

*Checklist items:

- A. Is a qualitative approach appropriate?
- B. Is the study clear in what it seeks to do?
- C. How defensible/rigorous is the research design/methodology?
- D. How well was the data collection carried out?
- E. Is the role of the researcher clearly described?
- F. Is the context clearly described?
- G. Were the methods reliable?
- H. Is the data analysis sufficiently rigorous?
- I. Is the data 'rich'?
- J. Is the analysis reliable?
- K. Are the findings convincing?
- L. Are the findings relevant to the aims of the study?
- M. Conclusions
- N. How clear and coherent is the reporting of ethics?
- O. Is the study relevant to the review being conducted?
- P. Overall assessment: As far as can be ascertained from the paper, how well was the study conducted?

Scoring:

The NICE checklist's 3-point criteria were used for appraising each item. A '1' signifies the paper achieved the highest level for quality for that indicator, and a '3' signifies the lowest level of quality.

Overall assessment:

++ All or most of the checklist criteria have been fulfilled, where they have not been fulfilled the conclusions are very unlikely to alter.

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- + Some of the checklist criteria have been fulfilled, where they have not been fulfilled, or not adequately described, the conclusions are unlikely to alter.
- Few or no checklist criteria have been fulfilled and the conclusions are likely or very likely to alter.

Appendix I Consolidated criteria for reporting qualitative studies (COREQ): 32-item checklist

Developed from:

Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. *International Journal for Quality in Health Care*. 2007. Volume 19, Number 6: pp. 349 – 357

No. Item	Guide questions/description	Reported on Page #
Domain 1: Research team and reflexivity		
<i>Personal Characteristics</i>		
1. Interviewer/facilitator	Which author/s conducted the interview or focus group?	Page 109
2. Credentials	What were the researcher's credentials? E.g. PhD, MD	Page 109
3. Occupation	What was their occupation at the time of the study?	Page 109
4. Gender	Was the researcher male or female?	Page 109
5. Experience and training	What experience or training did the researcher have?	Page 109
<i>Relationship with participants</i>		
6. Relationship established	Was a relationship established prior to study commencement?	N/A
7. Participant knowledge of	What did the participants know about the	N/A

Appendix I

the interviewer	researcher? e.g. personal goals, reasons for doing the research	
8. Interviewer characteristics	What characteristics were reported about the interviewer/facilitator? e.g. Bias, assumptions, reasons and interests in the research topic	Page 109
Domain 2: study design		
<i>Theoretical framework</i>		
9. Methodological orientation and Theory	What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis	Page 110
<i>Participant selection</i>		
10. Sampling	How were participants selected? e.g. purposive, convenience, consecutive, snowball	Page 109
11. Method of approach	How were participants approached? e.g. face-to-face, telephone, mail, email	Page 109
12. Sample size	How many participants were in the study?	Page 110
13. Non-participation	How many people refused to participate or dropped out? Reasons?	Page 110
<i>Setting</i>		
14. Setting of data collection	Where was the data collected? e.g. home, clinic, workplace	Page 109
15. Presence of non-participants	Was anyone else present besides the participants and researchers?	N/A

16. Description of sample	What are the important characteristics of the sample? e.g. demographic data, date	Page 110-111
<i>Data collection</i>		
17. Interview guide	Were questions, prompts, guides provided by the authors? Was it pilot tested?	Page 109
18. Repeat interviews	Were repeat interviews carried out? If yes, how many?	N/A
19. Audio/visual recording	Did the research use audio or visual recording to collect the data?	Page 109
20. Field notes	Were field notes made during and/or after the interview or focus group?	Page 109
21. Duration	What was the duration of the interviews or focus group?	Page 110
22. Data saturation	Was data saturation discussed?	Page 109
23. Transcripts returned	Were transcripts returned to participants for comment and/or correction?	N/A
Domain 3: analysis and findings		
<i>Data analysis</i>		
24. Number of data coders	How many data coders coded the data?	Page 109-110
25. Description of the coding tree	Did authors provide a description of the coding tree?	Page 113-116
26. Derivation of themes	Were themes identified in advance or derived from the data?	Page 110
27. Software	What software, if applicable, was used to manage the data?	Page 110

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28. Participant checking	Did participants provide feedback on the findings?	Page 124
<i>Reporting</i>		
29. Quotations presented	Were participant quotations presented to illustrate the themes/findings? Was each quotation identified? e.g. participant number	Throughout results
30. Data and findings consistent	Was there consistency between the data presented and the findings?	Yes
31. Clarity of major themes	Were major themes clearly presented in the findings?	Yes
32. Clarity of minor themes	Is there a description of diverse cases or discussion of minor themes?	Yes

Appendix J Interview schedules for intervention and usual care group

Intervention group interview schedule

Opening questions

Can you tell me about what it is like for you to have high blood pressure?

How did you feel when you were first told you had high blood pressure?

Can you tell me why you decided to sign up for the Home BP study?

I'm really interested in hearing about your experiences of using HOME BP, can you tell me all about it?

Can you tell me about anything that you have liked about the HOME BP study so far?

Can you tell me about anything that you have disliked?

Can you tell me about any advantages of using HOME BP?

And can you tell me about any disadvantages of using HOME BP?

How do you feel about your high blood pressure now?

Do you think you would choose to keep on using the HOME BP programme if it was still available after a year?

Why/ Why not?

Would you recommend the HOME BP programme to other people with high blood pressure?

Self-monitoring

Experiences of monitoring:

Can you tell me about what it was like when you were learning how to use your BP monitor at home?

Can you tell me about the first time you used your BP monitor at home in the study?

Can you tell me about what it has been like to monitor your blood pressure yourself?

How did it make you feel?

Had you ever monitored your own blood pressure before you took part in the HOME BP study?

If yes:

Can you tell me a bit more about this?

Can you tell me whether you've noticed any changes in how you monitor your blood pressure since you've started the HOME BP programme?

All: Can you tell me about any concerns that you have about monitoring your blood pressure?

Adherence to the monitoring schedule:

The HOME BP programme reminds you to monitor your blood pressure for 7 days every 4 weeks.

Can you tell me about what it has been like for you to try and monitor your blood pressure for 7 days every 4 weeks?

Can you tell me about the time of day you have been monitoring your blood pressure so far?

How do you feel about the instructions HOME BP gives about when to monitor?

Was there anything that helped you to monitor your own blood pressure?

Was there anything that made it harder to monitor your own blood pressure?

Can you tell me about any time when you had to skip your blood pressure monitoring or change when you did it in the day?

Can you tell me how you found it entering your readings on the HOME BP programme?

Feedback messages

Remember after you enter your readings on HOME BP, you see a message which says 'your readings were amber, or green'? What did you think about these messages?

Can you tell me about how you felt when you saw a message about your blood pressure readings on HOME BP?

How did you feel about monitoring your own blood pressure after reading that message?

Did you have any very high or very low readings (red/blue) when you were monitoring in the HOME BP study? How did you feel?

2. Medication change

Can you tell me about what it's like for you taking medication for your high blood pressure?

Have you been recommended to make a medication change during the HOME BP study?

If yes:

How did you feel about making a change to your medication when HOME BP recommended it?

Did you make this change to your medication?

If they chose to make a change:

Can you tell me about what it was like to make a medication change in the HOME BP study?

Can you tell me about how the medication change came about?

How did you get on with your new medication?

How would you feel if HOME BP recommended a medication change for you now?

If they chose not to make a change –

Can you tell me about why you decided not to change your medication?

How would you feel if HOME BP recommended another medication change for you now?

If no:

If patient has not been recommended a med change: How do you feel about changing your medication if your blood pressure stayed too high for too long?

Can you tell me about any concerns that you have about doing this?

All:

How did you feel about making changes to your medication before you took part in HOME BP?

3. HCP support

Can you tell me about the contact you have had with your GP or nurse so far in the HOME BP study?

Can you tell me about how you have found the support from your GP or nurse while you were taking part in the HOME BP study?

Can you tell me what you thought about receiving emails from your nurse about HOME BP?

If needed, follow-up questions:

Have you seen your GP about your blood pressure since the start of the study?

And what about appointments with the nurse?

Can you tell me about how you have found the emails from HOME BP?

4. Healthy changes

Can you tell me about anything else that you do to try and manage your high blood pressure?

There is an option on the HOME BP programme to look at online sessions about making healthy changes that can help lower your blood pressure, I wonder if you remember if you have seen it?

If no:

Can you tell about how you might feel about making healthy changes to help lower your blood pressure?

If yes:

Can you tell me about how you found the session on healthy changes?

How did you feel about making the healthy changes this session talked about?

If they chose a change: Can you tell me about what made you choose this/these ones?

How did you find the online session about xxxx (cutting down on salt/alcohol/eating a healthier diet/doing more physical activity/ losing weight)?

Can you tell me about what it was like for you trying out this healthy change?

How did making a healthy change like this make you feel?

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Or if they didn't choose any: Can you tell me about why you didn't want to choose a healthy change?

All: Can you tell me about any concerns that you have about making a new healthy change?

Is there anything else you would like to tell me about the HOME BP study that we haven't already talked about?

Usual care group interview schedule

General questions about BP

Can you tell me about what it is like for you to have high blood pressure?

How did you feel when you were first told you had high blood pressure?

Can you talk me through what (if anything) you currently do to manage/control your high blood pressure?

Can you tell me about how your GP and practice nurse are involved in helping you to control your high blood pressure?

How do you feel about monitoring your own blood pressure at home?

If they already monitor – can you tell me a bit more about this?

Can you tell me about what it's like for you taking medication for your high blood pressure?

Can you tell me how you feel about your GP making changes to your blood pressure medication?

HOME BP study experience

Can you tell me why you signed up for the Home BP study?

Can you tell me all about what it has been like for you being in the HOME BP study in the usual care group?

At the start of the HOME BP study, you had a baseline appointment with a nurse at your GP Practice – can you tell me about that?

How did you find it using the HOME BP programme to fill in your questionnaires online at the start of the study?

After you had completed your questionnaires, did you have an appointment with your GP to check your blood pressure medication? Can you tell me about this?

HCP support

Can you tell me about the contact you have had with your GP or nurse so far in the HOME BP study?

Can you tell me about how you have found the support from your GP or nurse while you were taking part in the HOME BP study?

Appendix K Example of a template email provided for supporters to send to patients.

Dear *(insert patient's name)*,

I hope that this email finds you well. I was just wondering how you are getting on with monitoring your BP, I hope this is going well.

I've been reading about all the benefits that eating a healthy diet and being more active can bring you. These habits are great for bringing down your BP, but also really fantastic for preventing cancer, dementia and heart disease! I wonder how you are getting on with your healthy habits.

Often people find that they slip up from time to time, the best way to start again is just to draw a line under it and decide that today is a new day- a new opportunity to do something positive for yourself.

(If you think your patient isn't doing a healthy habit then omit this highlighted section)

Remember, if you get stuck or have any problems you can always send me a message through HOME BP- I'll always do my best to help.

Take care,

(insert name)

HOME BP *(insert title and practice)*

Appendix L HCP questionnaire completed before and after online training at baseline

The self-reported questionnaires were answered using Likert Scales to indicate agreement, and were designed using social-cognitive theory (SCT). SCT constructs were identified as proposed theoretical mediators in the HOME BP logic model (Bandura, 1991) (Figure 2).

Prescribers

These questions are designed to get a better understanding of different aspects of hypertension management.

Self-efficacy

Please rate how sure you are that **you** could do these behaviours right now by using the sliding scales given below: (*not at all sure – very sure*)

1. Create individualised patient medication plans
2. Increase patient medication when BP remains too high
3. Integrate the HOME BP programme in to regular care

Perceived intervention acceptability for patients

Please rate how sure you are that **your patients** could do these behaviours right now by using the sliding scales given below: (*not at all sure – very sure*)

1. Self-monitor their blood pressure at home
2. Enter their blood pressure readings in to the HOME BP programme
3. Make medication changes to control their blood pressure

Outcome expectancies

Please rate how strongly you agree with each of the following statements:

(1 = strongly disagree, 2 = disagree, 3 = neutral, 4 = agree, and 5 = strongly agree)

1. BP monitoring will improve patient hypertension self-management
2. The HOME BP programme will improve patient hypertension self-management
3. Pre-planned medication changes will improve patient hypertension self-management
4. BP self-monitoring will improve patient BP control
5. The HOME BP programme will improve patient BP control
6. Pre-planned medication changes will improve patient BP control

Appendix L

Supporters

These questions are designed to get a better understanding of different aspects of hypertension management.

Self-efficacy

Please rate how sure you are that **you** could do these behaviours right now by using the sliding scales given below: (*not at all sure – very sure*)

1. Support patients to self-monitor their blood pressure
2. Use the HOME BP programme to support patients
3. Integrate the HOME BP programme in to regular care

Perceived intervention acceptability for patients

Please rate how sure you are that **your patients** could do these behaviours right now by using the sliding scales given below: (*not at all sure – very sure*)

1. Self-monitor their blood pressure at home
2. Enter their blood pressure readings in to the HOME BP programme
3. Make medication changes to control their blood pressure

Outcome expectancies

Please rate how strongly you agree with each of the following statements:

(1 = strongly disagree, 2 = disagree, 3 = neutral, 4 = agree, and 5 = strongly agree)

1. BP monitoring will improve patient hypertension self-management
2. The HOME BP programme will improve patient self-management
3. Pre-planned medication changes will improve patient hypertension self-management
4. BP self-monitoring will improve patient BP control
5. The HOME BP programme will improve patient BP control
6. Pre-planned medication changes will improve patient BP control

Appendix M HCP Process interview schedule

General opening question(s)

1. I'm really interested in hearing how you have got on with the HOME BP study so far, please can you tell me all about how you are finding it?
2. What did you think of the prescribers' guide?
3. How easy has it been to follow the guidance given in the prescribers' guide?
4. Overall, what have you liked about the HOME BP programme so far?
5. What have you disliked about the HOME BP programme so far?
6. How would you like to see the HOME BP programme improved?

More specific questions:

7. How have you found the baseline medication review with patients in usual care?
8. How have you found the baseline medication review with patients in the intervention group?
9. What worked well?
10. What worked less well?

If haven't discussed: How are you finding it deciding patients' potential medication changes in advance?

Now thinking about those in the intervention group:

With respect to changing a patient's medications while they were in the study:

11. How have you found the medication change process?
12. After you saw the email about the medication change, what happened next?
(If they don't say - Did you see a patient when the medication change was due? *Trying to find out whether the patient came in for an appointment or if the med change was done remotely*)
 - a. If yes – How did you come to meet with the patient?
 - b. Can you tell me more about this appointment? (Aiming to find out who initiated it – patient or GP)
13. Have you had any patients who have had a red or blue reading?

If yes, how did you find the process of dealing with this?

14. How has it been for you receiving emails from the HOME BP programme?

Questions about supporting:

15. How do you think patients are finding the study so far?

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16. How have you found it acting as both the prescriber and the supporter for the study?

17. Overall, how do you feel about supporting patients who are using HOME BP?

18. Thinking about patients' screening appointments where you took consent and baseline clinical measures – how did you find these?

- a. What did you find worked well?
- b. And what worked less well?

Prompt (if not covered in replies): Why do you think this is?

If they raise problems: Can you think of any solutions?

19. Thinking about the first optional support session at around 4 weeks after a patient is randomised, have any of your patients chosen to come in for an appointment with you about monitoring their blood pressure?

If yes: how have you found these appointments?

- a. What are you finding works well in this appointment?
- b. And what works less well?

If they raise problems: Can you think of any solutions?

If no: How would you feel about having one of these appointments if a patient did want to see you at this point?

20. Patients in the intervention group are asked to practice monitoring their blood pressure for one week. Did any patients email you their practice blood pressure readings?

If so, how did you find this process?

21. Thinking about the second optional appointment at around 10 weeks after a patient is randomised, have any of your patients chosen to come in for an appointment with you to talk about choosing a lifestyle change that they want to make?

If yes: how are you finding this?

- a. What are you finding works well in this appointment?
- b. And what works less well?

If any problems: Can you think of any solutions?

22. How have you found using the CARE approach? (Congratulate, Ask, Reassure, Encourage)

- a. What do you like about it?
- b. What do you dislike about it?
- c. If the supporter raises that they didn't use the approach or did something else instead then ask them 'Could you tell me about what you did in the support appointments with the patients.'

23. How easy has it been so far to follow the guidance given in the supporters' guide?

24. How has it been giving patient support either face to face, by email or by phone?

- a. What sort of things have you liked about these methods?
- b. What sort of things have you disliked about these methods?
- c. Why do you think that might be?
- d. Can you think of any solutions?

25. How has it been sending a support email to each patient once a month through the HOME BP programme?

26. Have you received any emails from patients? How has it been responding to these emails?

Is there anything else that you would like to tell me about the HOME BP programme that we haven't already discussed?

Do you have any questions at all before we finish?

Appendix N Sociodemographic and study details of qualitative and quantitative HCP samples

Table N-1. Sociodemographic and study details of qualitative and quantitative samples

	Participants providing qualitative data (n=27)			Participants providing quantitative data (n=125)		
	Prescribers	Supporters	Prescriber-supporters	Prescribers	Supporters	Prescriber-supporters
n	13	11	3	62	58	5
Gender	5 female (38%)	10 female (91%)	3 female (100%)	22 female (35%)	55 female (95%)	3 female (60%)
Mean n of patients in intervention group at each Practice (range)	5 (2-10)	5 (2-8)	7 (2-10)	4.3 (-1-12)	4.4 (1-12)	6.2 (2-10)
Mean n of weeks from randomisation of first participant to time of interview (range)	29 weeks (17-54)	27 weeks (20-43)	20 weeks (16-24)	N/A		
Mean duration of interview (range)	26:14 (14-37 minutes)	29:02 (11-62 minutes)	43:19 (37-53 minutes)	N/A		
Mean n of recommendations for medication change received by prescriber at point of interview (range)	3 (0-7)	N/A	3 (1-4)	N/A		

Appendix O Adherence rates for HCP target behaviours

Table O-1. Adherence rates for target behaviours

Target behaviour	N incidents of adherence	Total possible incidents of adherence (n)	% adherence
Prescriber adherence to planning three medication changes	231	283	81.63
Prescriber adherence to initiating recommended medication changes within 28 days	215	405	53.09
Prescriber adherence to contacting patient remotely about a medication change	74	196	37.76
Supporter adherence to sending monthly support emails to patients	1611	2865	56.23

Table O-2. Spearman's correlations between questionnaire measures post-training and adherence to intervention behaviours

	Prescriber adherence to planning 3 medication changes (n=67) ^a	Prescriber adherence to initiating recommended medication changes within 28 days (n=59) ^b	Supporter adherence to sending monthly emails (n=61) ^c
Mean score post-training			
Self-efficacy	0.07	0.27*	-0.19
Outcome expectancies	-0.04	0.08	-0.15
Perceived intervention acceptability for patients	-0.11	-0.01	-0.02

* $p < .05$

Table O-3. Contextual patient factors and HCP adherence to medication change recommendations (n=405)

Variable	Cases of adherence	Cases of non-adherence	Test statistic	Effect size
Mean systolic BP reading	140.0 mmHg	136.7 mmHg	$t = -4.10$	$d = 0.41$
Mean diastolic BP reading	84.3 mmHg	82.9 mmHg	$t = -1.92$	$d = 0.19$
Mean age of patient	63.6 years	62.6 years	$t = -1.22$	$d = 0.12$
Median n of monthly BP entries	4	6	$U = 14127$	$r^2 = 0.07$
Median n of medication change recommendations already received for patient in question	2	3	$U = 14018$	$r^2 = 0.08$

Chi-squared tests revealed no difference between prescribers' adherence to medication change for patients with lower BP targets due to diabetes and patients with standard targets ($\chi^2 (2, N = 403) = 1.16, p > .05$) . Patients aged over 80 years with adjusted targets could not be included due to small sample size (n=2).

Appendix P. Excerpt from coding manual for thematic analysis of qualitative HCP process interviews

Theme	Sub-theme	Code	Definition	Quote
Belief in the concept of HOME BP as a BP management tool		Fit with direction of Primary Care management of BP	General buy-in to the idea of the study and what it was trying to achieve.	"a more efficient, effective way of managing people with blood pressure, with high blood pressure. And, you know, minimising appointment time, and sort of, again, maximising patient, sort of, feeling of self-control" (p2)
		Promotes patient empowerment and compliance	Discussing advantages for patients of engaging in self-management, such as	"I like that it empowers the patients to-to-to self-manage. And, again, I think that that's important in lots of ways. Particularly in something like blood pressure where patients don't feel ill, so you're encouraging them to take a medication and they can't see why. So with Home BP they can see

		empowerment or improved compliance	what's happening with their blood pressure, and they can see what their medication's doing" (ps1)
	Regular, more accurate approach to monitoring BP readings	Comparisons of home readings to clinic readings for informing BP management.	"I'm sure that's more accurate than the kind of ad hoc way we do it at the moment with a mixture of home readings and surgery readings" (p10)
Supporting patients to manage their own blood pressure	Planning medication changes	Planning changes was straightforward or tricky	How easy was it to plan medication changes in advance? "it depends on their previous experience and what they've already had. Because sometimes you do find yourself slightly boxed into a corner about what medication choices you can make, and trying to come up with one medication change can sometimes be tricky ". (p3)

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Appendix Q Content analysis coding of patient emails to the HCP, in order of most to least common (n=616 emails)

Table Q-1. Content analysis codes of patient emails sent to HCPs (n=616)

Reason for patient email	Definition of code	Example quote	Ask the nurse emails (n=331)	Emails re practice readings (n=64)	Emails re amber feedback (n=125)	Emails re recent medication changes (n=96)	SUM (n=616)
Logistics of taking or entering BP readings	Comments or questions about timings of BP readings, delays in taking or entering BP readings	I apologise for the lateness in sending out the latest readings. We went away for a couple of weeks and I forgot to take the BP monitor with me. All back to normal now. As I am behind in the study, when would you like me to do the next readings?	92	21	9	2	124

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Hypothesising reasons for BP readings	Questions or statements associating BP readings with lifestyle or events	Pain In right shoulder making it extremely difficult to use it at all. Does that affect the blood pressure values?	29	26	44	6	105
Side effects of BP medication	Any mention of health issues which the patient links to BP medication	Dr xxxx put me on Candasartan , which I started taking last Thursday, (18th), but have had such back ache and feeling wiped out , that I've decided not to take any more.	22	1	14	26	63
Update on BP medication changes or general health	Any reference to changes to BP medication or other health conditions	I am under the renal clinic with problems with my kidneys, The hospital has stopped the following medications	29	1	14	18	62
Logistics of organising appointments	Any questions about booking or changing study appointments, picking up BP monitor at baseline	Is it possible for me to either see you or have a phone conversation with you when convenient please?	44	1	14	2	61
Concern re amber feedback	Disappointment or anxiety about amber feedback, or	I have not yet started taking the new medication Doxazosin 1mg. as this will now be	27	0	21	12	60

or reluctance to change medication	decision to wait for next month rather than changing medication (patient inertia)	3 types of medication which I am not happy about.					
Happy to have green feedback on BP, or noticed that BP readings have improved	Patient is pleased to be well-controlled or comments that their BP is better than it has been. Not specifically linked to a medication change	I am pleased to say that I am in the Green Zone and just have to continue with my medication. I will continue with my readings when requested.	49	5	2	1	57
Success or struggle with lifestyle change	Comments or questions about lifestyle change, both positive and negative	Regarding exercise, I have a specific walk which I do every day with just the occasional exception e.g. raining a lot.	43	1	10	1	55
User issues with BP monitor or HOME BP website	Any difficulty with using BP monitor or HOME BP website	I can't submit my first entry, what do I do?	40	8	5	1	54

Appendix Q

Concern re BP readings	Concern about readings being high, low or variable.	The BP readings were often higher than they should be at other times of the day.	23	6	11	7	47
Confusion over GP Practice communication	Questions about changes to medication regimen or issues of lack of communication from the Practice about raised readings	I've had a letter from Dr xxxx saying double dose of Ramipril all done and sorted and am doing that. Should I stop the bisoprolol?	24	4	5	7	40
Logistics of renewing medication	Comments or questions about prescription renewals	I'm going on holiday late on Thursday 19th January, but am nearly out of my 5mg Remipril capsules. Would you please forward a prescription for these to Boots?	12	0	11	11	34
Happy with change to BP medication	Patient is happy with their BP medication change, may include comments that BP is better	Seems to have been effective	10	1	0	21	32

	controlled since the change						
Not (or only recently) started new BP medication	Recent medication change was not started, or only recently started. This is associated with emails sent relating to recent medication changes	Having been abroad for 2 weeks I was unable to start the new medication until day 2. I have been taking the higher dose since day 2.	0	0	6	19	25
Ran out of medicine or stopped medication	Patient has not been taking their BP medication recently, either due to errors in prescription or own judgment to stop taking it due to side effects	I tried it for about 7 days but it gave me very bad indigestion, affected my sleep pattern and generally made me feel very ill so I stopped taking it and within a couple of days was back to normal	2	0	8	6	16
Query re what next change will	Patient requests a medication change, or states they will wait to	Could you please increase my Nifedipress 20mg from TWICE A DAY to THREE TIMES A DAY, as decided at our consultation	1	0	11	3	15

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be or request for med change	hear from the GP about their upcoming medication change. This is associated with emails sent relating to medication change recommendations						
Confidence with BP practice session	Only applies to emails re practice readings. Patient states they are confident, or not confident, with taking their own BP after completing the practice session. (added after coding emailed re practice readings)	I am not sure if I am doing this correctly. I thought this additional info will be useful. I feel that an appointment may help in using the equipment and obtaining accurate readings prior to my first online readings.	0	12	0	0	12

No or little change in BP since medication was changed	Patient describes seeing no or little change in BP since medication was changed. Associated with comments made re recent med changes.	So far it doesn't seem to have made any difference, although I have tried taking BP in afternoon/evening to see what happens!	2	0	1	7	10
Teamwork with GP, patient offering opinion on BP control	Patient suggests a course of action for their BP management	I believe things are going very well as I hope you will agree when you read my reply. Hope you see my rationale for a slight juggling of my planned potential medication interventions.	6	0	1	0	7

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