**UNIVERSITY OF SOUTHAMPTON**

FACULTY OF HEALTH SCIENCES

# An exploration of older case management patients' physical health, function and strength; and the feasibility of measures of muscle strength as an aid to monitoring

By

**Nicola Jane Barnes**

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**UNIVERSITY OF SOUTHAMPTON**

**ABSTRACT**

**FACULTY OF HEALTH SCIENCES**

**Doctor of Philosophy**

# AN EXPLORATION OF OLDER CASE MANAGEMENT PATIENTS' PHYSICAL HEALTH, FUNCTION AND STRENGTH; AND THE FEASIBILITY OF MEASURES OF MUSCLE STRENGTH AS AN AID TO MONITORING

**By Nicola Jane Barnes**

Community case management services provide targeted care to patients with long term health conditions (LTCs) and complex needs, at high risk of adverse events such as emergency hospital admissions. However, there is no standardised evidence informed programme for providing such care, including for patient monitoring. The complexity of older patients, those most likely to have multiple LTCs, and who often present with frailty and atypical symptoms, enhance the difficulty of on-going monitoring and targeting of care. There is an established relationship between ageing and LTCs, frailty and muscle strength, and function and service use, suggesting that muscle strength may be a useful aid to monitoring. Whilst muscle strength is a known indicator for future health, it is not known whether monitoring it is feasible or useful as a short term indicator in older people, especially those at high risk of adverse events. Patients are initially identified for case management by predictive modelling and/or clinical judgement, but little is known about the patients who go on to receive such care. The feasibility and usefulness of routine measures of muscle strength to help clinicians provide timely interventions were investigated alongside case management patients' health, functional and physical status.

An initial pilot study in healthy older adults (n=21) investigated four portable measures of strength, grip strength, sniff nasal inspiratory pressure (SNIP), peak inspiratory flow (PIF) and peak expiratory flow (PEF), and confirmed, via the collection of repeated measures at two time points one week apart, the reliability and acceptability of all but SNIP. A follow on feasibility study explored the acceptability and stability of the three successfully piloted measures in case management patients (n=8) and clinicians (n=5) via researcher administered questionnaire, with the reliability and stability of the measures assessed using a variety of statistical tests including intra-class correlation coefficients and Bland-Altman plots, on data collected over a maximum 7 week period. Concurrently measures of physical and functional ability and health were conducted. A third study analysed routine primary and secondary care case management patient data (n=101), allowing the development of a health and demographic profile of patients, including an assessment of frailty.

The pilot and feasibility studies confirmed the reliability and acceptability of three portable measures of strength, PIF, PEF and grip strength. The high level of muscle strength stability observed in patients over the short-medium term, despite adverse events, suggested that whilst monitoring muscle strength may be feasible it would not be useful over this time period. Analysis of routine primary and secondary care data, identified case management patients as predominately female, with age skewed towards the older old and experiencing high levels of deprivation. Multiple LTCs were commonly recorded, and a wide variety of conditions noted. Health service use varied greatly, with few patients recording frequent usage. A frailty index suggested that frailty was common, and highlighted the potential for the development of a useful frailty index using routine data to improve the targeting of case management services towards those who are most at risk.

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# Declaration of Authorship

I, Nicola Jane Barnes, declare that the thesis entitled "An exploration of older case management patients' physical health, function and strength; and the feasibility of measures of muscle strength as an aid to monitoring" and the work presented in the thesis are both my own, and have been generated by me as the result of my own original research. I confirm that:

- this work was done wholly or mainly while in candidature for a research degree at this University;
- 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;
- where I have consulted the published work of others, this is always clearly attributed;
- 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;
- I have acknowledged all main sources of help;
- 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;
- parts of this work have been published as:
    - Barnes N, Agyapong-Badu S, Walsh B, Stokes M, and Samuel D (2014) Reliability and acceptability of measuring sniff nasal inspiratory pressure (SNIP) and peak inspiratory flow (PIF) to assess respiratory muscle strength in older adults: a preliminary study. *Aging Clinical and Experimental Research* 26(2):171-176.
    - Barnes N, Agyapong-Badu S, Walsh B, Samuel D, and Stokes M (2012) Reliability and acceptability of sniff nasal inspiratory pressure and peak inspiratory flow measurement in adults over 65. *Age & Ageing* 41, (S2), supplement Communications to the British Geriatrics Society Spring Meeting 16-18th May 2012, Llandudno, ii83.

**Signed:**

**Date:** 18/04/2015

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Finally a big thank-you to my family, my husband Lloyd and children Ellie and Jake, for their encouragement and understanding whilst I have been distracted!

# List of abbreviations

| | |
|---|---|
| ACG | Adjusted Clinical Groups |
| ADL | Activities of daily living |
| A&E | Accident and Emergency department |
| BI | Barthel Index |
| CHD | Coronary heart disease |
| CI | Confidence Interval |
| 6CIT | Six item Cognitive Impairment Test |
| CM | Case management |
| $cmH_2O$ | Centimetre of water |
| COPD | Chronic obstructive pulmonary disease |
| DCLG | Department for Communities and Local Government |
| DH | Department of Health, UK |
| FI | Frailty Index |
| GMC | General Medical Council, UK |
| GP | General Practitioner |
| GS | Grip strength |
| HHR | Hampshire Health Record |
| HSE | Health Survey for England |
| IADL | Instrumental Activities of Daily Living |
| ICC | Intra-class correlation coefficient |
| IMD | Index of Multiple Deprivation |
| kg | Kilogram |
| $kg/m^2$ | Kilograms per metre squared |
| l/min | Litres per minute |
| LSOA | Local Super Output Area |
| LTC | Long term condition |
| MDC | Minimal detectable change |
| MDD | Minimal detectable difference |
| MIP | Maximal inspiratory pressure |
| NHS | National Health Service, UK |
| NICE | National Institute for Health and Clinical Excellence, NHS |
| ONS | Office of National Statistics |
| PARR | Patients At-Risk of Readmission |
| PASE | Physical Activity Scale for the Elderly |

PEF Peak expiratory flow

PIF Peak inspiratory flow

PIS Participant information sheet

PSNC Pharmaceutical Services Negotiating Committee

Q Question

QIPP Quality, Innovation, Productivity and Prevention

QOF Quality and Outcomes Framework, DH

SD/Std. Dev. Standard deviation

SEM Standard error of measurement

SBS Sickness behaviour scale

SHARE Survey of Health, Aging and Retirement in Europe

SNIP Sniff nasal inspiratory pressure

T Time point

UK United Kingdom

USA United States of America

VES-13 Vulnerable Elders Survey

# Section One
# Introduction and background

# Chapter 1 Introduction

The United Kingdom (UK) is experiencing an ageing population (Office of National Statistics (ONS) 2010), alongside increasing demand for health and social care services (Department of Health (DH) 2012a). As people age it is increasingly likely that they will have a long term health condition (LTC), such as diabetes, heart failure or chronic obstructive pulmonary disease. These are conditions that cannot be cured but can be managed to a greater or lesser extent by medication and/or therapy. Three out of five people aged 60 years and over are living with at least one LTC, and most over 75s are living with three or more LTCs (DH 2012a). LTCs have significant cost implications for the National Health Service (NHS) and health services across the globe, as people with LTCs are intensive users of primary and secondary care services (DH 2012a), particularly those associated with adverse events such as emergency hospital admissions. The Department of Health estimate that the treatment and care of people with LTCs accounts for nearly £7 in every £10 of the total health and social care spend in England (DH 2012a). For this reason there has been considerable effort spent in relation to the effective management of long term conditions. For over a decade improving the care of patients with LTCs has been a priority for health service providers and commissioners, despite which there is a lack of standardised evidence based programmes to provide this care, including within the NHS. One area in which evidence is lacking is the identification of patients with long term conditions who are most at risk from an adverse health event. This identification is important to aid the targeting of specialist LTC care, such as community based health case management, to those who need it most. Targeted care such as health case management provides multidisciplinary health and social care proactively to patients in their own homes, led and co-ordinated by a case manager, with the aim of preventing avoidable unplanned hospital admissions. This care may include physiotherapy, occupational therapy, medication review by a pharmacist, social care review and support, as well as nursing care, support and education.

By targeting care to those who need it most, when they need it most, it is hoped that patients are enabled to remain independent in their daily activities, avoid adverse health outcomes and achieve a prolonged higher quality life. Unfortunately targeting care and on-going monitoring assessment and diagnosis is made harder by atypical presentation, which is frequently observed in older, frail patients, who are likely to have multiple LTCs. A combination of the physiological changes of normal ageing and specific long term conditions, along with pathological changes associated with long term conditions in general, such as chronic inflammation, complicate diagnosis and treatment, and often result in more general functional disability rather than the more obvious disease specific symptoms observed in younger adults (Hunt *et al.* 2009). Enabling the identification of such functional declines in the presence of atypical presentation and complex

symptoms provided impetus to this research study, specifically in relation to older patients with LTCs already receiving targeted community based health case management.

Case management is a model of care, providing community based integrated care in a targeted manner to patients with multiple long term conditions and complex health needs who are at high risk of an adverse health event, such as an unplanned hospital admission, accident and emergency (A&E) attendance or fall. Care is co-ordinated for each patient by an experienced case manager, and varies from patient to patient according to their needs. Care frequently involves multiple health and social care professionals and services, and may involve physiotherapists, occupational therapists, social workers and pharmacists as well as nurses. Whilst care understandably varies between patients according to need, a large disparity between services across the country has been observed, with no standardised service framework (Challis *et al.* 2010). Anecdotally, increasing pressure on case management services is occurring, in terms of higher numbers of patients being referred for such care, compounded by no apparent increase in service capacity. Case management services cannot continue to follow such a trend without services reaching capacity, beyond which they will be unable to provide safe and effective care to existing or new patients. A strain on case management services in terms of patient numbers is also likely to place a strain on case management providers, placing staff wellbeing at risk. Drivers for the increasing numbers of referrals into case management services are expected to include:

- the increasing number of older people in the UK population;
- the increasing number of people living with LTCs;
- financial pressure on health care commissioners and providers, and linked targets for keeping people out of hospital;
- policies re-allocating funding from secondary care to primary care e.g. Better Care Fund programme (DH 2013);
- an increase in the number of people identified as being at risk of a hospital admission/ who may benefit from case management services;
- the lack of evidence informing case management practice, impacting effectiveness; and
- the lack of specific focus of the service and broad referral criteria.

A number of these drivers cannot be influenced by current health service commissioners or providers, such as the ageing population. Focus should be given to the areas that can be influenced, including ensuring that the current services are being provided efficiently. Better assessment and ongoing monitoring of patients receiving case management may enable more timely interventions by the case management team, increasing their effectiveness, and may allow

teams to manage larger numbers of patients. Improvements to monitoring may well open up the opportunity for patient self-monitoring with/without support of technology such as telehealth.

Lack of guidance and evidence regarding what should be monitored and assessed to enable timely interventions is likely to be contributing to the disparity between case management services across the country and inequality in its provision to patients. The presentation of atypical symptoms is likely to make assessment and monitoring using usual diagnostic methods and tools, such as symptom report, less useful. Thus research into the usefulness of monitoring alternative domains, such as function, is a priority. These alternative measures may prove more useful to the clinician in helping to detect imperceptible changes in health that precede the occurrence of a more significant functional decline, health event or crisis.

However, questions remain about which measures are feasible and useful. There is an established relationship between ageing and LTCs, both of which are associated with an increased degree of frailty and a reduction in functional ability and muscle strength, all of which are associated with health service use. This relationship suggests that muscle strength may be a useful aid to monitoring, helping identify patients at high risk of decline in health and function and resulting unplanned health service use, in particular hospital admissions. Muscle strength may be especially useful as its measurement can be objective, simple and non-invasive (Fried *et al.* 2001; Cawthorn *et al.* 2007; Syddall *et al.* 2010). However, the existing evidence focuses on longer-term changes (years) in muscle strength, health and function; there is insufficient information on the most appropriate measure to use, and the impact of changes over the short to medium term (weeks and months). There is also a lack of descriptive information about the patient group receiving case management services, so that, although muscle strength and its possible association with decline in health and function seems reasonable, little is known about this in this patient group.

The aim of the research described in this thesis was to examine muscle strength in patients receiving case management, comparing different measures, exploring stability, reliability and acceptability, over the short to medium term. Additionally the study aimed to explore the relationship between muscle strength, function and service use in this patient group and determine if case management could be aided by introducing muscle strength measures into on-going monitoring. Figure 1.1 demonstrates the key concepts underpinning the research, and the key questions unanswered by current published research.

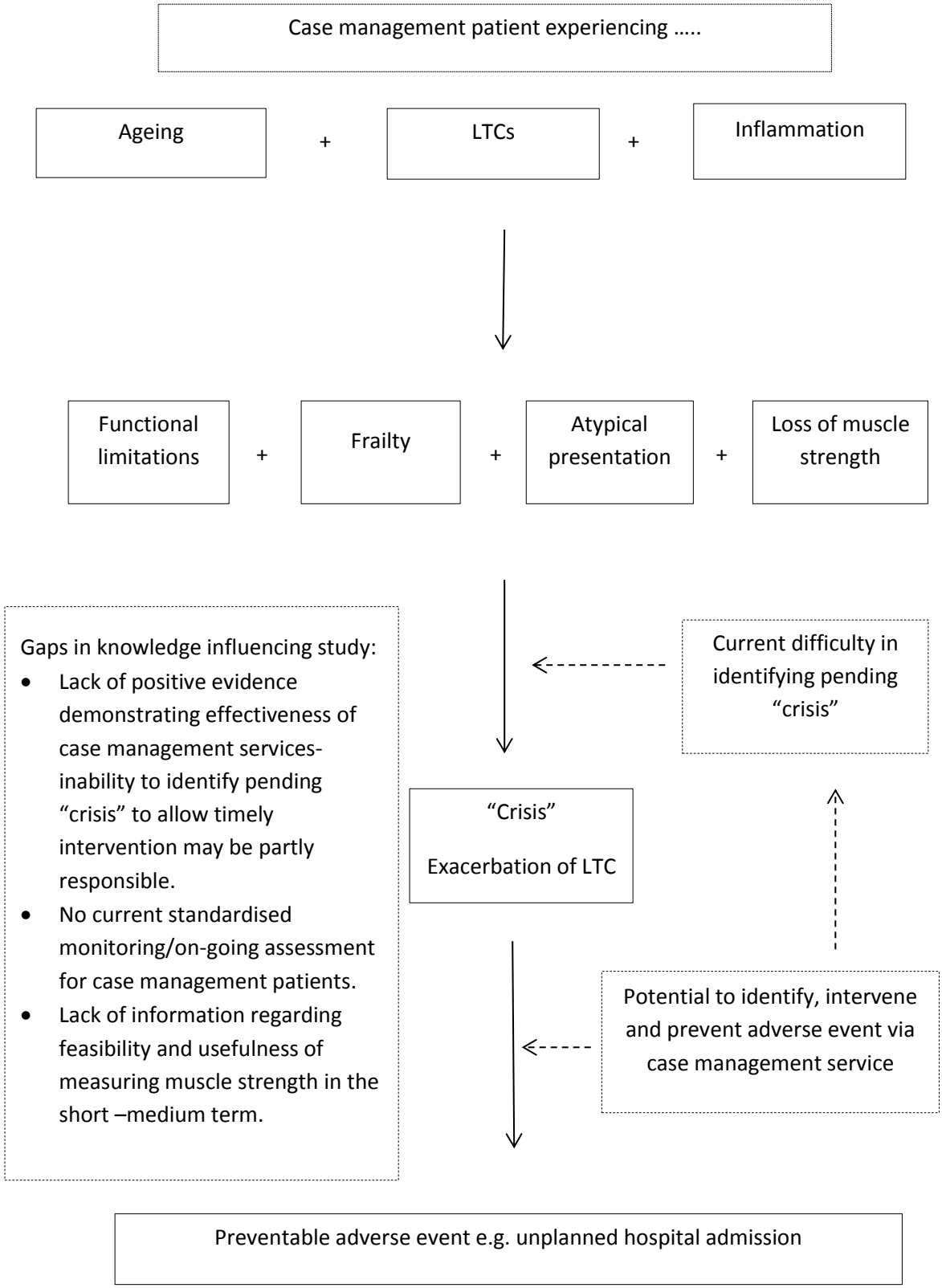



**Figure 1.1 Underpinning rationale to research study**

More specifically this thesis details three studies which contribute to this aim and knowledge gaps: a pilot study of four portable measures of muscle strength in self-reported, healthy, medically stable adults aged 65 years and over; followed by a feasibility study in case management patients of three measures of strength successfully piloted; and finally a study of routine primary and secondary care data collected on patients receiving case management services enabling a description of a case management patient cohort, including aspects of health, function, physical and social status.

The first study established the reliability and acceptability of portable measures of strength (the relatively new measures of sniff nasal inspiratory pressure (SNIP) and peak inspiratory flow (PIF), alongside the more established grip strength and peak expiratory flow (PEF)), in a sample healthy population aged 65 years and over. The second study, an observational, longitudinal study explored the feasibility of three successfully piloted measures of strength as monitoring aids in patients with LTCs receiving targeted case management services. The three measures found to be acceptable and reliable in the previous pilot study included PIF, PEF and grip strength. The feasibility study in patients aimed to investigate and consider the stability of muscle strength in the short to medium term, the acceptability of the measures to patients and clinicians, and to gather observational descriptive data on health and functional status. Observational muscle strength, health and functional data enabled an initial exploration into whether detectable changes in muscle strength may be related to changes in functional ability and adverse health events in the short to medium term. The third study involved the review and analysis of pseudonymised routine primary and secondary care data, gathered from a local combined access database. This database analysis allowed a large number of patient records to be analysed providing information on the health status of the patient group of interest, those receiving case management services, about whom ambiguity exists. All three studies are described in detail in Section Two.

The structure of the rest of this thesis is as follows. Section One, Chapter Two presents the literature relating to ageing, LTCs and their management, focusing on the management of patients with multiple LTCs, providing the background and setting the context for this research study, in particular within the NHS framework. Section Two details the empirical work undertaken including a methodological review, and then details each of the three studies in turn, through study aims to findings. Section Three contains a synthesis of the findings from the three research studies undertaken with discussion, conclusion and the implications for future research and potential impact on clinical practice considered.

# Chapter 2 Background and literature review

## 2.1 The ageing population

The UK has an ageing population; in 2009 16% (9.9 million) of the UK population were aged 65 years or older, by 2034 this is expected to increase to 23% (16.6 million) (ONS 2010). Within this changing demographic the fastest population increase has been in the oldest old, those 85 years and over, in the 25 years to 2009. By 2034 there are expected to be 3.5 million in this group, a growth of 250% from 2009 (ONS 2010). These trends within the UK present challenges for social and health care services, due to increasing health and social care needs associated with ageing. It has been suggested that public expenditure on social and continuing health care for older people will rise to £12.7 billion by 2022 (from £9.3 billion in 2010), to keep in line with the needs of the older demographic and cost pressures (Wittenberg *et al.* 2012), largely as a consequence of an increased prevalence of LTCs.

## 2.2 Long term conditions

As people age they commonly live with LTCs. These are health conditions that can be managed to a greater or lesser extent, with medication and/ or therapy but which may limit a person's independence, and increase their vulnerability to adverse events and reliance on health and social care services and informal carers (Cornwell 2012). Whilst there is no definitive list of LTCs, arthritis, diabetes, asthma, chronic obstructive pulmonary disease (COPD) and coronary heart disease, can all be classed as LTCs. Figure 2.1 illustrates those body systems involved in the most commonly reported LTCs in those aged 65 years and over in the UK.

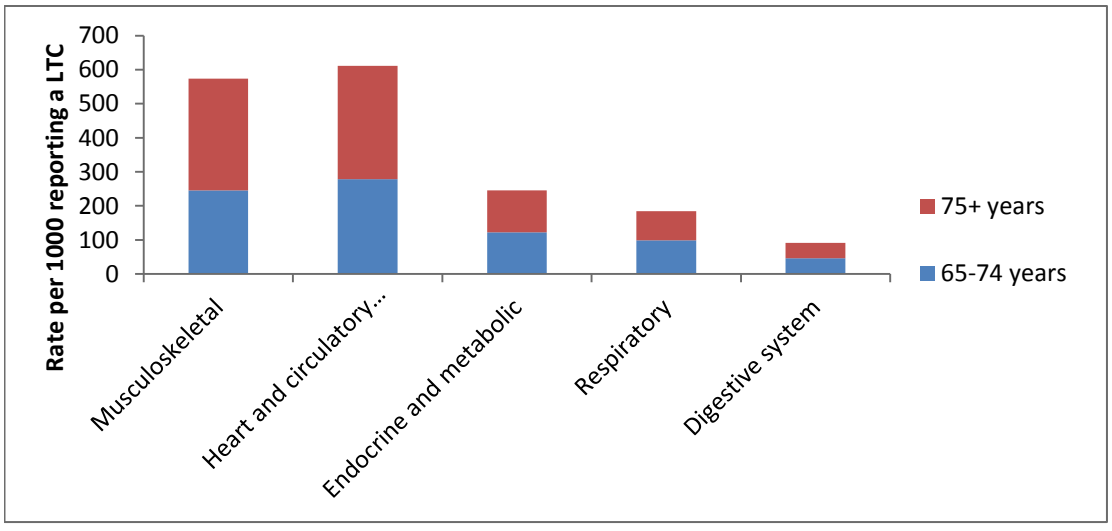



**Figure 2.1 Top 5 long-standing conditions groups reported in older people in the UK**

(General lifestyle survey 2010, ONS 2012)

Age is the most significant driver of the prevalence of LTCs, with three out of five people aged 60 years and over living with at least one LTC, and the majority of over 75s living with three or more (DH 2012a). With the ageing population it is predicted that the number of people with multiple LTCs will rise by 1 million, from 1.8 million in 2008 to 2.8 million in 2018, with an additional cost to NHS and social care services of £5 billion (compared to 2011)(DH 2012a). As the prevalence of LTCs increases with age, so does the prevalence of multiple LTCs, which complex interplay is likely to increase a person's vulnerability to an adverse event such as an unplanned hospital admission.

## 2.3 Ageing, long term conditions and hospital admissions

Patients over 65 years of age account for around 60% of hospital admissions and 70% of bed days within the NHS (Oliver 2012); it has been suggested that the main activity of general hospitals is the care of older people with multiple LTCs (Oliver 2008a, 2012). Both LTCs and age are risk factors for emergency hospital admission (Hunt *et al.* 2009; Purdy 2010); higher levels of recorded morbidity and chronic disease in general practice have been shown to be associated with higher rates of emergency admissions (Saxena *et al.* 2006).

There has been a 12% increase in the number of costly emergency admissions (£11 billion per year) in England from 2004/5 (4.4 million admissions) to 2008/9 (5 million admissions), and these account for approximately 65% of hospital bed days in England (2007/8) (Blunt *et al.* 2010). The DH defines emergency admissions as those that are unpredictable and arise at short notice due to clinical need. This 12% increase in the number of emergency admissions has been associated with a large rise in short-stay admissions, suggesting that less severe cases are being admitted, and highlights the potential for admission avoidance through better management in primary care, particularly of LTCs (Blunt *et al.* 2010, DH 2001).

Avoiding emergency hospital admissions is not only of concern due to their high unit cost when compared to other types of care, but also because of the disruption they cause to elective healthcare and the patient (Purdy 2010). The efficiency savings needed in the current economic climate require an urgent examination of areas of expenditure which may be avoidable, and this includes avoidable hospital admissions (DH 2010; Appleby *et al.* 2010). As two significant risk factors for emergency hospital admission are the presence of long term conditions and ageing, the importance of effectively managing patients with long term conditions within primary care is apparent (Hunt *et al.* 2009; Purdy 2010). Efforts have been made over at least the past 40 years to introduce and provide more proactive LTC management in the community to frail older patients

via numerous projects in worldwide healthcare programmes to help avoid unplanned hospital admissions (Johri *et al.* 2003). The New NHS white paper (DH 1997) paved the way for the first National Service Framework for a long term condition (coronary heart disease, DH 2000); numerous policy papers have since highlighted the need for improvements in long term condition management to enhance the quality of life of people with long term conditions, and reduce avoidable hospital admissions (DH 2011). Whilst highlighting the importance of the care of people with long term conditions, the NHS Outcomes Framework 2012/13 reiterates the need for further work before clear guidance on how to achieve this is provided (DH 2011). The NHS Quality, Innovation, Productivity, Prevention (QIPP) programme's long term condition stream specifically aims to reduce the number of unplanned hospital admissions by 20% and the length of hospital stays by 25%, encouraging supported care planning (DH 2011, DH2012b). It is also hoped that such improvements will improve the efficiency of long term condition management and eventually produce cost savings in the care of people with LTCs.

Hospital admissions for ambulatory care sensitive conditions, i.e. those admissions that can be reduced by timely effective ambulatory care (mainly primary and community health care services, social services, and outpatients' services), have increased even relatively recently. Between 2001 and 2011 hospital admissions in England for ambulatory care sensitive conditions increased by 40%, to just under 1 million admissions annually (Bardsley *et al.* 2013). Whilst a change in the demographic is likely to account for some of this rise, it is unlikely to account for all (Walsh *et al.* 2008). There is variation within the increase in ambulatory care sensitive conditions, with some conditions seeing a marked rise in admissions, for example chronic obstructive pulmonary disease (COPD) and epilepsy, whilst admissions for others such as congestive heart failure and angina have reduced, suggesting some positive impact of long term condition management services in primary care.

## 2.4 Long term condition management

Pro-active management of patients at high risk of admission in the community, rather than providing primarily reactive care, is one approach to curtail the rise in costly emergency hospital admissions (DH 2012a). The Kaiser Permanente Triangle (Figure 2.2) illustrates the approach supported by numerous NHS policies (DH 2004, 2005) to improve the management and care of patients with long term conditions. Supporting self-care for the majority of patients with long term conditions, educating patients and encouraging patients to manage their own conditions; specific disease management for those with multiple long term conditions, with nurses' actively supporting patients; and case management provided by a community matron or case manager for the most complex, high risk patients. The Kaiser Permanente Triangle indicates that the balance of LTC care should be weighted towards primary care and away from secondary care.

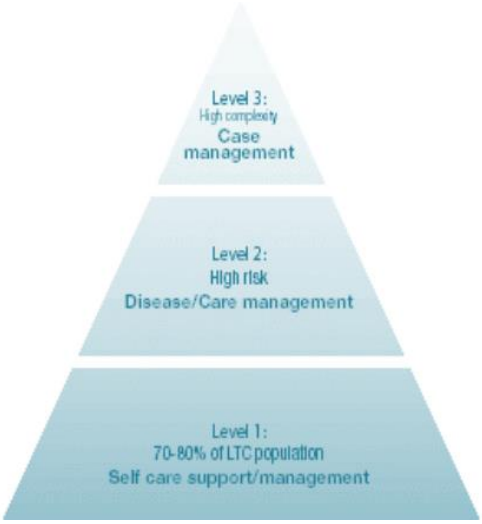



**Figure 2.2 Kaiser Permanente Triangle** (DH 2005)

The Wanless review (2007) of NHS funding and performance recommends work to ensure the correct balance of care between primary, secondary and social care, and concludes that the current NHS care model is still too focused on the acute hospital setting. Delivering better targeted, balanced and integrated care to patients who experience the most ill health forms the basis of two out of five Wanless review recommendations. Public consultation suggests members of the public want seamless, proactive and integrated health care services tailored to their needs, which will help them remain independent, ideally provided in the community or their home (DH 2012a). The long term conditions QIPP agenda attaches financial incentives to better LTC care and the reduction in avoidable hospital admissions for health and social care commissioners and providers (DH 2011). Most recently the Better Care Fund plan introduces a pooled budget for health and social care services to aid the implementation and provision of more integrated NHS and local authority services for older and disabled people (DH 2013).

It has been suggested that the variation in the number of emergency hospital admissions in England cannot be explained by variation in ill health alone, and that the impact and effectiveness of services to prevent emergency hospital admissions currently varies across the country (Audit Commission 2011). A number of interventions have been introduced to try and reduce the number of avoidable hospital admissions; unfortunately good quality evidence supporting many

of the interventions is lacking. Some interventions are supported by evidence showing a positive effect e.g. self-management amongst patients with LTCs, and integration of primary and secondary care. Features inhibiting more successful LTC management are frequently highlighted as the institutional divisions between primary and secondary care including within funding, administrative and clinical levels including the absence of shared electronic records, and a lack of shared aims across organisations and systems (Shaw *et al.* 2011; Nuffield Trust 2013a). Whilst integration of services at the patient level has long been discussed and evidenced, the need for integration at higher levels has more recently brought into focus (Shaw *et al.* 2011; Coulter *et al.* 2013; DH 2013). Figure 2.3 illustrates increasing levels of integration, starting from basic linkage to full integration ideally required. Where patients have complex social and healthcare needs, requiring input from primary, secondary, social and possibly tertiary care, effective integration becomes a more obvious need. Lack of integration may act as a barrier to the provision of effective and efficient services.

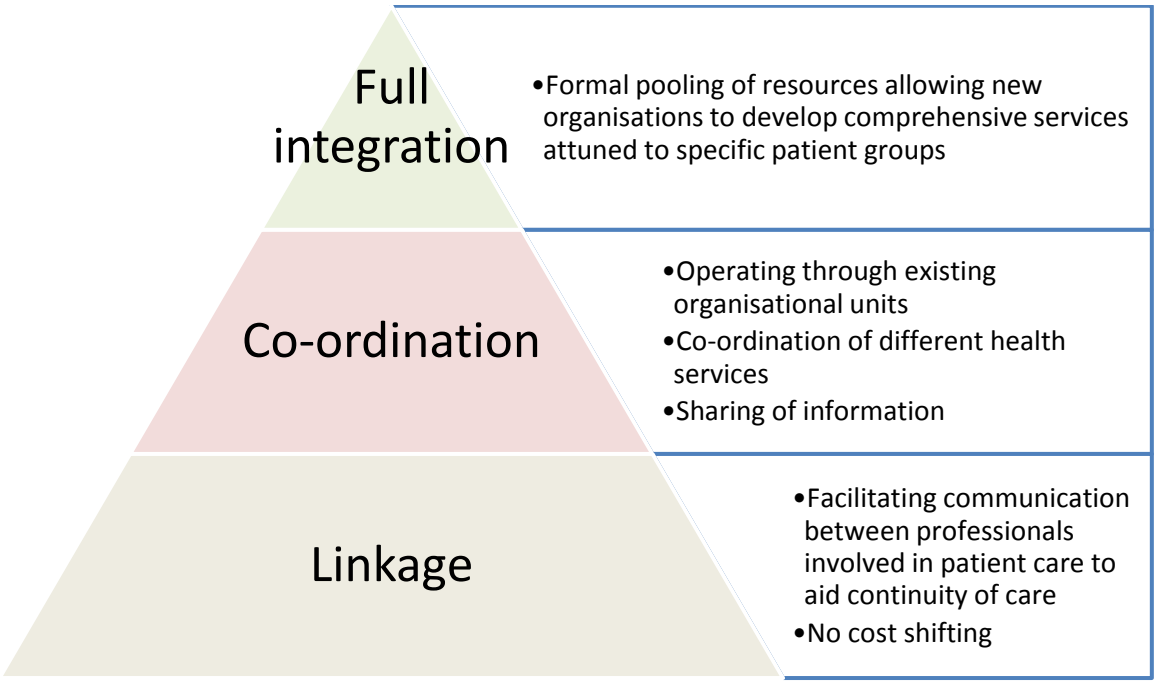



**Figure 2.3 Intensity of integration**

(Adapted from Leutz 1999 and Shaw *et al*. 2011)

Whilst older people are significant users of healthcare services, and are frequently the focus of policies and guidance, it appears that older patients are often not getting the best service when compared to other age groups (Oliver 2012). This may be influenced by the complex nature of older people's health and their care. Frequently multiple body systems are involved, with deficiencies in these body systems interplaying, complicating diagnosis and care and requiring holistic care with input from multiple health and social services. The complex interactions

between the body systems makes diagnosis less obvious and more difficult, with no single condition or disease state being responsible for the clinical and functional effects on the patient. Numerous other influences leading to poorer care of older people have been suggested, including a lack of training for clinicians compounded by a lack of interest of clinicians, age-based discrimination, the need for holistic care considering the multiple health care and social needs of older patients, and a lack of research influenced by all of these factors (Oliver 2008a, 2008b, 2012; Cornwell 2012).

Some interventions targeting patients with increasingly complex needs in the top tiers of the Kaiser Permanente Triangle, including intermediate care and generic community-based case management have little supportive evidence, with what evidence there is showing little or no beneficial effect or mixed results (Purdy 2010; Ross *et al.* 2011). Disease management as identified at level 2 of the Kaiser Permanente Triangle can vary between programmes; they aim to provide co-ordinated, proactive care with a disease specific approach to produce cost effective clinical outcomes (Radzwill 2002). The programmes comprise of proactively identifying those in the population with or at risk of specific disease states, with an emphasis on empowering and educating the patients to prevent and manage exacerbations and disease complications to improve overall health (Radzwill 2002). In order to prevent and effectively reduce the impact of exacerbations and reduce complications, monitoring needs to occur, both via self-monitoring by the patient with support of a specialist nurse and by healthcare professionals. Patient education is an important aspect of disease management, empowering patients to monitor their condition, and effectively respond to changes, improving the management of their condition. Monitoring may include a variety of measures including symptom report, blood tests e.g. diabetes, and PEF in asthma, many of which are also used as part of the initial screening process identifying patients who would most benefit from such intervention programmes.

In order for programmes of care for patients with long term conditions to be effective, there must be a way of identifying at risk patients and assigning appropriate levels of support. The importance of risk stratification within COPD disease management has been identified by the Global Initiative for Chronic Obstructive Lung Disease (GOLD 2011), who recommend a combined assessment of risk, considering not just symptoms and pulmonary function but the predicted future risk of exacerbations and co-morbidities, to guide appropriate support (Endicott *et al.* 2003). The importance of effective prognostic risk stratification has also been identified in heart failure case management (Smith *et al.* 2010). An example of such evidence supported disease management programmes is demonstrated by a Cochrane review of clinical services for chronic heart failure (CHF), which concluded that case management type interventions in heart failure

were effective at reducing CHF related admissions after 12 months follow up (n=1726 patients, OR 0.47, 95% CI 0.30-0.76, P=0.002), and all-cause mortality (n=2081 patients, OR 0.66, 95% CI 0.47-0.91, P=0.01) (Takeda *et al.* 2012). However, which component of the service was effective could not be concluded, although nurse telephone follow up was a common component. A prospective randomised active controlled study considering telehealth monitoring in heart failure case management, found that all patients receiving disease management had a reduction in the number of hospital days, compared to the previous 12 months (n=216, 42% reduction) (Wade *et al.* 2011). In this case regression to the mean should be considered, and no added benefit of telehealth monitoring was found (Wade *et al.* 2011). Blunt (2010) and others conclude that local clinicians and managers should develop higher-quality out-of-hospital care, work with patients to identify how they can be supported to reduce the risk of ill health and admissions, and identify those at high risk of future admission to target personalised support (Ross *et al.* 2011). Case management is one such service.

## 2.5 Case management

One approach that aims to improve the management of patients with complex/multiple LTCs and reduce hospital admissions in those most at risk of an adverse health event is community case management, led by a case manager (DH 2005). The case manager is usually a community matron, but may be an allied health professional or social worker who works with patients who have complex needs that require co-ordination i.e. those at level 3 of the Kaiser Permanente Triangle (Challis *et al.* 2010). The case manager works as part of an integrated team and is responsible for planning, monitoring and anticipating changes in needs, and co-ordinating care across the social and health care systems, as well as providing advanced nursing care if also a community matron (DH 2005). A model of care based around case management is likely to increase in the future due to pressures on the health service from the ageing population, the expected linked rise in the numbers of patients with multiple LTCs, and the need to reduce avoidable expenditure on emergency hospital admissions, but the model implemented needs to be an effective one.

Service models providing case management frequently evolve and include models such as community matron led case management, virtual wards, person centred co-ordinated/integrated care, to identify only the more reported and recent models. The virtual ward model is based on integrated multidisciplinary social and healthcare teams, clinically led on a day to day basis by a team leader, who is often a community matron or case manager. The virtual ward aims to work like a real hospital ward, with the same team members, meeting regularly for “ward rounds”,

whilst continuing to care for the patient in their own home. A definitive service description and evidence for the virtual ward demonstrating effectiveness and efficiency are awaited. Person centred co-ordinated / integrated care is another model of care providing case management type service, introduced to the NHS in 2013 it specifically highlights the expectation that the patient is at the centre of care decisions and provisions.

The case management approach aims to identify patients with highly complex health and social needs, allowing a case manager to deliver proactive care in the community, enabling them to remain at home longer and needing less unplanned reactive care (Thomas 2009; Challis *et al.* 2010). Although there is no single accepted definition for case management, it generally involves case finding (identifying patients to receive case management), assessment, care planning, co-ordination and implementation including self-care support and patient education, and monitoring and review, with the aim of improving quality of life for patients and reducing preventable expensive hospitalisation (Downes *et al.* 2009; Challis *et al.* 2010; Ross *et al.* 2011). This long list of services covered by case management indicates ideally a package of care, integrating primary, secondary and social care (Ross *et al*. 2011). Perhaps unsurprisingly the long list of services involved in case management means that case management programmes can vary greatly (Ross *et al.* 2011).

Variations in case management services across the country have been observed in both the initial identification and assessment process identifying those who would benefit most, and in the monitoring and review of patients once on the case load, often with a lack of clarity as to how the model of care should produce outcomes (Challis *et al.* 2010; Bardsley *et al.* 2013). Effective and efficient assessment and monitoring of patients on the caseload is important not just for the wellbeing of the patient but also for the efficiency of the service, as case management is a time-consuming and labour-intensive process (Ross *et al.* 2011). Within the NHS there is some ambiguity as to whether case management should be on-going or time-limited. The Department of Health (DH 2005) suggests case management should be an on-going process, although it has been suggested that patients should move between levels of care identified in the Kaiser Permanente Triangle (Figure 2.2), when appropriate, to free up capacity on the caseload (Challis *et al.* 2010; Ross *et al.* 2011).

### 2.5.1 Case finding

Case finding is the term given to identifying those patients with LTCs, at highest risk of an emergency hospital admission. Initial case finding (the identification of those patients in the population at level 3 of the Kaiser Permanente Triangle) for case management is carried out using

a variety of methods, including clinical judgement referrals and risk stratification predictive modelling using computer software. The aim is to identify patients who are most at risk of hospitalization in the future, such as those who have long term conditions, are older adults, and/or are accessing out of hours services frequently, or who have been admitted to hospital recently and/or frequently. Data used to produce the predictive model via computer software varies depending on the program, but frequently includes age, hospital admissions over the previous twelve months, admission method, diagnosis and co-morbidities. However, at present no case finding model has been identified as the most effective. The specific referral criteria, the targeting of case management services and the approach taken to case management again varies across the country (Challis *et al.* 2010; Purdy 2010).

The lack of specific focus of case management services and their broad referral criteria is likely to be leading to some confusion, and driving increased caseloads. Case finding tools have been continually evolving since the introduction of case management. The "Patients At-Risk of Readmission", PARR, case finding tool introduced to the NHS in 2005, focused on risk stratifying approximately 5% of a population who had already had an emergency hospital admission, in particular identifying patients with ambulatory sensitive conditions. Such tools have continually evolved since their introduction, with the growing desire to identify not just those patients who have already had an admission but also identifying those in a whole general practice population who may not yet have had an admission but are at future risk of one; such scoring is generally used to identify between 0.5-5% of a general practice population. Patients with the highest risk scores are then clinically reviewed and if appropriate a referral made to appropriate services such as case management. Following the initial case finding process, the case manager will then co-ordinate the patient's care, and review the continued suitability of community based case management care for the patient, including an evaluation of the impact of the case management interventions.

### 2.5.2 Evaluations of case management

There is currently mixed evidence for generic (i.e. non-disease specific) case management, the service that is provided to vulnerable patients with multiple LTCs. The evaluation and comparison of case management services is difficult due to the significant variation between them and the complexity of the service (Challis *et al.* 2010); there are no validated and recommended comprehensive evaluation tools for case management type services (Bardsley *et al.* 2013).

National analysis of hospital data and large case controlled studies have not demonstrated the expected reduction in hospital admissions and bed days since the introduction of case

management to the NHS (Gravelle *et al.* 2007; Purdy 2010; Roland *et al.* 2012). Smaller quantitative studies in some areas of the country have noted a positive impact on hospital admissions, especially elective admissions, bed days and outpatient attendance (Peretz *et al.* 2007; Downes *et al.* 2009; Thomas 2009; Bardsley *et al.* 2013). The observed impact of case management services cannot be attributed to the case management service alone, with other factors such as substitution of care to be considered (Bardsley *et al.* 2013). Numerous qualitative studies have reported positive patient and carer experiences, including better access to health care, increased psychological support and better communications with health professionals (Sheaff *et al.* 2009; Ross *et al.* 2011). Contradicting the numerous positive observations, a study of 16 pilot integrated care sites appointed by the Department of Health found that whilst integrated care services were viewed positively by staff involved, patients reported some negative effects, such as feeling less involved in decisions around their care, and finding it harder to see a GP/nurse of their choice, suggesting that patients wishes are not always at the forefront of developments (Roland *et al.* 2012). At the patient level, service evaluation is frequently based on subjective opinion (of the case manager) regarding the impact of a specific intervention on a patient, and whether an unplanned hospital admission was prevented. The accuracy of subjectively identifying the absence of an event such as an unplanned hospital admission occurring is questionable, and somewhat assumes accuracy of the risk stratification tool that identified the patient in the first place as being at high risk. The presence of an objective measure could usefully demonstrate a lack of deterioration in that measure or an improvement. For example with the right support and clinical care a patient may be able to improve their management of their LTC, allowing them to increase or maintain their level of physical activity, which may help them maintain or increase their muscle strength, a potential objective measure. Clinical markers do not appear to be used in evaluation of case management services at a patient level. Such objective measures have been suggested as a potentially useful service evaluation tool that would benefit from further investigation (Bardsley *et al.* 2013).

Whilst generic case management as a whole lacks high quality evidence of a positive impact, reasons for this have been suggested and certain aspects of case management do have more positive evidence, and suggest potential for some reduction in costs. The lack of impact of case management services may be partially due to the identification of more cases due to increased case finding (Gravelle *et al.* 2007; Sheaff *et al.* 2009). The lack of time allowed for changes in healthcare services (including case management) to become established and demonstrate their effectiveness has been reported as a potential problem area in service evaluation (Thomas 2009; Oliver 2013). Better integration between social and health care has been noted in the recent years, with some evidence that integration between social and primary and secondary care may

be effective in reducing admissions (Purdy 2010; Sutcliffe *et al.* 2010). A summary evaluation of the first year of an integrated care pilot in the UK, acknowledged a lack of reduction in emergency admissions, whilst observing an increase in diagnosis of some long term conditions, including dementia, positive reports from healthcare professionals (feeling that collaborative working had improved), and from patients feeling involved in their care plan (Nuffield Trust 2013a).

Self-care support is a common aspect of case management, reported in nearly three quarters of case management cases, and one aspect that appears to have good evidence (Challis *et al.* 2010). On review much of the positive evidence is anecdotal, with the patients reporting their views for the studies self-selecting, and as such, likely to be more motivated and engaged in self-care than those patients whose views were not given (Challis *et al.* 2010). Even the term self-care may describe numerous interventions e.g. The Expert Patient Programme, disease specific programmes, self-help groups, and education. Still the results suggest limited modest evidence for improvements, most frequently in the psychological aspects of living with a long term condition, rather than physical or clinical aspects. Lack of long term follow up and evaluation means the longer term effects on health and quality of life are unclear (Offredy *et al.* 2009). Merging case and disease management has been proposed, and is likely to be occurring already, with the potential for decreasing cost and increasing effectiveness and satisfaction (Lob *et al.* 2000; Radzwill 2002; Owen 2004). However, identifying those patients who would most benefit from services, and matching the right patient to the right intervention is challenging (Radzwill 2002).

Investigations into the programmes of case management, aiming to establish an evidence base, have served the purpose of making the differences in the services more apparent, and it is clear that trying to fit both aspects of the services and the outcomes into categories is difficult, and means that the effects of the intervention are unlikely to be fully captured (Challis *et al.* 2010). The lack of a standardised case management programme and effective outcome markers, and difficulties in capturing the effects of case management services, is acknowledged, and may be contributing to the paucity of positive evidence (Offredy *et al.* 2009; Abell *et al.* 2010). The diversity of models of case management and the lack of convincing evidence of their effectiveness suggests that there is room for modification and improvement. Improved monitoring and detection of decline in health status is one possible route to achieve this, however, the literature has raised difficulties in monitoring.

## 2.6 Case management patient monitoring

Monitoring and review of patients and the impact of interventions are a necessary aspect of a pro-active service such as case management (Downes *et al.* 2009; Challis *et al.* 2010; Ross *et al.* 2011). Anecdotally this aspect of case management appeared weak, with no standardised approach taken. A literature search and review was conducted to identify evidence regarding monitoring practices and difficulties, and potential areas for investigation as part of this study, aiming to improve monitoring of patients.

### 2.6.1 Search strategy

An initial search strategy was developed to identify published literature related to case management, and more specifically the patient assessment and monitoring tools that may be utilised as part of case management (Appendix 1), to guide the research study and its areas of focus. The Cumulated Index of Nursing and Allied Health Literature (CINAHL) database was primarily used, due to its comprehensive cover of literature relevant to the subject area. Search terms related to case management, monitoring and LTCs were initially utilised (Appendix 1). Whilst the literature search initially focused on monitoring practices within case management services, both generic and disease specific case management, it was expanded to consider the monitoring of LTCs and health more generally, to identify potential areas of monitoring that would not just monitor a specific disease state or symptom but would be able to take into account the cumulative effect of multiple disease states, as experienced by case management patients.

### 2.6.2 Patient monitoring

The frequency of visits made by case management teams to patients on their caseloads range from daily to three monthly (Downes *et al.* 2009). Surprisingly the monitoring and review of patients receiving case management are not frequently reported as a focus for case managers (Challis *et al.* 2010), but monitoring symptoms and changes in health have been shown to be an important component of disease-specific intervention and in reducing avoidable hospital admissions. The benefits of monitoring many conditions are clear, and can allow treatment to target specific outcomes, which is an established concept in many LTCs, for example diabetes, hypertension and rheumatoid arthritis. Treatment to target enables treatment to be adjusted to achieve both the best short term outcomes, e.g. controlling symptoms of rheumatoid arthritis to improve quality of life, and long term outcomes, which may include modifying disease progression and prevention of complications (Firth 2011). Physical activity levels and function have also been recently suggested as a feasible and potentially useful clinical marker of health in patients with chronic illnesses in primary care, specifically in COPD, and may be used to assess the impact of rehabilitation programs on quality of life (Esteban *et al.* 2010; Walker *et al.* 2008; Richardson *et al.* 2012). With a logical relevance to activities of daily living, it has recently been suggested that

increasing physical activity may improve patient centred outcomes in COPD patients (Esteban *et al.* 2010; Walker *et al.* 2008). The absence of research focused on describing the physical and functional status of case management patients and the area of on-going monitoring assessments means that there is no current evidence base on which to form decisions on what to monitor and how to interpret the results in this patient group.

Further evidence is required to identify effective monitoring practices, especially in light of recent practice observations where less experienced and less qualified team members are being delegated more of the direct patient contact. The lack of timely identification of a decline in health leaves the clinician unable to intervene and manage the patient's care effectively to prevent adverse events such as an unplanned hospital admission. The presence of atypical symptoms and frailty, more likely in older patients with multiple morbidities, provide further challenges to monitoring, enhance the difficulty of identifying the beginning of a decline in health, and require further consideration.

### 2.6.3 Frailty

Frailty is associated with both increasing age and multiple chronic conditions, and is also independently associated with poor health outcomes and institutionalisation (Figure 2.4) (Fried *et al.* 2001; Rockwood *et al.* 2006; Cawthorn *et al.* 2007; Hubbard *et al.* 2010; Syddall *et al.* 2010). In an ageing population, managing the increasing numbers of frail people and the consequences of frailty will become more important.

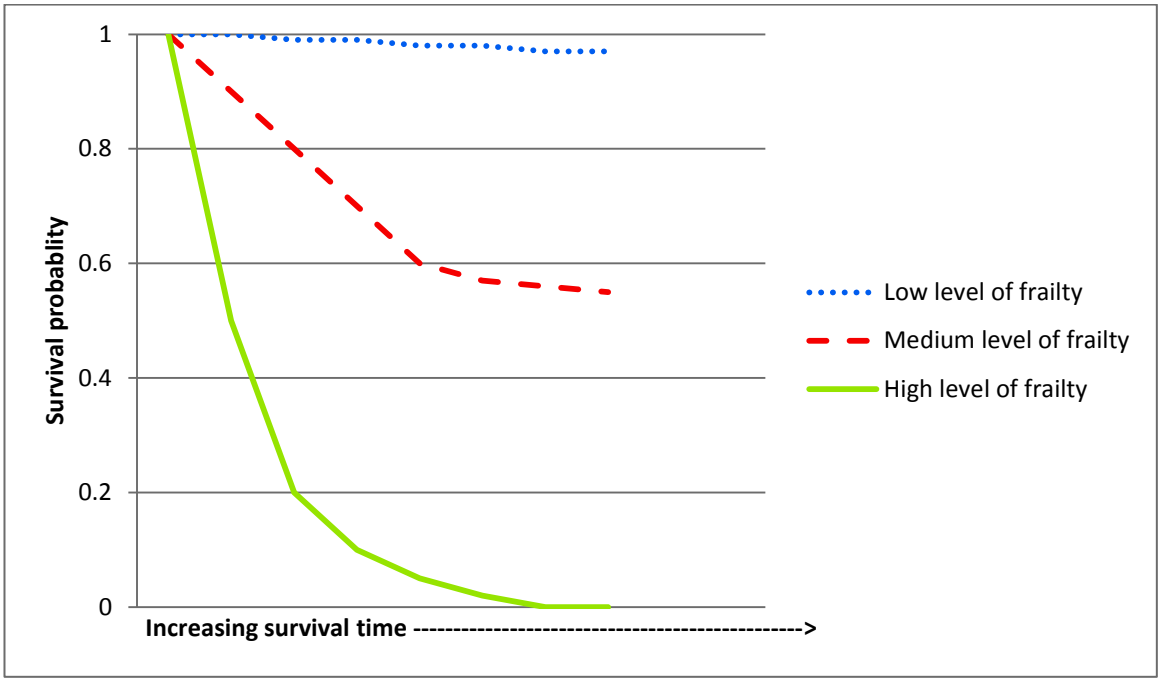



**Figure 2.4 The effect of frailty on survival**

(Figure for illustration of concept purposes only, adapted from Howlett and Rockwood 2013)

Case management is targeted towards patients whose ability to adapt is compromised, such that a small challenge to their health and function cannot be met, meaning they are at high risk of an unplanned hospital admission (DH 2005). Frail patients exhibit a lack of reserve, such that when challenged e.g. by an infection or injury, they have a lack of adaptive capacity to cope, and often present atypically, but with common high level generic and functional problems such as delirium (Song *et al.* 2010). This description of a frail patient exhibiting a lack of reserve and the following consequences resonates with the expected characteristics of a patient receiving case management. Whilst a frail patient is vulnerable, this vulnerability may be enhanced by certain factors (e.g. social vulnerability), whilst mitigated by others (e.g. exercise) (Howlett and Rockwood 2013).

Although there is no accepted definition of frailty in a clinical context, recent research has found concurrence on the symptoms (Fried *et al.* 2001; Cawthorn *et al.* 2007; Syddall *et al.* 2010). Frailty is accepted as being multifaceted, with many aspects to it and influences upon it, as demonstrated in Figure 2.5. Frailty's association with mortality and morbidity, increased service use and adverse outcomes e.g. falls, hospital admissions, has been clearly demonstrated (Fried *et al.* 2001; Cawthorn *et al.* 2007; Syddall *et al.* 2010). However, questions remain about the characteristics of the case managed population, including the presence of frailty.

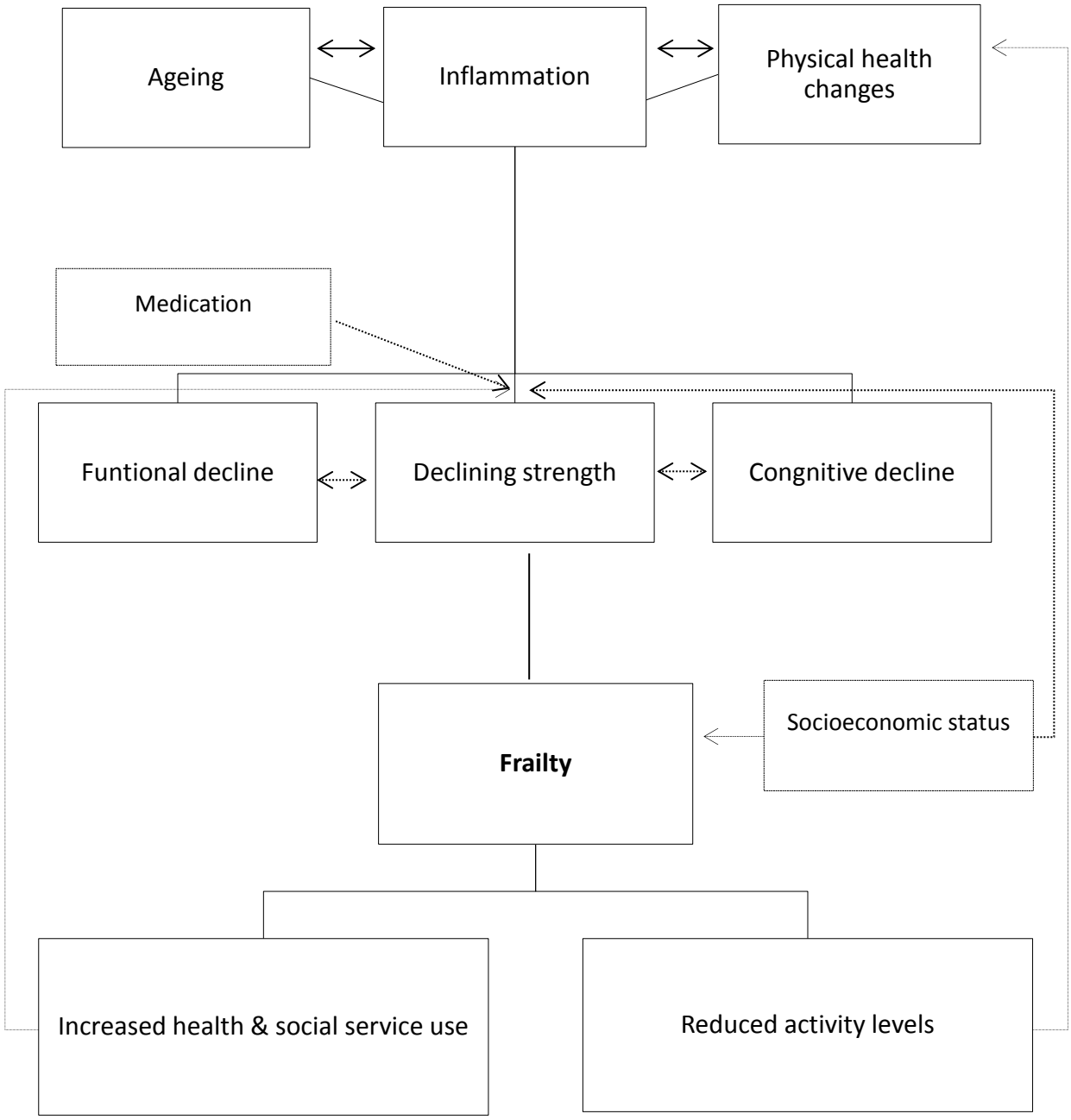



**Figure 2.5 Influences on the progression of frailty**

Whilst it may be accepted that health is likely to decline with age, a number of trajectories may be followed (Figure 2.6). Some people demonstrate high, long, stable periods of good health and non-disablement, while others show high level stable disablement, and some follow a trajectory where a large sudden disablement occurs following an adverse event, yet another group may follow a trajectory for health marked by alternating periods of decline and recovery (Taylor *et al.* 2011). Within case management services, where patients are often identified through previous

admissions or high service use, it is anticipated that patients may be following this fourth trajectory of health, experiencing alternating periods of decline and recovery. The focus of clinical management is to detect the onset of periods of decline and intervene to ensure that adverse consequences are avoided (e.g. hospital admission). In order to achieve this there needs to be a sensitive measure of decline. A measure researched and developed with a sensitivity to the service context, where case management patients frequently present atypically, complicating the identification of declines in health.

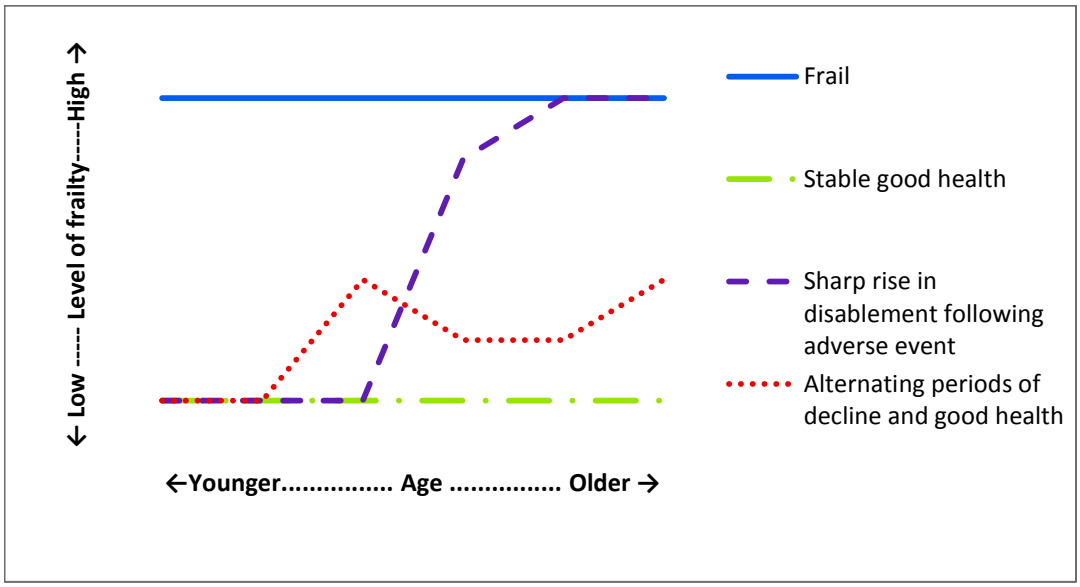



**Figure 2.6 Potential frailty trajectories**

(Adapted from Rockwood *et al.* 2007, 2010; Song *et al.* 2010)

### 2.6.4 Atypical presentation

Atypical presentation is especially common and troublesome in older frail patients with multiple chronic conditions that further complicate the identification of declines in health (Hunt 2009), hence identifying and employing objective, effective monitoring aids and tools is likely to be beneficial. Non-specific atypical presentation, frequently observed in elderly patients, makes it harder for the clinician to assess their patient and make an accurate and timely diagnosis. The presentation of non-specific symptoms, sometimes referred to as "geriatric syndromes" include loss of mobility and cognition, falls and incontinence. These "geriatric syndromes" commonly reduce the patient's ability to carry out activities of daily living, increasing their reliance on support networks (formal and non-formal) and may act as a precursor to an emergency hospital admission (Hunt *et al.* 2009). Whilst it is not entirely clear why atypical presentation occurs, causes of, or the predisposition to some are known. For example, with ageing the ability to regulate the body's temperature effectively reduces, meaning that, unlike younger counterparts,

when older people have an infection they do not present with a fever, but with an atypical symptom, such as confusion. Confusion is a common presenting symptom in older patients with a urinary tract infection, but is rarely observed in younger patients with the same infection (Oboh 2010). Chronic inflammation associated with ageing and long term conditions, also referred to as inflammaging, is thought to contribute to such atypical symptoms and sickness behaviours, which may also include falls, loss of muscle strength, fatigue, reduced appetite, and depression (Hunt *et al.* 2009). A challenge such as an infection can further elevate the inflammation and the associated effects, increasing the risk of adverse events and enhancing the importance of identifying and treating infections in older people with long term conditions. Whilst inflammation can be measured, via identification of inflammatory markers present in blood, an invasive blood test is required, that is less conducive with frequent monitoring than non-invasive measures of alternative domains. Muscle strength may be such a measure.

Atypical presentation enhances the danger of a patient's health declining in an imperceptible way that is not recognised by their care team, leaving the patient unidentified as being at immediate risk of hospital admission (Offredy *et al.* 2009), or a potentially serious adverse event, such as a fall;  supporting the need for objective monitoring . In fact these adverse health events, such as a fall, often act as the first red flag, highlighting the need for an intervention (Oliver 2007). If not acted on the patient may be unnecessarily admitted to hospital, with serious consequences for the individual and health service.

### 2.6.5 Study areas of focus

The literature identified around case management and the monitoring of patients highlighted the potential for improvements in monitoring, with monitoring generally not being seen as an area of focus for case managers. The presence of multiple LTCs and other vulnerabilities such as frailty and atypical presentation, frequently observed/expected in case management patients, supports the investigation into non-disease specific monitoring of health. Measures of physical activity and function were identified in the literature as potentially useful clinical markers of health (Esteban *et al.* 2010; Walker *et al.* 2008; Richardson *et al.* 2012). Measures such as these may be particularly useful in patients experiencing multiple disease states, where it is the cumulative effect of these, as in deficits in frailty, which is important. More generic areas of monitoring are of additional benefit where typical disease specific symptoms may not be present, present too subtly or present too late to allow timely intervention.

The study presented in this thesis focuses on non-disease specific clinical markers of health, i.e. physical and functional ability, and frailty, primarily using muscle strength as a proxy marker of

these. There is an established relationship between ageing and chronic illness, inflammation, frailty and muscle strength, and function and service use over the long term, which suggests that muscle strength may be a useful aid to monitoring (Figures 1.1 and 2.5). From Figure 2.5 it can be seen that decreasing muscle strength is central to the processes associated with frailty; it is influenced by ageing, inflammation, medication, and decreased activity, and has a direct impact on function and independence. Muscle strength may be an objective measure which could indicate the effects of pathophysiological changes before they are manifested in physical or functional declines, which can lend itself to repeated use in a community setting. Whist frailty is multi-faceted, evidence points to the measurement of multiple aspects to allow an assessment, which may limit its repeated use by clinicians visiting patients at home, when time constraints are present. This study considers that functional ability and muscle strength may be used as potential suggestive markers of frailty that may be more quickly obtained, and suitable for repeated assessments in the community. A lack of function may be a result of a lack of muscle strength, with reduced activity leading to further loss in strength. Unfortunately measuring functional ability is usually subjective, often relying on patient self-report. This is especially relevant when limitations occur of instrumental activities of daily living, related to running a household including managing household shopping, cleaning and expenses, rather than more basic personal activities such as toileting, bathing, moving up and down stairs. Muscle strength is the aspect repeatedly identified in the literature as an objective measure that lends itself to repeated monitoring in the clinical setting of interest. The areas of focus are considered further in Chapter 4.

## 2.7 Conclusion

The ageing UK population will mean an increased demand for health and social care services (DH 2012a). Unfortunately with age, health frequently declines. Large numbers of older people live with LTCs, with most over 75s living with at least three long term conditions (DH 2012a). Effective management of patients with long term conditions is a priority for the NHS. However, there is a lack of standardised effective evidence informed programmes to do this. The complexity of older patients with multiple morbidity, who often present with frailty and atypical symptoms enhance the difficulty of on-going monitoring and the targeting of care to enable a patient to remain independent, avoid adverse health outcomes and enable better quality of life for longer. There is an established relationship between ageing and LTCs, frailty and muscle strength, and function and service use. Hence muscle strength may be a useful aid to monitoring. Muscle strength has been especially selected for study as its measurement can be objective, simple and non-invasive (Fried *et al.* 2001; Cawthorn *et al.* 2007; Syddall *et al.* 2010), unlike inflammation which requires invasive and expensive blood tests. The literature around muscle strength, function and frailty measurement are considered in more detail in Section Two. However, the existing evidence focuses on longer-term changes in muscle strength, health and function, and there is insufficient information on the most appropriate measure to use, and the impact of changes over the short to medium term, as highlighted by Figure 1.1. In order to begin to fill in the gaps in knowledge identified here, three research studies, described in Section 2 were conducted (Figure 2.7).

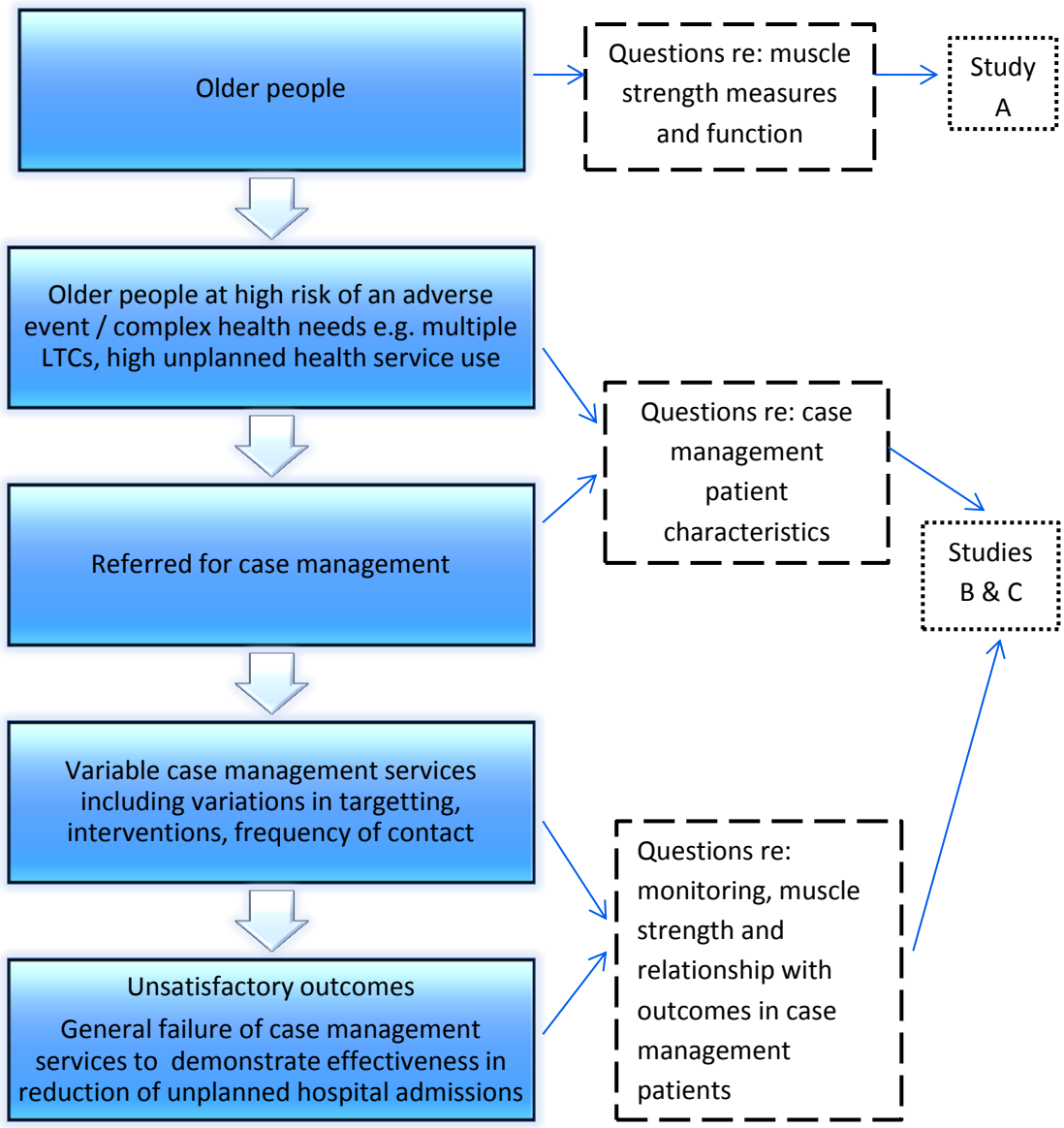



**Figure 2.7 Knowledge gaps addressed by research study**

Chapter 3 introduces the overall study design along with the overarching research aim and objectives. Chapter 4 presents the methods and literature regarding muscle strength measurement and other study variables. Prior to exploring the feasibility of measures of muscle strength in patients receiving community case management, more information was needed regarding the reliability and acceptability of the measures of strength in a sample of medically stable older adults aged 65 years and over. Therefore, a pilot study was designed to confirm that the measures of strength could be obtained reliably and accurately by the researcher, and that the tests appeared acceptable to both participants and operators. This pilot study is also referred to as Study A within this thesis. Study specific design, methods, and results for the pilot study in healthy individuals, Study A, are all included in Chapter 5. The observational feasibility study in case management patients is referred to as Study B within this thesis, the design, methods and results for which are described in Chapter 6. Chapter 7 details the exploration and findings of a case management patient cohort using database analysis of routine primary and secondary care data, Study C. The findings from all three studies are brought together in Section Three, accompanied by a discussion. Conclusions and implications as a result of the findings conclude the thesis.

# Section Two

# Empirical work

# Chapter 3 Research aims, objectives and research questions

The overarching research aim, objectives and research questions are detailed here in Chapter 3. Each question has been attributed to Study A (pilot study of measures of strength in healthy older people), B (feasibility study of measures of strength in case management patients) or C (analysis of routine primary and secondary care data of case management patients) or a combination of these (Figure 2.7). Study specific aims, objectives and questions for studies A, B and C are detailed at the start of Chapters 5, 6 and 7 correspondingly.

The literature review (Chapter 2) demonstrated a lack of information on and understanding of the case management patient group, with little to explain the clinical and functional needs of the patients receiving case management beyond the broad service targeting criteria. The review also identified the potential for improvement in the case management service; the reduction in hospital admissions expected following the introduction of case management services has not been observed. The underperformance with regard to hospital admission avoidance has led to numerous changes to case management services, but the evidence supporting such changes is weak. The absence of a standardised evidence informed monitoring practice in case management was also noted, and could be contributing to the observed underperformance. Improved monitoring and targeting within the case management service may enable more timely interventions to more successfully prevent adverse events and ensure resources are directed towards those at most immediate risk. Many of the routine methods of clinical monitoring become less useful in frail patients and those with multiple morbidities, who present atypically, and whose health may fluctuate on a seemingly low level quite frequently. Whilst there is evidence to suggest that muscle strength may be a beneficial aid to monitoring in such a patient group, there is no consensus on what muscle strength measure would be most feasible and useful in community dwelling patients receiving case management services. These knowledge gaps informed the overarching research aim.

## 3.1 Aim and objectives

The overarching research aim of the study was:

**To explore the feasibility, acceptability and usefulness of non-invasive muscle strength monitoring in older patients receiving case management.**

In order to achieve this aim, questions about the functional status and muscle strength of the patient group needed to be addressed, along with questions about the reliability, stability and acceptability of measures of muscle strength in the patient group, following consideration of baseline data in healthy older people.

Five research objectives were developed to achieve the aim and aid study design. The initial two objectives aimed to clarify that accurate readings could be obtained using the measures selected. In order for a clinical measure to be useful it is essential that a clinician can obtain an accurate reading that allows an accurate assessment to be made.

1. Assess the inter-rater reliability of four non-invasive measures of strength (grip strength, PEF, PIF and SNIP) by collecting and analysing repeated measures in healthy older adults over a one week period, by two operators.

2. Assess the intra-rater reliability of the non-invasive measures of strength by collecting and analysing repeated measures in healthy older adults and case management patients over a one week period, by one operator.

A third objective focused on the acceptability of the measures. An unacceptable measure is less likely to be used, and may affect the accuracy of results, with a patient underperforming if a measure is disliked.

3. Investigate the acceptability of the muscle strength measure to older adults and clinicians, by gathering feedback via questionnaires from healthy older adults, case management patients and clinicians.

Two final objectives aimed to gather much needed data on case management patients, a patient group for which little published data exists, potentially resulting in a lack of understanding regarding their needs. Whilst evidence supports muscle strength as an indicator of future health in the long term, providing basis for this research, it was not known whether changes in muscle strength would be observed in the short-medium term and whether any observed changes would relate to notable changes in health or functional status over the same time period.

4. Explore the stability of muscle strength, by gathering repeated measures of muscle strength (of successfully piloted muscle strength measures) over a 7 week period, in case management patients, alongside data regarding health service use, health/ symptoms and function.

5. Explore the health, physical and functional status of patients receiving case management, by gathering baseline data (using validated measures where available) from case management patients direct and utilising routine healthcare data.

The objectives led to an observational approach that included a pilot and a feasibility study, to begin the exploration into the feasibility, acceptability and usefulness of monitoring muscle strength in patients receiving case management.

## 3.2 Research questions

In order to address the overarching aim and more specific objectives, five research questions were posed.

1. "Can four non-invasive measures if strength (grip strength, PEF, PIF and SNIP) be measured reliably in a) older people with stable good health, b) case management patients?"

2. "Are the measures of strength acceptable to a) older people, b) patients, c) clinicians?"

3. "Are there measurable declines in the muscle strength measures (grip strength, PEF and PIF) over a seven week period in patients receiving case management?"

4. "Are any observed changes in muscle strength associated with wellbeing, function and health status and health service use?"

5. "What is the health, physical and functional profile of patients receiving case management?"

Three studies, A, B and C, shared an observational approach to obtaining data to answer the posed research questions and begin the exploration into the feasibility and usefulness of measures of strength as aids to monitoring.

## 3.3 Study design

The overall design approach was a pilot and feasibility study. Three studies contributed to the overarching aim of exploring the feasibility of strength measurement in case management patients.

Study A was designed as a descriptive, observational pilot study involving self-reported "healthy", medically stable older adults, aged 65 years and over to assess the inter and intra rater reliability of the measures of strength and the acceptability of the measures; the gathered data enabling a response to questions 1a and 2a posed in Section 3.2. The findings from pilot Study A, informed

the study specific aim, research questions, design and methodology of the follow on feasibility study, Study B, involving case management patients and clinicians.

Study B was an observational, longitudinal study, exploring the feasibility of the successfully piloted measures of strength. Case management patients and clinicians were recruited to assess the reliability, stability and acceptability of the measures of strength, answering questions 1b, 2b, 2c, 3 and 4 (Section 3.2). Study B also gathered data regarding the health and functional and physical profile of case management patients, to aid the formulation of a response to question 5, along with data from Study C.

Study C involved analysis of routine primary and secondary care case management patient data extracted from the Hampshire Health Records (HHR) database, to enable a profile of case management patients health, function and physical to be developed (in response to question 5).

The studies shared a number of methods, which are discussed in Chapter 4. Further detail on methods, conduct and results are in Chapters 5, 6 and 7.

# Chapter 4 Methods

This chapter reviews the methods and presents the background literature supporting their selection. The study variables are considered in turn. The primary variable, muscle strength is considered in detail, and specifically within the context of frailty. Whilst the literature review identified muscle strength as a potentially useful aid to monitoring, there is a lack of conclusive evidence directing the inclusion of one particular measure of muscle strength above all others. The choice of measure is discussed further in this chapter, considering current evidence whilst being mindful of the desire for the measure to be suitable for use by vulnerable case management patients, who are likely to be demonstrating a high level of frailty, and who are living in their own home. A review of the selection of the other study variables, including measures of physical and functional ability, health and symptoms, and acceptability of the measures of strength, are included to address the set of research questions, and follows the review of muscle strength measures. Study specific methods and protocols are covered in detail in the relevant study chapter (Chapters 5-7).

## 4.1 Muscle strength measurement

As already stated there is no standardised monitoring practice for case management patients, driving variation in monitoring practice and potentially impeding the provision of effective case management services. It may be that due to the association between inflammation, muscle strength, function and service use, monitoring muscle strength may allow the identification of a decline prior to this being evident in function or service use. A significant decrease in muscle strength may indicate that an important but otherwise oblique decline in health and/ or function has occurred or is imminent and requires investigation and intervention to prevent a significant adverse event from occurring. If so, it would be possible to detect a change in muscle strength, which shows that a challenge or health event is occurring before more apparent symptoms become present, allowing timely intervention. However, it is not known whether published normative values for muscle strength are likely to be observed in this patient group, or how muscle strength changes over the short to medium term in these patients and whether any changes in strength link with health, wellbeing, functional ability and adverse outcomes.

There is a well reported reduction in muscle strength expected with normal ageing from 65 years onwards of 1-2% per annum, but changes in muscle strength over a shorter time period and specifically in frail older people with multiple LTCs, such as those receiving case management are unknown (Skelton *et al.* 1994; Bassey 1998; Tietjen-Smith *et al*. 2006; Forrest *et al.* 2007). A literature search focusing on changes in muscle strength (both improving and declining) in older people (≥ 65 years of age) was conducted in a structured manner (22/06/2011, Appendix 2). This search and following review focused on grip strength, the most widely reported portable measure of strength. The resulting articles from CINAHL and MEDLINE were reviewed and the number narrowed by selecting only studies with data collection over the short and medium term i.e. less than one year (Table 4.1). After review of the resulting articles, six were identified as relevant. These articles provided further support for investigating muscle strength monitoring over the short-medium term, and provided information regarding the potential size of change for sample size calculations. All six of the reported studies were based around an intervention occurring, most frequently an exercise intervention, making their findings not immediately transferrable to their proposed use as a monitoring aid in case management patients. Some articles did report a change in muscle strength following the withdrawal of such interventions, whilst others included control groups, broadening the information they provided regarding potential changes in muscle strength over the short to medium term (Table 4.1). The articles indicated that measurable changes in muscle strength can occur over a time period of 10-26 weeks, supporting the further investigation described in this thesis.

| Study (Lead author, year) | Setting / Intervention | % mean change observed |
|---|---|---|
| Hagen, 2003 | 10 week exercise program in UK care homes (n=20) | + 34% |
| | Change observed 10 weeks after stopping above exercise program | - 8% |
| | 10 week occupational therapy program in UK care homes (n=20) | + 72% |
| | Change observed 10 weeks after occupational therapy program above stopped | - 14% |
| | Control group (UK care homes) (n=20) | - 11% |
| Hara, 2007 | 13 week exercise program in Japan for those living in nursing homes / visiting health care facilities (n=27) | + 17% |
| | 26 week exercise program in Japan for those living in nursing homes / visiting health care facilities (n=27) | + 15% |
| | Control group (n=17), change observed at 13 weeks | - 6% |
| | Control group (n=17), change observed at 26 weeks | - 8% |
| Wolf, 2003 | Control group in USA (n=54), change observed at 15 weeks | - 8% |
| | 15 week Tai Chi course (n=59) | - 3% |
| | 15 week computerised balance training (n=50) | - 4% |
| Ha, 2010 | 13 week nutritional support of acute stroke patients in Norway (n=56) | + 11% |
| | Control group (n=65) | - 1% |
| Nakagawa, 2008 | 12 week exercise program in Japan for general older people (n=44) | 0% |
| | 12 week exercise program in Japan for frail (n=30) | 0% |
| Shin, 2009 | 8 week exercise and education program in South Korea (n=26) | + 14% |
| | Control group (n=22) | 0% |

**Table 4.1 Published studies selected by literature review exploring changes in grip strength over the short-medium term**

### 4.1.1 Selection of measures of muscle strength

Multiple measures of strength were included for study to achieve the broad research aim due to the lack of specific research into their use as a monitoring tool in a frail older population. Criteria were established (based on Rotherham Doncaster and South Humber NHS Foundation Trust Medical Devices Management Policy 2011), to aid the selection of measures for the study, these were: safety (especially considering their use in a patient's home where hazards e.g. trip hazards may be present, lack of immediate facilities to clean equipment effectively, and the involvement of frail patients); portability (as clinicians would need to transport equipment between patients' homes, and a car should not be necessary as parking close to a patients home cannot be guaranteed if a piece of heavy, bulky equipment needs to be carried); cost (both initial and on-going expense e.g. consumables, servicing); acceptability to patient and clinician; training and staff (to operate measuring equipment, obtain reliable readings, and evaluate the readings); reliability of the measuring equipment; and potential for telehealth application.

The criteria aimed to ensure that selected measures of strength could be integrated with current practice in the community without any insurmountable difficulties. Possibly the most important aspect when selecting equipment that is not listed in the criteria above is the clinical requirement and usefulness. With current knowledge the clinical benefit of monitoring muscle strength is unknown, leading to the posed research questions. Strict values and cut-offs (e.g. for cost price) were not applied, but consideration was given to each aspect. Missing data regarding strength measures and the criteria set out did not automatically discount a measure but informed the research questions. These criteria led to some measures being considered and rejected despite good validity and reliability as measures of muscle strength or function. Functional limitations have been associated with poorer physical performance tests, especially in frail adults (Louie *et al.* 2010). More functional proxy measures of lower body strength, with clear relevance to activities of daily living (ADLs), such as the timed up and go test, sit to stand test and walking speed were considered, but deemed impractical to carry out in a patient's home, with a potentially frail patient with significantly impaired mobility, where space may be limited, trip hazards present and an unacceptable risk of falling (Shumway-Cook *et al.* 2007; Cesari *et al.* 2009). Practicality is also an issue, as some of these tests require use of a standardised seat to allow comparison with published normative values, which makes them less suitable for on-going home monitoring. Quadriceps strength is frequently referred to in published work involving frail older adults (Sherrington *et al.* 1997; Mizner *et al.* 2005). The importance of good lower body strength is clear when we consider everyday tasks such as standing from a chair or getting out of bed, but direct measures of leg muscle strength requires bulky equipment or invasive techniques that are not compatible with repeated use in patients' own homes. The correlation between grip strength and

lower body and trunk strength has been demonstrated in a number of studies, with the former lending itself to use in the community (Visser *et al.* 2000; Newman *et al.* 2006; Tsubaki *et al.* 2010).

### 4.1.2 Grip strength

Grip strength has been strongly linked to morbidity, mortality, functional performance, disability, cognition and lower quality of life (Fried *et al.* 2001; Adams *et al.* 2004; Alfara-Acha *et al.* 2006; Dourado *et al.* 2006; Newman *et al.* 2006, 2009; Sayer *et al.* 2006; Cawthorn *et al.* 2007; Syddall *et al.* 2009; Xue *et al.* 2010). Grip strength has been shown to be reliable and has been suggested as the single best measure of age-related change in muscle strength (Lauretani *et al.* 2003; Hairi *et al.* 2010). However, a lack of data on changes in grip strength over the short and medium term in community dwelling patients with chronic conditions means its usefulness as a monitoring aid in the proposed patient population is unknown. The possible role of grip strength for predicting subsequent health and risk of hospitalisation in community dwelling older people has been repeatedly highlighted, accompanied by recommendations for further research into changes in grip strength over time, and especially in the value of measuring change in the shorter term (Cawthorn *et al.* 2009; Cooper *et al.* 2011). Grip strength lends itself to clinical use in primary care, being portable, reliable and easy to perform (Cruz-Jentoft *et al.* 2010), above lower body strength measures and a battery of tests such as the Short Physical Performance Battery, whilst providing a marker of physical performance (Stevens *et al.* 2012). Its practicality and ability to provide an indication of physical performance in younger old (i.e. 65-74 years of age) community dwelling individuals has been observed (Stevens *et al.* 2012). Practically, the equipment, although portable, is still relatively heavy and bulky to be carried around by a clinician and has a significant cost associated with it, both in the initial purchasing and routine calibration. For this reason alternative measures were also considered.

The correlation between grip strength and lower body and trunk strength has been demonstrated in various populations, including in healthy middle to old aged populations (Visser *et al.* 2000; Newman *et al.* 2006; Tsubaki *et al.* 2010). Visser *et al.* (2000) reported a positive association between grip and lower extremity performance in participants, (males n=216, r=0.079, 95% CI 0.042-0.116, P=0.0001; females n=233, r=0.046, 95% CI -0.009-0.101, P=0.11). However, grip strength has limited functional relevance to mobility, posture and stability (Hunter *et al.* 1998), and acts only as a proxy measure for lower limb muscle strength. Consideration also needs to be given to the suggestion that a greater loss in lower body strength occurs with age than grip strength, meaning that grip strength may give an over optimistic indication of lower body strength

in older men (n=9, r=0.35) and women (n=9, r=0.05) (Samuel *et al.* 2012). Even so a decrease in grip strength has been strongly linked to morbidity, mortality, functional performance, disability, cognition and lower quality of life, and demonstrates clinical relevance (Fried *et al.* 2001; Alfara-Acha *et al.* 2006; Dourado *et al.* 2006; Sayer *et al.* 2006; Cawthorn *et al.* 2007; Newman *et al.* 2009; Syddall *et al.* 2009; Xue *et al.* 2010).

Despite limited evidence regarding changes in muscle strength over the short to medium term, a review of cohort studies suggesting changes in grip strength over the short to medium term indicated that a decrease of 8-24% over 13 weeks (range 8-26 weeks) could be expected in the proposed patient group (Table 4.1).

#### *4.1.2.1 Grip strength changes over time*

Small interventional studies, involving older and potentially frail populations identified as being the most similar to the proposed patient group, have observed changes in grip strength ranging from a 15% decrease with no intervention to a 73% increase with a positive intervention, within a 12 week period (Hagen *et al.* 2003; Hara *et al.* 2007; Ha *et al.* 2010; Table 4.1). Other influences causing a reduction in grip strength have been observed and continue to be found e.g. medication and diabetes (Ashfield *et al.* 2010). Beloosesky *et al.* (2010) suggested that grip strength may be used as a marker to estimate future functional motor outcome post-hip fracture repair, to allow additional interventions to be employed to increase muscle strength and functional outcomes. None of the studies identified (Table 4.1) involved observing changes in strength over the short term in community dwelling patients with chronic conditions and without an acute event/intervention occurring (e.g. stroke, exercise intervention); it is not known whether monitoring muscle strength in case managed patients will be useful. The inclusion of multiple indicators of strength was further justified by the lack of information on the sensitivity of grip strength to change over the relevant time period and the previously mentioned disadvantages of using grip strength in clinical practice (Section 4.1.2). The multiple indicators of strength included grip strength and respiratory measures acting as proxy measures of muscle strength.

### 4.1.3 Indirect muscle strength measures

Respiratory muscle strength in frail, older people has been less well studied than grip strength (Watsford *et al.* 2007; Buchman *et al.* 2009). However, there are inexpensive, simple, reliable measures of respiratory function such as PEF, that are a common part of clinical practice in the management of patients with respiratory disorders (they are rarely used in those without) and these could easily be included in regular monitoring of patients if they were found to be a good proxy indicator of strength and associated risk of declining health and function. Respiratory tests are often somewhat limited by their lack of specificity to measure either pulmonary function or respiratory muscle strength alone. Despite this lower pulmonary function and respiratory muscle strength have been associated with mobility disability and total mortality in the elderly, although some contradictory findings have been reported regarding their predictive value for all-cause mortality (Cook *et al.* 1991; Buchman *et al.* 2009; Vaz Fragoso *et al.* 2007).

#### *4.1.3.1 Peak expiratory flow*

PEF is an inexpensive, quick, simple to use, reliable portable measure of respiratory function commonly used in clinical practice in the management of patients with respiratory disorders. A reduced PEF in older people has been repeatedly linked to declining health and as an independent predictor for mortality over five years (n=3582, relative risk per 100l/min decrease of mortality over 5 years = 1.27 (95%CI 1.19-1.36), p<0.0001, Cook *et al.* 1991), so despite it not being a measure of respiratory muscle strength exclusively, it is another indicator of the relationship between strength and declining health and mortality, and its monitoring may prove useful as a predictor of declining health and function (Vaz Fragoso *et al.* 2007). It is recommended that PEF alone is not used for measuring the strength of respiratory muscle, due to it concurrently assessing pulmonary function (Cruz-Jentoft *et al.* 2010). Therefore, less familiar respiratory measures were also considered, including peak inspiratory flow (PIF) and inspiratory pressures.

#### *4.1.3.2 Peak inspiratory flow*

PIF has received little focus in the literature; a commercially available measuring device only recently became available, which may account for the lack of research. The Clement Clarke In-Check Oral PIF meter is inexpensive, portable and requires little training in its use; beyond this a lack of published data means few conclusions can be drawn regarding its potential. However, the addition of the measurement of PIF may help produce a more robust picture of respiratory muscle strength than PEF alone. A small study suggested that PIF correlates with age (n=40, r=-0.5, p<0.005); the lack of large scale population studies precludes this being confirmed (Janssens *et al.* 2008). Much of the published research focuses on patients with COPD, present in

approximately half of the patients receiving case management in England (Challis *et al.* 2010), but no clear picture has yet emerged of the relationship between COPD and PIF. A small study exploring the effect of inspiratory muscle training in patients with COPD, suggested that PIF could be improved significantly by inspiratory muscle training (n=60, p<0.001), hence demonstrating PIF as an indirect measure of muscle strength, and supporting the expected correlation between increasing inspiratory muscle strength and improving PIF (Weiner 2006). The impact of COPD on PIF has been questioned, with limited evidence suggesting that the existence of COPD alone does not reduce the PIF (n=26 COPD patients, n=14 healthy control participants, p=0.68, Janssens *et al.* 2008), indicating that PIF may be a useful marker of inspiratory muscle strength in patients with and without COPD. Although a reduction in PIF was observed in COPD patients experiencing dyspnoea (n=37, *R*=0.48, p<0.001), leading to a suggestion that monitoring PIF may be useful in COPD patients (Taube *et al.* 2011). Any measure used as a clinical monitoring tool needs to be reliable and acceptable. PIF has been reported as being a harder manoeuvre to perform than the frequently used PEF (Nairn *et al.* 1963). To summarise, further work investigating PIF and the In-Check Oral meter is needed before any conclusion can be made regarding its usefulness as a monitoring aid in clinical practice, in patients with and without COPD. The likely presence of a chronic respiratory disease, such as COPD, and the lack of specificity of measures of respiratory muscle strength, may reduce the usefulness of respiratory measures of strength. However, the interplay between pulmonary function and respiratory muscle strength may mean that a reduction in a respiratory measure is still a valid indicator of reduced muscle strength (Buchman *et al.* 2009). Peak nasal inspiratory flow, as opposed to oral (as referred to above i.e. PIF) is used for assessing nasal airway patency, but there is no evidence to suggest it may be used as a proxy measure of respiratory muscle strength, unlike inspiratory pressures (Ottaviano *et al.* 2008, 2012).

#### *4.1.3.3 Inspiratory pressures*

Inspiratory pressures are another proxy measure of inspiratory muscle strength, which can be measured non-invasively via the mouth (maximal inspiratory pressure, MIP) or nose (sniff nasal inspiratory pressure, SNIP). MIP is the more established of these two measures, but was considered and rejected for use in this study due to reported difficulties in performing the manoeuvre, demonstrated by an observed large learning effect, meaning that repeated assessments over a number of time points are required before maximal values are obtained (Evans *et al.* 2009; Terzi *et al.* 2009). SNIP has been seen to be a more pleasant experience for participants than the manoeuvre for MIP, but is a relatively newer measure with commercially available equipment only recently becoming available (Prigent *et al.* 2004). Initial published small studies involving SNIP (using non-commercially available equipment) have found it to be a reliable

measure of inspiratory respiratory muscle strength, especially the diaphragm (Maillard 1998; Fitting 2006; Colville *et al.* 2007), and has also been found to be less sensitive to a learning effect, which is expected from MIP and possibly peak flow measurements (Terzi *et al.* 2009). A previous study involving healthy young adults (n=10, 9 male) reported intraclass correlation coefficients (ICCs) for within subject variation of SNIP (ten readings per participant) ranging from 0.85-0.92, with between session reproducibility established at one day maintained after one month (Maillard 1998). Predicted normal values for healthy people aged up to 80 years have also been reported (age 66-80 years, n=20) (Uldry 1995). Once again more work is required on SNIP, a proxy measure of inspiratory muscle strength, to further establish its reliability, stability over time, and acceptability, to support research into its use in a frail older population.

### 4.1.4 Conclusion

The review of methodological literature led to the development of three separate studies to meet the overarching study aim (Section 3.3). Four muscle strength measures were selected for inclusion in the initial pilot study, grip strength, PEF, PIF and SNIP. The detailed protocols for the four strength measures are found in Section 5.5.1.The pilot study aimed to confirm the reliability and acceptability of the muscle strength measures in a healthy older population, prior to the follow-on feasibility study in case management patients, involving those measures successfully piloted. The feasibility study was designed not only to provide data regarding feasibility, including acceptability and reliability, but to provide normative muscle strength data for a case management patient cohort, as well as begin to explore whether muscle strength changed in a detectable manner over the short term, and whether changes, if observed, occurred concurrently to changes in health and function. The third study involved routine primary and secondary care data, hence variables were limited by the dataset, as such no muscle strength measures, direct or proxy were available. However, the presence of data covering multiple variables allowed the presence of frailty to be considered.

## 4.2 Frailty measurement

It is expected that many case managed patients will be frail, as anecdotally they are experiencing many of the aspects of and influences on frailty (Figure 2.5), such as, multiple co-morbidities, and reduced physical and functional ability. The presence of frailty in a case management population requires confirmation due to a lack of evidence on this patient group, hence the inclusion of a frailty measure within this research study. It may be that the expected high degree of frailty amongst case management patients produces a ceiling effect for frailty measures, where by all are defined as frail. Therefore, measuring or identifying frailty may add no new benefit. Such an effect was reported in 2011 amongst severely functionally disabled community dwelling adults (Au *et al.* 2011). The expected cross over between case managed and frail patient populations, and the clear link between muscle strength, frailty and decline in health/ poor health outcomes over the longer term, are useful in signposting the potential of monitoring muscle strength in the case management patient group.

Frailty can be considered and identified in a number of ways, including as a syndrome, by clinical judgement or by a deficit count. Fried *et al.* (2001) identified frailty as a syndrome, defined as the presence of at least three of the following symptoms:

- Weight loss: Fried *et al.* defined weight loss as 10lb or more in the past year;
- Muscle weakness: as defined by cut-off values for grip strength (Table 4.2);
- Exhaustion;
- Slow walking speed;
- Low activity.

Observational data from the research studies contained within this thesis were compared with Fried's definition above. Where direct comparison was not possible due to a variation in the data collected, details are provided in the chapter detailing each study (Chapters 5 and 6) into how data were handled.

A count of deficits is an alternative method of identifying frailty, with some suggestion that the more items counted the more accurate the resulting frailty score, especially in patients at the more frail end of the scale, but a large count is likely to be impractical in a clinical setting due to time constraints (Hubbard *et al.* 2009). Current research exploring clinical frailty scales suggests a count of between 40-50 items is optimum (Davis *et al.* 2011). The use of a deficit count with a large number of items considered has been demonstrated as better at discriminating amongst people at the more frail end of the frailty scale than a criterion based system of identifying frailty such as the Fried system, which is more suited to population studies (Fried *et al.* 2001; Hubbard *et*

*al.* 2009). The clinical judgement approach to identify frailty is also likely to be based on subjective consideration of similar factors. Whilst the frailty scales in development do demonstrate the expected link between a diagnosis of frailty and adverse health outcomes, limitations include their subjectivity and the skill required to interview the patient successfully to achieve an accurate frailty score.

The development of a clinical frailty scale for use in healthcare settings has been the focus of a number of research studies (Rockwood *et al.* 2005; Rolfson *et al.* 2006; Lopez *et al.* 2012; Drubbel *et al.* 2013). However, a robust fully validated tool is not yet available. The aim of healthcare services is not only to extend a person's life, but also to increase their quality of life. If it is possible to detect, respond to and slow a decline in health, it is hopeful that the period of better quality life can be prolonged. Whilst frailty assessment is being increasingly utilised in the secondary care setting, for example the use of Comprehensive Geriatric Assessment by geriatricians within the NHS secondary care setting, frailty assessment is seemingly underutilised in the community setting. Frailty assessment may enable better planning and provision of care, but the lack of tools to enable quick, objective assessments of frailty within the community acts as a barrier to this potential for improvement (Donald 1997). The methods of identifying and measuring frailty considered so far, via clinical judgement, syndrome and deficit count, have flaws, with no method objective, simple and quick to perform. Hence identification of frailty through the use of routine data or by muscle strength as a marker of frailty are considered further as methods that may lend themselves more freely to use in community dwelling case management patients.

### 4.2.1 Muscle strength as a marker of frailty

Muscle weakness has been identified as a symptom of frailty, and is a symptom that appears to lend itself to use in monitoring in patients' homes as it can be measured objectively, safely and non-invasively (Fried *et al.* 2001). Muscle weakness has been shown to be a predictor of health, function, and service use in the long term, while loss of muscle strength has also been associated with declines in both physical and mental health including chronic disease, cognition and depression, as well as part of normal ageing (Bassey *et al.* 1998; Newman *et al.* 2009; Oboh 2010). The established relationship between ageing and chronic illness, frailty and muscle strength, and physical function and service use, and the identified gaps in the evidence when considering using muscle strength provides the background to this study (Figure 1.1).

Grip strength is a frailty indicator that appears in a number of frailty measuring systems, where cut-off values are employed, as shown in Table 4.2 (Fried *et al.* 2001; Rockwood *et al.* 2007; Hubbard *et al.* 2009).

**Table 4.2 Fried's frailty criteria - grip strength cut-off values**

(Fried *et al.* 2001)

| ***Gender*** | **BMI** | **Cut off for grip strength (kg) criterion for frailty** |
|---|---|---|
| ***Male*** | ≤24 | ≤29 |
| ***Male*** | 24.1-26 | ≤30 |
| ***Male*** | 26.1-28 | ≤30 |
| ***Male*** | >28 | ≤32 |
| ***Female*** | ≤23 | ≤17 |
| ***Female*** | 23.1-26 | ≤17.3 |
| ***Female*** | 26.1-29 | ≤18 |
| ***Female*** | >29 | ≤21 |

As previously mentioned patients with long term conditions and complex health needs receiving case management are already likely to be frail, and therefore, likely to have a maximal grip strength value below the cut-off values presented in Table 4.2. Multiple measures of strength were selected due to the lack of evidence on the feasibility, reliability and usefulness of muscle strength monitoring in a frail elderly patient population. The routine primary and secondary care Hampshire Health Records (HHR) dataset accessed during Study C (Section 3.3) lacked muscle strength data, but provided data on a number of variables from different domains including demographic information, health and service use, from which a preliminary frailty index based on a count of deficits from routine data was developed.

### 4.2.2 Frailty Index (Study C)

A frailty index was developed based on a simple count of deficits from available HHR data. Frailty indices have been suggested as a way of considering health conditions and other risk factors formally and objectively, to provide a useful way to quantify accumulations of relatively small deficits across multiple systems (Pena *et al.* 2014). Evidence suggesting that it is the number of deficits that is important, not what the deficit is (Theou *et al.* 2014). A frailty scale has previously

been developed and presented using primary care routine data in the Netherlands, on a community dwelling population, which successfully demonstrated that the scale could be used to predict the risk of adverse health outcomes in an elderly community dwelling population (Drubbel *et al.* 2013). Numerous frailty scales or indices are available, with much commonality between them (Theou *et al.* 2014). Whilst ideally a frailty scale would include aspects across multiple body systems, this study was limited by the data recorded on the HHR, and the reliability of this data. For the majority of HHR variables, data were coded such that 1 represented the presence of a problem and 0 represented the absence of a problem. Exceptions to this are detailed below. Both graded scales and dichotic, yes/no scales, have both been shown to be effective (Pena *et al.* 2014). A simple count of deficits recorded on the HHR was used to produce a frailty count/ index using 19 points of reference (further detailed in Chapter 7), these items included:

a. Obesity: 1 point if obesity flag or body mass index (BMI)>30kg/$m^2$ recorded.
b. Deprivation/socio-economic status: 1 point if resident in the two most deprived Index of Multiple Deprivation (IMD) deciles.
c. Age: weighted by the formula age (years)/100 to give value between 0-1.
d. LTCs: 1 point for each LTC flag recorded, to a maximum of 14. Where flags had a low incidence, i.e. <10% incidence, flags were combined with other related flags to form overarching groups.
e. Polypharmacy: 1 point if 5 or more drug groups prescribed excluding analgesia, laxative, antibiotics, which are all likely to be used on an acute when required basis.
f. Falls: 1 point if fall recorded (across the 2 year data period).

For each patient, a frailty score was calculated by dividing the sum of deficits (a-f above) by the number of items considered i.e. 19. Adverse outcome measures considered alongside the frailty index included:

- A&E attendances (across the 2 year data period);
- hospital admissions (across the 2 year data period);
- frequency of community care team contact; and
- frequency of outpatient attendances (across the 2 year data period).

## 4.3 Demographic data

A variety of other independent variables were noted during the literature review as showing correlation with one or more measures of strength or LTCs, including age and gender, hence data were collected on these (Chapter 2 and Section 4.1). Women generally have lower muscle strength values compared to men, with lower height and weight tending to be associated with lower strength values. The prevalence of reported LTCs or disability appear correlated with socio-economic classification, with lower socio-economic classification associated with a greater number reporting a LTC (both limiting and non-liming LTC) (ONS 2012), and frailty (Lang *et al.* 2009). Social inequalities mediated by co-morbidity appear to exist when looking at the prevalence of frailty in the community (Syddall *et al.* 2010). An estimation of participants socio-economic status/ level of deprivation was obtained by attributing each participants residential postcode (Studies B and C) to the corresponding electoral ward (Study B) or Lower layer Super Output Areas (LSOA) (Study C). LSOAs are geographical areas, sub-divisions of electoral wards, used for providing data on a smaller population than electoral wards allow. LSOAs usually have a mean population of 1500. The Index of Multiple Deprivation (IMD) 2010 rank was then obtained, providing comparative data for England (Department for Communities and Local Government (DCLG) 2011). This data enabled the development of a demographic summary of a case management patient group, about whom little is currently known.

## 4.4 Body composition

Height, weight and BMI show varying degrees of correlation with muscle strength, including specifically grip strength (Samson *et al.* 2000; Miller *et al.* 2009). BMI appears to correlate with certain LTCs with a higher BMI associated with diabetes, arthritis, cardiovascular disease; concurrently weight loss appears to improve complications of diabetes and arthritis (DH 2007). It has been demonstrated that BMI also correlates with frailty, with low and very high BMI linked to increased levels of frailty (Hubbard *et al.* 2010).

## 4.5 Chronic diseases and medication

Medication and LTCs have been associated with lower muscle strength specifically, and frailty more generally (Figure 2.5) (Rockwood *et al.* 2005; Ashfield *et al.* 2010; Castaneda-Sceppa *et al.* 2010). Both a higher simple count of co-morbidities and medication, and the presence of specific chronic conditions and medication have been associated with frailty and grip strength in older people (Rockwood *et al.* 2005; Ashfield *et al.* 2010; Lopez *et al.* 2012). Collection of a simple count of chronic diseases and medication enabled a demographic profile of the study participants and

allowed some consideration as to whether the target, sample population for each study was recruited.

## 4.6 Function and physical activity

Measuring health and function is particularly difficult, with no gold standard instrument (Louie *et al.* 2010). Each approach has its strengths and limitations, with the optimal measurement strategy to measure the same phenomenon using several approaches (Gupta 2008). Measures that would be sensitive to small changes in health, for use in the patient group, and applicable to healthy older people were required. However, with increasing age some level of functional impairment can be expected, even in a self-reported healthy population, and it was hoped this could be detected. Levels of physical activity (collected via the Physical Activity Scale for the Elderly (PASE); Appendix 3) are likely to impact on the muscle strength i.e. someone undertaking regular strenuous weight bearing exercise is likely to be stronger than someone who does not. PASE is a 12 item scale measuring physical activity over the previous seven days. Scores were calculated as per standard scoring instructions, using weights and frequency values for each type of activity providing a score between 0 and 400 or more; scores were compared with published normative values (Washburn *et al.* 1993).

Barthel Index (BI; Appendix 4) and the Vulnerable Elders Survey-13 (VES-13; Appendix 5) were both included as measures of functional ability. Both instruments are free to use, quick and easy to administer and score with little/ no training required. BI is widely used in clinical practice and research, including in community services, to aid assessment of a frail older patient's ability to live independently. The BI is very quick to perform, but it is not comprehensive and omits certain areas of functioning, including domestic and social aspects (Gupta 2008), which may have a significant impact on a patients vulnerability or frailty. The BI is also relatively insensitive to small changes in functional ability that may be expected in the patient group of interest and has a known ceiling effect whereby it cannot detect somewhat less significant impairments to more domestic functional ability (Gupta 2008), hence VES-13 was included alongside the BI.

The VES-13 was developed as a function based screening tool for community dwelling older adults to identify people at risk of health deterioration (Saliba *et al.* 2001), and includes functional aspects seen in frailty scales (Rockwood *et al.* 2007) and domestic aspects not included in the BI. The VES-13 is targeted towards the vulnerable old, especially relevant to the patient group, but appears to be rarely used in published research (McGee *et al.* 2008). Self-reported functional limitations are not just associated with physical difficulty carrying out that task, but also with

other health and personal characteristics e.g. mood, hence self-reported limitations can provide information more than just task difficulty (Louie *et al.* 2010).

Other measures of function, health and physical activity were considered and rejected due to a lack of relevance to frail patients with long term conditions living in their own homes or a likely lack of sensitivity for use in these patients (Appendix 6 summarises the other measures considered and reasons for rejection). The presence of frailty and the likelihood of some degree of functional limitations make a floor effect a likely occurrence. These other measures considered included the Short Form-36 which was rejected due to the likely floor effect that would be experienced and lack of sensitivity to small changes in health and ability (McHorney 1996); the Euroqol, frequently used in population research, was also felt to be limited by a lack of content relevant to the patient group meaning it was unlikely to detect the small changes in health and ability expected in the patient group. Unsuitability for use in routine clinical practice e.g. prolonged administration or scoring times (e.g. Sickness Impact Profile that consists of 136 questions), a focus on the negative aspects of poor health that may be unhelpful and possibly psychologically harmful for regular administration to vulnerable patients, was also a consideration. Patients with multiple long term conditions, experiencing inflammaging are known to be at risk of depression and feelings of lack of enjoyment, to focus on such negative feelings was of concern (Hunt *et al.* 2009).

## 4.7 Symptoms/health experience

The Sickness Behaviour Scale (SBS) used in Study B (Appendix 7) was developed by the Memory Assessment and Research Unit, Southampton, to collect data from patients and their carers regarding any sickness behaviours they are experiencing. This tool was initially developed as part of a safety and tolerability study of Entanercept in patients with Alzheimer's disease. It has undergone preliminary validity testing, and is currently being validated in clinical groups, including this one, to see if it may be useful as an aid in initial and monitoring assessments. Many of the sickness behaviours include the atypical symptoms (Section 2.6.2), often related to ageing, chronic inflammation and frailty, and frequently observed in frail patients. Whilst there is no current approved marking/scoring scheme for the SBS, descriptive analysis was carried out. Patients were asked to report falls, associated with atypical presentation in older frail patients, and an adverse event associated with inflammaging (Hunt *et al.* 2009), as well as out of hours / unplanned health service use.

## 4.8 Acceptability of measures of strength

Researcher administered questionnaires with structured and semi-structured components obtained feedback on the muscle strength measures in relation to ease of completion and preference ranking in studies A and B (Appendices 8 and 9). Any measure to be used in routine clinical practice needs to be acceptable to the patient and clinician, hence structured feedback from participants was gathered, based on Hughes *et al.* (2011).

## 4.9 Conclusion

Table 4.3 summarises the study variables and highlights in which study (A, B or C) each is included. The following three chapters detail each of these three studies in turn, including their specific objectives and associated research questions, data collection protocols, analysis and finally the results, which leads to the assimilation and discussion of the three studies' findings in Chapter 8.

**Table 4.3 Study variables and their input into the studies**

| Variable | Study including variable |
|---|---|
| Muscle strength<br>(Grip strength, PEF, PIF, SNIP) | A, B (Grip strength, PEF, PIF only) |
| Frailty | A, B, C |
| Demographics and body composition<br>(Age, gender, height/weight, socio-economic status) | A, B, C |
| Chronic diseases and medication | A, B, C |
| Physical activity and function<br>(PASE, BI, VES-13) | A, B |
| Symptoms and service use<br>(SBS) | A, B, C |
| Acceptability of muscle strength measures | A, C |

**Study A:** Pilot study of measures of strength (Chapter 5)

**Study B:** Feasibility study of measures of strength in case management patients (Chapter 6)

**Study C:** Analysis of case management patients' routine health records (Chapter 7)

# Chapter 5 Study A: Pilot study involving measures of strength in healthy older adults

## 5.1 Introduction and research aim

This chapter details the specific research questions, methods and results for the pilot study, Study A, in healthy older adults. Whilst piloting the measures of strength selected for investigation, the study aimed to explore the reliability and acceptability of using simple, portable, non-invasive measures of muscle strength in healthy older adults aged 65 years and over. The study specific objectives below were developed to achieve the study aim.

### 5.1.1 Study specific objectives

- To examine whether four non-invasive measures of strength (grip strength, PEF, PIF, and SNIP) could be measured reliably in healthy participants aged 65 years and over.
- To evaluate whether four non-invasive measures of strength (grip strength, PEF, PIF and SNIP) were acceptable to participants and operators.

### 5.1.2 Study specific questions

The following questions were posed to meet the research objectives:

1. Can PEF, PIF, SNIP and grip strength be measured consistently and accurately by two operators, including the researcher, in people aged 65 and over?
2. Do participants and operators show a preference / dislike for any particular measure?
3. Are any unexpected side effects/ problems experienced or observed by participant or operator?
4. How long does each muscle strength test take to administer?
5. Are grip strength, PEF, PIF and SNIP values in this older adult group consistent with published normative values?

## 5.2 Study design and target population

A descriptive, observational pilot study was conducted involving self-reported "healthy", medically stable older adults, aged 65 years and over. Observational data were gathered at two time points, one week apart. A healthy sample population was required, containing participants who were medically stable and therefore whose health, function and physical ability, including their muscle strength, would remain stable between visit one and two, to allow reliability and accuracy to be assessed. Measures of strength were obtained by two raters, in collaboration with another post-graduate research student to allow assessment of inter-rater reliability as well as intra-rater reliability.

## 5.3 Inclusion and exclusion criteria

The inclusion and exclusion criteria aimed to allow recruitment of a healthy sample population aged 65 years and over who were medically stable, and hence whose muscle strength would not fluctuate significantly between visit one and two, allowing reliability assessment. The exclusion criteria aimed to exclude participants who had an active/unstable illness; whose strength measure readings would be more likely to change over the one week data collection period, which would not allow intra-rater reliability to be assessed. Older people (65 years and over) were targeted due to their relevance to the patient group of interest (patients receiving case management). A health screening questionnaire was utilised to assess whether participants met the exclusion/inclusion criteria (Appendix 10).

**Inclusion Criteria**

Self-reported healthy, medically stable men and women aged 65 years of age and over, receiving no case management.

**Exclusion Criteria**

Adapted from Greig *et al.* (1994) (* as/ similar to Greig criteria for medically stable elderly participants).

1 Serious, active/unstable chronic illness
    a. * Cardiac illness: myocardial infarction, symptoms of aortic stenosis, acute pericarditis, acute myocarditis, aneurysm, severe angina, clinically significant valvular disease, uncontrolled dysrhythmia, claudication, within the previous two years.
    b. * Thrombophlebitis or pulmonary embolus within the previous two years.

c. * History of cerebrovascular disease within the last two years or clinically significant on-going symptoms e.g. hemiplegia.
d. * Bone fracture sustained within the previous six months.
e. Unexplained fall within the previous two months.
f. Any reason for loss of mobility greater than one week in the previous two months, or greater than two weeks in the last year.

2 Mild, active/unstable illness
a. * Acute febrile illness within last two weeks.
b. Symptoms of acute illness e.g. cough, nasal congestion.
c. Shortness of breath.

3 Active systemic disease
a. * Uncontrolled metabolic disease e.g. diabetes, thyroid.
b. * Major systemic disease diagnosed or active within last two years e.g. cancer, rheumatoid arthritis, except where medically stable.

4 Preclude participation/consent
a. * Severe airflow obstruction: via nose or mouth.
b. * Significant emotional distress, psychotic illness, cognitive impairment or depression active within the last two years.
c. * Severe osteoarthritis or rheumatoid arthritis affecting hands and ability to grip.
d. Non-English speaking.
e. Muscle weakness e.g. neurological disease.

## 5.4 Recruitment strategy

Participants were recruited via volunteer response to a poster/ leaflet (Appendix 11) placed in clubs and centres around Southampton (Appendix 12), or by word of mouth. The clubs and centres approached were selected for their proximity/ ease of access to the University of Southampton, Highfield Campus, where data collection occurred, and the type of activity they offered. Fitness of participants was considered, with recruitment targeted via the type of club/ activity where posters and leaflets were displayed, towards those with a more sedentary lifestyle (so to be more relevant to the patient population, whilst still being medically stable enough to remain stable for the data collection period). This meant that sports centres and gyms were not approached to display posters or leaflets. Figure 5.1 illustrates the recruitment process.

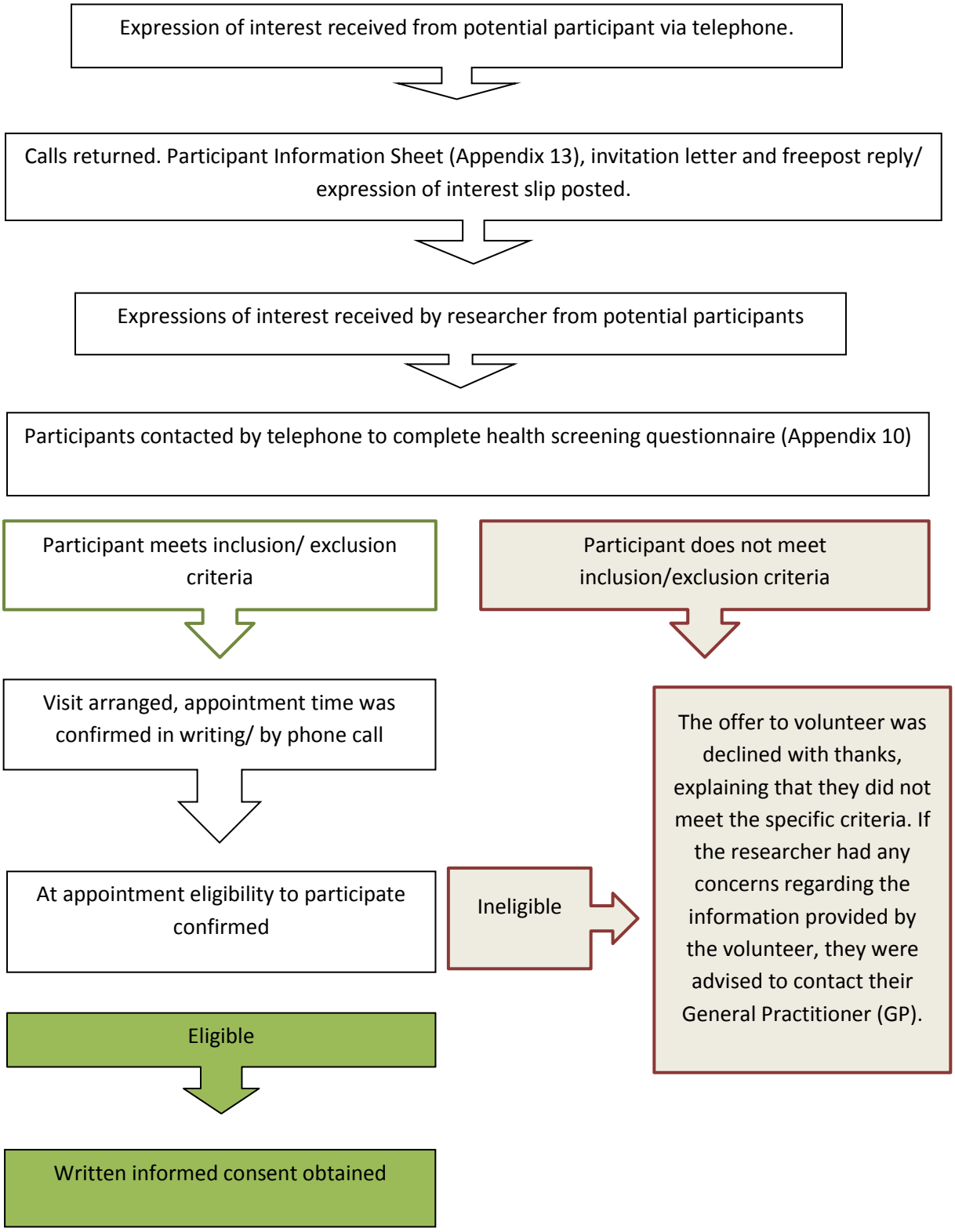


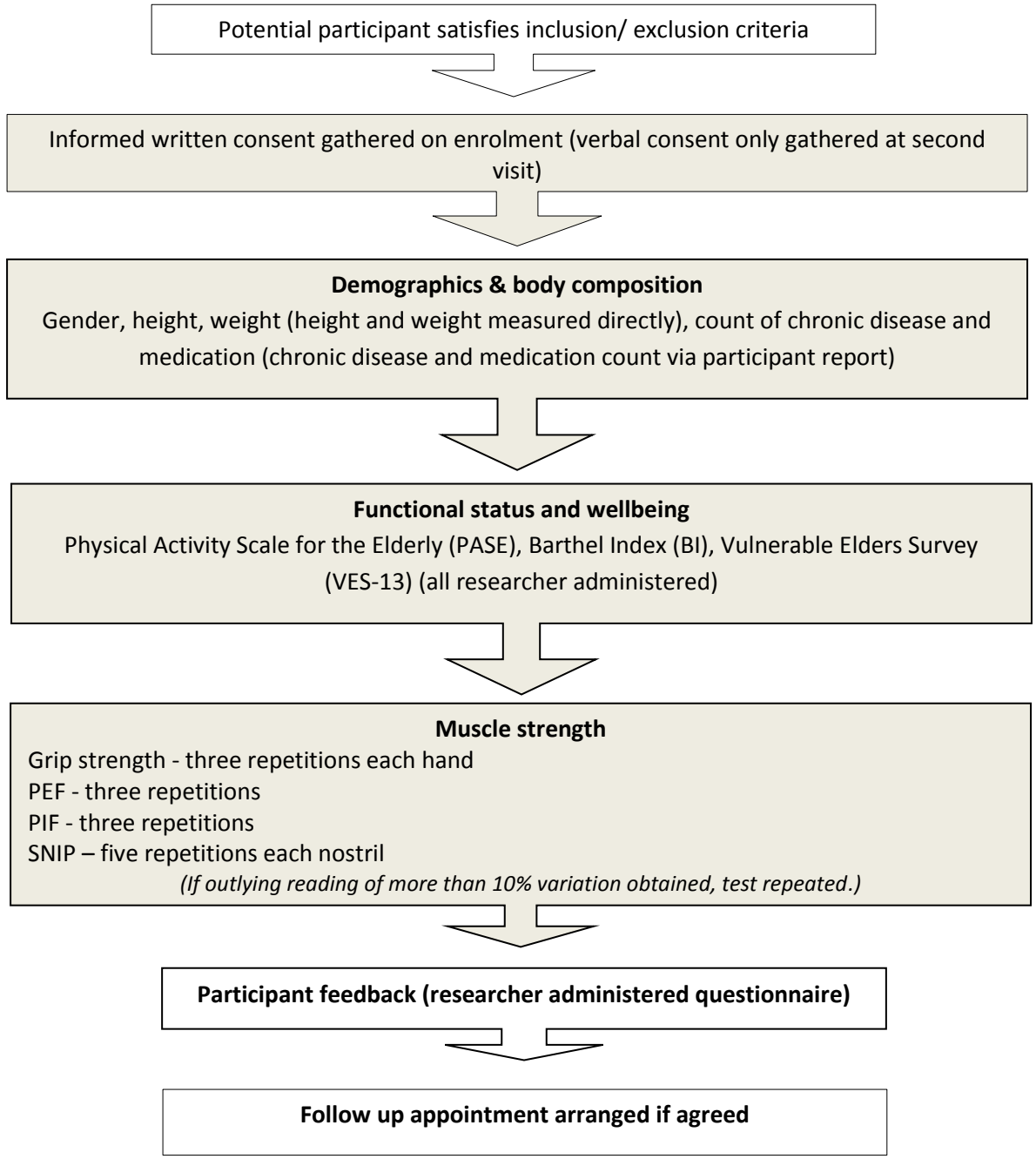

**Figure 5.1 Recruitment process for Study A**

Recruiting older people into clinical research studies is known to be difficult (McMurdo *et al.* 2011). The recruitment and data collection strategy employed took common difficulties into consideration, for example travel difficulties, with the researcher ensuring participants were confident in their travel plans to the study location prior to enrolment, and providing reimbursement of travel expenses and free at point of use taxi service where necessary.

## 5.5 Data collection protocol and study setting

Training sessions were completed by the researcher with colleagues within the Faculty of Health Sciences, University of Southampton, with completion of all data collection tools; feedback from these sessions informed the data collection protocol (Figure 5.2).

Study participants were invited to attend an initial 1 ½ hour appointment at the Highfield Campus, University of Southampton. At the end of the first visit participants were invited to attend a ½ - 1 hour follow-up visit.




N.B. Shaded boxes highlight activities occurring at both data collection time points.

**Figure 5.2 Data collection protocol for Study A**

### 5.5.1 Protocol for the measurement of muscle strength

Participants were tested in a sitting position on two occasions, one week apart, at the same time of day (to allow the participant to have a similar pre-test experience and try to negate the effects of muscle fatigue caused by activities of daily living e.g. carrying shopping or exercise class). Innes (1999) found that measuring grip strength at varying times of day should be of no concern to clinicians, but did find that activity-specific warm-ups had an impact. The influence of work and leisure on grip strength has been identified (Innes 1999) and the possible impact of daily activities and leisure activities led to participants being tested one week apart, on the same day of the week and similar time of day where possible, to allow for re-test and analysis of intra-rater reliability. A rest period of at least half a second between each exertion and one minute at the end of each test was included (Appendix 13 details the standard operating procedures for each measure). A random order to conduct the strength measures was generated prior to the first visit (via www.random.org, true random number generator; both measure and operator selected randomly). This order was maintained for the follow-up visit. Ahead of data collection all equipment were calibrated to ensure accuracy of measures, and then maintained in line with the manufacturers' guidance.

#### *5.5.1.1 Grip Strength*

The JAMAR® Hydraulic Manual Hand Dynamometer (Figure 5.3) was chosen for the study, a widely reported and recommended measure of grip strength (Innes 1999), along with an established testing procedure described below. The JAMAR® Hydraulic Manual Hand Dynamometer was readily available, and is one of two hand dynamometers available via the approved NHS supply chain. It is also frequently used to and referred to in published research, as a reliable and valid measure of grip strength. Whilst other makes are available, with variations in size, weight, ease of reading results, the JAMAR® was selected due to its immediate availability, ease of future availability for use in practice via the NHS supply chain and evidence supporting its validity, and enabling comparison with published normative values. Prior to the commencement of data collection the grip dynamometer was calibrated by an approved external

**Figure 5.3 JAMAR® manual hand grip dynamometer**

calibration company.

Participants were asked to perform the test three times with each hand, and the maximal value was used in analysis. Participants were tested in an upright sitting position, with their shoulder adducted and neutrally rotated, elbow flexed at 90°, forearm in neutral position, and wrist between 0° and 30° dorsiflexion and between 0° and 15° ulnar deviation. The JAMAR® Hand Dynamometer handle position was standardised at the second handle position from the inside for all participants. Participants were encouraged to provide maximal effort by giving the instructions "ready, set, go, squeeze as hard as you can…..harder!.....harder!.....stop". Whilst some patients may have preferred a smaller or larger handling position, this choice was removed to enable a standardised approach to be taken. A trial attempt was provided before any recordings were made, to allow for technique to be assessed and corrected if needed, as well as allowing participants to become familiar with the equipment and the manoeuvre.

#### *5.5.1.2 Respiratory muscle strength*

Three respiratory measures were chosen, PIF (Clement Clarke In-Check Oral, Figure 5.4), PEF (Clement Clarke Mini-Wright Standard Range, Figure 5.5), and SNIP (Micro Medical MicroRPM, Figure 5.6).

**Figure 5.4 Clement Clarke In-Check Oral Peak Inspiratory Flow meter**


**Figure 5.5 Clement Clarke Mini-Wright Peak Expiratory Flow meter**

Participants were asked to perform PIF and PEF three times, in a sitting position, as upright as possible, giving maximal effort. A trial attempt was provided for both manoeuvres before any recordings were made, to allow technique to be assessed and corrected if needed, and to allow the participant to become familiar with the equipment and the manoeuvre. Although it is standard practice when obtaining PEF and PIF measurements to have the patient stand, recent evidence does not support the need to stand, demonstrating no significant difference in PEF values whether sitting or standing (Vaswani *et al.* 2005; McCoy *et al.* 2010). Considering the evidence and the potential lack of ability of patients to stand in Study B, an upright sitting position was chosen. For PIF participants were asked to fully exhale then inhale forcefully through their mouth, taking a short sharp breath in of around one second in duration. For PEF participants were asked to take a deep breath in then exhale/ blow as hard and fast as they could through the mouthpiece.

**Figure 5.6 Micro Medical MicroRPM Respiratory Pressure meter**

Participants were asked to perform the SNIP manoeuvre five times each nostril, in a sitting position, as upright as possible, giving maximal effort. Participants were asked at the bottom of the tidal breathing cycle, to close their mouth and perform a forceful, maximal inspiratory sniff in through their nose. A trial attempt was provided before any recordings were made, to ensure the correct size nasal probe had been fitted by the researcher, and technique to be assessed and corrected if needed, and allow the participant to become familiar with the equipment and the manoeuvre.

## 5.6 Data management

All data were imported into SPSS statistical software package (version 19) from Excel. Data were double entered to check for errors, and cleaned via frequency tables obtained in Excel, prior to export. Excel was also used for presentation of data.

## 5.7 Data analysis

SPSS software was used for statistical analysis, including calculation and examination of the central tendency and dispersion of the values obtained for the measures of strength.

Inter- and intra- rater reliability was examined with reference to the performance accuracy data for each piece of equipment (Appendix 13), and published normative values (Appendices 14-16). The assessment of strength by the two different operators at the first visit allowed inter-rater reliability to be assessed. The return of the participants for a second visit allowed intra-rater reliability to be assessed. These assessments of reliability allowed consideration of the stability of the measures over a one week time period. A number of statistical tests were used during analysis as it is recognised that no single test was sufficient to fully reflect reliability (Whittaker *et al.* 2007). Inter-rater and intra-rater reliability was estimated by intraclass correlation coefficients (ICC model 3,1) (Shrout *et al.* 1979), Bland-Altman plots to identify bias (Bland *et al.* 1986), and standard error of measurement, and minimal detectable difference to consider normal variation (Ellasziw *et al.* 1994). Interpretation of the intraclass correlations was based on the Portney and Watkins (2000) interpretation values:

>0.75 excellent;
0.50-0.75 good;
< 0.50 poor; and
≥ 0.90 required for clinical measurements.

Grip Strength was also analysed with reference to Fried's frailty criteria (Table 4.2).

Analysis of the Interviewer administered questionnaire included descriptive statistics using data from Likert scales, and content analysis of qualitative data from open-ended questions.

## 5.8 Ethical considerations

The study was approved by the Faculty of Health Sciences Ethics Committee, University of Southampton in June 2011. Numerous factors were considered to ensure the protocol was developed ethically. This included training sessions completed by the researcher with colleagues from within the Faculty of Health Sciences, prior to protocol submission which informed the study protocol. The provision of the Participant Information Sheet (PIS, Appendix 13), encouraged participants to ask questions and helped ensure informed consent was obtained. Risk assessments were completed in accordance with University of Southampton Health and Safety Policy (2008), covering participants, researchers, location and equipment. The travel arrangements of participants to the venue were confirmed at the time of arranging the first visit. Due to the need for participants to be able to travel to the venue the number of socio-economic groups covered was likely to be limited. By allowing reimbursement of travel expenses and the variety of locations used for advertising the study an attempt was made to try and mitigate this. Recruitment was restricted to participants able to communicate in spoken English, as funding was not available to provide interpreters or aids.

### 5.8.1. Data Protection and anonymity

Participant names were not included on the data collection forms (Appendix 18), instead an identifying number was used, a record of which was kept separately in a locked filling cabinet along with the consent form (Appendix 19) to be accessed only for audit/emergency purposes. All data were kept and handled in a manner complying with the University of Southampton Data Protection Policy (2008). Permission was requested from participants at the time of obtaining written consent allowing the researcher to share information with the participants GP should anything be identified during the study that may impact on their health; permission was granted on all occasions.

## 5.9 Sample size

A target sample of 40 participants (20 males and 20 females), with a minimum acceptable sample size of 19 was proposed (Bland *et al.* 1996; Walter *et al.* 1998). The sample size was supported by Walter *et al.* (1998) who stated that n=19 is sufficient for inter- and intra-rater reliability between either two raters or two time points, and by sample size calculation for within subject standard deviation accepting 10% standard error (Bland *et al.* 1996). All participants were invited back one week later in order to repeat the muscle strength tests only, to allow intra-rater reliability to be checked.

Sample size calculation (Bland *et al.* 1996):

$1.96^2$ / (2 * standard error $^2$ * (no. of measurements per subject -1)) = n

Where number of measurements = 6, based on minumum number of repetitions required for any of the included measures of strength.

Accepting 10% standard error: $1.96^2$ / (2 * $0.10^2$ * (6-1)) = 38

Accepting 20% standard error: $1.96^2$ / (2* $0.20^2$ * 5) = 10

## 5.10 Results

### 5.10.1 Recruitment

Recruitment and data collection took place between July and November 2011. Twenty-one self-reported healthy adults (65-84 years) were recruited. The total number of participants fell below the target sample size, but above the minimum acceptable sample size. Below target recruitment occurred due to the recruitment process taking longer than expected; the difficulty experienced in recruitment informed the design and proposed timescale for Study B, with longer time being allowed for recruitment and data collection. All 21 participants attended two appointments one week apart. Potential participants were excluded at the screening stage due to not being medically stable, having significant physical symptoms that would prevent completion of the strength measures and cognitive impairment.

### 5.10.2 Demographic features of the sample

Of the 21 participants recruited, 13 (62%) were female. The higher proportion of females was in line with the higher life expectancy for females in the UK, and reflects the gender balance in the general older population, where 127 women for every 100 men aged 65 years and over are observed (ONS 2010).

The mean age for the group was 73.4 years (age range: 65-84 years), males were slightly younger with a mean age of 72.6 years, and females slightly older, mean age 74.0 years (Table 5.1).

The mean BMI for both males and females fell within the overweight category (Table 5.1), corresponding with published data for England suggesting that over two-thirds of healthy adults aged 65 years and over have a BMI that classifies them as overweight or obese (DH 2012c).

The presence of a diagnosed chronic medical condition and the taking of regular prescribed medication were common amongst the study participants (Table 5.1), corresponding with published data reporting that three out of five people aged over 60 years in England have a long term condition (DH 2012a).

**Table 5.1 Summary characteristics of Study A participants**

| | **Males (n=8)** Mean ± standard deviation (SD) | **Females (n=13)** Mean ± SD |
|---|---|---|
| **Age (years)** | 72.6 ± 4.3 | 74.0 ± 7.4 |
| **Body mass index (BMI)** | 26.3 ± 3.4 | 28.6 ± 5.7 |
| **No. of reported regular prescribed medication** | 2.8 ± 2.2 | 1.7 ± 1.4 |
| **No. of reported diagnosed chronic conditions** | 2.1 ± 0.9 | 1.8 ± 1.3 |
| **Maximal grip strength (kg)** | 39.1 ± 6.1 | 23.6 ± 5.6 |
| **Maximal PEF (l/min)** | 496.3 ± 73.8 | 323.5 ± 69.4 |
| **Maximal PIF (l/min)** | 303.8 ± 59.6 | 225.4 ± 56.6 |
| **Maximal SNIP ($cmH_2O$)** | 72.8 ± 19.9 | 60.8 ± 19.1 |
| **BI** | 99.4 ± 1.8 | 99.2 ± 1.9 |
| **VES-13** | 0.63 ± 0.51 | 1.7 ± 1.7 |
| **PASE** | 180 ± 68 | 117 ± 42 |

### 5.10.3 Functional status

The group demonstrated a high level of independence, as expected in a self-reported healthy population, with very high BI scores (99.3 ± 1.7; maximum achievable score i.e. highest functional ability is 100) and VES-13 scores (1.4 ± 1.2; maximum achievable score i.e. highest functioning is 0, while a score over 3 identifies a person as at higher risk (four times that of a person scoring 3 or less) of functional decline and death in the following one to two years) (Saliba *et al.* 2001). Some functional limitations were recorded via VES-13, notably in women, for which there may be competing explanations. While it is known that women tend to live longer than men, it is also recognised that women tend to have poorer health status, although it is not clear why (Hubbard *et al.* 2011). One possible factor that may be particularly relevant in a self-selecting "healthy" group such as this, may be that men and women report their health status differently, considering different abilities within their lives (Hubbard *et al.* 2011). The relatively small functional difficulties identified by the VES-13, even in this self-reported healthy group, support the use of VES-13 in community dwelling older populations, which is particularly relevant to this research study focusing on a community dwelling patient group. The results suggest that VES-13 is likely to detect smaller changes in functional ability than is possible with BI, which demonstrated a ceiling effect as expected from the literature (Gupta 2008; McGee *et al.* 2008).

### 5.10.4 Muscle strength and physical activity levels

PEF, PIF, grip strength and PASE values recorded generally agreed with published norms (Depledge *et al.* 1985; Mathiowetz *et al.* 1985; Nunn *et al.* 1989; Washburn *et al.* 1993), except for grip strength and PASE score (sample group PASE score 180 ± 68, preliminary published norm 102 ± 53.7 (Washburn *et al.* 1993)) in men which were slightly higher than the published norm (Mathiowetz *et al.* 1985). SNIP values appeared slightly below published values (n=100, Uldry *et al.* 1995); a higher mean age and BMI noted in this feasibility study may offer some explanation for this. PEF and PIF were within expected normal ranges for male and female participants. The mean maximal grip strength for females was within the normal range, but for males was above the expected value, this was in line with the men's above average PASE score (Washburn *et al.* 1993).

Considering the grip strength scores alongside Fried's frailty criteria (Fried *et al.* 2001), three participants' (14% of group, all female) grip strength values fell below Fried's frailty cut off values (Table 4.2), suggesting a degree of frailty may have been present. Published data from community dwelling cohorts, suggests a prevalence of frailty (based on Fried's criteria, Fried *et al.* 2001) at between 3.8% - 16.3% (Song *et al.* 2010). Along with "frail" grip strength values in these three participants a degree of functional impairment was detected by VES-13 in these participants, no degree of functional disability was noted via BI, and respiratory values were normal in all three cases. Despite not being able to confirm correlations between variables due to the small sample size, the findings and suggestion of correlation between grip strength and functional ability, which has been previously well reported, but not with the respiratory measures does support the use of respiratory measures only as part of a battery of measures at this stage. Thus a number of measures of strength and function were also included in the feasibility study (Study B) in patients.

#### *5.10.4.1 Reliability of measures of strength*

Intra-rater and inter-rater reliability estimated through ICCs (Tables 5.2 and 5.3), suggest that grip strength, PEF and PIF showed significantly greater reliability, compared to SNIP. Below target recruitment led to reliability being calculated for males and females combined and not separately. As females generally have lower strength, lower values are likely, including variability, which may have led to an over estimation of reliability. The ICC estimations were in line with prior published ICC figures for these measures where available (Innes 1999; Fonseca *et al.* 2005; Kamide *et al.* 2009; Abizanda *et al.* 2012).

**Table 5.2 Intra-rater reliability of grip strength, SNIP, PEF and PIF for Rater 1 (Study A)**

| | DAY 1 | | DAY 2 | | ICC (95%CI) | SEM | MDD |
|---|---|---|---|---|---|---|---|
| | **Females (n=13)** Mean ± SD | **Males (n=8)** Mean ± SD | **Females (n=13)** Mean ± SD | **Males (n=8)** Mean ± SD | | | |
| **Grip strength (kg)** | 22.5 ± 6.3 | 37.1 ± 7.6 | 22.3 ± 5.8 | 37.5 ± 7.6 | 0.97 (0.93-0.99) | 1.64 | 4.55 |
| **SNIP ($cmH_2O$)** | 44.8 ± 22.1 | 66.7 ± 21.8 | 53.3 ± 25.1 | 56.5 ± 30.3 | 0.76 (0.49-0.9) | 11.94 | 33.10 |
| **PEF (l/min)** | 303.8 ± 85.2 | 470.6 ± 78.6 | 306.1 ± 67.7 | 466.9 ± 72.3 | 0.95 (0.88-0.98) | 23.81 | 66.00 |
| **PIF (l/min)** | 200.4 ± 66.3 | 280.0 ± 75.8 | 213.5 ± 65.8 | 282.5 ± 57.0 | 0.92 (0.81-0.97) | 20.39 | 56.52 |

Abbreviations: CI, confidence interval; SD, standard deviation; ICC intra class correlation co-efficient; SEM, standard error of measurement; MDD, minimal detectable difference; GS, grip strength; PEF, peak expiratory flow; PIF, peak inspiratory flow; SNIP, sniff nasal inspiratory pressure.

*Measurements are mean ± SD. Based on maximal of 6 readings for GS (3 per hand), 3 for PEF and PIF and 10 (5 per nostril) readings for SNIP.

Figures 5.7 – 5.10 illustrate the between day variation observed with one rater for grip strength, SNIP, PEF and PIF, and demonstrate a larger magnitude of difference for SNIP than for grip strength with SNIP apparently showing increasing error at lower values.

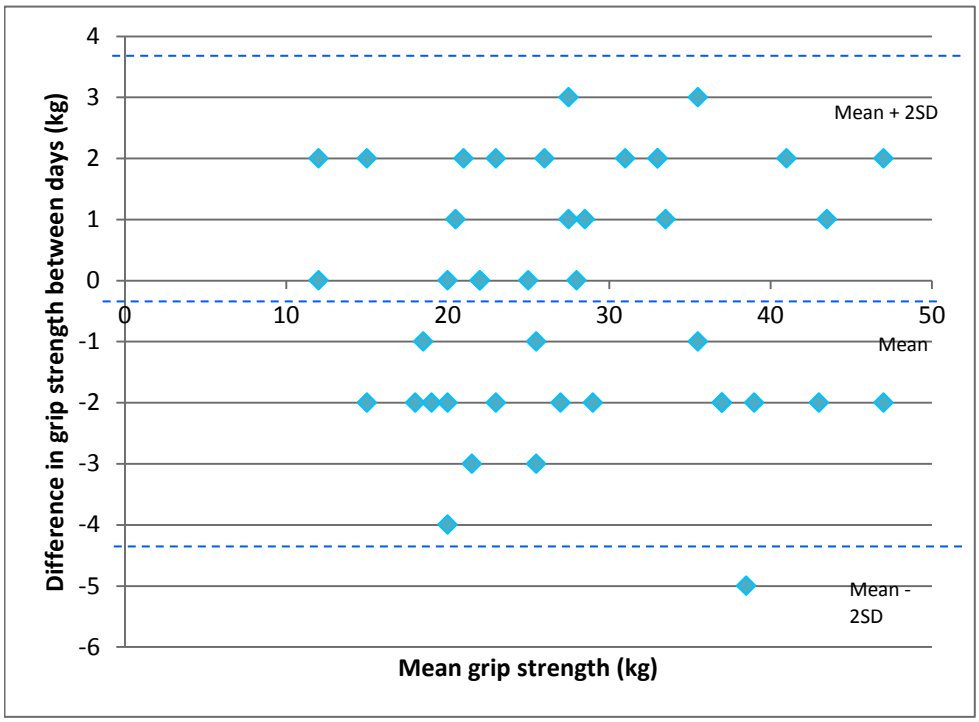



**Figure 5.7 Bland-Altman plot showing between day variation for grip strength**

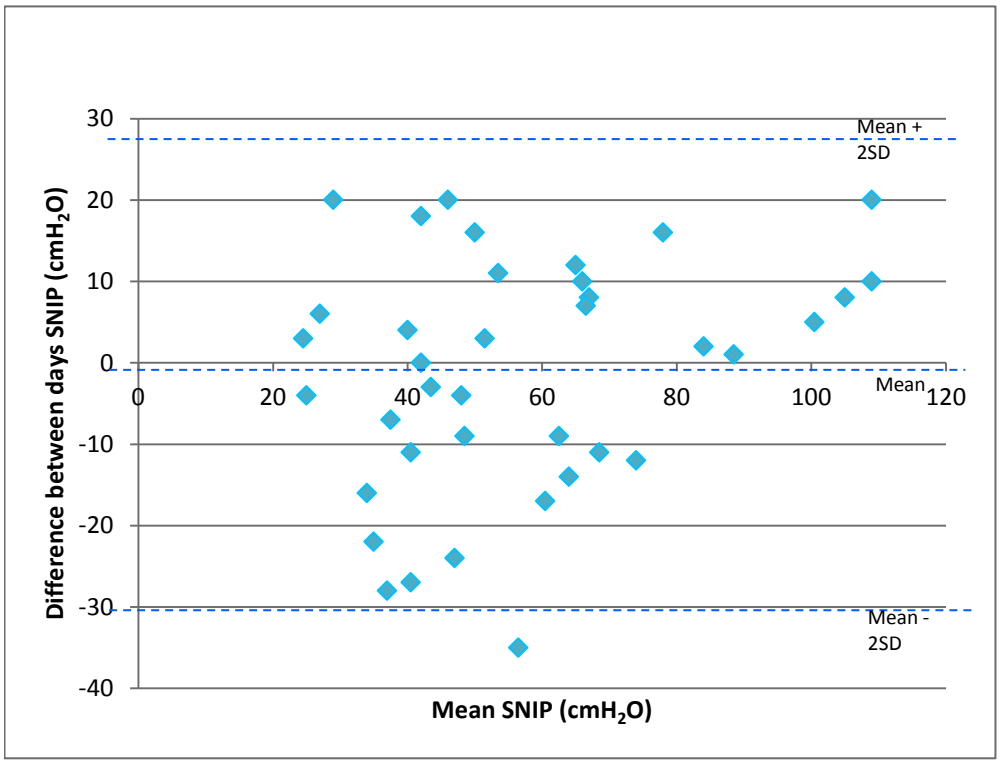



**Figure 5.8 Bland-Altman plot showing between day variation for SNIP**

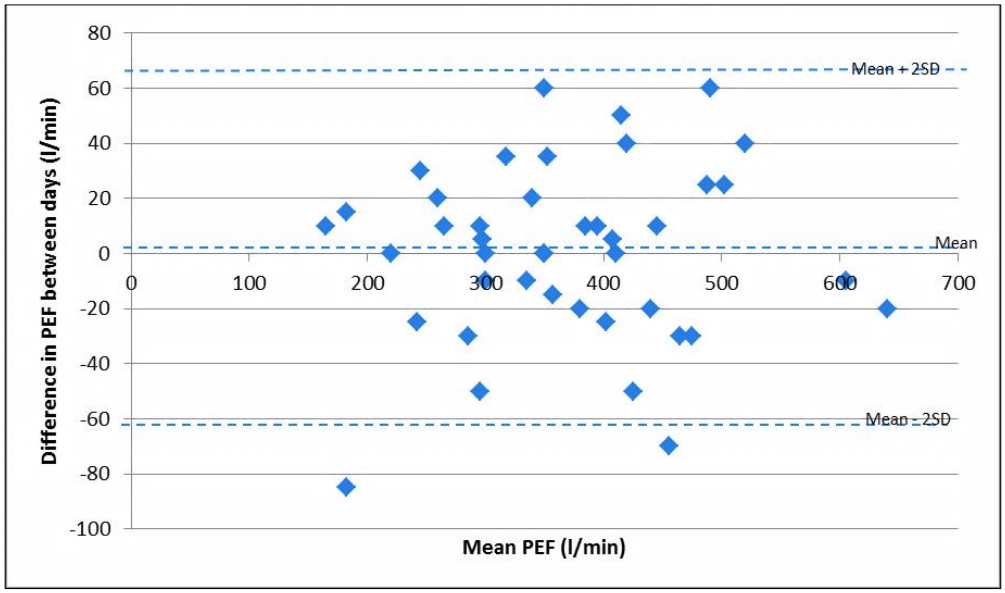



**Figure 5.9 Bland-Altman plot showing between day variation for PEF**

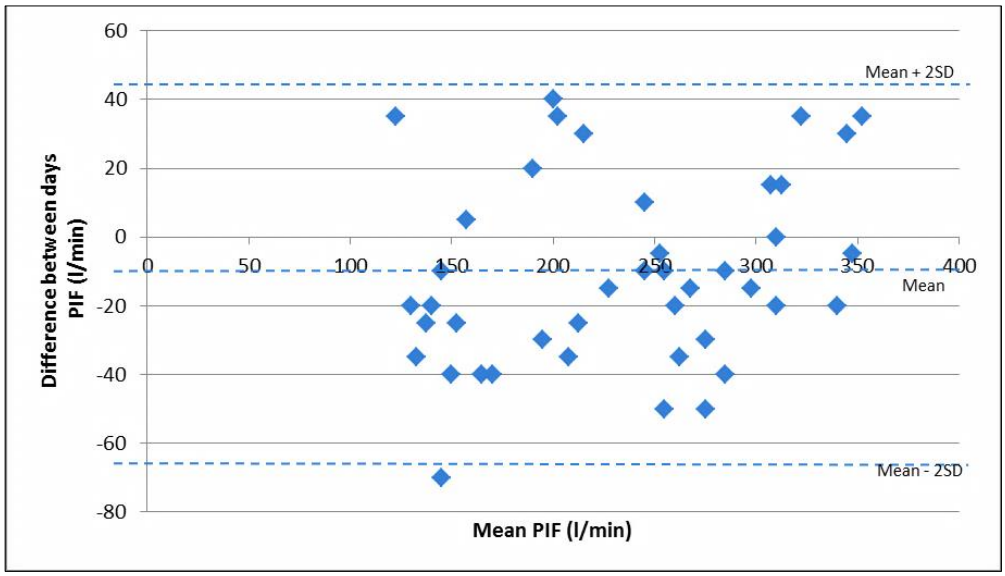



**Figure 5.10 Bland-Altman plot showing between day variation in PIF**

**Table 5.3 Inter-rater reliability of grip strength, SNIP, PEF and PIF (Rater 1 & 2)**

| | ICC (95%CI) | SEM | MDD |
|---|---|---|---|
| **Grip strength (kg)** | 0.99 (0.97-1.00) | 0.96 | 2.66 |
| **SNIP ($cmH_2O$)** | 0.88 (0.70-0.95) | 8.47 | 23.48 |
| **PEF (l/min)** | 0.98 (0.94-0.99) | 15.38 | 42.63 |
| **PIF (l/min)** | 0.97 (0.92-0.99) | 12.80 | 35.48 |

* Calculated using maximal values from day 1.

Bland-Altman plots (Figures 5.11- 5.14) for between rater differences demonstrate increasing magnitudes of difference from grip strength, to PEF and PIF and finally SNIP. The Bland-Altman plot for SNIP again shows apparent increasing error at lower values.

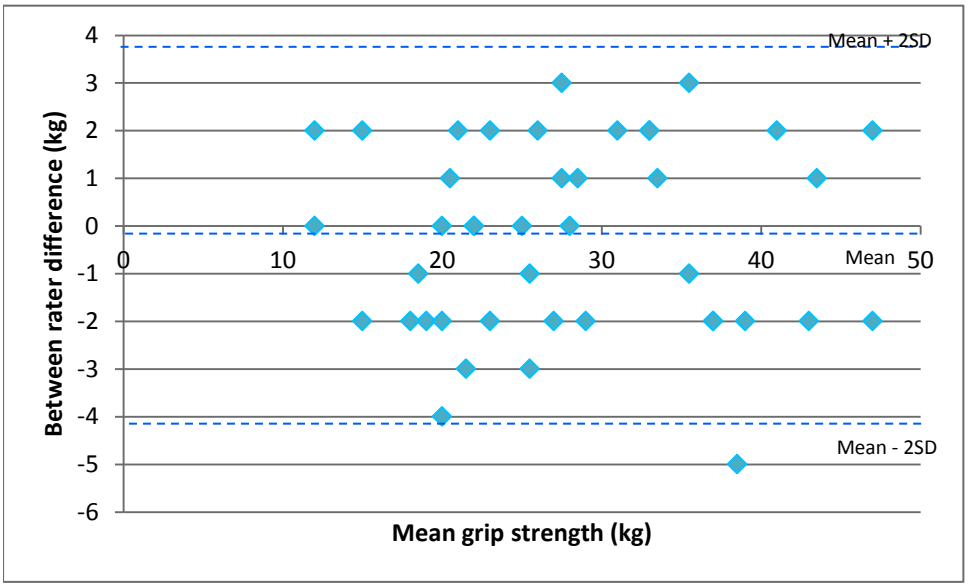



**Figure 5.11 Bland-Altman plot demonstrating between rater variation for grip strength**

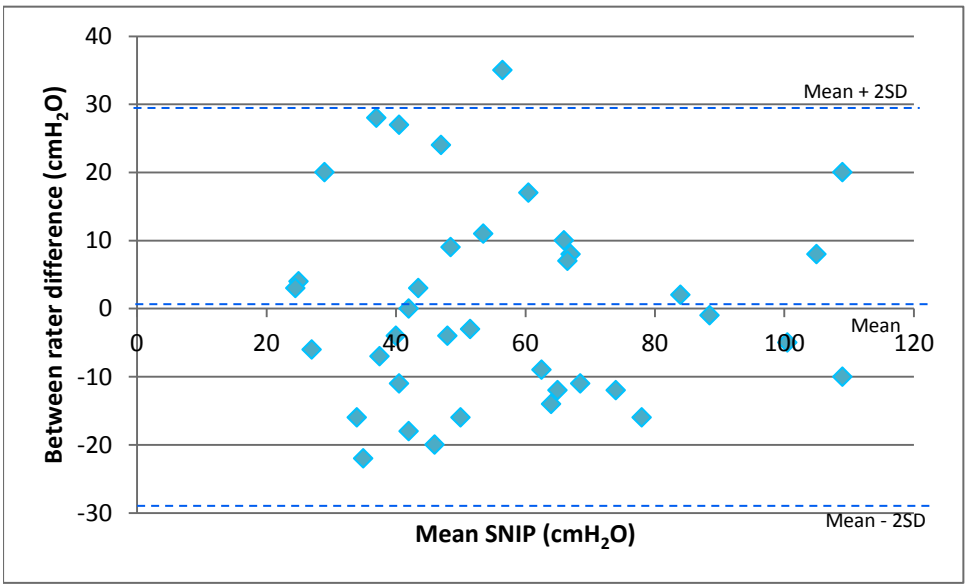



**Figure 5.12 Bland-Altman plot demonstrating between rater variation for SNIP**

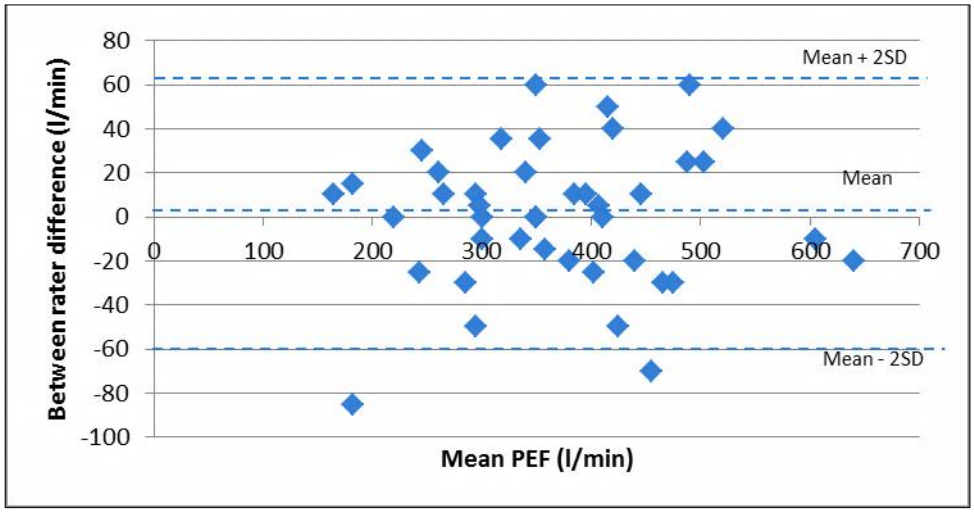



**Figure 5.13 Bland-Altman plot demonstrating between rater difference for PEF**

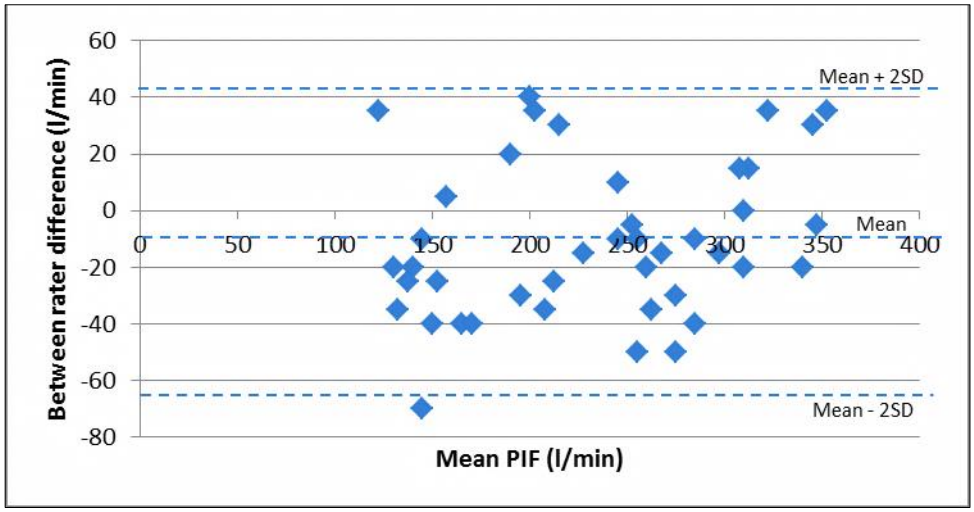



**Figure 5.14 Bland-Altman plot demonstrating between rater difference for PIF**

The reliability estimates for the strength measures were in line with previously published work (Innes 1999; Fonseca *et al.* 2005; Kamide *et al.* 2009; Abizanda *et al.* 2012), and demonstrated that grip strength, PEF and PIF could be measured consistently and accurately in people aged 65 years and over by the operators and remained stable over the one week testing period. SNIP was the least reliable measure; ICC falling below the recommended 0.90 to ensure validity for clinical measurements (Portney and Watkins 2000). Previously published reliability figures for SNIP, when assessing using Portney and Watkins (2000) validity requirements also were below 0.90 (Maillard *et al.* 1998). The Bland-Altman plots for SNIP also demonstrated proportionally wide limits of agreement when compared to the other three measures of strength, and showed SNIP's apparent increasing error at lower values, limiting its clinical use. The poor reliability of SNIP could be due to numerous reasons that need to be mentioned, including poor operator technique and the

possibility that there may be a considerable learning effect that may mean that with further repetitions the reliability may have increased.

### *5.10.4.2 Acceptability*

Participants found grip strength generally the most acceptable strength measure, followed by PEF and PIF, with SNIP the least preferred (Table 5.4).

**Table 5.4 Participant feedback and time to complete measures of strength**

| ***Questions 1-4 Likert scale 1-5, where 1 is strongly disagree, to 5 strongly agree (mean score)*** | **PEF** | **PIF** | **SNIP** | **Grip** |
|---|---|---|---|---|
| **1.“It was easy to understand what I had to do”** | 4.9 | 4.7 | 4.7 | 5 |
| **2.“It was easy to do”** | 4.9 | 4.6 | 4.5 | 4.8 |
| **3.“It was comfortable to do”** | 4.8 | 4.7 | 4.4 | 4.5 |
| **4.“I would recommend the test to anyone”** | 5.0 | 5.0 | 4.8 | 5.0 |
| **5.Tests’ ranking in order of preference (1 to 4, where 1 is most preferred to 4 is least preferred):** | | | | |
| **Mean** | 1.6 | 2.5 | 3.0 | 1.8 |
| **Mode** | 2 | 2 | 4 | 1 |
| **Time taken, in minutes, to complete 3 repetitions for PEF, PIF and grip strength, and 10 for SNIP** | 1.4 | 1.5 | 4.0 | 1.2 |

Incomplete SNIP readings were obtained on four occasions, due to incorrect technique, displacement of the nasal probe, dislike of test, and submaximal effort observed. These difficulties may become increasingly troublesome when used in a patient population, especially where frequent use may be required, and may lead to unacceptable levels of patient burden. Incomplete PEF and grip strength readings were obtained on one occasion due to coughing and acute soft tissue infection respectively. PIF was completed on all occasions. No other unexpected side effects or problems were observed.

Participants rated SNIP as the least easy and comfortable test to perform and the least preferred to complete, followed by PIF (Table 5.4). Neither the participants nor operators found the SNIP easy to perform, with incorrect technique, displacement of the nasal probe and submaximal effort observed.

The most common improvement suggested by participants for PIF and PEF were availability of different sized mouthpieces. Participants also suggested a recessed marker for PEF to prevent the inadvertent blocking of it by fingers and an erroneous reading. In relation to grip strength the

main participant recommendation for improvement was an improved grip surface, offering increased grip and comfort.

The time taken to complete all repetitions of one measure of strength with one operator was generally less than 4 minutes (Table 5.4); grip strength (one hand only), PEF and PIF took the shortest time (1.5 minutes or less), which corresponds with the lower number of repetitions required.

## 5.11 Conclusion

The reliability estimates for all four of the strength measures were in line with previously published work (Innes 1999; Fonseca *et al.* 2005; Kamide *et al.* 2009; Abizanda *et al.* 2012), and demonstrated that grip strength, PEF and PIF could be measured consistently and accurately in people aged 65 years and over by the operators and remained stable over the one week testing period. SNIP was the least reliable measure; ICC falling below the recommended 0.90 to ensure validity for clinical measurements (Portney and Watkins 2000). Previously published reliability figures for SNIP, when assessing using Portney and Watkins (2000) validity requirements also fall below 0.90 (Maillard *et al.* 1998). Bland-Altman plots for between day and inter-rater reliability of SNIP also demonstrated proportionally wide limits of agreement when compared to the other three measures of strength, and show SNIP's apparent increasing error at lower values, limiting its clinical use. Whilst reasons for the observed poor reliability of SNIP may not be equipment alone, and may be due to a learning effect and poor operator technique, these reasons support its unsuitability for use as a measure of strength in most clinical practice as training needs would be high and patient burden too great. Participants found grip strength generally the most acceptable strength measure, followed by PEF and PIF, with SNIP the least preferred (Table 5.4).

The slower than expected recruitment observed in the pilot study was considered in the development of the follow on feasibility study proposal, with longer recruitment and data collection periods proposed than initially planned.

In conclusion, the results from this pilot study indicate that PIF, PEF, and grip strength are both reliable and acceptable in older adults aged 65 years and over. SNIP did not demonstrate high enough reliability to recommend use as a clinical measure, and was the least acceptable to participants. The excellent reliability and acceptability of PIF, PEF, and grip strength justified their inclusion in the follow on feasibility study in case management patients (Study B), detailed in Chapter Six. The aim of which was to explore the feasibility, acceptability and usefulness of using measures of muscle strength to monitor health status in older people receiving community case

management, as a way of improving patients' on-going assessment, to enable case managers to target care effectively.

# Chapter 6 Study B: Feasibility of using measures of muscle strength in the routine monitoring of case management patients

## 6.1 Introduction and research aim

This chapter details the study specific objectives and methods of the observational, longitudinal feasibility study, Study B, exploring the feasibility of three measures of strength as a monitoring aid in patients with long term conditions, aged 65 years and over, receiving community case management, as well as briefly covering the impact of the results of the prior pilot study on this study's design.

If a simple measure of muscle strength could be found to be a useful indicator that can predict/ detect declining health, it may act as a red flag, alerting the clinician to the need for intervention. Although muscle strength has been associated with longer-term declines, it has not been established as an indicator of shorter-medium declines associated with adverse health outcomes which would make it a useful monitoring tool. Therefore, a study was needed of short to medium term muscle strength changes in the patient group, and any concurrent observed changes in health and function.

### 6.1.1 Study specific objectives

To address the aim of this study, five study specific objectives were developed:

1. To examine whether three non-invasive measures of strength (grip strength, PEF, PIF) could be measured reliably in patients receiving case management.

2. To investigate whether grip strength, PEF and PIF remained stable over the short to medium term in case managed patients.

3. To evaluate whether three non-invasive measures of strength (grip strength, PEF and PIF) were acceptable to patients and clinicians.

4. To explore the relationship between muscle strength, and health and functional status.

5. To begin to explore the physical and functional profile of patients receiving case management.

### 6.1.2 Study specific questions

To meet the objectives five study specific research questions were posed:

1. Can grip strength, PEF and PIF be measured reliably in patients receiving case management?

2. Are there measurable declines in grip strength, PEF and PIF over a seven week period in patients receiving case management?

3. Are the measures of strength acceptable to patients and clinicians?

4. Are changes in strength associated with changes in wellbeing, function, health status and health service use?

5. What is the physical and functional profile of patients receiving case management?

## 6.2 Study design and sample population

An observational, longitudinal, feasibility study was conducted, exploring the feasibility of three measures of strength as monitoring aids, to provide initial data for the development and evaluation of a case management monitoring procedure using measures of strength. This study involved repeated assessments of physical, health and functional status including muscle strength, in case management patients, at a minimum of two time points, maximum five time points over a maximum seven week period. Data on patients' health, physical and functional profile including health service use were gathered via patient recall and the use of questionnaires collecting data on symptoms, function, daily activities and service use. The reliability of the three non-invasive measures of strength, successfully piloted in Study A, (grip strength, PEF and PIF) was assessed using repeated measures over a one week period. The stability of muscle strength over the short-medium term was addressed by repeated measurement once a fortnight for a maximum of seven weeks (five time points). The acceptability of the measures of strength to patients and clinicians was explored by collection of patient and clinician feedback via researcher administered questionnaires. Data collection took place in patients' homes and clinicians' place of work.

The results from the prior pilot study indicated that the measurement of grip strength, PEF and PIF appeared feasible in a 65 years and over sample population, hence were included in this patient group study. Difficulties in recruiting participants in a suitable time frame for the prior pilot study led to an expanded recruitment period for this feasibility study, which increased from an initially designed six months, to twelve months to allow for slower recruitment. The suggestion of the presence of frailty, when referencing against Fried *et al.*(2001) grip strength frailty cut-off

values (Table 4.2), in some of the self-reported "healthy" pilot study group, re-enforced the expectation that many patients receiving case management are frail. The "healthy" Study A participants who had a "frail" grip strength value (when referenced against Fried *et al.* (2001) cut-off values (Figure 4.2)), only had at most one other "frail" indicator e.g. low activity as identified by PASE or an "at risk" VES-13 score. Non had three indicators as suggested necessary by Fried *et al.* (2001). Whilst unfortunately there is no accepted and recommended measure of frailty for use in the community dwelling older population, the variety of observational data collected in this study, including two measures of functional ability aid such an assessment. Both the commonly used BI (Appendix 4) and less used but possibly more sensitive to small changes, VES-13 (Appendix 5), were included to help an assessment of the incidence of frailty in the patient group.

## 6.3 Sample size

A target sample of 10-12 case management patient participants, developed from sample size estimations (Table 6.1), and a convenience sample of 3-5 clinician participants for feedback of the measures of strength, were proposed. Sample size estimations for patients were achieved using Stata software and a random order system to generate 250 simulation data sets to a predefined structure (Table 6.1; Appendix 20).

**Table 6.1 Sample size estimations using Stata output**

| | Grip Strength | Adequate sample size |
|---|---|---|
| ***Expected mean/starting level for patient group (from Study A)*** | 28.1kg (SD 9.6) | - |
| ***Estimated maximum decline for patient group over a 12 week period (from literature review, Table 4.1), calculated using an expected correlation between different time points of 0.9 (from Study A and literature review, Table 4.1)*** | Simulation 1: 45% | 8 |
| | Simulation 2: 35% | 10 |
| | Simulation 3: 25% | 12 |

The generated data sets were based on changes in grip strength observed in a small number of studies identified during the literature review (Section 4.1.2; Table 4.1). The data sets were then analysed using repeated measures of analysis of variance, and applying the BOX correction for correlation (power 80%, $p \leq 0.05$). The results indicated that a sample size of 10 would be sufficient to identify a 35% change in strength (calculations based on grip strength), and a sample size of 12 sufficient to identify a 25% change in strength.

## 6.4 Inclusion and exclusion criteria

The inclusion criteria allowed patients and clinicians across two NHS Trusts to be approached for participation in the study to help achieve the target sample size. The exclusion criteria aimed to avoid placing unnecessary burden on especially vulnerable patients, including patients receiving end of life care, and reducing the risk of adverse events to both patients and researcher, whilst still allowing recruitment of a representative sample of case managed patients.

**Inclusion Criteria for patients**

Men and women aged 65 years of age and over receiving case management from Solent NHS Trust or Southern Health NHS Foundation Trust.

**Exclusion Criteria for patients**

1 Enrolled in any other research study

2 Preclude consent

   a. Significant (moderate/ severe) cognitive impairment or lack of capacity to consent.

   b. Unable to communicate without significant aids e.g. Non-English speaking.

3 Preclude participation/ collection of data

   a. Significant emotional distress or psychotic illness active within the last six months.

   b. Receiving end of life care.

   c. Current illness that would preclude data collection, including acute exacerbation of COPD or asthma.

   d. Upper limb pathology that would limit participation e.g. bone fracture within the previous six months.

   e. Identified as high risk patients with regards to lone working safety by their referring community care and nursing team.

**Inclusion and exclusion criteria for clinicians:**

**Inclusion criteria**: Providing on-going care to patients receiving case management within Solent NHS Trust or Southern Health NHS Foundation Trust.

**Exclusion criteria**: Enrolled in any other research study; unable to communicate in English without significant aids.

## 6.5 Ethical considerations

The study received ethical approval from Southampton B Ethics Committee in July 2012.
As there was no substantial reason for including significantly cognitively impaired patients in the study, good clinical research practice was followed, and fully informed consent obtained from participants. To aid this the Six Item Cognitive Impairment Test (6CIT) (Appendix 21) was used as a screening tool to help ensure patient participants had the necessary level of cognition to consent. Where 6CIT identified mild cognitive impairment a formal assessment of capacity was made. (If moderate or severe cognitive impairment was identified, the patient was referred back to their case manager.) Capacity was to be presumed unless 6CIT identified impairment (Figure 6.1, Church *et al.* 2007). In line with General Medical Council (GMC) guidance (2008), capacity was only presumed lacking if the participant failed to understand, retain, use or weigh up the information given to them. Recall techniques were used to ensure that patients were aware of what taking part in the study involved and the choice they had about taking part.

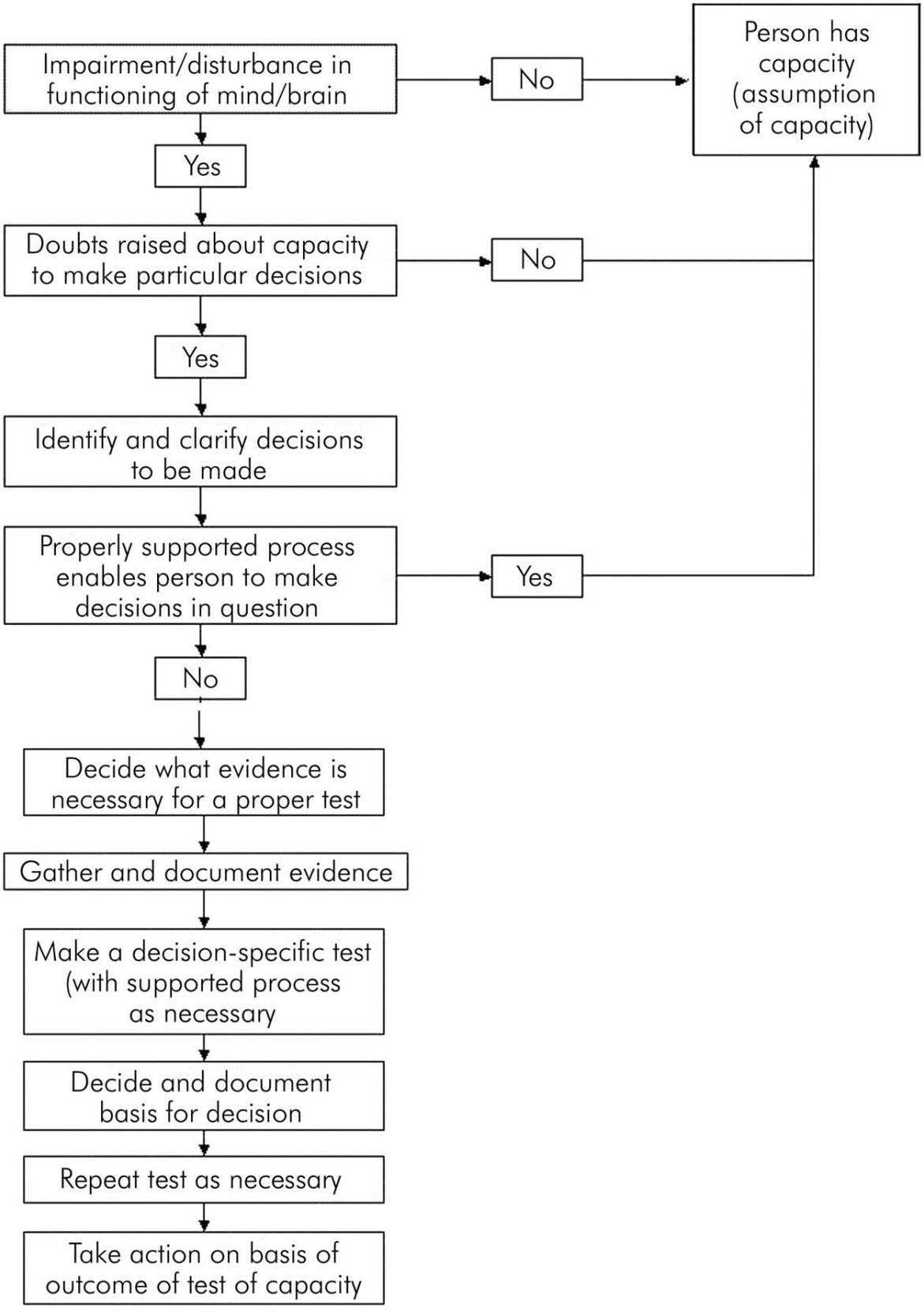



**Figure 6.1 Mental capacity assessment recommendations (Royal College of Psychiatrists guidance)**

(Church *et al.* 2007)

### 6.5.1 Six Item Cognitive Impairment Test

As it was predicted that many members of the patient group were likely to be frail, therefore at increased risk of cognitive decline, the use of 6CIT as a screening tool was agreed to be appropriate (Brooke *et al.* 1999, Mitnitski *et al.* 2011). 6CIT is recognised by The Royal College of General Practitioners and the National Institute for Health and Clinical Excellence (NICE), as a useful quick to administer (2.5-4 minutes) cognitive impairment screening tool in primary care, with high sensitivity and specificity, including in mild dementia (NICE 2006). On comparison with the Mini-Mental State Examination, a tool more commonly recognised by many health care professionals, 6CIT appears to correlate highly, whilst being administered in approximately half the time (2.5 minutes) (Tuijl *et al.* 2011). Where 6CIT indicted mild cognitive impairment, an assessment of capacity was made.

### 6.5.2 Assessment of capacity

Four core questions were used to help establish whether a patient had the capacity to make the decision to participate in the study based on accepted criteria for establishing capacity in line with GMC guidance (2008):

- Can the patient understand the information given about the study?
    a. "What is your understanding of what the study is about?"
- Can the patient weigh up the information?
    a. "What will taking part mean for you?"
- Can the patient retain the information?
    a. A recall question will be used following up on a point discussed earlier on in the conversation e.g. "Can you remember, if you decide to take part, how long will I be visiting you for?"
- Is the person able to communicate their decision?
    a. "You have been given a lot of information, have you decided what you'd like to do about the study?"

If yes to all, the patient was assumed to have capacity, if no to any, it was to be assumed that the patient lacked capacity to consent and was ineligible to participate in the study.

## 6.6 Recruitment strategy

Patients were recruited following a collaborative identification process involving the case manager and researcher, with reference to the study inclusion and exclusion criteria. Suitable patients were recruited via an invitation pack containing a participant information sheet (PIS) and invitation letter (Appendix 22). If after receiving the invitation pack the patient wished to participate, they submitted a written "note of interest" reply slip to the researcher via a freepost envelope, or by a verbal expression of interest. Upon receiving an expression of interest the researcher completed the screening questionnaire over the telephone (Appendix 23).

## 6.7 Data collection protocol

In patients the study variables, including PEF, PIF, and grip strength were assessed alongside usual monitoring which continued to be managed by the patient's case manager. The measures of muscle strength were carried out in a randomised order, following the operating procedures detailed in Section 5.5 and Appendix 13. Figures 6.2 and 6.3 illustrate the data collection protocols for initial and follow-up visits with patients (data collection forms Appendix 24).

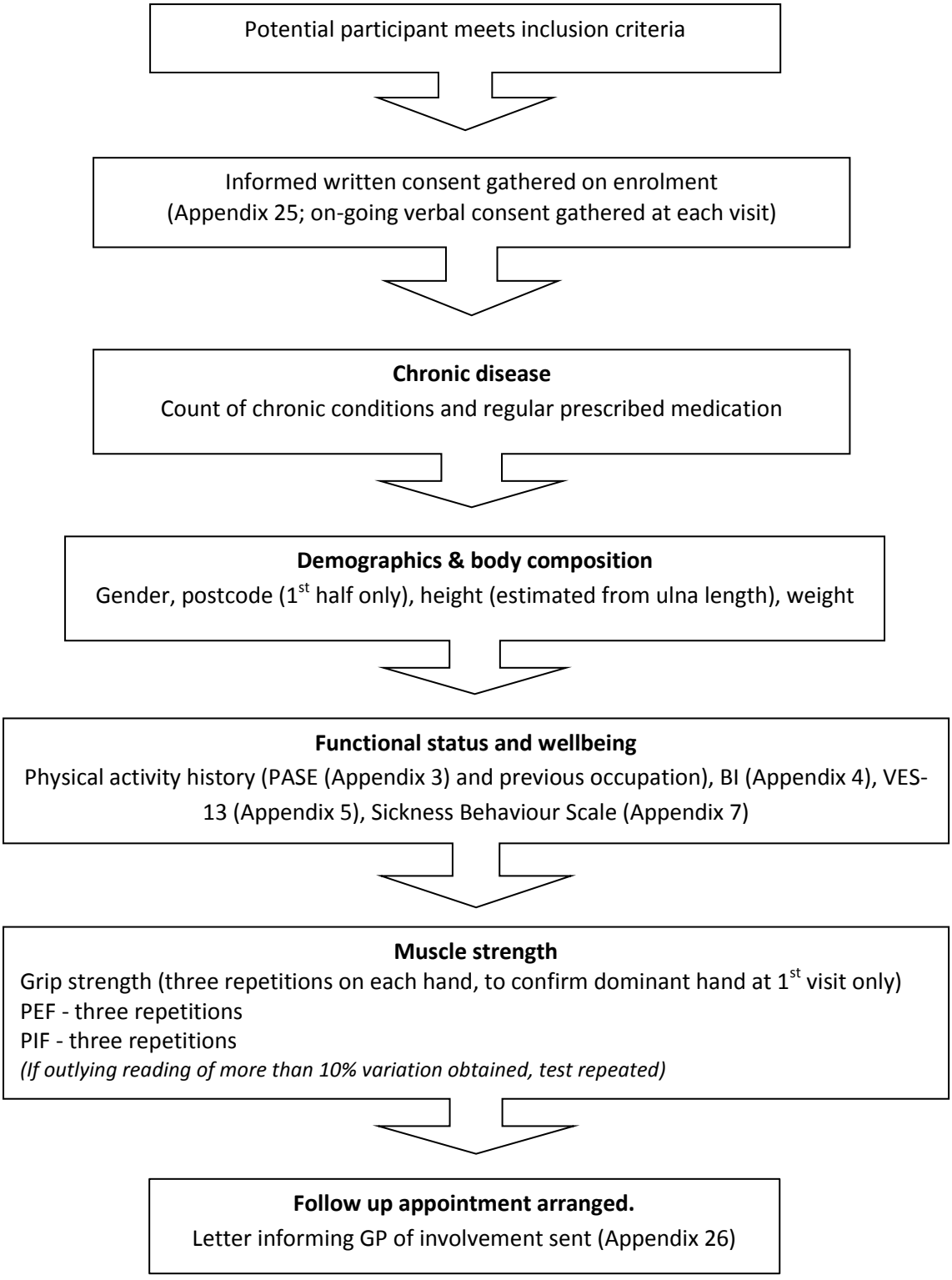



**Figure 6.2 Data collection protocol for patients' first and final visit**

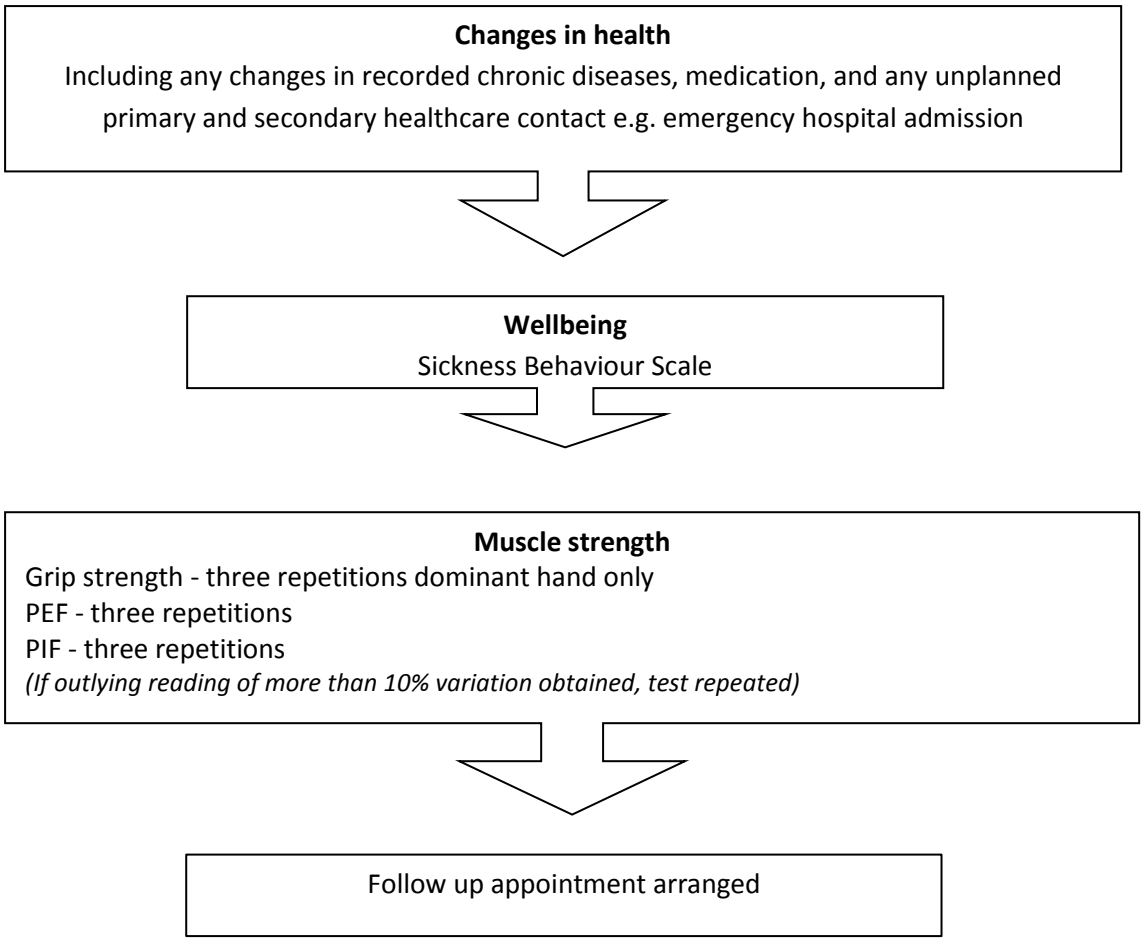



**Figure 6.3 Data collection protocol for patients' follow-up visits**

Clinicians who expressed an interest in providing feedback of the measures of muscle strength were provided with a Participant Information Sheet (Appendix 27) for their consideration. They were asked to contact the researcher directly to participate and a visit was arranged by the researcher to their workplace, at a convenient time, when written consent (Appendix 28) was obtained prior to data collection. They were provided with the opportunity to handle and use the equipment before answering the feedback questionnaire (researcher or self-administered) (Appendix 9).

## 6.8 Data management

Data were gathered in Microsoft Access 2010, and then imported into Excel and SPSS statistical software package (version 19). Data were double entered to check for errors.

## 6.9 Data analysis

One aim of analysis was to find whether any of the muscle strength measurements showed potential for use as a red flag marker, indicating that through routine monitoring of these, a change in health is occurring/ imminent to enable proactive care to be provided to prevent a significant adverse event. To do this, information was required on whether and how the strength measurements changed over a short - medium term period (seven weeks) and whether any changes appeared to relate to changes in health. Excel and SPSS software were used for statistical analysis, including calculation and examination of the central tendency and dispersion of data obtained from the measures of strength and the health status indicators. Test-retest reliability allowed consideration of the stability of the measures, and was assessed with reference to performance accuracy data for each piece of equipment (Appendix 13), using all available data points. A number of statistical tests were used during the analysis, including Bland-Altman plots, ICCs, SEM and MDD as detailed in 5.7, as it has been recognised that no single test is sufficient to fully reflect reliability (Whittaker *et al.* 2007).

Data collected from questionnaires covering health and functional status, and the acceptability of the measures of strength were analysed using Excel, and included calculation and examination of the central tendency and dispersion. A health and functional status profile of the case management patient sample group was produced, using data collected via questionnaires and patient recall (Section 6.7). Acceptability data were analysed similarly using descriptive statistics when quantitative, with qualitative data from open-ended questions anaylsed using content analysis. Conceptual content analysis aimed to draw together concepts and words frequently used by the interviewees to identify possible issues and areas for improvement regarding the measures of strength.

## 6.10 Results

### 6.10.1 Recruitment

The recruitment of patients and clinicians into the feasibility study are considered separately in Sections 6.10.1.1 and 6.10.1.2.

#### *6.10.1.1 Patient recruitment*

Recruitment and data collection took place between October 2012 and November 2013. Eight adults (69-91 years) were recruited, just below the adequate sample size of 10, adequate for detection of a minimum 35% change in muscle strength. Of the eight participants, seven were observed for the maximum seven week period and on five separate occasions; one participant was observed for the minimum study period of one week only, on two separate occasions. No drop-outs or withdrawals were recorded. Four potential participants were excluded at the screening stage due to having significant physical symptoms that would prevent completion of the strength measures (n=1), suggestion of moderate to severe cognitive impairment at screening (n=2), and communication difficulties that would preclude data collection (n=1).

Under-recruitment was due to the lower than expected response rate to the recruitment strategies. Lack of response to the initial planned recruitment strategy led to amendments to the protocol, which included alternative recruitment methods, a reduction in frequency of follow up visits, and reduction in the length of the data collection period. The initial recruitment round, where invitation packs were delivered by hand to patients by a member of their case management team, resulted in only two participants being successfully recruited into the study. Screening one active case load with regard to the study inclusion/exclusion criteria, by the case manager with the support of the researcher, identified 81 patients suitable to receive a study invitation pack. 51 named packs were provided to the case management team for distribution by hand to the identified patients. From these packs four responses were received (three expressing a willingness to participate, one declining to participate), and resulted in two participants being recruited into the study. The third willing responder died prior to screening. Feedback from members of the case management team involved in the initial recruitment drive suggested that this recruitment method was too burdensome for the case management team and patients, and did not allow patients questions to be answered in a timely manner. This feedback informed the first substantial amendment to the study, approved by Southampton B NHS Ethics Sub-Committee in December 2012.

The second recruitment round, in line with the first substantial amendment, involved patients being invited by a member of the case management team by telephone to receive a study invitation pack by post. This combined telephone and postal strategy, resulted in a further two participants being recruited (Figure 6.4). Figure 6.5 illustrates the common reasons for exclusion during the second recruitment round.

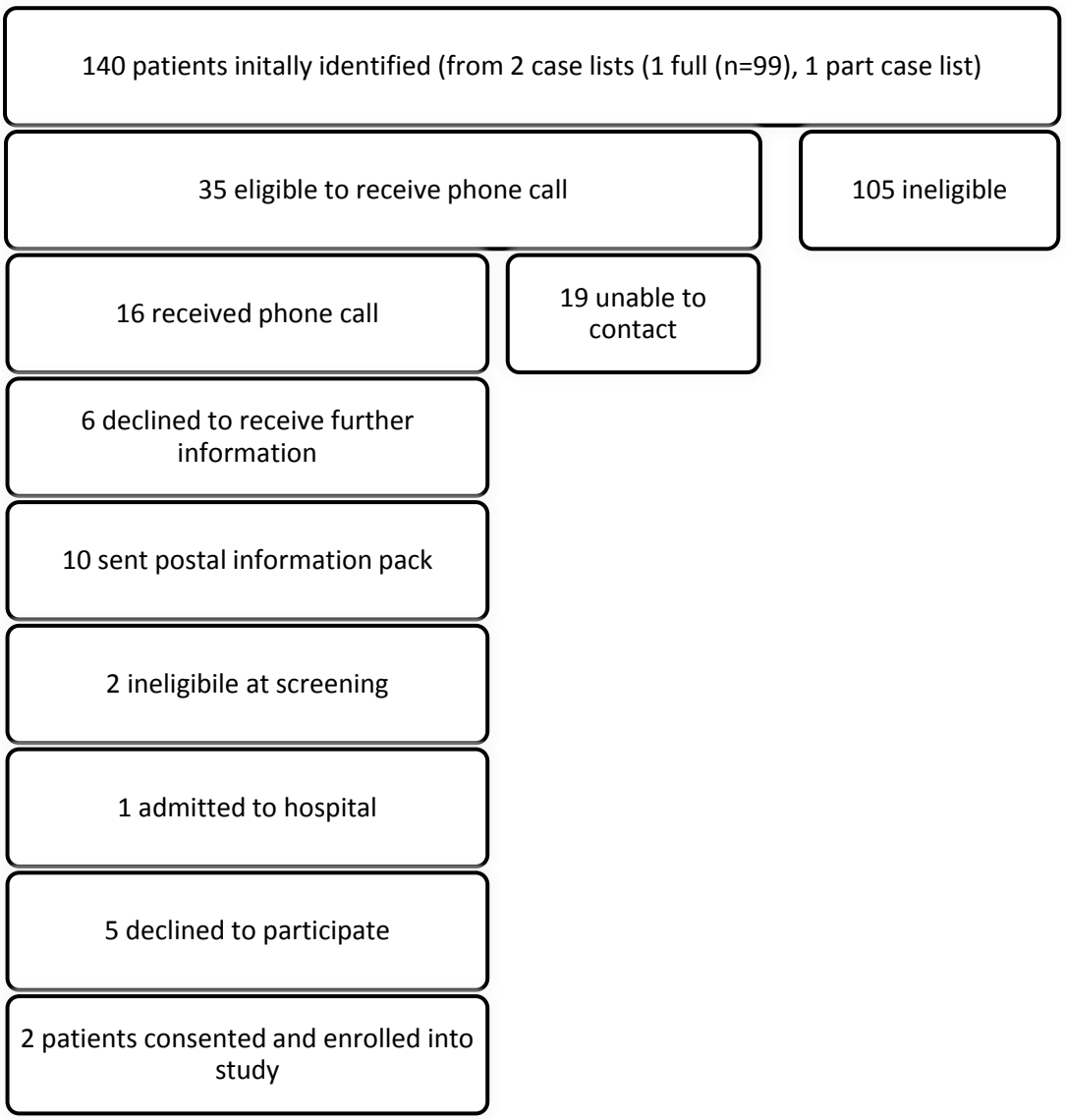



**Figure 6.4 Results of second recruitment round**

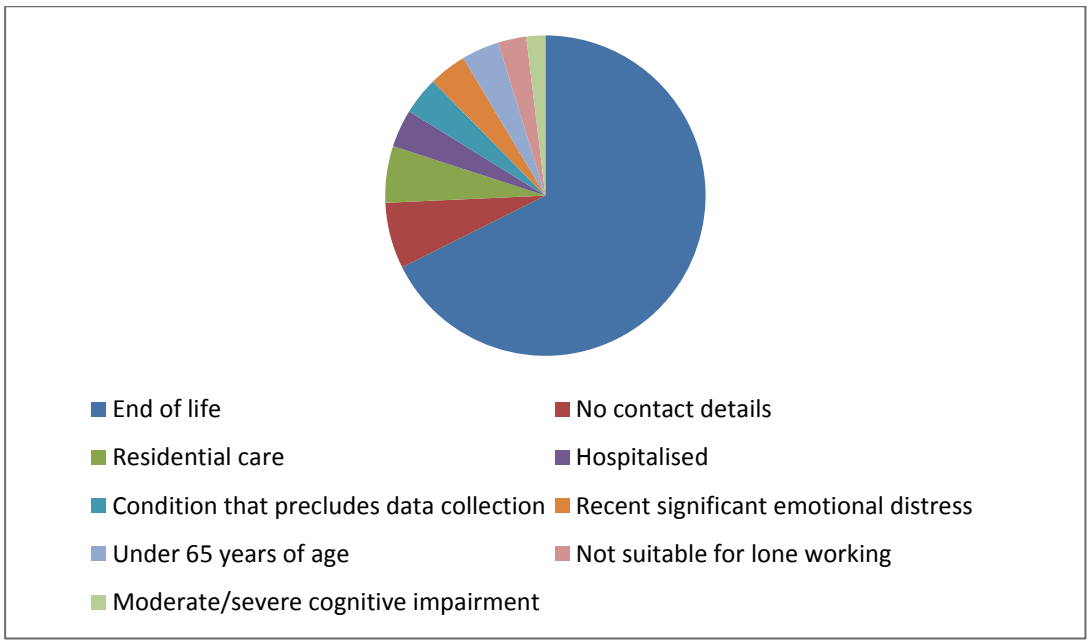



**Figure 6.5 Classification of patients ineligible to receive recruitment phone call in the second recruitment round**

Following the approval of a second amendment a third recruitment drive occurred, in line with the amendment, during which postal invitation packs were sent out by case managers direct to patients identified again by a collaborative approach by the case managers and researcher, as meeting the inclusion/exclusion criteria. Four participants were successfully recruited into the study after this third recruitment round (Figure 6.6).

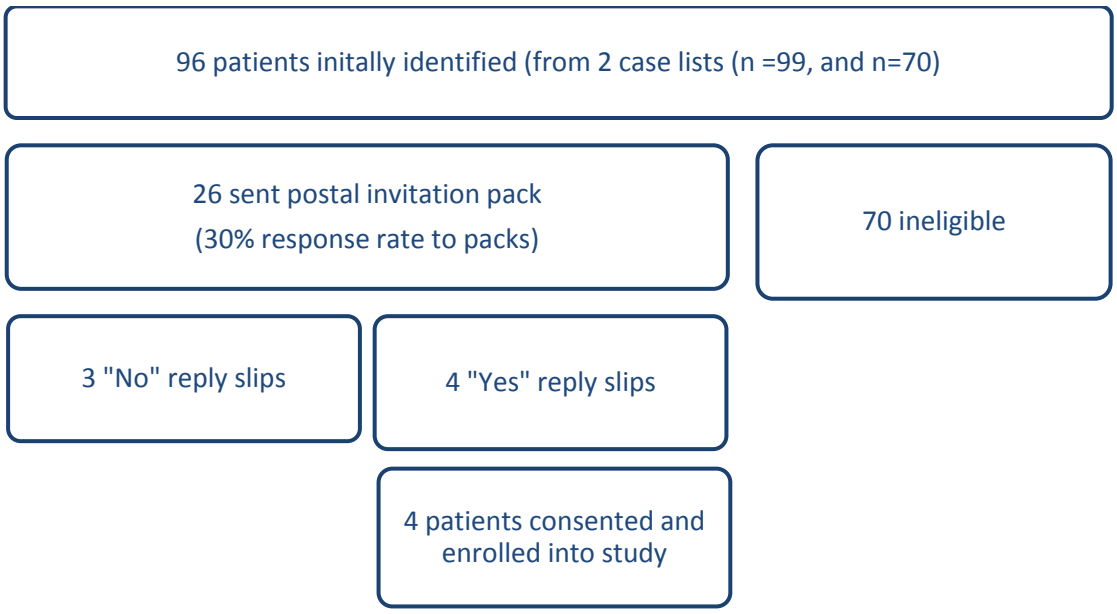



**Figure 6.6 Summary of third, postal recruitment round**

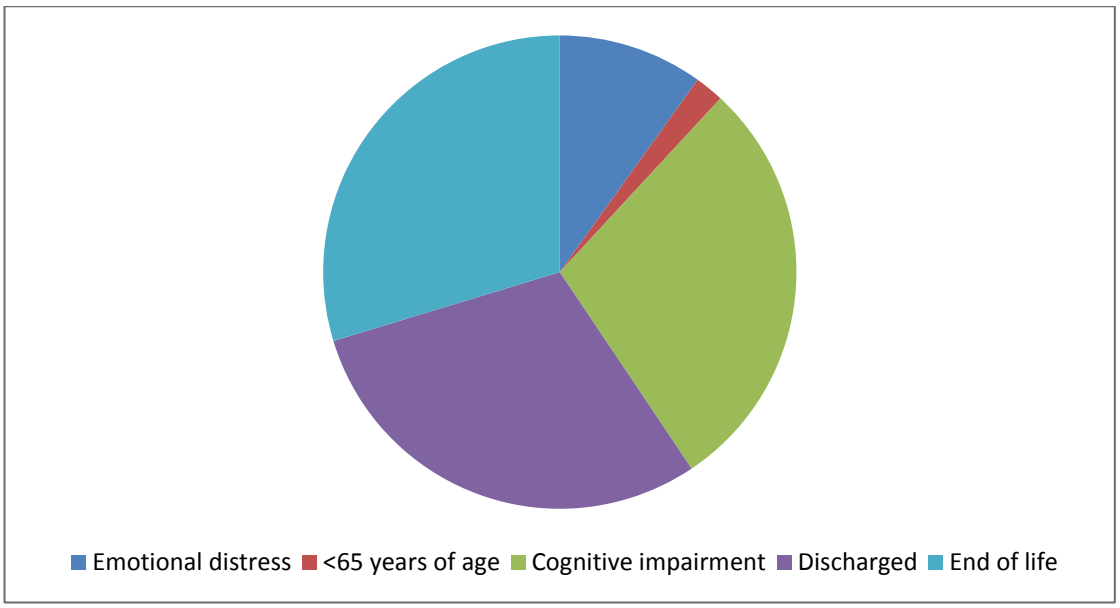



**Figure 6.7 Reason for ineligibility to receive postal invitation for the feasibility study in the third recruitment round**

Figure 6.7 illustrates the reasons identified via the collaborative approach, involving the researcher and the case managers, for excluding patients from receiving postal invitation packs direct from their case manager.

A recent UK study (Roberts *et al.* 2014) also reported recruitment difficulties in community dwelling older patients (who had been referred to community rehabilitation programmes); an extended recruitment period (18 months) resulted in approximately half the number of recruits (n=47) compared to the other settings recruited from (inpatients n=101, nursing home residents n=100).

### *6.10.1.2 Health care professional recruitment*

Healthcare professionals involved in providing case management services were recruited from one NHS Trust, with feedback on the measures of muscle strength obtained from a convenience sample of 5 members of a community care team involved in providing case management service (1 nurse and 4 physiotherapists). The bias towards physiotherapists is likely to have impacted on the feedback provided, this is discussed further in Chapter 8.

### 6.10.2 Demographic features of the patient sample

Of the eight participants recruited, five (63%) were male (Table 6.2). The mean age for the group was 81.5 years (age range 69-91 years), males were slightly older with a mean age of 82.8 years, and females slightly younger, mean age 79.3 years.

The BMI of participants ranged from 26 to 32 kg/$m^2$ for both males and females (where available) and all participants fell within the overweight or obese categories. This is a higher proportion than published data, which indicates that over two-thirds of healthy adults aged 65 years or over have a BMI that classifies them as overweight or obese (DH 2012c). Numerous studies have suggested that in older people a higher BMI (suggested between 23-30 kg/$m^2$) is more optimal than lower values and is associated with lower levels of adverse events (Kvamme *et al.* 2012; Deschamps *et al.* 2002); where BMI was calculable, 83% of study participants had a BMI between 25-30 kg/$m^2$. BMI was not available in patients where a measure of weight or height was unable to be taken (two participants).

The number of diagnosed co-morbidities ranged from one to five, with coronary heart disease diagnosed in half of the participants. No participants reported a diagnosis of COPD, one patient reported a history of asthma. Correspondingly the use of regular prescribed medication was common amongst the study participants, with all but one taking regular prescribed medication.

**Table 6.2 Summary characteristics of Study B participants**

| | Males (n=5) | Females (n=3) |
|---|---|---|
| | Mean ± SD | Mean ± SD |
| **Age (years)** | 82.8 ± 8.8 | 79.3 ± 6.4 |
| **Body mass index (kg/m$^2$)** | 27.3 ± 1.8 | 29.2 ± 4 |
| **No. of reported regular prescribed medication** | 4.4 ± 2.9 | 5.7 ± 3.9 |
| **No. of reported diagnosed chronic conditions** | 2.2 ± 1.2 | 2.3 ± 1.9 |
| **Maximal grip strength (kg)*** | 29.2 ± 11.5 | 16.7 ± 3.1 |
| **Maximal PEF (l/min)*** | 410.0 ± 163.6 | 188.3 ± 46.5 |
| **Maximal PIF (l/min)*** | 283.0 ± 76.9 | 116.7 ± 35.1 |
| **BI** | 89.5 ± 18.5 | 64.2 ± 34.3 |
| **VES-13** | 5.8 ± 3.6 | 6.2 ± 1.2 |
| **PASE** | 81.3 ± 57.7 | 33.5± 4.4 |

*Based on maximal value obtained over all data visits

The socioeconomic status of the patients was estimated by attributing their first half of their postcode to an electoral ward. The IMD ranking of the ward was then identified. Four participants were linked to an IMD in the 10$^{th}$ decile (where 1$^{st}$ is most deprived, 10$^{th}$ is least deprived), two in the 9$^{th}$ decile, one in the 6$^{th}$ decile, and one in the 5$^{th}$ decile. Whilst using data at electoral ward level (calculated from the first half of patient's postcodes), reduces the accuracy of the socioeconomic estimation, doing so reduces the risk of participant identification, and was used to help maintain anonymity of the results.

### 6.10.3 Functional status

The cohort of patients studied demonstrated a high level of variation in levels of independence, with BI scores ranging from very low to very high (range 20-100; mean 80.0 ± 27.5; maximum achievable score i.e. highest functional ability is 100) and VES-13 scores (range 2-10; mean 5.9 ± 2.9; maximum achievable score i.e. highest functioning is 0, while a score over 3 identifies a person as at higher risk (four times that of a person scoring 3 or less) of functional decline and death in the following one to two years) (Saliba *et al.* 2001). The BI scores observed were similar to a cohort of patients in England admitted to hospital with ill-defined conditions (n=35, mean BI 78.8 ± 19.7, Hunt 2009). Seven of the eight participants had a score of 3 or more on the VES-13. Levels of physical activity, as measured by the PASE, also varied widely (range 7-146). When compared to the summary characteristics of the self-reported healthy participants in the pilot study, the case management group appeared older, with more chronic conditions, requiring more

medication, with lower functional ability and lower physical muscle strength. Table 6.3 allows a visual comparison between the groups involved in the pilot and feasibility studies (Studies A and B); small samples mean that this could not be explored statistically.

**Table 6.3 Summary characteristics of case managed patients (Study B participants) and healthy older adults (Study A participants)**

| | **Case management patients (n=8, 38% female)** Mean ± SD | **Self-reported healthy (n=21, 62% female)** Mean ± SD |
|---|---|---|
| **Age (years)** | 81.5 ± 7.7 | 73.5 ± 6.3 |
| **Body mass index** | 28.0 ± 2.4 | 27.8 ± 5.0 |
| **No. of reported regular prescribed medication** | 4.9 ± 3.3 | 2.1 ± 1.8 |
| **No. of reported diagnosed chronic conditions** | 2.3 ± 1.5 | 1.9 ± 1.2 |
| **Maximal grip strength (kg)*** | 23.2 ± 10.7 | 28.1 ± 9.7 |
| **Maximal PEF (l/min)*** | 313.0 ± 164.4 | 367.4 ± 109.0 |
| **Maximal PIF (l/min)*** | 194.7 ± 100.0 | 235.2 ± 73.8 |
| **BI** | 80.0 ± 27.5 | 99.3 ± 1.5 |
| **VES-13** | 5.9 ± 2.9 | 1.3 ± 1.5 |
| **PASE** | 63.4 ± 50.7 | 141 ± 52.0 |

*Values based on maximal readings obtained (all data collection visits)

The sickness behaviour scale (SBS) showed some homogeneity in symptoms reported by study participants (Table 6.4). The most commonly reported symptoms, of the 25 assessed by the SBS, reported on over 50% of occasions by study participants were hyperalgesia, problems with orientation in time, difficulties with short term memory, myalgia, and anxiety. Other symptoms reported by participants on more than a quarter of occasions, include somnolence, fatigue, depression, and malaise.

**Table 6.4 Sickness Behaviour Symptoms questionnaire results**

(Appendix 7 for details of questions)

| Symptom | Frequency of symptom report |
|---|---|
| Hyperalgesia (Question (Q) 25) | 68% |
| Orientation in time (Q16) | 65% |
| Short term memory (Q15) | 59% |
| Myalgia (Q24) | 59% |
| Anxiety (Q1) | 51% |
| Somnolence (Q9) | 41% |
| Fatigue (Q6) | 38% |
| Depression (Q2) | 27% |
| Malaise (Q8) | 27% |
| Helplessness (Q3) | 24% |
| Concentration (Q12) | 24% |
| Appetite (Q18) | 24% |
| Headaches (Q26) | 22% |
| Psychomotor speed (Q14) | 19% |
| Visual hallucinations (Q11) | 14% |
| Adipsia (Q19) | 14% |
| Listlessness (Q7) | 11% |
| Rapid Eye Movement (REM) sleep disturbance (Q10) | 11% |
| Nausea (Q21) | 11% |
| Orientation in place (Q17) | 8% |
| Temperature regulation (Q23) | 8% |
| Apathy (Q4) | 5% |
| Social interaction (Q5) | 5% |
| Executive function (Q13) | 5% |
| Weight loss (Q20) | 5% |
| Diarrhoea (Q22) | 5% |

### 6.10.4 Muscle strength and physical activity

PEF, PIF, grip strength and PASE values obtained were generally lower than those observed in the "healthy" older participants of Study A, and for PASE were also below published norms (Table 6.2). Group PIF and grip strength mean values for both male and females were within the normal

range (Depledge *et al.* 1985; Mathiowetz *et al.* 1985; Nunn *et al.* 1989; Washburn *et al.* 1993). For males, PEF values fell at the lower range of normative published values (Nunn *et al.* 1989). For females, grip strength and PIF values fell at the lower end or just below normative published values, with PEF values falling below published norms (Nunn *et al.* 1989). With reference to the published normative muscle strength data, the maximal readings observed in the eight patients were categorised as high (above normal range), normal (within normal range) or low (below normal range) to allow consideration of agreement between the three strength measurement by such category. There was one case of agreement in category between the three measures, i.e. where grip strength, PEF and PIF values were all categorised as low. Agreement in category between two strength measures occurred in between three (PEF and PIF or grip strength and PEF) and five (grip strength and PIF) cases. Where agreement in category occurred, the categories were low or normal. Considering the grip strength scores alongside Fried's frailty criteria (Table 4.2) (Fried *et al.* 2001), three participants' (50% of participants in the calculable group (n=6) grip strength values fell below Fried's frailty cut-off values (the calculable group did not include those whose BMI was incalculable)). Along with "frail" grip strength values in these participants functional impairment was detected by VES-13 in these participants. Little or no degree of functional disability was noted in these patients via the BI; which may suggest impairment in instrumental activities of daily living rather than more basic physical problems.

#### *6.10.4.1 Reliability of measures of strength*

Intra-rater reliability, estimated through ICCs, using the first two data collection time points that occurred one week apart (Table 6.5), suggested that grip strength, PEF and PIF demonstrated excellent reliability across the short-medium term. The ICC estimations were in line with prior published ICC figures for these measures where available (Innes 1999; Fonseca *et al.* 2005; Kamide *et al.* 2009; Abizanda *et al.* 2012).

**Table 6.5 Intra-rater reliability of grip strength, PEF and PIF***

| | Mean ± SD | ICC (95%CI) | SEM | MDD |
|---|---|---|---|---|
| **Grip strength (kg)** | 22.4 ± 10.6 | 0.991 (0.954-0.998) | 1.01 | 2.80 |
| **PEF (l/min)** | 306.3 ± 165.6 | 0.980 (0.902-0.996) | 23.42 | 64.92 |
| **PIF (l/min)** | 180.3 ± 102.8 | 0.967 (0.847-0.993) | 18.67 | 51.75 |

Abbreviations: CI, confidence interval; ICC intra class correlation co-efficient; SEM, standard error of measurement; MDD, minimal detectable difference; GS, grip strength; PEF, peak expiratory flow; PIF, peak inspiratory flow.

*Measurements are mean ± SD. Based on maximal of 3 readings for grip strength, 3 for PEF and PIF, at 2 data collection points 1 week apart.

The between day variations observed with one rater for grip strength, PEF and PIF, at the first two time points (1 week apart), are illustrated in Figures 6.8-6.10. Despite small samples the Bland-Altman plots suggest that good agreement between days was generally observed.

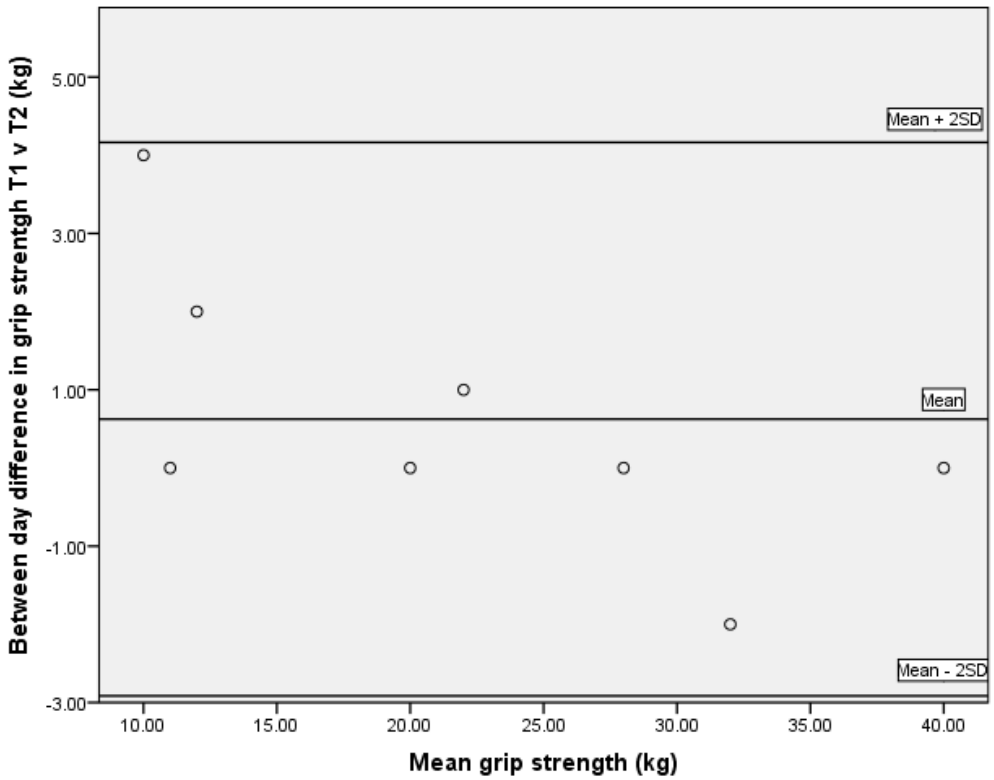



**Figure 6.8 Bland-Altman plot showing between day variation (time points (T) 1 and 2, 1 week apart) for grip strength**

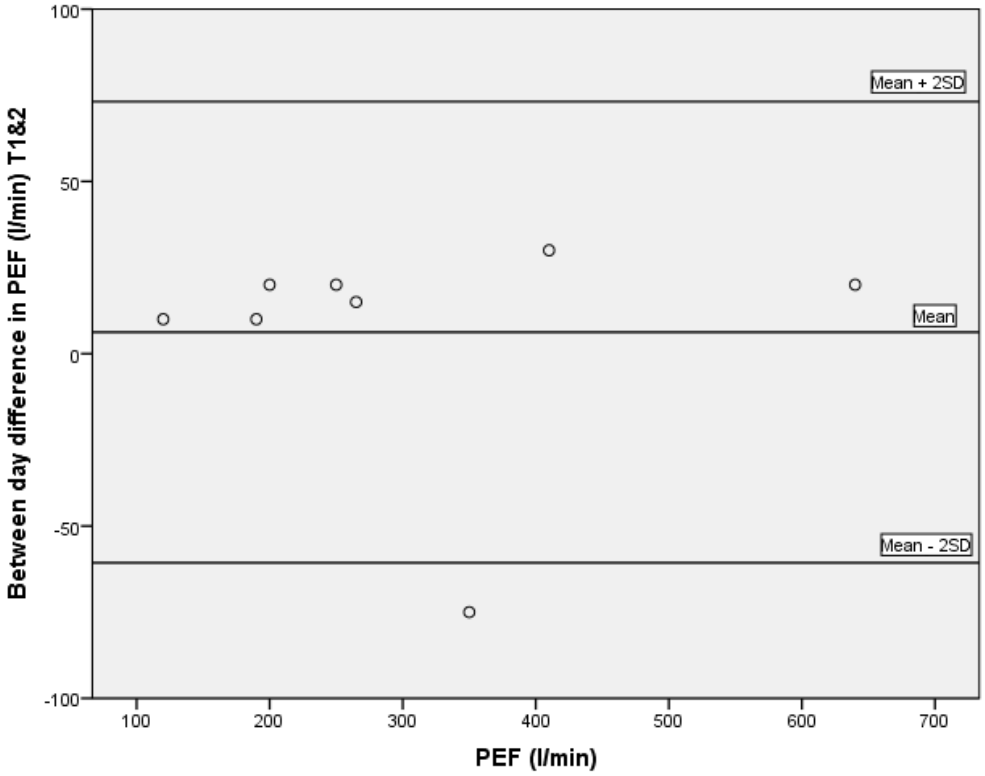



**Figure 6.9 Bland-Altman plot showing between day variation (time points 1 & 2, 1 week apart) for PEF**

It was noted that the outlying PEF reading (Figure 6.9) did not correspond to any other reduction in strength, or significant adverse event such as a fall, hospital admission or unplanned health service contact. However, the patient did report a feeling of helplessness via the SBS at the time of the lowest reading, that was not present at the time of the highest reading, difficulty concentrating was also recorded at the three lowest time points, that was absent at the time of the highest reading, which may have had an impact on the effort given during the tests, or may indicate a sub-clinical decline in health status. The patient had no reported history of respiratory disease.

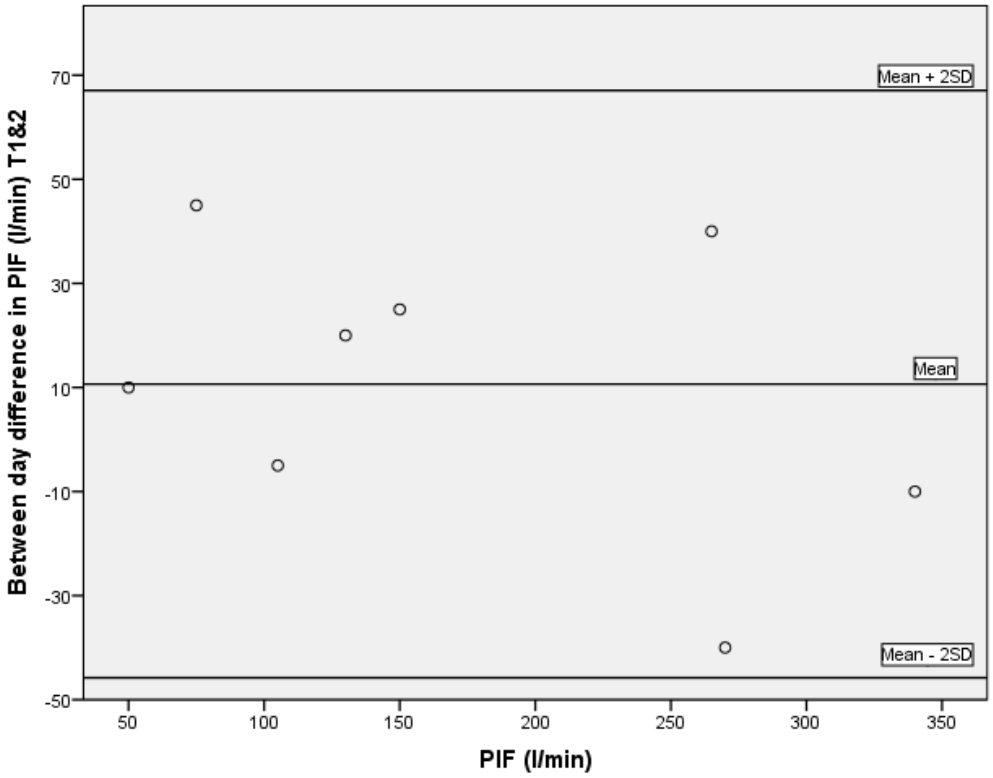



**Figure 6.10 Bland-Altman plot showing between day variation (time points 1 & 2, 1 week apart) for PIF**

Between day reliability estimated through ICCs calculated using data collected at all five time points, across seven weeks, are shown in Table 6.6.

**Table 6.6 Between day variation (all 5 time points) in grip strength, PEF and PIF***

| | Mean ± SD | ICC (95%CI) | SEM | MDD |
|---|---|---|---|---|
| **Grip strength (kg)** | 23.2 ± 10.7 | 0.988 (0.963-0.998) | 1.17 | 3.24 |
| **PEF (l/min)** | 313.0 ± 164.4 | 0.988 (0.964-0.998) | 18.01 | 49.92 |
| **PIF (l/min)** | 194.7 ± 100.0 | 0.923 (0.794-0.984) | 27.75 | 76.92 |

Abbreviations: CI, confidence interval; ICC intra class correlation co-efficient; SEM, standard error of measurement; MDD, minimal detectable difference; GS, grip strength; PEF, peak expiratory flow; PIF, peak inspiratory flow.

*Measurements are mean ± SD. Based on maximal of 3 readings for grip strength, 3 for PEF and PIF, across a maximum of 5 data collection periods and 7 weeks.

Figures 6.11-6.14 illustrate via Bland-Altman plots the between day variation observed with one rater for grip strength, PEF and PIF, between the first time point and final time point, seven weeks apart. Due to the small sample size conclusions should be treated with caution. However, the plots demonstrate that good agreement between days was generally observed, and thus suggests stability over a clinically significant period, with changes unlikely to be observed during a treatment period.

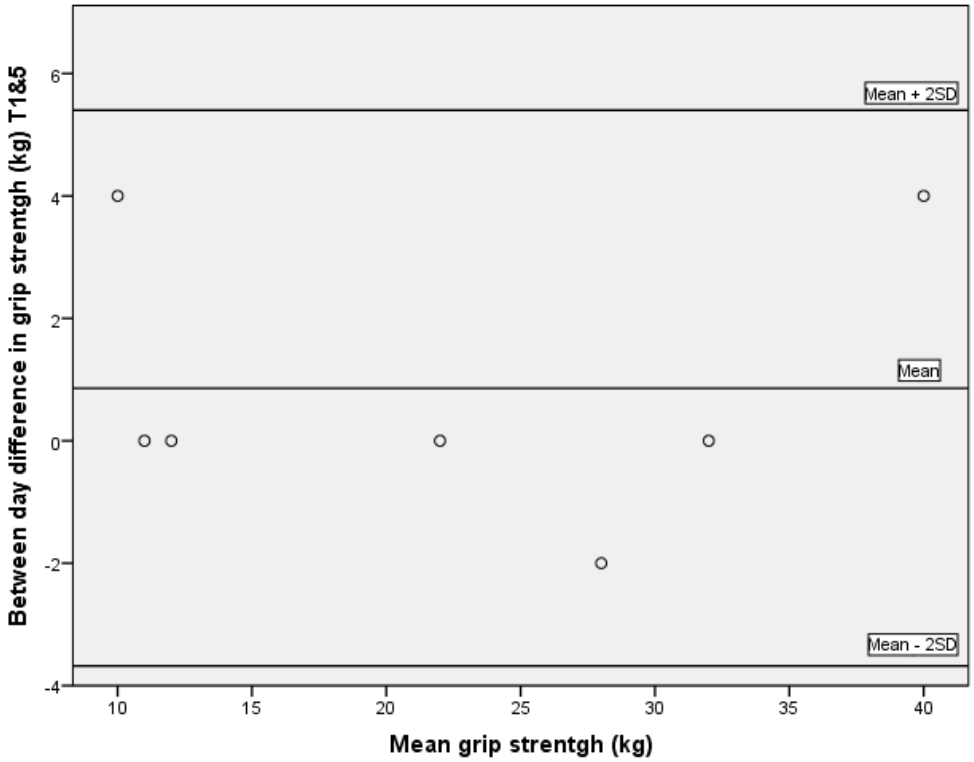



**Figure 6.11 Bland-Altman plot showing between day variation, time points 1 & 5 (7 weeks apart), for grip strength**

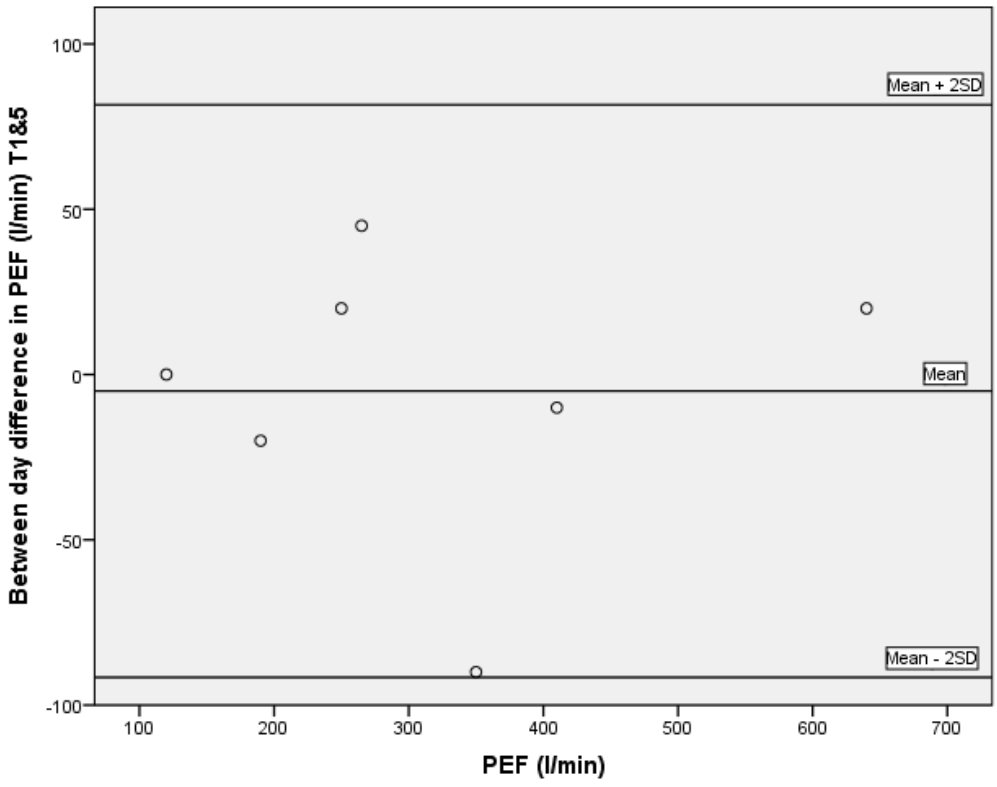



**Figure 6.12 Bland-Altman plot showing between day variation, time points 1 & 5 (7 weeks apart), for PEF**

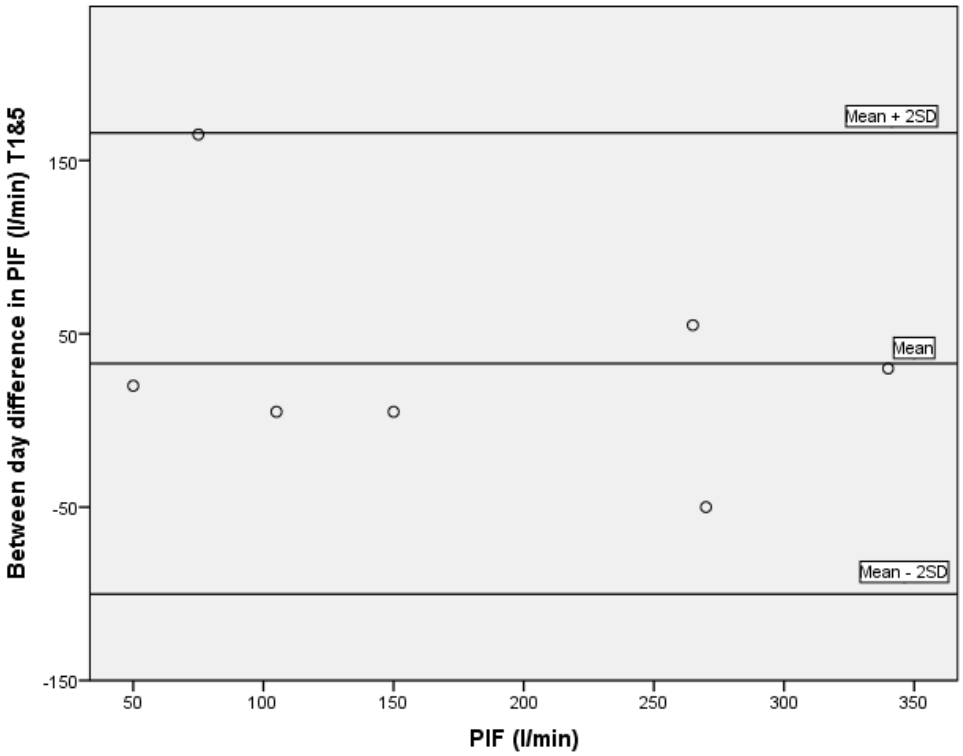



**Figure 6.13 Bland-Altman plot showing between day variation, time points 1 & 5 (7 weeks apart), for PIF**

Both Bland-Altman plots for PIF illustrate that in the majority of participants an increase in readings from time point one was observed, which would support the suggestion that there is an observable learning effect with PIF consistent with that observed in the pilot study.

The reliability estimates for the strength measures were in line with previously published work (Innes 1999; Fonseca *et al.* 2005; Kamide *et al.* 2009; Abizanda *et al.* 2012), and demonstrated that grip strength, PEF and PIF could be measured reliably in patients receiving case management. ICCs for all measures were above the recommended 0.90 to ensure validity for clinical measurement. However, the lack of variability in the muscle strength values observed suggest that further work would be required to demonstrate whether muscle strength changes significantly enough over the short-medium term to be a useful marker of declining health or function, and support their use as a repeated measure. Observations from this study noted little change in muscle strength over the short-medium term, despite adverse health outcomes, falls, A&E attendance and hospital admissions occurring, suggesting a lack of usefulness as aids to monitoring.

### *6.10.4.2 Acceptability*

Patients found grip strength generally the most acceptable strength measure (Table 6.7). Whilst grip strength was repeatedly identified as the easiest to understand how to perform and to perform, it was rated the least comfortable to perform.

**Table 6.7 Acceptability of measures of muscle strength to patients**

| *Questions 1-4 Likert scale 1-5, where 1 is strongly disagree, to 5 strongly agree (mean score)* | **PEF** | **PIF** | **Grip strength** |
|---|---|---|---|
| 1."It was easy to understand what I had to do" | 4.0 | 3.9 | 5.0 |
| 2."It was easy to do" | 3.9 | 3.6 | 4.5 |
| 3."It was comfortable to do" | 4.9 | 5.0 | 4.4 |
| 4."I would recommend the test to anyone" | 5.0 | 5.0 | 5.0 |
| 5.Tests' ranking in order of preference (1 to 3, where 1 is most preferred to 3 is least preferred): | | | |
| Mean | 1.8 | 1.9 | 1.8 |
| Median | 2 | 2 | 1 |
| Mode | 2 | 2 | 1 |
| Time taken, range in minutes, to complete 3 repetitions for PEF, PIF and grip strength | 0-6 | 0-4 | 0-5 |

Complete strength readings were recorded on all occasions. No unexpected side effects or problems were observed.

**Table 6.8 Patients' positive and negative responses to the question "How could the measures be improved?"**

| Patients' comments | |
|---|---|
| **Positive** | **Negative** |
| No changes to measures required | Smaller mouthpieces (PIF and PEF)<br>Technique for all<br>Easy to block moveable marker on PEF meter<br>Better grip surface for grip strength (better grip and comfort) |

The most common improvement suggested by patient participants for PIF and PEF were availability of different sized mouthpieces, with participants also suggesting a recessed marker for PEF to prevent the inadvertent blocking/ moving of it by fingers leading to an erroneous reading

(Table 6.8). Regarding grip strength the main participant recommendations were for an improved grip surface, offering increased grip and comfort. Whilst grip strength was favoured amongst patients, it performed less well with members of case management teams. Feedback from the health professionals illustrated their concern with the practical implications of being required to carry heavy, bulky equipment, with a general concern for all measures regarding the ability of patients to complete the tests and the time taken to perform them (Tables 6.9 and 6.10).

The time taken to complete all repetitions of one measure of strength was generally less than six minutes (Table 6.7); these times were longer than those recorded in the pilot study with healthy individuals. The requirement for a longer recovery time between exertions was observed in the patient group, compared to the healthy participants in the pilot study, to allow the patients to perform the measures comfortably and to apparent maximal effort. All repetitions were completed on all occasions.

**Table 6.9 Case management team members' feedback regarding measures of strength**

| *Question 1 Likert scale 1-5, where 1 is strongly disagree, to 5 strongly agree (mean score)* | **PEF** | **PIF** | **Grip strength** |
|---|---|---|---|
| 1. "Do you think the majority of your patients would be able to perform this test?" | 3.6 | 3.4 | 3.2 |
| 2. "Would you be happy to ask your patients to perform this test each visit?" (Number of responses) | 3 Yes<br>1 No<br>1 n/a | 2 Yes<br>1 No<br>2 n/a | 2 Yes<br>2 No<br>2 n/a |
| 3.Tests' ranking in order of preference (1 to 3, where 1 is most preferred to 3 is least preferred): | | | |
| Mean | 1.4 | 2.4 | 2.2 |
| Median | 1 | 3 | 2 |
| Mode | 1 | 3 | 2/3 |

**Table 6.10 Case management team members' positive and negative comments following open questions regarding the measures of muscle strength used in the study**

| Case management team members' comments | |
|---|---|
| **Positive** | **Negative** |
| Objective measure | Side effects of PIF and PEF, including coughing |
| | Cognitive impairment |
| | Difficulty understanding and following instructions |
| | Correct technique |
| | Bulky, heavy equipment |
| | Time to do |
| | Effect of posture on the validity of readings |
| | Sensitivity of measures |
| | Usefulness |
| | Pain |
| | Easier/comfier grip needed |
| | Expense |

There was a bias in the professions of those participating in the study, with the majority being physiotherapists. Whilst many of the comments expressed may be relevant to all members of the case management team, there is likely to be variation in their main concern. It should be noted that the one positive comment was expressed by a physiotherapist, who frequently utilised subjective measures of strength, and could see the benefit of utilising an objective measure above a subjective measure.

### 6.10.5 Frailty

Observations were made on all patients using the data collection tools indicated below, corresponding to Fried *et al.* (2001) frailty definition (Section 4.2). Frailty was considered present if patients displayed at least three of the following symptoms:

- Weight loss: reported via the SBS;
- Muscle weakness: grip strength data were compared with Fried *et al.* (2001) cut-off values (Table 4.2);
- Exhaustion: considered present if fatigue or somnolence was reported via the SBS;
- Slow walking speed: whilst not a direct measure of walking speed, if difficulty in walking ¼ mile was reported via the VES-13, slow walking speed was considered present;

- Low activity: if activity measured via PASE fell outside of the normal range.

50% of study patients presented with three or more of the above symptoms and may be considered frail.

## 6.11 Conclusion

Recruitment for this feasibility study in patients receiving case management was challenging, whilst ample numbers of patients on case lists were evident, there was a difficulty in accessing these patients and gaining a response. A low response rate to the recruitment strategies was observed (e.g. 30% response rate to the postal recruitment drive) along with a higher than expected refusal rate (e.g.75% for combined phone and postal recruitment drive), and higher than expected rate of loss at screening (up to 50%). Recruitment of older people into research has been shown to be difficult, with refusal rates of up to 54%, exclusion rates of up to 49%, and drop-out rates of 5-37% previously reported (McMurdo *et al.* 2011). A near adequate sample size of 8 was achieved; whilst the feasibility study had no participants drop out, a high refusal rate was observed. An additional observational study utilising routine data was included to enable the gaps in knowledge regarding the physical and functional profile of case management patients to be more fully addressed. Method details and results of this third study, using the pseudonymised Hampshire Health Record, follow in Chapter Seven. Despite under recruitment in Study B, data collected were analysed to provide information on the reliability and acceptability of the measures of strength, as well as information on the health, physical and functional status of case management patients. The reliability estimations and patient and clinician feedback suggested that PIF, PEF, and grip strength are reliable and acceptable to case management patients aged 65 years and over. Grip strength, PEF and PIF demonstrated relatively high reliability to recommend use as a clinical measure. However, the high level of stability observed over the seven week data collection period suggests that repeated measurement of grip strength, PEF and PIF would not be beneficial over the short to medium term, as the measures appear to remain stable over this period. However, further investigation with a larger sample size would be required to confirm this and to explore the relationship between muscle strength and clinically relevant outcomes, but the data strongly suggests that this may not be a fruitful avenue for future research due to the overall stability of these measures. It may be more beneficial to focus future research on the predictive nature of a one off measure of muscle strength. The data did demonstrate the feasibility of all of the measures of strength, PEF, PIF and grip strength in such a patient group. PEF was highlighted as being the most acceptable to the healthcare professionals and one that many will be familiar with and have easy access to, and of low cost, therefore, may be more favoured as a clinical measure.

# Chapter 7 Study C: Analysis of Hampshire Health Records

## 7.1 Introduction and study aim

This chapter details methods and findings for Study C, a retrospective analysis study of health records, from the Hampshire Health Record (HHR). Anonymised records of patients aged 55 years and over, receiving community case management from Southern Health NHS Trust were analysed, with the aim of providing much needed information on the clinical and functional needs of patients receiving case management. The HHR provides a record of all primary care activity, hospital admissions and GP practice information. This database analysis study was conceived in response to the small sample in the feasibility study, Study B, in patients receiving case management (Chapter 6).

### 7.1.1 Study specific research objective and questions

The objective of the study was to explore the physical health and functional profile of patients receiving case management. Two research questions were posed to meet this objective by analysis of routine HHR data:

1. What is the physical health and functional status of patients receiving case management?

2. What is the profile of health service use for case management patients?

A study was designed to answer these questions via the use of routine data recorded on the Hampshire Health Record, for a cohort of patients receiving case management, providing a description of the cohort's health and functional status.

## 7.2 Study design and sample population

The initial literature review (Chapter 2) identified the lack of specific descriptive data regarding the case management patient group. With an absence of information on the physical, health and functional status of case management patients noted. It was originally anticipated that this would be addressed via study B. However, the number of participants enrolled into the feasibility study was too small to meet this objective, hence an alternative approach was taken, using routine primary and secondary care data gathered on the HHR database. This study involved analysis of pseudonymised routine data extracted from the HHR database, from the records of patients identified as receiving case management services, via the virtual ward model (the model of care providing case management services to patients within the approved NHS Trust at the time of the study). Using routine data in research has the benefit that the change of use is very unlikely to add any burden to participants. Such databases are also relatively easily accessible to researchers, especially if anonymised or pseudonymised. Increasing integration between primary and secondary services including data collection and access is occurring, increasing the usefulness of such routine data.

## 7.3 Health record dataset

The study received ethical approval from Southampton B Ethics Committee in March 2013 (as an amendment to Study B). To allow the identification of case managed patient records from the pseudonymised HHR database, a list of NHS numbers of patients identified as receiving case management via the virtual ward model from Southern Health NHS Foundation Trust were provided by the Trust, to the Senior HHR Information Analyst. Once the HHR records were flagged, pseudonymisation of data occurred. Informed consent was deemed not required by the Ethics Committee and the HHR governance board. A data sharing agreement already existed between Southern Health NHS Foundation Trust and the HHR. However, permission to use the pseudonymised HHR database for analysis was required from the HHR Advisory Group prior to use. A proposal was approved and agreed by the HHR Advisory Group, chaired by Wessex Local Medical Committee (December 2012).

A minimum of 100 HHR patient records and a maximum 1000 records were utilised. By identifying a minimum of 100 records the risk to confidentiality of personal data were minimised, with the potential ability of the researcher to identify patients from the pseudonymised data reduced to an acceptable level. By not allowing more than 1000 records, the data set was kept to a manageable size, considering the resources of the study. A list of 2250 NHS numbers of patients receiving case management via the virtual ward service was provided by Southern Health NHS Trust in October 2013 to the named Senior Information Analyst at the NHS South Commissioning Support Unit. Patients were originally identified for admittance onto the virtual ward by risk stratification tools (Adjusted Clinical Groups, ACG) and/ or clinical judgement. The 2250 patients were identified from eight virtual wards, with one virtual ward from each locality within the Trust included. Each virtual ward was overseen by one Community Matron. An exercise was undertaken by the Senior Information Analyst to filter this list to show only those NHS numbers which were suitable for inclusion in the final dataset, with reference to the inclusion/exclusion criteria and approved proposal.

### 7.3.1 Inclusion and exclusion criteria

**Inclusion criteria:** Patients flagged as receiving case management/ on a virtual ward caseload from Southern Health NHS Foundation Trust, aged 55 years and over.

The reduction in age limit, in comparison to that utilised in the feasibility study, was introduced to meet the minimum acceptable number of records extracted for confidentiality purposes, in compliance with governance and ethics approvals.

**Exclusion criteria:** Patients receiving end of life care and those with mental health as the primary reason for receiving case management.

In addition to the exclusion criteria above records were also excluded where:

- the NHS number could not be pseudonymised in line with the standard HHRA pseudonymisation within the project time frame; (Due to time constraints placed on the HHR analyst, approximately 700 records were excluded for this reason. The pseudonymisation process, which occurred in order to comply with ethical and governance procedures, was a very time consuming process.)
- the NHS number was duplicated on the list provided by the Trust; and/or
- the virtual ward admission date was so close to the present that HHR data were unavailable both one year before and after the admission date (approximately 1400 records).

After filtering a core group of 101 patients remained. For all 101 patients the virtual ward admission date was between May and August 2012.

## 7.4 Study variables

The study variables aimed to obtain information on the same parameters as Study B, allowing for the limits of the dataset. Nationally recognised Read codes are the main way data are entered onto the HHR database, where this was the case it is noted below. An entry of a Read code for specific "risky" events is often referred to as a flag. The study variables included were:

a. Obesity: identified by either the presence of an obesity flag or BMI>30kg/$m^2$ calculated or recorded, as per Study B (Section 4.4).
b. Socio-economic status and residential area: identified by IMD decile, as per Study B (Section 4.3), and rural/urban classification of patient residence.
c. Age: recorded at the time of case management start date; age at time of study recruitment was recorded in Study B (Section 4.3).
d. LTCs: identified by the presence of one or more of the 24 LTC specific flags available. Study B relied on patient self-report of LTCs (Section 4.5).

e. Medication: the exact details of prescribed medication were unavailable. A list of medication groups (grouped by British National Formulary (BNF) category) prescribed to the patient within the 31 days prior to the case management start date was available; Study B relied on patient self-report (Section 4.5).
f. Falls: identified by the entry of a fall flag at any point during the two year data collection period; Study B relied on self-report of falls.
g. Health service use included:
    - A&E attendances (across the 2 year data period)
    - Hospital admissions (across the 2 year data period)
    - Community care team contact frequency – Calculated by the number of visits to the patient by Southern Health's Community Care Teams, who provided case management services, where the weekly rate is the daily rate multiplied by seven. The daily rate was calculated by counting the number of visits from community care team per patient, where those visits occurred between the patient's case management start date and the date of the latest available data at the time of running the final report (8th December 2013), and then dividing by the number of days between those dates. This end date was used as no case management end date per patient was provided by Southern Health NHS Trust.
    - Number of outpatient attendances (across the 2 year data period)

## 7.5 Data management

Data were imported into Microsoft Excel 2010 and analysed using SPSS (version 21). Data were cleaned via frequency tables, which identified outliers and allowed errors to be dealt with. Errors were observed in height, weight and BMI parameters where differences in measurement units resulted in erroneous values, these were corrected. Excel and SPSS were used for descriptive analysis and the presentation of data.

## 7.6 Data analysis

Data analysis included calculation and examination of the central tendency and dispersion of the data obtained from the health status indicators including frailty, calculated via the frailty index detailed in Section 4.2.2. Associations between levels of frailty and service use outcomes were explored using parametric and non-parametric statistical tests.

## 7.7 Results

### 7.7.1 Demographics

Of the 101 patients identified, a quarter (24.8%) were male. The higher proportion of females was in line with the higher life expectancy for females in the UK (ONS 2010). The patients' age (at the time of case management start date) was provided. The mean age for the group was 79 years (SD ± 9.8; range 58-97 years. Figure 7.1 illustrates a skewed age distribution, skewed towards the older old. Age is a clearly demonstrated risk factor for having a long term condition, having multiple long term conditions and frailty (DH 2012a; Fried *et al.* 2001).

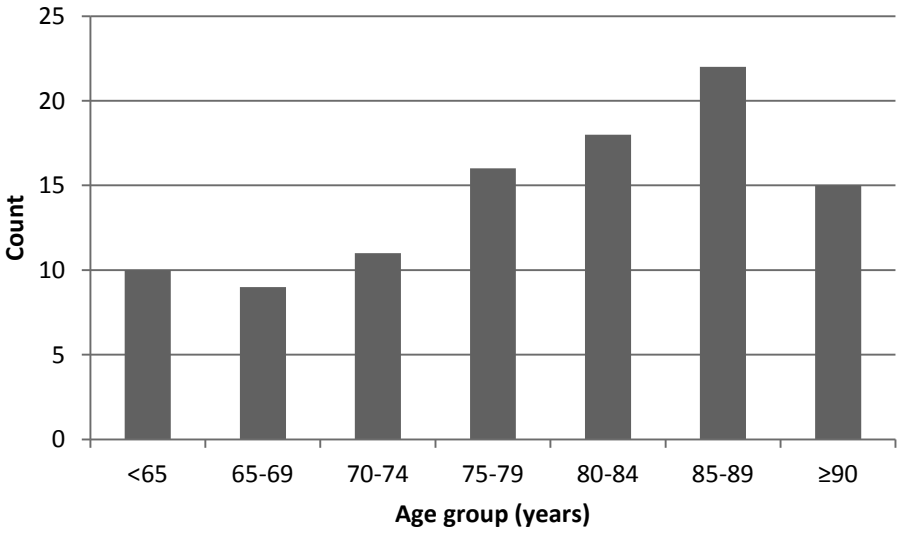



**Figure 7.1 Distribution of case management patients by age**

Rural urban classification, based on the patient's postcode indicated that the majority of patients resided in an urban city or town location (73.3%), and where recorded, the remaining patients resided in a rural town and fringe location (10.9%), or rural village and dispersed location (11.9%). (LSOAs were used in the rural urban classification (Section 4.3). A LSOA was attributed to each patient postcode, to provide the data. This method had some potential for inaccuracy due to changing LSOA codes or boundaries, between the time of recording in the database and the analysis. This is also true for IMD values, identified in the same manner. The median IMD decile was 9, suggesting a higher than average level of deprivation (i.e. 1 least deprived, 10 most deprived) and an increased vulnerability.

### 7.7.2 Health conditions

The mean sum of long term condition flags per patient was 4.55, range 0-11 (Figure 7.2). 92.1% had at least two long term condition flags recorded. Considering that three out of five people aged 60 years and over are living with at least one LTC, and the majority of over 75s are living with three or more LTCs (DH 2012a), a higher level than this may be expected in case managed patients with complex health needs.

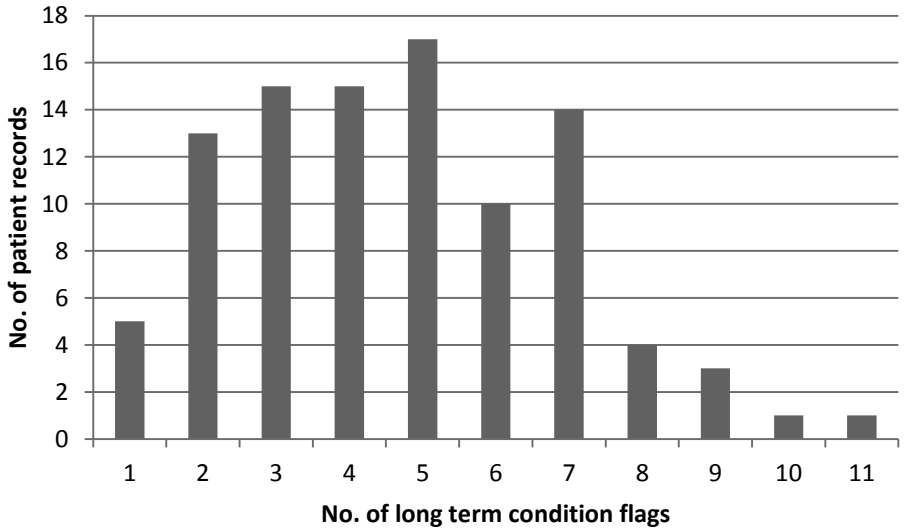



**Figure 7.2 Presence of multiple long term condition flags in records**

The most commonly recorded long term condition was hypertension, recorded in nearly two thirds of records (Table 7.1). This is in line with published data on the prevalence of hypertension within England, indicating that 65% of men aged 65-74 years and 79% of men aged 75 years an over have diagnosed hypertension; for women the corresponding values are 63% and 79% (Townsend *et al.* 2012). This was followed by obesity; whilst the obesity flag was recorded on 46% of records, a corresponding BMI was only recorded in 26 of these cases. The mean group BMI (27.5kg/$m^2$, SD ± 6.7kg/$m^2$) falls within the overweight category. Five patient records had an underweight BMI noted (<18.5kg/$m^2$). 36.6% of BMI values were recorded either after virtual ward admission or in the 6 months previous, which is suggestive of a recent, more relevant value in under half of cases.

Numerous LTC flags appear to overlap somewhat, with risk factors for a condition, for example hypertension appearing alongside stroke/TIA, leading to a tendency to over report. Table 7.2 shows the prevalence of LTCs by broader diagnostic group, rather than by individual flag as shown in Table 7.1.

**Table 7.1 Frequency of LTC flags on HHR records**

| LTC flags within HHR | Percentage of patients with flag on records |
|---|---|
| Hypertension | 62.4% |
| Obesity | 45.6% |
| Chronic Kidney Disease | 42.6% |
| Neurological Condition | 40.6% |
| Depression | 32.7% |
| Chronic Obstructive Pulmonary Disease | 31.7% |
| Diabetes | 25.7% |
| Coronary Heart Disease | 22.8% |
| Anxiety | 21.8% |
| Heart Failure | 20.8% |
| Stroke TIA | 18.9% |
| Atrial Fibrillation | 17.8% |
| Cancer | 12.9% |
| Osteoporosis | 10.9% |
| Vascular Disease | 9.9% |
| Renal Disease | 6.9% |
| Asthma | 5.9% |
| Dementia | 5.9% |
| Hypothyroidism | 5.9% |
| Peripheral Arterial Disease | 4.0% |
| Rheumatoid Arthritis | 3.0% |
| Epilepsy | 2.0% |
| Mental Health | 2.0% |
| Learning Disabilities | 0.0% |

Table 7.2 cross tabulates the LTC flags on records, grouped by diagnostic area.

**Table 7.2 Presence of LTC/multiple LTC flags by diagnostic group**

| | Cardiac/ vascular | Renal | Neurology | Mental health | Endocrinology | Musculo-skeletal | Respiratory | Cancer |
|---|---|---|---|---|---|---|---|---|
| **Cardiac/ vascular** | 80% | 41% | 35% | 32% | 46% | 11% | 28% | 11% |
| **Renal** | 41% | 43% | 18% | 16% | 29% | 6% | 10% | 7% |
| **Neurology** | 35% | 18% | 43% | 21% | 21% | 7% | 19% | 7% |
| **Mental health** | 32% | 16% | 21% | 40% | 22% | 5% | 16% | 5% |
| **Endocrinology** | 46% | 29% | 21% | 22% | 55% | 6% | 17% | 6% |
| **Musculo-skeletal** | 11% | 6% | 7% | 5% | 6% | 14% | 6% | 1% |
| **Respiratory** | 28% | 10% | 19% | 16% | 17% | 6% | 35% | 2% |
| **Cancer** | 11% | 7% | 7% | 5% | 6% | 1% | 2% | 13% |

Clarification of LTC flags/ groups used in the table above: Cardiac/ vascular includes atrial fibrillation, coronary heart disease, heart failure, hypertension, stroke/ transient ischaemic attack, vascular disease and peripheral arterial disease; Renal includes renal and chronic kidney disease; Neurology also includes epilepsy and dementia; Mental health also includes depression and anxiety flags; Endocrinology includes obesity, diabetes and hypothyroidism; Musculoskeletal includes osteoporosis and rheumatoid arthritis; Respiratory includes asthma and COPD.

Whilst the exact details of prescribed medication were unavailable, a list of medication groups (grouped by British National Formulary (BNF) category) prescribed to the patient within the 31 days prior to the case management start date was provided (Table 7.3). This was generated by matching the prescription Read codes against the BNF table of contents to create a set of broad groupings from the individually prescribed medications. This suggested that the mean number of regular medication groups prescribed for the group was 4.2 ± 3.5. Medication groups usually prescribed on an acute/when required basis were excluded from this count (i.e. antibiotics, analgesics, laxatives, acute diarrhoea medication, also excluded were dressings and appliances).

**Table 7.3 Prescribing trends in HHR records**

| Drug group | % of patient records indicating group prescribed |
|---|---|
| Drugs for hyperlipidaemia | 29 |
| Non-opioid analgesics | 29 |
| Anti-platelets | 25 |
| Loop diuretics | 25 |
| Angiotensin-converting enzyme inhibitors | 24 |
| Vitamin D | 24 |
| Prostaglandin analogues | 21 |
| Opioid analgesics | 20 |
| Proton pump inhibitors | 18 |
| Beta-adrenoceptor blocking drugs | 17 |
| Antidepressants | 17 |
| Selective beta 2 adrenoceptor stimulants | 17 |

In 2008, Patient Safety First identified four groups of high risk medicines that when adverse incidents occur they have a significant/ serious impact on the patient. These were:

1- Anticoagulants (warfarin and heparin) – recorded on 5% of the cohort patient records.
2- Injectable sedatives, whilst injectable use unlikely to be prescribed in the community, sedatives and anxiolytics (including oral dosage forms) were recorded in 12% of cohort patients.
3- Opioids – a frequently prescribed medicine in this cohort, recorded on 20% of cohort records.
4- Insulin – recorded on 2% of cohort records.

Since 2011 community pharmacists in England have been asked to focus medication usage reviews on four target high risk medicine groups, again medicines whose overuse or underuse may pose a significant, preventable risk, these groups are:

1- Diuretics (prescribed for 26% of cohort patients)
2- Non-steroidal anti-inflammatory drugs (prescribed for 3% of cohort patients)

3- Anti-platelets (prescribed for 25% of cohort patients)
4- Anti-coagulants (prescribed for 5% of cohort patients)

Antibiotics were also commonly recorded on patient records (35%). Notable as an infection can pose a significant challenge to vulnerable older people, leading to a significant adverse event.

### 7.7.3 Physical function and falls

Very limited data regarding function were identified on the records. No BI scores were recorded, although there was the ability to do so. Data were identified regarding falls in the year prior to virtual ward admission, and in the subsequent year. This data indicated that falls occurred in 15% of patients in a 12 month period prior to virtual ward admission (Table 7.4 and Figure 7.3), and in 11% of patients the year following admission onto the virtual ward. Of the patients who had a fall in the year prior to virtual ward admission, one third went on to have at least one fall recorded in the subsequent year. Of the 11% of patients who fell in year 2, 66% had no fall recorded in the previous year. Published falls data suggests that the prevalence of falls in older people is higher than that observed here, with an expected 30% of those aged over 65, and 50% of those aged over 80 falling in a year (Age UK 2012).

**Table 7.4 Falls data**

| | **No. of falls recorded in 12 months prior to virtual ward admission** | **No. of falls recorded in 12 months post virtual ward admission** |
|---|---|---|
| **Number of patients flagged as having a fall** | 15 | 11 |
| **Median number of falls for whole group (n=101)** | 0 | 0 |
| **Range of number of falls recorded** | 0-4 | 0-2 |

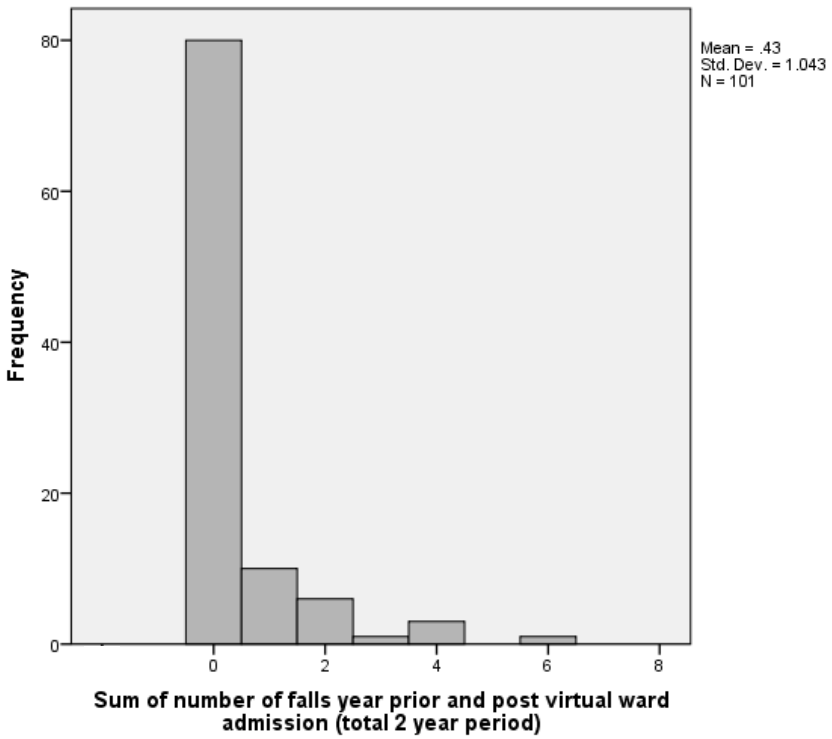



**Figure 7.3 Sum of falls year prior to and post virtual ward admission**

A Wilcoxon signed-rank test suggested that a statistically significant reduction in falls following virtual ward admission occurred (z=-1.968, p=0.049, Appendix 29).

### 7.7.4 Health service use

The 101 patients identified recorded a sum of 1725 bed days in the 12 month period before their virtual ward admission, decreasing to 840 days in the 12 month period following admission (Table 7.5). Whilst a reduction in some secondary care service use appeared apparent, and was supported by Wilcoxon signed-rank statistics, this was likely to be due to regression to the mean (Figures 7.4-7.11) (Appendix 29).

**Table 7.5 Sum of number of hospital attendances/ length of stay for group (n=101)**

| Service type | Year before case management (CM) start date | | Year after CM start date | |
|---|---|---|---|---|
| | Sum (episodes) | Sum total length of stay (days) | Sum (episodes) | Sum total length of stay (days) |
| **Hospital admissions – Elective (median, range)** | 96 (0, 0-13) | 177 (0, 0-32) | 107 (0, 0-31) | 112 (0, 0-31) |
| **Hospital admissions - Non-elective (median, range)** | 123 (1, 0-5) | 1548 (5, 0-129) | 82 (0, 0-8) | 728 (0, 0-75) |
| **Outpatient attendance (median, range)** | 563 (4, 0-31) | n/a | 455 (3, 0-23) | n/a |
| **A&E attendance (median, range)** | 131 (1, 0-6) | n/a | 96 (0, 0-10) | n/a |

10% of patients were responsible for 42% of bed days over the two year data collection period.

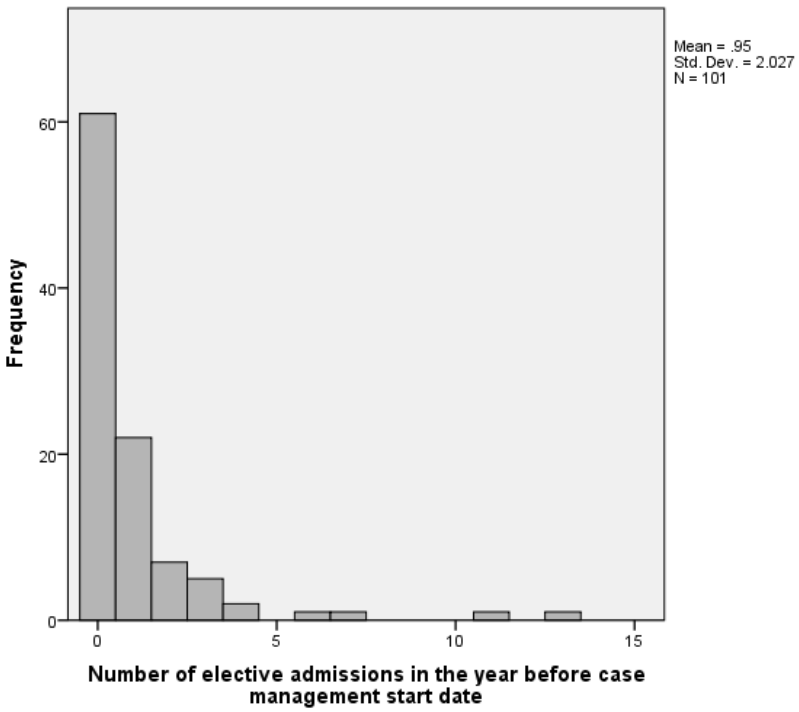



**Figure 7.4 Elective admissions recorded in the 12 months prior to case management**

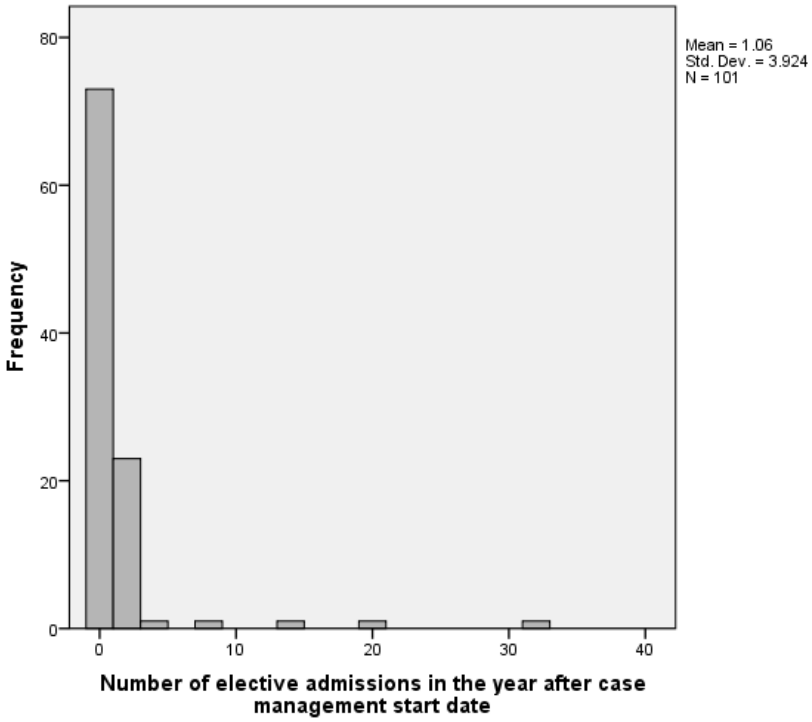



**Figure 7.5 Elective admissions recorded in the 12 month period post case management start date**

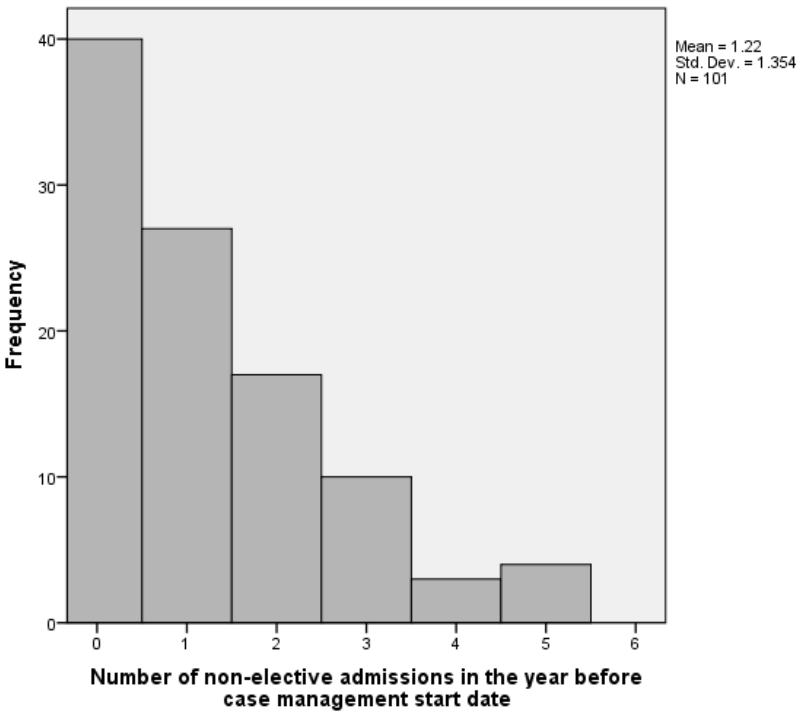



**Figure 7.6 Non-elective admissions recorded in the 12 months prior to case management**

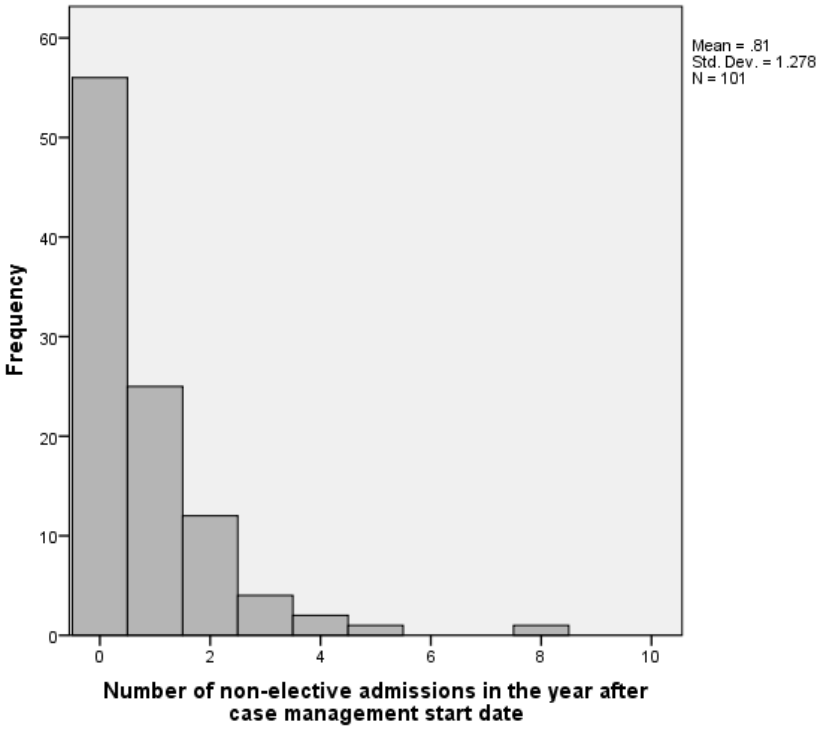



**Figure 7.7 Non-elective admissions recorded in the 12 month period post case management start date**

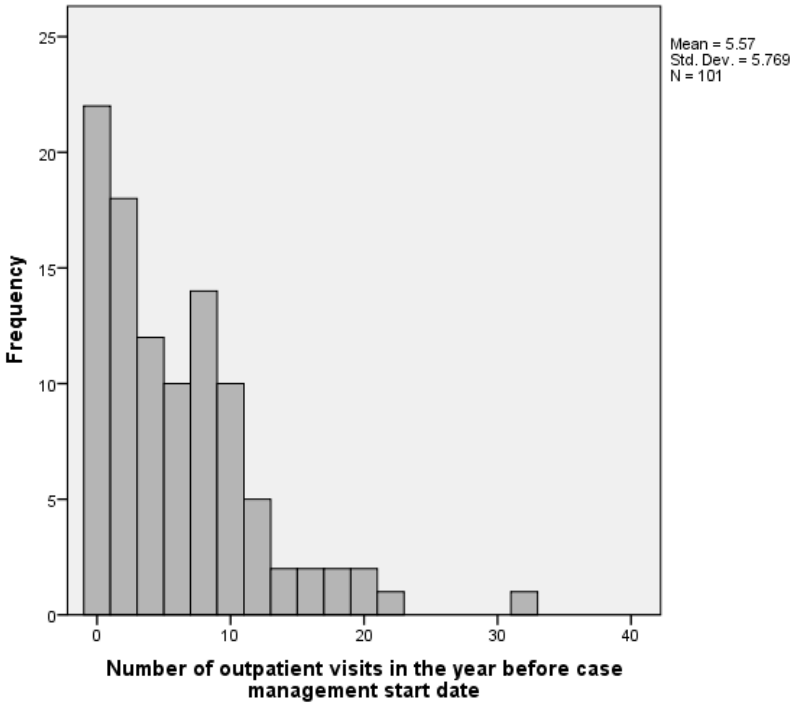



**Figure 7.8 Outpatient attendance in the 12 months prior to case management**

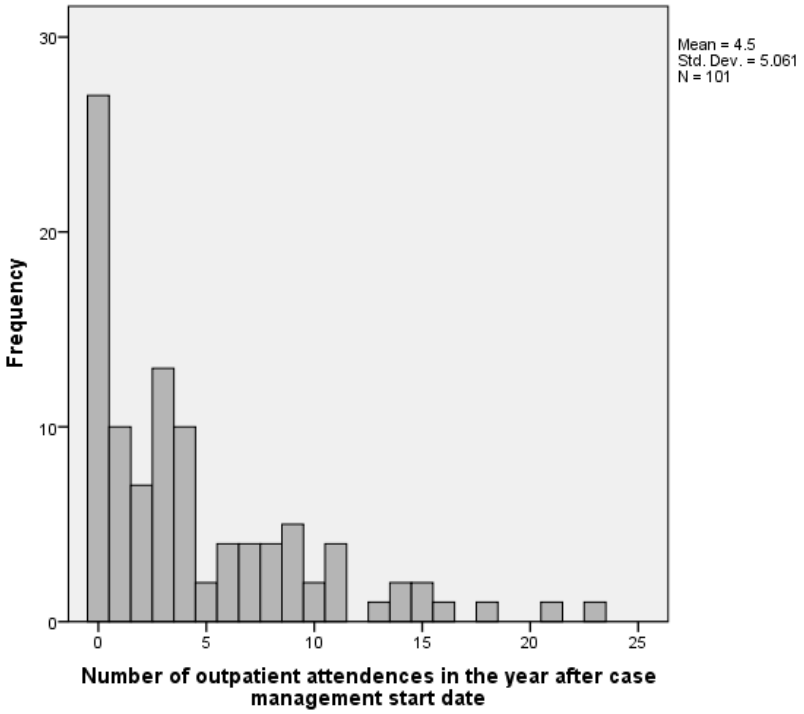



**Figure 7.9 Outpatient attendance in the 12 months post case management start date**

As expected, outpatient services were commonly accessed, which along with usage of other health services, such as case management teams and acute hospitals, indicates a high disease burden (Figures 7.8 and 7.9) (May *et al.* 2014). Speciality care, such as is likely to be indicated by

outpatient contact is a suggestive marker of patients at tier 3 of the Kaiser Permanente triangle. The most commonly accessed specialities were general medicine (56 patients accessed), cardiology (52 patients accessed), general surgery (47 patients accessed), trauma and orthopaedics (41 patients accessed), ophthalmology (35 patients accessed). Notably 24 patients accessed the geriatric medicine speciality.

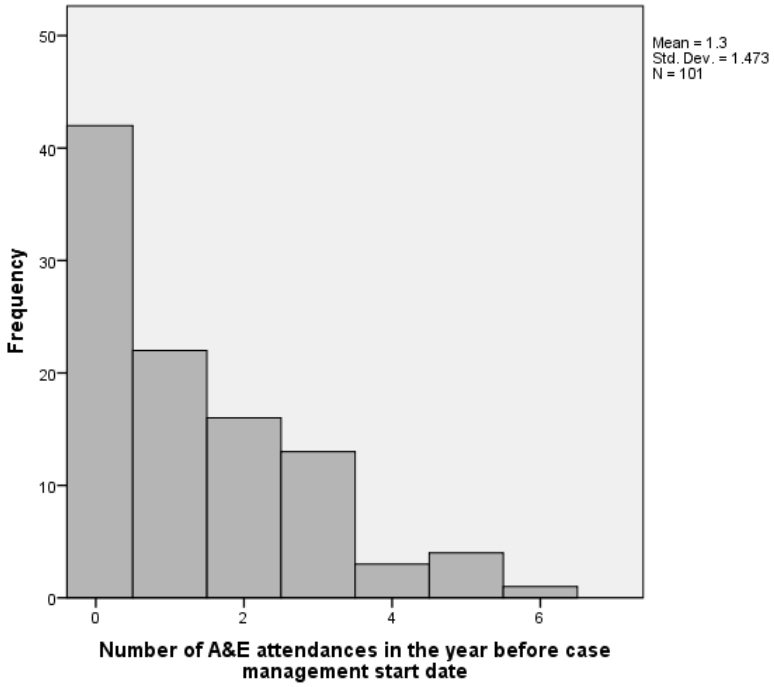



**Figure 7.10 A&E attendance in the 12 months prior to case management**

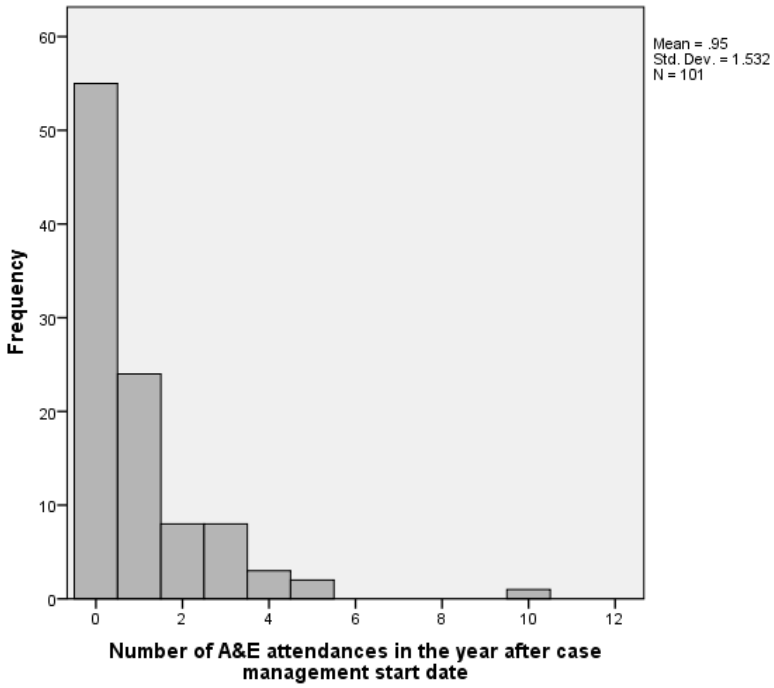



**Figure 7.11 A&E attendance in the 12 month period after case management start date**

The number of visits recorded by a member of the case management team to each patient ranged from 0 to 8.14 per week (median = 0.36), and 0 to 32.55 over a 28 day period (median = 1.42) (Figure 7.12).

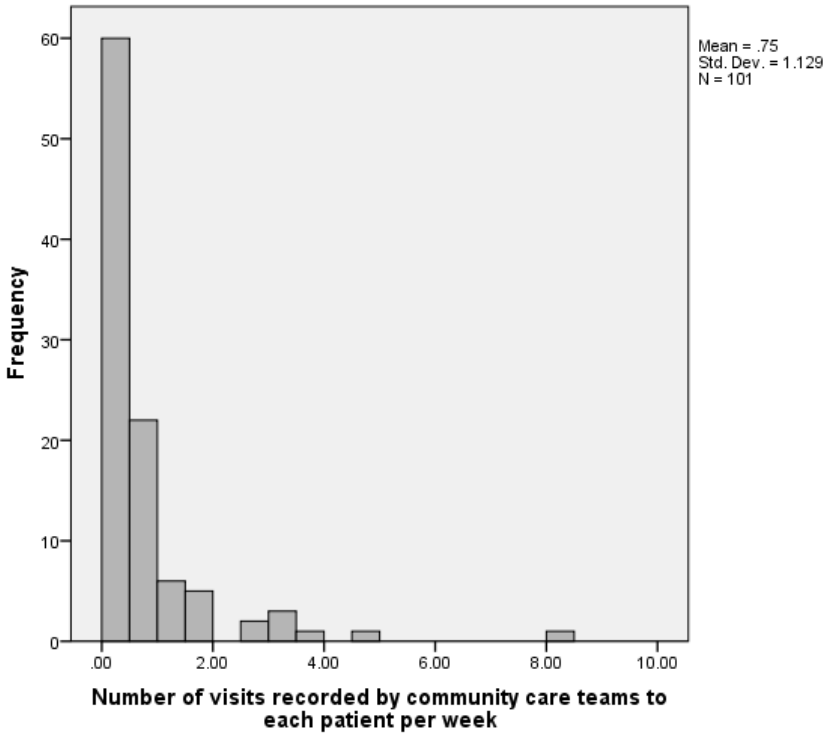



**Figure 7.12 Visits from Case Management team per week**

Chi square tests suggested no relationship between the variables (long term condition, gender, age, IMD, age, falls, all type hospital admissions, frequency of visits by case management team) and A&E admissions (Appendix 30). This may be due to the large number of patients with no A&E admissions recorded. No relationship was suggested (chi square test) between the number of long term conditions recorded and the frequency of visits by a case management team member (Appendix 30).

### 7.7.5 Frailty Index

Frailty scores ranged from 0.08 to 0.64 (Figure 7.13). The submaximal limit observed was in agreement with upper limits of between 0.6-0.7 commonly reported in frailty scales (Lucicesare *et al.* 2010). The lowest frailty index (FI) score was attributed to a patient with no other deficits/ risk factors present apart from old age. Table 7.6 shows the frailty scores produced from the HHR data, both of the total study population (n=101) and with the scores split into tertiles.

**Table 7.6 Baseline characteristics of total study population and by Frailty Index tertile**

| Variables | Mild frailty FI < 0.30 (n=34) | Moderate frailty FI 0.30<0.40 (n=39) | Severe frailty FI ≥0.40 (n=28) | Total study population (N=101) |
|---|---|---|---|---|
| **Women, n (%)** | 27 (79%) | 26 (67%) | 23 (82%) | 76 (75%) |
| **Age, mean ± SD** | 77 ± 12 | 79 ± 7 | 82 ± 9 | 79 ± 10 |
| **Frailty Index (FI) score, mean ± SD** | 0.20 ± 0.06 | 0.33 ± 0.03 | 0.49 ± 0.08 | 0.33 ± 0.13 |
| **CM team contact/week, median (IQR)** | 0.31 (0.16-0.62) | 0.33 (0.20-0.69) | 0.60 (0.30-1.22) | 0.36 (0.20-0.78) |
| **Outpatient contact/month, median (IQR)** | 0.27 (0.04-0.53) | 0.46 (0.15-0.71) | 0.27 (0.13-0.69) | 0.29 (0.13-0.63) |
| **At least 1 A&E attendance, n (%)** | 22 (65%) | 27 (69%) | 19 (68%) | 68 (67%) |
| **Multiple A&E attendance, n(%)** | 16 (47%) | 23 (59%) | 15 (54%) | 54 (53%) |
| **At least 1 hospital admission** | 23 (68%) | 31 (79%) | 23 (82%) | 77 (76%) |
| **Multiple hospital admissions** | 20 (59%) | 25 (64%) | 20 (71%) | 65 (64%) |

Cut-off values for the identification and categorisation of frailty using a frailty index have been reported as a score of ≤ 0.08 as non-frail, and a score ≥0.25 as frail, with scores between these classes as pre-frail (Song *et al.* 2010). When considering the Frailty Index scores calculated from HHR data and these cut-off values, 1 case management patient could be classed as non-frail, 19 as pre-frail, and 81 as frail.

Chi-square tests showed no statistical difference between FI tertiles in A&E attendance (at least 1 attendance) ($X^2$ (2, N=101) =0.174, $p$=0.917), in multiple A&E attendances ($X^2$ (2, N=101) =1.037, $p$=0.595), in hospital admissions (at least 1 admission) ($X^2$ (2, N=101) =2.151, $p$=0.341), or in multiple hospital admissions ($X^2$ (2, N=101) =1.065, $p$=0.587). Regarding single and multiple

hospital admissions a non-significant trend was observed with frailer patients seemingly experiencing more admissions.

ANOVA analysis of age by tertile reported no significant difference in age between FI tertiles (*p*=0.192). However, a non-significant trend of older patients having more severe frailty was observed.

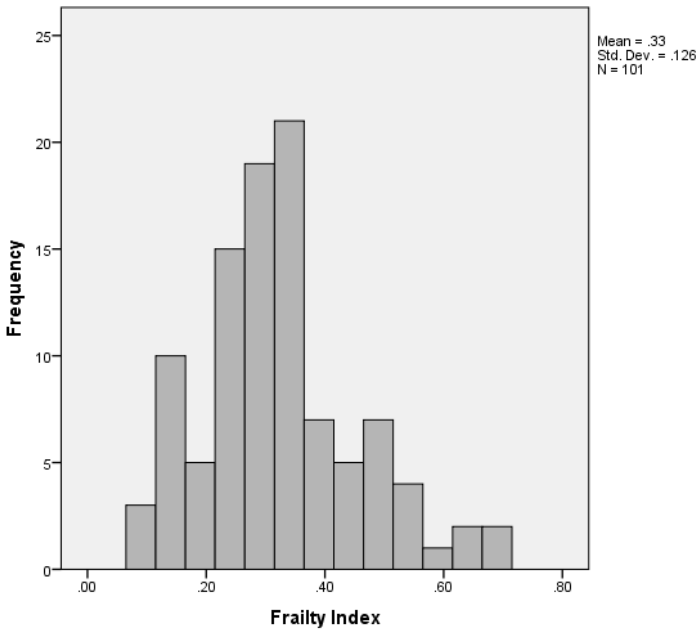



**Figure 7.13 Distribution of frailty index scores**

Kruskal-Wallis tests between tertiles for case management team contact and outpatient department contact indicated no significant differences (p=0.065 and p=0.089 respectively) (Appendix 31).

## 7.8 Conclusions

The HHR pseudonymised database provided a useful broad set of information on a cohort of patients receiving community case management, gathered across both primary and secondary health care settings. Identification of relevant records occurred through an indirect process due to the lack of reliable recording of virtual ward admission codes within the records. With increased use of the HHR by care providers and associated support over time this would be expected to increase, allowing a more direct, easier route of identification. Concern regarding lack of reliable coding must be considered when using the data, where conditions/service use may be underreported or incorrectly recorded. Measures of functional status in particular were lacking in the records. Data were available to allow development for the first time of a profile of a case

management patient group including demographic and health information, including a frailty index.

The age of patients on the virtual wards, receiving case management appeared to be skewed towards the older age groups, with the majority of patients being female, in line with the higher life expectancy for females in the UK (ONS 2010). Overwhelmingly patients had multiple LTCs, as was expected as one of the main aims of case management services is improved management and care for patients with multiple long term conditions. There appears to be a high degree of variability between patients within the group for example in the occurrence of falls, hospital admissions, length of hospital stay and frequency of visits by the case management team. The observed reduction in falls following virtual ward admission may have been due to regression to the mean, and without a comparative group, cannot be assumed to be due to the effectiveness of the service, especially as a large number reported no falls. The number of reported falls was low, and may indicate that falls are underreported in this patient group, either by the patient or the healthcare professionals. Whilst a reduction in some secondary service use may appear apparent, this is likely to be due to regression to the mean, and without a comparative group, cannot be suggestive of the effectiveness of the service (Figures 7.4-7.11). Downes *et al.* (2009) reported frequency of case management visits from daily to three monthly, the HHR data adds support to such a wide variation.

The frailty index indicated that all but one of the case management patients included in the study had a least a mild degree of frailty, when the scores were considered alongside previously published frailty classification values (Song *et al.* 2010), and could be used to stratify patients by frailty level with 28% of Study C patients identified as experiencing severe frailty. The apparent variability of the patient group is discussed further in Chapter 8.

A full discussion of the data from this and the previous two studies follows in Chapter 8, presented initially by research question then by study. The findings from the study as a whole are concluded in Chapter 9, with the implications of the findings and recommendations for future research considered.

# Section Three

# Discussion and implications for future research

# Chapter 8 Discussion

## 8.1 Introduction

The research described in this thesis was conceived in response to the continued focus of health services internationally on improving the care of patients with multiple LTCs. The increasingly aged UK population is linked to an increasing number of people living with multiple LTCs. Community based services designed to improve clinical outcomes and patient experiences are being relied upon to manage patients with LTCs effectively, and prevent avoidable hospital admissions. So far the expected reductions in avoidable hospital admissions have not been observed, suggesting room for improvement. The literature review highlighted the lack of clarity around the clinical needs of the patient group and monitoring practices employed by case management teams. Such services would likely benefit from a standardised, evidence informed approach, allowing fair and effective targeting of services, and objective monitoring of patients receiving such care. In response to the identified knowledge gaps five overarching research questions were posed, and addressed by the studies reported in this thesis.

Summary responses to these five research questions, formulated from the study findings, are now presented by question. These succinct responses are followed by more in-depth discussion of the full findings from each of the three studies in turn, followed by consideration of the limitations of the studies, and finally a synthesis of the data from the three studies where data allowed.

### 8.1.1 Response to research question 1

**"Can four non-invasive measures of strength (grip strength, PEF, PIF and SNIP) be measured reliably in a) older people with stable good health, b) patients receiving case management?"**

Study A confirmed an excellent level of intra-rater and inter-rater reliability (estimated by ICCs and Bland-Altman plots) for grip strength, PEF and PIF but not SNIP in self-reported "healthy" older people, with stable good health. Study B demonstrated good intra-rater reliability for the successfully piloted measures of strength (grip strength, PEF and PIF), and further more suggested that the measures remained stable over a seven week period in older case management patients, despite adverse events such as falls, A&E attendances and hospital admissions occurring. The excellent reliability of the three measures, grip strength, PEF and PIF, demonstrated by these two studies, was agreement with the literature (Innes 1999; Fonseca *et al.* 2005; Kamide *et al.* 2009; Abizanda *et al.* 2012).

### 8.1.2 Response to research question 2

**"Are the measures of strength acceptable to a) older people with stable good health, b) case management patients, and c) clinicians?"**

Older people with stable good health (Study A participants) and case management patients (Study B participants) reported a high degree of acceptability for grip strength, PEF and PIF. The pilot study, Study A, identified SNIP as the least acceptable of the four measures to participants, with incomplete readings recorded due to participant dislike of the test. Therefore, SNIP was deemed unacceptable for inclusion in the follow-on feasibility study. The case management patients who participated in the feasibility study reported grip dynamometry as generally the most acceptable measure. However, grip dynamometry was considered the least acceptable of the measures to clinicians, who raised concerns about the practicality of carrying around a sizeable and relatively heavy piece of equipment. Alternative grip dynamometers may be more acceptable to clinicians, and should be considered by future researchers proposing use in such a setting. The respiratory measures were deemed more acceptable to clinicians; the familiarity of such measures and more practical considerations such as their smaller size and weight are likely to have informed this view. In order for any measure to be considered acceptable by clinicians, a demonstration of its ability to aid clinical practice is essential. Suggestions for improvements to all of the muscle strength measures were made by Study A and B participants, most frequently suggesting an alternative grip surface for the grip dynamometer and the availability of different sized mouthpieces for the respiratory measures, to improve the comfort of the user.

### 8.1.3 Response to research question 3

**"Are there measurable declines in grip strength, PEF and PIF over a seven week period in patients receiving case management?"**

Muscle strength, measured by the proxy measures PEF, PIF and grip dynamometer, remained stable over the seven week data collection period in case management patients (Study B), with no significant changes occurring despite adverse health outcomes occurring. The sample size calculations indicated that a sample size of 10 would have been sufficient to detect a 35% change in muscle strength, and a sample size of 12, sufficient to detect a 25% change. No change was apparent with the near adequate sample size of 8 in Study B. This stability suggests that repeated monitoring of muscle strength would not add any beneficial information to the clinical picture to aid the clinician.

### 8.1.4 Response to research question 4

**"Are any observed changes in muscle strength associated with changes in wellbeing, function and health status?"**

The high level of stability observed in strength (in case management patients during Study B), despite adverse health events occurring, including falls and hospital admissions suggests that changes in health status, function and service use are not associated with simultaneous measurable changes in muscle strength. No measures of strength were identified in the HHR dataset, but the development of a frailty index allowed some exploration of the presence of frailty and health service use. The HHR data indicated a non-significant trend of an increasing frequency of hospital admissions with increasing levels of frailty, with which lower muscle strength is often associated. A non-significant trend was observed in the HHR data suggesting that those with severe frailty (rather than mild-moderate) had more frequent contact with their case management team.

### 8.1.5 Response to research question 5

**"What is the health, physical and functional profile of patients receiving case management?"**

Studies B and C identified a wide variation in the health, physical and functional status of case management patients. The muscle strength values and levels of physical activity obtained for the case management patients (Study B) fell below those observed in the healthy older pilot study participants, and were at the lower end or below published norms. Of the three measures, PEF values were most frequently recorded below published normal values (in 63% of patients, considering their maximal value over the total data collection period). The functional ability of case management patients (Study B) again varied greatly, with a wide range of BI scores observed; the group mean score suggestive of moderate dependency in activities of daily living (Shah *et al.* 1989). Interestingly the additional functional measure, VES-13, which considers more instrumental activities of daily living identified the majority of the patient group as being at higher risk of functional decline or death in the next 2 years, indicating that the patients were generally experiencing difficulties in instrumental activities of daily living rather than more basic functional ones such as toileting. Multiple LTCs and regular prescribed medication were commonly reported and supported by DH population data; surprisingly they were not reported in all cases (Study B and C). Identifying frailty through either a frailty index (Study C) or with reference to Fried *et al.* (2001) frailty syndrome (Study B) resulted in the majority of case management patients being identified as frail. The findings from Studies B and C are compared and contrasted further in Section 8.6.

Each study is now addressed in turn, providing a more detailed discussion of the findings, followed by a consideration of the limitations of the studies.

## 8.2 Study A

The initial pilot study in "healthy" older participants concluded that PIF, PEF, and grip strength were reliable and acceptable in older adults aged 65 years and over. SNIP did not demonstrate high enough reliability to recommend use as a clinical measure, and was the least acceptable muscle strength measure to participants.

The reliability estimates for all four of the strength measures were in line with previously published work (Innes 1999; Fonseca *et al.* 2005; Kamide *et al.* 2009; Abizanda *et al.* 2012), and demonstrated that grip strength, PEF and PIF could be measured consistently and accurately in people aged 65 years and over by the two operators and remained stable over the one week testing period. SNIP was the least reliable measure, ICC falling below the recommended 0.90 to ensure validity for clinical measurements (Portney and Watkins 2000). Previously published reliability figures for SNIP, when assessed using Portney and Watkins (2000) validity requirements also fall below 0.90 (Maillard *et al.* 1998). Bland-Altman plots for between day and inter-rater reliability of SNIP demonstrated proportionally wide limits of agreement when compared to the other three measures of strength, showing SNIP's apparent increasing error at lower values, limiting its clinical use. There were numerous potential reasons for the poor reliability of SNIP, including poor operator technique and a considerable learning effect, which may have meant that with further repetitions the reliability may have increased. Whilst reasons for poor reliability may not be equipment alone, a significant learning effect and poor operator technique give support to the conclusion that SNIP is unsuitable for use as a measure of strength in most clinical practice as training needs would be high and patient burden too great. Participant feedback also placed SNIP as the least acceptable of the three muscle strength measures (Table 5.4). Participants found grip strength generally the most acceptable strength measure, followed by PEF and PIF (Table 5.4). Both the excellent reliability and acceptability of PIF, PEF, and grip strength justified their inclusion in the feasibility study in case management patients (Study B).

A demographic profile of the group suggests that those in the target population were recruited. Participant's age ranged from 65-84 years, with a mean age of 74, suggesting that age was evenly distributed across the range. The upper age limit for participation meant that no participants were in the older-old age group (85 years and above). The common observance of an overweight BMI and the presence of LTCs corresponded with population norms for this age group. As expected in a self-reporting health population a high level of functional independence was observed, as indicated by BI and VES-13. Some functional limitations were noted via VES-13 in women; in a self-selecting "healthy" group such as this, it must be considered that men and women report their health status differently, considering different abilities within their lives

(Hubbard *et al.* 2011). PEF, PIF and grip strength values recorded generally agreed with published norms; grip strength and PASE scores in men were slightly higher than published norms (Depledge *et al.* 1985; Mathiowetz *et al.* 1985; Nunn *et al.* 1989; Washburn *et al.* 1993). SNIP values appeared slightly below published values, with concerns already mentioned regarding technique and reliability, as well as a higher mean age in comparison with published norms offer some explanation for this (Uldry *et al.* 1995). Considering the grip strength scores alongside Fried *et al.* (2001) frailty criteria and grip strength cut-off values , 14% of the group recorded maximal grip strength values below the frailty cut-off values (Table 4.2), suggesting a degree of frailty. This figure is supported by the literature suggesting a prevalence of frailty between 3.8% - 16.3% in community dwelling populations (Song *et al.* 2010). A higher level is expected in the case management patient group.

## 8.3 Study B

Study B was an observational, longitudinal study involving case management patients, designed to investigate the feasibility of using muscle strength measures as an aid to monitoring. Data regarding case management patients' physical, health and functional status were gathered and assessed against published norms, whilst the reliability, stability and acceptability of the muscle strength measures were also addressed.

The group mean PIF and grip strength values for both male and females fell at the lower end of the normal range (Depledge *et al.* 1985; Mathiowetz *et al.* 1985). PEF values fell below published norms (Nunn *et al.* 1989). Although PEF is rarely used in patients without COPD or asthma, similarly low results were observed in hospital inpatients admitted for ill-defined conditions, most of whom did not have a respiratory condition (Hunt 2009), supporting the suggestion that respiratory function is linked to "poor health" generally, and not just in those with respiratory conditions. Although it is standard practice when obtaining PEF and PIF measurements to have the patient stand, patients remained seated in this study protocol. At the time of protocol development it was envisaged that many patients would be unable to stand without difficulty or a safety risk, to perform the measures. This difficulty and risk, along with recent evidence demonstrating no significant difference in PEF values whether sitting or standing, informed the data collection protocol (Vaswani *et al.* 2005; McCoy *et al.* 2010). It should be considered that sitting may have impacted on both PEF and PIF, resulting in below maximal values being obtained. All patients were asked to sit as straight as possible whilst performing PEF and PIF. In practice there was a great variability in the ability of patients to sit straight, which is likely to have restricted inspiratory and expiratory movements, again resulting in lower values. Intra-rater

reliability was assessed via repeated measures within the first week, with the stability of the measures over a seven week period assessed using all five time points over the seven week data collection period.

The reliability estimations and acceptability feedback suggest that PIF, PEF, and grip strength are reliable and acceptable to case management patients aged 65 years and over. Between day reliability, estimated through ICCs and Bland-Altman plots indicate that grip strength, PEF and PIF demonstrated excellent reliability across the short and short-medium term. The ICC estimations were in line with prior published ICC figures, where available, for these measures (Innes 1999; Fonseca *et al.* 2005; Kamide *et al.* 2009; Abizanda *et al.* 2012). Grip strength, PEF and PIF demonstrated high reliability, and along with previous published reliability data support the acceptance of these as reliable clinical measures. However, the lack of variability in the muscle strength measurements observed over the seven weeks, especially considering the occurrence of adverse outcomes during this time suggests that repeated measurement of grip strength, PEF and PIF would not be beneficial over the short to medium term. Further investigation with a larger sample size would be required to confirm this conclusively, but these results indicate that this may prove fruitless.

The low muscle strength values observed in the case management patients may mean that a reduction of 25-45%, the percentage change that sample size calculations were based on was unlikely to occur, and that measurable changes were and are unfeasible. A single predictive measurement may provide a more useful marker, rather than repeated measurements over the short-medium term. A single measurement, for example on referral, may help to highlight patients most at risk of an adverse health outcome, as previous studies have identified the predictive value of muscle strength for longer term future health outcomes, with the largest body of evidence supporting grip strength above PEF and PIF which lack evidence of this nature (Cawthorn *et al.* 2009; Cooper *et al.* 2011; Roberts *et al.* 2014). The predictive value of muscle strength measures in the shorter term and when used in already frail patients requires further confirmation. This may need the muscle strength measures to become a more routine part of clinical practice to enable a calculation in the reduction in values over time, which may prove more predictive than comparison of values against normative data, especially where concurrent disease states affecting the measure e.g. rheumatoid arthritis affecting grip strength are present. Consideration of the observed outlying PEF reading (Figure 6.9) found that a low PEF reading occurred at the same time as the patient reported feeling helpless (a feeling that was not reported when higher PEF readings were obtained), and a feeling that may have resulted in the participant performing sub-maximally, alternatively this low reading may indicate a sub-clinical

decline in health status. No other reduced strength measurements or significant adverse events such as a fall, hospital admission or unplanned health service contact were recorded at the same time.

The development of a case management patient profile was limited in Study B by the small sample size; data from Study C considered alongside data from Study B follows in Section 8.6. The apparent vulnerability to adverse health outcomes of the patients observed varied, with some displaying numerous risk factors e.g. multiple LTCs, polypharmacy, older age, with others displaying minimal. When the data on physical activity, muscle strength and symptoms gathered from patients were compared to Fried *et al.* (2001) frailty syndrome definition (Section 6.10.5), 50% of participants' were classed as frail. The age of participants tended towards sub-categories of old age often referred to as the middle old (75-84 years) to older old (85 years and over; mean 81.5 years), increasing their vulnerability. BMI for all participants classified them as overweight or obese, yet another risk factor for frailty. The number of longer term conditions reported by patients varied, ranging from 1-5, the lower value somewhat surprising as multiple LTCs are a driver for case management services. Notably no participants in the feasibility study came from the four most deprived IMD deciles (indicated by electoral ward), again an impact on frailty, with six of the eight participants coming from the least two deprived IMD deciles, putting few within the most vulnerable group with regard to deprivation. Functional impairment was detected by VES-13 in every one of the participants (all but one scoring a significant 3 or above, Section 6.10.3). BI values ranged from maximal (no functional dependency) to low. The VES-13 and BI data indicated that the majority of patients were experiencing impairment in instrumental activities of daily living for example grocery shopping, rather than more basic physical problems such as getting dressed or toileting. Unfortunately the HHR dataset (Study C) did not include any functional indicators. However, where data allowed, the inclusion of Study C enabled the case management patient group described here to be compared with the larger patient cohort in Study C, patients from within the same or neighbouring NHS Trust.

## 8.4 Study C

The sample of 101 HHR patient records demonstrated a high degree of variation in the health profile of patients receiving case management services. A quarter of the sample were male, with patient's age ranging from 58-97 years; a skewed age distribution was illustrated, skewed towards the older old. The presence of multiple LTC flags was prevalent, although the mean value of four suggests that this is lower than may be expected when case management is targeted at those with the most complex needs, and expected to have multiple LTCs. Medication associated with adverse events including opioids, diuretics and anti-platelets were commonly recorded (Section 7.7.2); case management patients frailty is likely to increase their susceptibility to such adverse events (Section 7.7.2). Antibiotics were also commonly recorded, notable as an infection can pose a significant challenge to frail older people, leading to a significant adverse event. Falls data indicated that falls occurred in 11-15% of case management patients annually (Table 7.4 and Figure 7.3), and of the patients who had a fall in the year prior to virtual ward admission, one third went on to have at least one fall recorded in the subsequent year. This prevalence is lower than the 30-50% expected in this age group (Age UK 2012), and may be indicative of data inaccuracies. Acute secondary care service use varied greatly, with the majority of records indicating low usage, and a minority reporting frequent or long stay admissions to hospital and/or A&E attendance. A broad range of specialist outpatient services were commonly, and in some cases frequently accessed. Over half of patients recorded contact with general medicine and cardiology outpatient services, with only a quarter accessing specialist geriatric care. Geriatricians are increasingly likely to measure frailty. However, there is currently no recommended frailty assessment for case management patients.

The FI provided a way of quantifying frailty, utilising the large volume of data obtained regarding risk factors for adverse health events, along with adverse event occurrence. Analysis of The Survey of Health, Aging and Retirement in Europe (SHARE) study (Theou *et al.* 2014) supported the idea that with regards to frailty, it is the number of deficits that is important, not what the deficit is (Theou *et al.* 2014). As frailty is multifaceted ideally a frailty measure would include aspects of health, function and social support, with a measure with broader coverage expected to provide more accurate results than a more narrow, focused one. The FI developed using the routine HHR data, was limited by the data available but allowed inclusion of 19 aspects of frailty, including age, long term conditions, deprivation, falls history, and polypharmacy. All but age were dichotic. Considering the content of the HHR, and the multifaceted nature of frailty, data were notably missing regarding social support and function, which is likely to have led to the underestimation of frailty.

FI scores were calculated to give a value of between 0 (minimum, no frailty) and 1 (maximum, highest level of frailty). The maximum calculated score using HHR data was 0.64, consistent with other published studies involving frailty indices (Lucicesare *et al.* 2010). When calculating frailty scores using frailty scales/indices, it appears impossible to accumulate every deficit, with a submaximal threshold observed that rather than go over, a patient will die (Theou 2014). Datasets from across different countries analysed using different FIs, found values to be closely comparable (Hubbard and Rockwood 2011). Comparing the FI scores calculated from the HHR data, with FI scores and cut-off values (cut-off value for frailty ≥0.25) produced using a variety of frailty indices in a general community dwelling older population, suggests that the case management patient group shows much higher levels of frailty (80.2%) than that observed in general older populations (22.7%, Song *et al.* 2010). The common presence of frailty was as anticipated in the patient group, receiving services targeted at those most vulnerable patients with complex needs. The mean FI score calculated from the HHR data was similar to that observed in day hospital attendees using a FI developed by Rockwood, and correlates with the Clinical Frailty Score classification of "moderately frail - help needed with activities of daily living", which the VES-13 data supports (Hubbard *et al.* 2009). The FI reported here (developed from the HHR data) corresponds with those scales that are more discriminatory at the moderate to severe end of frailty, beneficial in an frail case management group, when discrimination off those patients at highest risk is likely to be beneficial to allow targeting of services and intervention (Hubbard *et al.* 2009). In developing a FI from routine data, this study demonstrates the potential for and viability of developing such a scale from routine primary and secondary care data, such as that held on the HHR. Future studies would be required to develop the frailty index further, using a larger population. It may be that a submaximal score could be identified around or above which a persons' ability to remain living at home (rather than within an institution) becomes unviable or unsafe, or may highlight the need for extra support or intervention. This would need to be confirmed by studies involving patients residing in alterative settings, such as nursing or residential homes.

The splitting of FI scores into tertiles allowed groups of patients, particularly at either end of the FI range, to be considered further and compared. Whilst no significant difference between the frequencies of patient contact with the case management team was identified, there was a suggestion that patients with higher frailty score had more frequent contact with their case management team. Challis *et al.* (2010) reported a wide variation in the frequency of visits to patients by case management team members, weekly contact occurring in between less than 25% and 50% of cases. The median value for frequency of case management contact from the HHR data was 0.36 contacts per week, i.e. the majority of patients received less than once weekly

contact. The apparent low frequency of contact with patients, recorded on the HHR by the case management team is somewhat unexpected as case management is considered an intensive service involving frequent contact which was not observed in the majority of cases, demonstrating within group variability. The validity of this observation may be questionable, contact may have been underreported and the absence of a case management finish date may mean that the frequency of contact has been underestimated. No significant difference in outpatient contact was identified between FI tertiles; a non-significant trend in the frequency of outpatient and case management team contacts in the upper tertile was seen (Table 7.6). A small degree of care shifting between the case management team and the outpatient departments may be occurring, a larger study may confirm. A non-significant upward trend in hospital admissions was observed with increasing levels of frailty, with those in the lower quartile reporting less of all types of admissions and A&E attendance. One characteristic of patients across all levels of frailty was a notably high level of deprivation, the median IMD decile was 9.

At the lower end of the frailty scale, the lowest scoring tertile included patients who had no or few deficits except for old age. A large proportion of HHR records also recorded 0-1 case management team contacts per week, no hospital admissions in the year prior to or after case management start date, and no A&E visits in the year prior to or after. This lack of service use is surprising when case management services were proposed as an intensive service, with frequent unplanned secondary case use often acting as a referral trigger (Challis *et al*. 2010), but may be indicative of the broader patient group, anecdotally being targeted more recently, aiming to identify a larger cohort of patients at risk of future admissions. The HHR records containing low levels of health service use or FI scores may highlight patients for whom case management is not the most appropriate service, and suggest that such patients would be supported better by a different, less intensive and most likely less costly approach. It may be that some patients were wrongly identified as receiving case management services, or that other data such as high out of hours primary care usage would indicate the reason for inclusion but were not explored here, or that usage of such services or presence of risk factors have not been recorded.

## 8.5 Limitations of the studies

The intention of the study as a whole was to explore the feasibility, acceptability and usefulness of measures of muscle strength to monitor health and detect/predict declining health in older people receiving community case management, as a way of improving patients' on-going assessment, to enable case managers to target care more effectively. This was addressed by three separate studies A, B and C. Many of the study variables were shared, allowing comparison of data between the sample populations, which highlighted some of the limitations of the studies.

### 8.5.1 Representativeness of samples and sampling bias

As already discussed the Study A descriptive data suggested that members of the target population were recruited, and that a representative adequately sized sample was obtained, despite slower than expected recruitment. Slow recruitment was also experienced in Study B. Recruitment data for Study B indicated that there were substantial numbers of eligible patients on case management case lists, but that there was difficulty in accessing these patients and gaining a response (Section 6.10.1). It was also apparent that a substantial proportion of patients on the case lists utilised (Study B) were ineligible to participate due to them receiving end of life care and having significant cognitive impairment, exclusions for the HHR study too, which may reflect changes to case management services locally and the expectation of whom the service provides for. The number of patients appearing on case lists, but awaiting discharge from the system, may suggest a lack of resources to allow teams to maintain up to date case lists. Demographic data gathered once enrolment had occurred allowed the representativeness of the samples to be considered.

The gender balance in the patient groups (Study B and C) was notably different. The HHR cohort (Study C) was predominantly female (75%), with a much lower proportion observed in Study B (38% female). The much lower proportion of women observed in Study B suggests that this sample (Study B) may not have been representative of a typical case management population. The increased level of frailty often observed in older women, i.e. those likely to be on a case management case list, as borne out in Study C, may have had a bearing on their decision not to volunteer to participate in the feasibility study; they may have felt participation a bigger burden and the increasing likelihood of them living alone may have increased their concern around their own safety, in the same way consideration was given to the researcher's safety as a lone worker. Women's vulnerability to an adverse health outcome may be linked to their social vulnerability; for example women's higher life expectancy increases their risk of being widowed, and are more likely to lack the support of a spouse when a challenge to their health status occurs (Hunt 2009). The dominance of women in the HHR study could be attributed to a number of factors, including

females' longer life expectancy, and the apparent increased incidence of frailty in women, meaning that whilst women may live longer, they have a tendency to live longer with poorer health (ONS 2010; Hubbard *et al.* 2011).

The HHR data (Study C) suggested that the age of patients receiving case management was skewed towards older age groups, with over 50% aged 80 years or older; the feasibility study (Study B) data demonstrated agreement with this. The recruitment data from Study B supports this further, indicating that as expected the majority of case management patients were aged 65 years and over, with relatively few exclusion due to the patient being aged below 65 (Figure 6.6). This association with older age is in line with the general shift in the demographic of the UK population, where over the last 25 years the largest growth has been in the over 85s (ONS 2010). This also sits comfortably with data indicating that the majority of over 75s live with three or more LTCs (DH 2012a), meaning complex health and social needs are likely, involving multiple body systems and making older people more likely to receive case management services.

The socioeconomic deprivation status (indicated by IMD) of Study B participants suggested that they were living in significantly less deprived areas than those usually receiving case management services, as indicated by HHR data. Socio-economic status may have acted as a barrier to participation in the research study, and is often given as a barrier to participation in health care programmes (Protheroe *et al.* 2013; Shanmugasegaram *et al.* 2013). The patients recruited into Study B were from higher socio-economic groups than HHR data suggests is normal for case management patients. No participants in the longitudinal study came from the four most deprived IMD deciles (indicated by electoral ward), with six of the eight participants coming from the least two deprived IMD deciles. Whereas the median IMD decile indicated on HHR records was the 9$^{th}$ decile (where 1 is the least deprived and 10 is the most deprived), indicating that a proportional majority lived in the most deprived areas. Whilst these findings were somewhat expected, with literature relating deprivation and socio-economic status to frailty and vulnerability (Lang *et al.* 2009; Syddall *et al.* 2010), the median decile is striking. The effect of socioeconomic deprivation on a patient's ability to self-care, an important component of LTC management, may offer some explanation. Higher deprivation is likely to mean a patient has a higher burden of daily life and reduced capacity to self-care, meaning that less intensive forms of LTC management may be unsuccessful, prompting case management (Coventry *et al.* 2014). The disparity in deprivation between Study B and C patients should inform future study design and methodology. The increased burden of daily life experienced alongside deprivation is likely to have influenced patients' perceived ability to participate in a research study (May *et al.* 2014). Participants ability to communicate at all stages of the study, from showing an interest in

participating (e.g. in Study B by post or telephone) is also linked to their functional ability, meaning that poorer functioning patients are less able to participate.

Study C was designed in response to the limitations of a small sample size in Study B. Study C enabled an exploration into the health, function and service use of case management patients via analysis of routine primary and secondary care data. Whilst a significant proportion of patient HHR records were excluded due to the time consuming pseudonymisation process required by governance and ethics, a sample size of 101 was achieved. In future it may be more appropriate to use the analytic anonymised dataset where possible for research, to prevent such exclusions.

Findings regarding recruitment from this study should be considered in future research study design. The data suggests that the case management patient group is broad; future studies should be clear about their population of interest, and ensure that the study design including recruitment strategies enable a representative sample.

### 8.5.2 Measurement bias/error

Study A and B included self-report and recall of symptoms and activities by participants; consideration of the data needs to be mindful of recall errors and bias, a potential issue in research in older people (Raina *et al.* 2002). However, validated reliable measures were used where available, including BI and VES-13, whilst at the time of the study the SBS was undergoing validation tests in various clinical groups, including the one studied here.

Standardised protocols for administration of the muscle strength measures, training and the inclusion of a pilot study aimed to minimise measurement errors. PEF and PIF measurements may have been impacted by the deviation from the standard operating practice of performing the measures whilst standing. This was not possible in a number of patients due to mobility limitations, with some patients also limited in their ability to maintain an upright posture, restricting respiratory movements and PEF and PIF values. Concern regarding the impact of concurrent disease states on the validity of the muscle strength readings was expressed by the clinicians participating in Study B. Due to the presence of multiple LTCs and the association of these with ageing, the presence of a disease state affecting the measures selected, respiratory or grip strength is likely in a broader population, although not observed here. Lower grip strength values have been reported in patients with rheumatoid arthritis, compared to those without (Bearne *et al.* 2007). In some cases this may inhibit readings being taken, and would require further investigation in broader populations.

Unidentified errors may have occurred in the HHR data analysed in Study C. The reliability of coding in the HHR was raised as a potential issue from the start by the HHR team and possibly highlighted by the lower than expected number of falls (Section 7.7.3). Whilst there is some evidence that disease registries may improve the quality of care provided to some people with long term conditions, clearly these registries only work if the data is reliable, consistently providing accurate information without exclusions or erroneous admissions (Singh 2005). There are numerous obvious areas of missing potentially useful information on the HHR, including information on patients' social support, functional ability and out of hours primary care service usage. The latter leaves a gap in knowledge when considering unplanned service use, with high use being suggestive of a patient at high risk of an adverse health event.

The appropriateness of the LTC flags used within the HHR needs to be considered. The Department of Health defines a long term or chronic condition as a condition that cannot be cured, but can be managed through medication and/or therapy. Some of the conditions flagged in the HHR as an LTC do not strictly fit with the DH definition, such as obesity and depression, with some, including obesity and hypertension, being risk factors for the development or existence of other LTCs such as CHD and diabetes. Evidence of medicalisation of such risk factors. There also appears to be opportunity for duplication, whereby a condition may be reported by two flags e.g. hypertension and CHD and vascular disease. The LTC flags are based on the DH Quality and Outcomes Framework targets. Hypertension, chronic kidney disease and obesity were the most frequently recorded flags; these three condition registers have the highest number of QOF points associated with their maintenance. QOF points are linked to financial incentives, and it should be considered that this may disproportionally encourage their use over "less valuable" flags. By basing LTC flags on QOF targets alone, it leaves open the potential for clinically significant LTCs to go unrecorded. For example whilst 5 million people in the UK report a musculoskeletal condition, there is no QOF register for it (ONS 2012). The majority of the most frequently recorded LTCs on the HHR records (Table 7.1), are in line with expectations based on QOF 2010/11 data and data regarding the targeting of case management services (Challis *et al.* 2010), suggesting a representative sample. The patients observed in the feasibility study varied widely in the health conditions they reported. Whilst the sample was small, somewhat surprisingly multiple long term health conditions were not always present, with a number of patients reporting no or one LTC as defined by the DH, suggesting that patients not traditionally targeted for case management were receiving care via the case management service. These patients not reporting multiple LTCs were receiving rehabilitation following an accident or had a history of frequent falls.

A notable observation from the demographic data from Study C was the prevalence of deprivation, indicated by IMD deciles. IMDs produced by the UK government are not a direct measure of socio-economic status, but are calculated from a series of parameters including income, employment, health deprivation and disability, education, barriers to housing and services, crime and living environment. IMD calculated on an electoral ward level, as occurred in Study B, gives rise to the opportunity for the IMD to give a false suggestion of the level of deprivation a patient is experiencing. This can be especially notable in cities (two of which were included in the recruitment region) where there is the chance for areas of extreme deprivation and wealth to exist side by side. Whilst it is more likely to result in an underestimation to occur, due to a few very wealthy areas raising the IMD value, the converse should be considered at an individual patient level.

## 8.6 Data synthesis

The design of three separate studies to address the research objectives, two involving case management patients, but drawing from different datasets encourage a synthesis of the findings. The findings presented by study variable follow, where findings from more than one study are relevant and where not previously discussed in this Chapter.

### 8.6.1 Muscle strength

Grip strength, PEF and PIF values observed in the Study B case management patients were frequently at the lower end of or below the published normative range. Group mean values demonstrated that the case management patient group had lower strength values, for all three measures, than the self- reported healthy participants in Study A. This was despite the much higher proportion of males in the case management group, who generally have higher levels of strength, thus would be expected to raise the group mean value in the case management group. The male participants in Study B displayed wider variation in grip strength, PEF, PASE, and VES-13, than the females, suggesting the outliers, with more extreme readings, had a notable impact on the group mean values.

The main findings from Study A and B regarding the reliability and acceptability of the measures of strength have already been reported in 8.1.1 and 8.1.2. In addition, the preference for the grip strength measure of participants in both studies was clear, with both groups ranking it as their most preferred measure, despite similar suggestion for improvement to the grip surface.

### 8.6.2 Frailty

Frailty was assessed in different ways in each study, with results indicating that frailty was considerably more prevalent in case management patients than self-reporting "healthy" participants, as was expected. The presence of frailty highlights a vulnerable patient, at higher risk of adverse events, for whom case management may be an appropriate service. Study B identified 50% of patients as frail, using Fried *et al.* (2001) frailty syndrome definition and the presence of three of more frailty symptoms. Study C used a FI developed from the routine data available, and identified 80% of patients as frail, using previously reported and accepted frailty score cut-off values (Section 7.7.5). The findings from these two studies illustrate that frailty is much more prevalent in case management patients than the up to 23% reported in general community dwelling older populations (Song *et al.* 2010). The FI used in Study C was also able to discriminate between levels of frailty, additionally identifying pre-frail patients, and patients with the most severe degree of frailty.

### 8.6.3 Function and physical activity

Comparative information on the detailed functional status of case managed patients is distinctly lacking, both in the literature and within this study. A level of functional impairment and vulnerability was commonly identified in Study B via the VES-13. When comparing the summary mean values for BI, VES-13 and PASE for the healthy older participants in Study A, with the case management patients in Study B, the values for the case management patients indicate a substantial increase in functional limitations and difficulties in completing activities of daily living, and a reduction in the level of physical activity undertaken (Table 6.3). The HHR data provided little information regarding the functional status of patients. While it was possible to record a BI score on the HHR, with a dedicated BI field available, no records analysed had a value entered in this field. BI scores obtained from the feasibility study ranged from very low to maximal. VES-13 scores whilst still showing variation, did identify the majority (7 out of 8) of patients as vulnerable, i.e. at a higher risk of functional decline and death in the following one to two years (Saliba *et al.* 2001). A study in a similar community dwelling population receiving case management in the USA (n=175) observed less variation in activities of daily living scores, than in instrumental activities of daily living (IADL) (Schien *et al.* 2005). However, the groups median IADL score was high and suggested independence in line with community dwelling older adults (Schien *et al.* 2005). The most commonly reported daily living support required by patients in the feasibility study was with housekeeping, in particular heavy housework, such as scrubbing floors, cleaning windows, and shopping (including for groceries). This supports the idea that should a breakdown in social support, such as their organised support for grocery shopping occur, they are left extremely

vulnerable if no replacement support system is able to be implemented quickly, which may predispose an adverse health event.

### 8.6.4 Health experiences and symptoms

Multiple LTCs were prevalent in all three studies, in line with population data for over 75s reporting that most are living with multiple LTCs (DH 2012a). However, the mean number reported by case management patients and HHR patients was lower than originally anticipated for patients receiving a service originally intended for patients with the most complex LTC needs. Correspondingly prescribed medication was frequently recorded.

There was some agreement between the prescribed medication groups recorded on the HHR and recalled by patients in the feasibility study, and the reported LTCs. The appearance of lipid lowering drugs, which include statins, as the most frequently prescribed drug group is unsurprising when lipid lowering medication is prescribed not only for the treatment of hyperlipidaemia but also for primary and secondary prevention of cardiovascular events, hence patients with a diagnosis of hypertension, CHD, vascular disease, diabetes and obesity are likely to also be assessed as having an increased risk of an cardiovascular event, and thus lipid lowering medication is indicated. Over recent years prescribing recommendations for statins have been controversial, notably due to the risk of the potentially serious side effect of myopathy, and less serious but troublesome side effect of myalgia. This single side effect from this single group of drugs may have a particular troublesome effect on frail patients, already at an increased risk of adverse events, and already experiencing hyperalgesia and muscle weakness. This concern is particularly notable when considering muscle strength as a monitoring aid in case management patients. Hyperalgesia and myalgia are likely to reduce levels of physical activity, leading to further muscle strength loss, and requiring the patient to take regular “high risk” analgesia.

It was noted that over 25% of HHR records included “high risk” medicines (as defined by Patient Safety First, Pharmaceutical Services Negotiating Committee (PSNC) and NHS Employers). These medicines are considered to have the potential to cause serious and preventable adverse events, including by omission, that could have a significant impact on the patient should they occur, and include the following medication frequently found on the HHR records, opioids, anti-platelets, anticoagulants, and opioids. Prescribed pain relief appears frequently on the HHR records, linking in with the frequently reported symptoms of hyperalgesia and myalgia, both associated with inflammation, reported via the SBS in the feasibility study participants.

Symptoms of depression were also commonly reported via the SBS (depression reported on more than 25% of occasions, anxiety reported on more than 50% of occasions). Depression was also frequently recorded on HHR records (32% of records), with antidepressants correspondingly occurring as a frequently prescribed medication group. This is in line with consensus that depression is more common in patients with long term health conditions, with a reported 20% of patients with a chronic physical health condition having depression (NICE 2009). However, the observed discrepancy between the frequency of antidepressants prescribing and the depression Flag (HHR data) suggests that under-treatment may be occurring, or that there is scope for intervention. The data considered so far suggests that the burden of disease upon case management patients is large, and when considered alongside the burden of daily life, and the burden of treatment, especially if patients are expected to take an active part in their disease management, may be overwhelming (May *et al.* 2014). The burden of daily life is likely to be greater where patients are experiencing functional dependency.

Falls were recorded in a maximum of 15% of HHR patient records annually, a figure lower than expected and discussed in Section 8.5.2. Comparatively, and more in line with the expected prevalence of falls, 25% of Study B patients reported a recent fall. Whilst "falls" patients are targeted for some case management services, published comparative data on the prevalence of falls in case management patients is lacking (Challis *et al.* 2010). The incidence of falls reported here are similar to those published in frail community dwelling Chinese population, including patients receiving case management service in China (n=390, 23% reported falls in previous 90 day period, Leung *et al.* 2010), but below the NICE reported annual expected incidence of 30% in those aged over 65 (Age UK 2012).

Studies B and C identified that a number of study participants were lacking expected risk factors including a lack of multiple LTCs and unplanned secondary care usage prior to case management, which along with recruitment data regarding those patients identified as ineligible to participate in Study B, suggests that the expectations of case management services have changed or a bigger stratum of the population are being identified for referral to such services.

### 8.6.5 Health service use

Study C provided the most comprehensive health service use data within this thesis. Only one patient in Study B reported unplanned health service use, an A&E attendance and unplanned hospital admission during data collection; similarly the majority of HHR records had no A&E attendances or unplanned hospital admissions noted. However, the data collection period for Study B was relatively short, reducing the likelihood of unplanned health service use occurring. The low levels of unplanned secondary case use demonstrated by HHR data may be indicative of the broader patient group being targeted for case management services, of data errors, of inappropriate targeting or successful admission avoidance; further research would be required to clarify.

## 8.7 Conclusion

The measurement of muscle strength by PIF, PEF and grip dynamometry in case management patients appears feasible, but repeated measurements over the short to medium term do not appear to be useful. Whilst muscle strength measurements were acceptable to the patient population and demonstrated excellent reliability, they appear to remain stable over the short to medium term, suggesting that repeated measures of muscle strength would not add any beneficial information to the clinical picture for the clinician, despite being feasible.

Routine primary and secondary care data and information regarding patients on case management case lists demonstrated a high degree of variation in their health profile, and suggested that the group of patients receiving such targeted care is much broader than originally intended. Health care service, identified from the HHR, varied greatly, with the majority recording low usage, and a minority reporting frequent or long stay admissions to hospital and/or A&E attendance, and intense contact with their case management team. The high level of variation suggests the potential for improvements in targeting. Routine data such as the HHR data has the potential to improve targeting, both within a case management service and of the service itself. The lack of standardised assessment for targeting, both of a case management service and within a case management service has been highlighted as lacking in numerous published research studies (Abell *et al.* 2010). A frailty index developed from routine data may help identify the patients who would benefit most from case management interventions. The range of frailty scores and the submaximal level observed in the HHR study were in line with previously published values and allowed the identification of populations with similar values, suggesting the FI from HHR data could discriminate between individuals with differing levels of frailty, including at higher levels of frailty. The non-significant trend in outcomes between the FI tertiles observed indicates that further studies are required to confirm the FI's usefulness and validity.

# Chapter 9 Conclusion and Implications

This research study's findings, and the accompanying discussion presented in Chapters 5-8 have implications for health services and researchers. The implications and recommendations are presented in this final chapter, followed by the concluding remarks of the thesis.

## 9.1 Implications of the study

The overarching aim of the research study was to explore the feasibility, acceptability and usefulness of non-invasive muscle strength monitoring in older patients receiving pro-active case management. The need for effective, proactive, co-ordinated, patient-centred care, for patients with long term conditions is repeatedly highlighted (Shaw *et al.* 2011; Coulter *et al.* 2013), with the aim of reducing costly and disruptive emergency hospital admissions (Purdy 2010). The risks to an individual patient admitted as an emergency include a hospital acquired infection, a breakdown of social support, and a loss of patient's confidence in their ability to maintain independence (Hunt 2009). However, there is a lack of standardisation within and between case management services across the NHS, and this includes in the targeting of services and on-going monitoring of patients.

The complexity of older patients with multiple morbidities, most likely receiving case management services, and who often present with frailty and atypical symptoms enhance the difficulty of on-going monitoring and targeting of care. Effective monitoring and the targeting of interventions in a timely manner are likely to enable patients to remain independent, avoid adverse health outcomes and enable better quality life for longer. The established relationship between ageing and LTCs, frailty and muscle strength, and function and service use, suggests that muscle strength may be a useful aid to monitoring.

Three portable, direct and indirect measures of strength were investigated through a pilot and feasibility study, in the hope of identifying a reliable measure, that was acceptable to patients and clinicians and could identify a decline prior to this becoming evident in function or service use. Such a measure would allow case managers to provide timely interventions to avoid adverse events. Whilst the study showed the measures of grip strength, PEF and PIF as reliable and acceptable to patients, the measures remained stable over the short-medium term, despite adverse health events occurring, suggesting that routine monitoring would not aid clinical practice. Whilst further studies would be required in a larger patient group to confirm this, the findings presented in this thesis suggest that this would be fruitless.

As well as investigating the monitoring of muscle strength, the study aimed to develop a profile of case management patients, providing much needed information on their physical, functional and health status. The research presented in this thesis highlights the wide variation in the health, physical and functional status and health service use of patients receiving case management services, along with the disparity within NHS case management services. The study findings imply that muscle strength values obtained in case management patients can be expected to be at the lower end of published normal values. The association between muscle strength and function highlighted in the literature review, and the low muscle strength values observed in this study, should enhance awareness of the associated problems this may cause, particularly in patients' ability to complete activities of daily living.

Case management patients demonstrated a level of dependency in activities of daily living, identified by the VES-13, highlighting the importance of reviewing the functional needs of patients and providing holistic care, addressing both health and social needs. Dramatic variations were observed in the health history of patients in the 12 months prior to them receiving case management, including in their reported health conditions, secondary care service use and functional adverse events such as falls.

The wide variation in health care service use appears to continue after case management commences, with differences observed not just in secondary care service usage, but in the frequency of contact between patients and case management teams, with very few patients appearing to receive intensive contact expected from case management. Despite this the frailty index did indicate that the majority of case management patient were frail, which has implications for the interventions employed especially with reference to the burden of treatment and functional limitations mentioned above (May *et al.* 2014). Expecting patients with a high disease burden and burden of daily life to self-manage aspects of their health may overwhelm them (May *et al.* 2014). The observed variations in health and service use imply that many of the assumptions made about the targeting of case management services were wrong, and that both the patients being supported by such services and the services themselves are not who or what may be expected upon reading the related literature and supporting policies. Further clarity of the service, in its aims, the clinical needs of the patient group, and the interventions would benefit commissioners and providers, and be useful for patients, relatives, referring clinicians and others in contact with costly case management services.

The variation observed in patients and services draws attention to the potential for improving targeting both within and of the case management service. A service that ideally targets those patients with complex needs most at risk of an adverse health outcome, the most vulnerable frail

patients. However, the number of patients identified by both HHR data and the feasibility study who appeared to lack vulnerability, and appeared not to be at the highest risk of an adverse health event call into question the current targeting and assessment approach, although data inaccuracies and omissions may have played a part in this conclusion.

Objective measures of frailty are increasingly preferred over subjective measures of vulnerability, and provide the opportunity to demonstrate fair provision of services, especially when the association between chronological age and health status can be extremely variable (Romero-Ortuno 2014). The use of an objective measure of frailty including multiple aspects of patients care and lives including health, functional and social needs, has the potential to aid targeting. This study demonstrated that such a measure, has the potential to be developed using routine data, such as that on the HHR. Greater integration between primary, secondary and social care services, including at an administration level increases the feasibility of producing a useful FI including aspects of health, function and social support, whilst allowing monitoring of health service use and adverse outcomes. The patients identified by such a measure would have a complex mix of social and health problems, as observed in some patients in this study, which makes them especially vulnerable to challenges to their health or functional ability. Patients with such complex needs will require services sequentially and simultaneously in a variety of settings from multiple providers, hence the importance of integration, an important aspect of case management services, allows for greater efficiency and effectiveness (Brown and McCool 1992).

The lack of clarity around what is expected from integrated care has been highlighted as a major barrier to promoting such care (Kodner *et al.*2002; Bardsley *et al.* 2013); integration is required not just to be at the service provision level but at service organisational, planning, administration, leadership and funding (Kodner *et al.* 2002; Shaw *et al.* 2011; Coulter *et al.* 2013). The responsiveness and integration of services to allow them to counter any challenges is important. To allow responsiveness, the case management service needs to be effective and efficient, allowing case managers to focus and respond to those patients at highest risk. The percentage of patients identified as suitable for case management, via risk stratification at a general practice level, is set to increase from 1% to 5% of a general practice population. This is only feasible if the case management service expands in line, or if effective targeting occurs within the service, to provide the most intense service to those most at risk. Data gathered in this study suggests that very few patients are receiving intensive contact from a case management service.

During the development of the study presented here local case management services evolved, changing from a more traditional community matron led case management model to an increasingly integrated virtual ward model of care. The observed pace of change within such

services is often rapid, but supporting evidence driving changes frequently appears to be lacking. Oliver (2013) highlighted the need for sustained changes to improve results, suggesting that at least a decade of sustained improvement is required to observe benefits, and singled out case management as an example where change has been implemented with a lack of evidence and lack of time given to it to improve care.

This study demonstrated further the difficulties faced by researchers in recruiting older people, and case management patients in particular into research studies. Researchers wishing to recruit case management patients, or those in a similar community dwelling patient group should consider the experiences reported in this thesis. Study design, including all aspects of recruitment, should consider the observations made regarding the socio-economic status of participants in Study B, who appeared to be from the opposite end of the socio-economic spectrum than was normal for this patient group. Alternative recruitment methods or data collection protocols, including data collection locations, should be considered in future research design.

## 9.2 Recommendations for further research

The lack of variability in the muscle strength measurements observed during the feasibility study suggests that repeated measurement would not be useful; investigation with a larger sample size would be required to confirm this and any relationship between muscle strength and clinically relevant outcomes in the short-medium term. However, the feasibility study data strongly suggests that this may not be a fruitful avenue for future research. It may be more beneficial to focus future research on the predictive nature of a one off measure of muscle strength. A longitudinal observational study gathering a single measure of strength, with follow up identifying adverse outcomes (including out of hours service use, unplanned hospital admissions, falls, move to residential care) over the short –medium term, ideally via routine data to reduce the burden of participation is suggested.

Routine data, such as the HHR dataset utilised here, has the potential to provide useful information on the case management patient population, especially where shared access and recording occurs across primary, secondary and social care. Such data are suggested as a primary source for further research. Frailty scales are increasingly used in secondary care; the results from this study highlight the potential benefits and the feasibility of producing a frailty scale for use in primary care, using routine data. The potential for improvement in the targeting of case management services has been highlighted. Such an index would enable the identification of the frailest patients i.e. those most vulnerable to a challenge to their health, function and ability to carry out activities of daily living, and could be used for initial assessment and on-going

monitoring. Further studies to develop a validated frailty scale require larger, more diverse populations, in multiple residential settings (Pialoux *et al.* 2012; Ravindrarajah *et al.* 2013). It is hoped that such a scale would be able to identify a frailty score around or above which the need to intervene is apparent. An observational study, utilising the anonymised HHR dataset is suggested. Retrospective data analysis with reference to a FI, including aspects of health, function, socioeconomic deprivation and social support would help fulfil this need. The resulting stratification via a frailty scale would be beneficial not just to case managers to enable them to target their most intensive service at their most vulnerable patients, but to providers and commissioners of services. The breadth and availability of routine information, such as that held on the HHR makes it a valuable source of information, and somewhat negates recruitment difficulties that can lead to unrepresentative samples, especially if an anonymous data set is used. It should be remembered that a frailty score represents a relative increased risk of an adverse event and not an absolute one, and one that can be increased or decreased. For example the risk posed by multiple LTCs and reduced physical and functional ability may be somewhat mitigated by robust social support, and may reduce following an increase in physical activity (Howlett *et al.* 2013). By making the FI easy to calculate, patient's frailty score could be recalculated and evaluated regularly, as a potential aid to within service targeting, patient monitoring and service evaluation.

## 9.3 Concluding remarks

The potential for improvements to targeting within case management services has been highlighted, both by the variations in the health, function and service use of patients observed in this study, and the absence of robust evidence supporting and informing the model of care. Whilst monitoring muscle strength to aid the provision of timely interventions appears unlikely to be useful in the short-medium term, frailty assessment showed some potential. This study demonstrated that developing a frailty index from routine data is feasible, and may help highlight patients most at risk of adverse health events. A frailty index has the potential to aid targeting of care within the service, offering a way of objectively assessing and monitoring a patient's level of vulnerability to adverse health events. Such an index also has the potential to aid the initial targeting of the service and service evaluation. Frailty appears to be prevalent in case management patients, and is an important consideration in care planning, with likely implications regarding the choice of interventions.

# Appendices

# Appendix 1 Initial literature search strategy

An initial literature search strategy was developed to identify articles related to case management and the monitoring of long term conditions. Initial searches were conducted between 12/10/2010 and 28/11/2012 to identify literature addressing case management and monitoring of long term health/chronic conditions. The CINAHL (Cumulated Index of Nursing and Allied Health Literature) database was primarily used due to its comprehensive selection of journals relevant to the subject area, along with the MEDLINE database where disease specific information was sought (containing medical and health journals). Abstracts of the identified articles were reviewed by the researcher. Reference lists from relevant articles were reviewed for identification of potentially relevant articles. As well as the databases searched above, the Department of Health, the National Institute of Clinical Excellence, the Kings Fund and Nuffield Trust websites were monitored frequently for newly released and related publications.

a) Criteria for selecting studies

The following criteria were used to select studies for inclusion in the initial review:

i. The study was published in a English language journal;
ii. The study included adults over the age of 65.

b) Nomenclature

Firstly studies looking at case management generally were identified. A number of search terms were utilised (terms referred to in DH publications) identified to capture the relevant articles including case management, community matron, case manager, and managed care (856 CINAHL articles identified). As well as considering generic case management, studies reporting to disease specific case management were also reviewed (78 CINAHL articles, supplemented by 56 MEDLINE articles).

Secondly the review aimed to identify studies looking at the monitoring of long term conditions, within and outside of case management (search terms utilised case management AND tool/clinical assessment (65 CINAHL articles), monitoring AND long term/chronic conditions (298 CINAHL articles).

Thirdly articles relating to the more general monitoring of health were identified (search terms measurements of health / disease trajectories (545 CINAHL & MEDLINE articles).

# Appendix 2 Selection of studies for inclusion in Table 4.1

A literature search was conducted in a structured manner, of MEDLINE and CINAHL initially on 22/06/2011 in order to identify studies addressing increases and decreases in muscle strength. The search terms were divided into two groups: “improving strength” and “declining strength”. The search resulted in 233 articles in MEDLINE and 161 in CINAHL.

The bibliographic details of all the retrieved articles (*n = 394)* were stored in EndNote. First, the overlapping articles that were identified in the literature search of the various database searches were included only once. All abstracts were then reviewed by the researcher. At this screening stage articles were deemed to be relevant if the study measured changes in strength either directly (any muscle) or by a proxy measure.

**a. Criteria for selecting studies**

The following criteria were used to select studies for inclusion in this review:

1. the study was published in an English language journal;
2. the study included adults over the age of 65.
3. the study included grip strength.

**b. Nomenclature**

All studies looking at changes to muscle strength; interventions were commonly noted and these included low intensity to high intensity exercise programmes and weight bearing and non-weight bearing exercise.

**c. Nature of the evidence**

Four different types of study design were noted. First cross-sectional studies where people were divided into groups based upon their degree of frailty, and their muscle strength was compared. Secondly cross-sectional studies where people were divided into age groups and their muscle strength compared. Thirdly, longitudinal studies where the focus were on within subject changes in strength over time, these were predominantly where an intervention was made. Some of the longitudinal studies involving interventions were randomised controlled trials.

**d. Limitations**

The search focused on grip strength and although included results for other muscles groups from studies the initial search was limited by the inclusion of the term “grip strength”. This was to done to reduce the number of articles to a more manageable number for review (a search in CINAHL alone following the inclusion criteria stated in section 2b above but excluding the term “grip strength” resulted in 1082 articles) and increase their relevance to this research study.

# Appendix 3 Physical Activity Scale for the Elderly



Questionnaire removed due to copyright.

# Appendix 4 Barthel Index of activities of daily living

Questionnaire administered by researcher:

**Feeding**

0 = unable

5 = needs help cutting, spreading butter, etc., or requires modified diet

10 = independent

**Bathing**

0 = dependent

5 = independent (or in shower)

**Grooming**

0 = needs to help with personal care

5 = independent face/hair/teeth/shaving (implements provided)

**Dressing**

0 = dependent

5 = needs help but can do about half unaided

10 = independent (including buttons, zips, laces, etc.)

**Bowels**

0 = incontinent (or needs to be given enemas)

5 = occasional accident

10 = continent

**Bladder**

0 = incontinent, or catheterized and unable to manage alone

5 = occasional accident

10 = continent

**Toilet Use**

0 = dependent

5 = needs some help, but can do something alone

10 = independent (on and off, dressing, wiping)

**Transfers (bed to chair, and back)**

0 = unable, no sitting balance

5 = major help (one or two people, physical), can sit

10 = minor help (verbal or physical)

15 = independent

**Mobility (on level surfaces)**

0 = immobile or < 50 yards

5 = wheelchair independent, including corners, > 50 yards

10 = walks with help of one person (verbal or physical) > 50 yards

15 = independent (but may use any aid; for example, stick) > 50 yards

**Stairs**

0 = unable

5 = needs help (verbal, physical, carrying aid)

10 = independent

TOTAL (0–100):

The Barthel ADL Index: Guidelines

The index should be used as a record of what a patient does, not as a record of what a patient could do. The main aim is to establish degree of independence from any help, physical or verbal, however minor and for whatever reason. The need for supervision renders the patient not independent. A patient's performance should be established using the best available evidence. Asking the patient, friends/relatives and nurses are the usual sources, but direct observation and common sense are also important. However direct testing is not needed. Usually the patient's performance over the preceding 24-48 hours is important, but occasionally longer periods will be relevant. Middle categories imply that the patient supplies over 50 per cent of the effort.

Use of aids to be independent is allowed.

# Appendix 5 Vulnerable Elders Scale

Vulnerable Elders Survey (VES-13)
(Reference: JAGS. December 2001; 49(12), 1691-1699)

1. Age_____ (One point for age 75-84, 3 points for age 85 or greater)

2. In general, compared to other people your age, would you say that your health is:
   A. Poor, * (1 Point)
   B. Fair,* (1 Point)
   C. Good
   D. Very Good, or
   E. Excellent

3. How much difficulty, on average, do you have with the following physical activities: (SCORE 1 POINT FOR EACH * RESPONSE, MAXIMUM OF 2 POINTS)

| | No difficulty | A little difficulty | Some difficulty* | A lot of difficulty* | Unable to do* |
|---|---|---|---|---|---|
| Stooping, crouching or kneeling | | | | | |
| Lifting, or carrying objects as heavy as 10 pounds | | | | | |
| Reaching or extending arms above shoulder level | | | | | |
| Writing, or handling and grasping small objects | | | | | |
| Walking a quarter of a mile | | | | | |
| Heavy housework such as scrubbing floors or washing windows | | | | | |

4. Because of your health or a physical condition, do you have any difficulty: (SCORE 4 POINTS FOR ONE OR MORE * YES RESPONSES IN THIS SECTION)
   A. Shopping for personal items (like toilet items or medicine)?
   - YES>> Do you get help with shopping? YES* NO
   - NO
   - DON"T DO>> Is that because of your health YES* NO

   B. Managing money (like keeping track of expenses or paying bills)?
   - YES>> Do you get help with managing money? YES* NO
   - NO
   - DON'T DO>> Is it because of your health? YES* NO

   C. Walking across the room? USE OF CANE OR WALKER IS OKAY
   - YES>> Do you get help with walking YES* NO
   - NO
   - DON"T DO>> Is that because of your health? YES* NO

   D. Doing light housework (like washing dishes, straightening up, or light cleaning?
   - YES>> Do you get help with light housework? YES* NO
   - NO
   - DON'T DO>> Is that because of your health? YES* NO

   E. Bathing or showering?
   - YES>> Do you get help with bathing or showering? YES* NO
   - NO
   - DON"T DO>> Is that because of your health? YES* NO

# Appendix 6 Choosing measures of health

"Ten steps for assessing and choosing a quality of life measure for clinical practice (Carr, A.(Ed.) Quality of Life)

1. Are the domains covered relevant?
2. What population and setting was it developed and tested in and are these similar to those planned for use
3. What is the validity, reliability, responsiveness, and appropriateness of the measures?
4. What were the assumptions of the assessors when determining validity?
5. Are there floor and ceiling effects?
6. Will it measure differences between patients or over time – and at what power?
7. Who completes the measure? (Patient, family, professional (and what effect will this have, will they be willing to complete it)?
8. How long does the measure take to complete?
9. Do staff and patients consider it easy to use?
10. Who requires training and information about the measure?"

**Table A- 1 Summary of considered measures of health**

| Measure considered | Reason for rejection |
|---|---|
| ***Function:*** | |
| Rapid Disability Rating Scale (Linn, 1982) | Limited validity and reliability |
| Functional Status Index (Jette, 1980) | Limited validity and reliability and time to administer |
| Patients Evaluation conference System (Harvey and Jellinek, 1981) | Limited validity and reliability and time to administer |
| Functional Activities Questionnaire (Pfeffer, 1982) | Limited validity and reliability |
| Health Assessment Questionnaire (Fries, 1980) | Similar to BI and VES-13 |
| Medical outcomes Study Physical functioning Measure (Stewart, 1992) | Limited validity and reliability |
| Functional Autonomy Measurement System (Hébert, 1984) | Limited validity and reliability and time to administer |
| Functional Independence Measure (Granger and Hamilton, 1987) | Training needed to administer |
| PULSES Profile (Moskowitz and McCann, 1957) | Limited validity and reliability |
| Katz Index of ADL (Katz, 1959) | Limited validity and reliability |
| Kenny Self-Care Evaluation (Schoening *et al.*, 1965) | Limited validity and reliability and time to administer |
| Physical Self-Maintenance Scale (Lawton and Brody, 1969) | Limited validity and reliability |
| Disability Interview Schedule (Bennett and Garrad, 1970) | Limited validity and reliability |
| Lambeth Disability Screening (Patrick *et al.*, 1981) | Limited validity and reliability and time to administer |
| OECD Disability Questionnaire (OECD, 1981) | Limited validity and reliability |
| Functional Status Rating System (Forer, 1981) | Limited validity and reliability and time to administer |
| London Handicap Scale (Harwood *et al.*, 1994; Harwood and Ebrahim 1996) | Lack of focus on physical function |

| | |
|---|---|
| The Sickness Impact Profile (Deyo *et al.*, 1982, 1983; Bergner 1988, 1993) | Time to administer |
| The Short Form-36 Health Survey Questionnaire (Stewart and Ware, 1992, Ware *et al.*, 1993, Murray *et al.* 1998, McHorney 1996) | Time to administer, acceptability, floor effect, no assessment of support/collaboration. |
| The Short Form-12 Health Survey Questionnaire (Ware *et al.*, 1995, 1996) | Floor effect |
| The Short Form-8 Health Survey (Tuner-Bowker *et al.*, 2003) | Useful in population studies, less useful in patient groups |
| The Euroqol (Euroqol Group, 1990) | Methodological problems |
| Nottingham Extended Activities of Daily Living Questionnaire (Nouri and Lincoln, 1987) | Similar to BI and VES-13 |
| Modified Rankin Scale (Van Swieten *et al.*, 1988) | Reliable and valid in stroke patients. Lack of knowledge re: use in alternate patient groups. |
| Physical functioning inventory (Whetstone *et al.*2001) | Reliable and effective in detecting early disability in IADLs, ADLs and mobility. Less reliable for moderate to strenuous tasks. 15min – 1 hour to administer, burden too high for use. |
| ***Health:*** | |
| Self reported health (Dening *et al.* 1998, Zhao *et al.* 2010) | Over 75's: studies suggest tendency to rate overall health as good despite increasing symptoms, symptoms increased likelihood of receiving social and health services. Mismatch between health perceptions and functional limitations, which may prevent older people seeking/ receiving help that may benefit from. |
| ***Inflammatory markers:*** (Hunt *et al.* 2009, Wouters 2006, Schaap *et al.* 2009, Brinkley *et al.* 2009, Wu *et al.* 2007, Kuo *et al.* 2006, Bautmans *et al.* 2010) | Lack of evidence (& researcher experience & training in phlebotomy) to justify patient burden. |
| ***Muscle mass***: (Kehayias *et al.* 1997, Rolland *et al.* 2003, Chien *et al.* 2010) | Lack of evidence and concurrence on measuring effectively in frail older adults community setting (i.e. patients homes). |
| ***Muscle strength:*** | |
| Gait speed (Newman *et al.* 2009) | Impractical |
| Timed up and go test (Connelly *et al.* 1996) | Impractical & falls risk |
| Sit to stand (Bohannon 1998) | Impractical, standardised chair required |
| 6 minute walking distance (Troosters *et al.* 2010 | Impractical |
| Isometric lower limb muscle strength (knee extensor strength, quadriceps strength; Hunter *et al.* 1998) | Impractical, heavy, bulky, expensive equipment required, lack specificity to everyday tasks of the elderly, training needs of operator |
| Isokinetic contractions (Hunter *et al.* 1998) | Training needs of operator, learning effect, risk of muscle damage |
| Upper body functional fitness tests (arm curl, lift and reach, chair stand; Rhodes 2000 *et al.*, Benton *et al.* 2009) | Impractical equipment required e.g. standard chair, evidence suggest inappropriate in target patient group |
| Mouth inspiratory pressure (Evans *et al.* 2009; Terzi *et al.* 2009) | Significant learning effect, unpleasant manoeuvre to perform |
| Sniff nasal inspiratory pressure (feasibility study results) | Lack of reliability & unpleasant to perform |

# Appendix 7 The Sickness Behaviour Scale (Study B)

Questionnaire removed due to copyright.

# Appendix 8 Feedback questionnaire: Study A & B

N.B. Study B only included questions on PEF, PIF and grip strength.

**A. INTRODUCTION**

1. Introduction: I would like to ask you a few questions about each of the strength measures and how you found them to complete. This will help us to decide which tests are suitable for studying further.

**B. PEAK EXPIRATORY FLOW (PEF-** sharp breath out**) USABILITY – PLEASE CAN YOU SAY HOW MUCH YOU AGREE WITH THE FOLLOWING STATEMENTS ON A SCALE OF 1 TO 5 WHERE 1 IS STRONGLY DISAGREE TO 5 STRONGLY AGREE**

2. It was easy to understand what I had to do. 1 2 3 4 5
3. It was easy to do. 1 2 3 4 5
4. It was comfortable to do. 1 2 3 4 5

**PEF GENERAL QUESTIONS**

5. I would recommend the test to anyone. 1 2 3 4 5
6. How do you think the test could be improved? (OPEN QUESTION)

**C. PEAK INSPIRATORY FLOW (PIF** – sharp breath in) **USABILITY – PLEASE CAN YOU SAY HOW MUCH YOU AGREE WITH THE FOLLOWING STATEMENTS ON A SCALE OF 1 TO 5 WHERE 1 IS STRONGLY DISAGREE TO 5 STRONGLY AGREE**

7. It was easy to understand what I had to do. 1 2 3 4 5
8. It was easy to do. 1 2 3 4 5
9. It was comfortable to do. 1 2 3 4 5

**PIF GENERAL QUESTIONS**

10. I would recommend the test to anyone. 1 2 3 4 5
11. How do you think the test could be improved? (OPEN QUESTION)

**D. SNIFF INSPIRATORY PRESSURE (SNIP –** sniff ) **USABILITY – PLEASE CAN YOU SAY HOW MUCH YOU AGREE WITH THE FOLLOWING STATEMENTS ON A SCALE OF 1 TO 5 WHERE 1 IS STRONGLY DISAGREE TO 5 STRONGLY AGREE**

12. It was easy to understand what I had to do. 1 2 3 4 5
13. It was easy to do. 1 2 3 4 5

14. It was comfortable to do. 1 2 3 4 5

**SNIP GENERAL QUESTIONS**

15. I would recommend the test to anyone. 1 2 3 4 5

16. How do you think the test could be improved? (OPEN QUESTION)

**E. GRIP STRENGTH USABILITY – PLEASE CAN YOU SAY HOW MUCH YOU AGREE WITH THE FOLLOWING STATEMENTS ON A SCALE OF 1 TO 5 WHERE 1 IS STRONGLY DISAGREE TO 5 STRONGLY AGREE**

17. It was easy to understand what I had to do. 1 2 3 4 5

18. It was easy to do. 1 2 3 4 5

19. It was comfortable to do. 1 2 3 4 5

**GRIP STRENGTH GENERAL QUESTIONS**

20. I would recommend the test to anyone. 1 2 3 4 5

21. How do you think the test could be improved? (OPEN QUESTION)

**F. DREAMTIME**

22. Can you rank the tests in order of preference?
    1 = most favourite =

    2 = second favourite =

    3 = third favourite =

    4 = least favourite =

23. Is there anything else you would like to add? (OPEN QUESTION)

24. Can you comment on how easy these questions were to understand and answer? (OPEN QUESTION)

# Appendix 9 Feedback questionnaire for clinicians (Study B)

N.B. Space for written answers shown reduced.

**Feedback questionnaire for clinicians**

**INTRODUCTION**

Introduction: I would like to ask you a few questions about each of the strength measures and what you think of them. This will help us to decide which tests are suitable for studying further.

**PLEASE CAN YOU SAY HOW MUCH YOU AGREE WITH THE FOLLOWING STATEMENTS ON A SCALE OF 1 TO 5 WHERE 1 IS STRONGLY DISAGREE TO 5 STRONGLY AGREE**

**PEAK EXPIRATORY FLOW USABILITY**

1. Do you think the majority of your patients would be able to perform this test?

If not, can you please explain envisaged difficulties.

2. Would you be happy to ask your patients to perform this test at each visit?

If not, could you please explain why?

3. How do you think the test could be improved? (OPEN QUESTION)

**PEAK INSPIRATORY FLOW USABILITY**

4. Do you think the majority of your patients would be able to perform this test?

If not, can you please explain envisaged difficulties.

5. Would you be happy to ask your patients to perform this test at each visit?

If not, could you please explain why?

6. How do you think the test could be improved? (OPEN QUESTION)

**GRIP STRENGTH USABILITY**

7. Do you think the majority of your patients would be able to perform this test?

If not, can you please explain envisaged difficulties.

8. Would you be happy to ask your patients to perform this test at each visit?

If not, could you please explain why?

9. How do you think the test could be improved? (OPEN QUESTION)

**DREAMTIME**

10. Can you rank the tests in order of preference?

    Most preferred = 1 =

    2 =

    Least preferred = 3 =

11. Is there anything else you would like to add? (OPEN QUESTION)

12. Can you comment on how easy these questions were to understand and answer? (OPEN QUESTION)

# Appendix 10 Screening questionnaire for Study A

**Screening Questionnaire**

**Identification number: _____**

**Surname:** _____

**First Name:** _____

**Date of birth:** _____ **Gender:** Male / Female (please circle).

**Telephone No:** _____

*N.B. To be completed in this study by researcher with the participant over the telephone. Format allows self-completion for use in Sandra Agyapong-Badu's later study.*

**Screening Questionnaire**

The following information is required before you are able to partake in this study. If you answer yes to any of the following questions, it is important that you make this known to the researcher. Please take your time to read all questions and answer honestly. If you do not understand a question or need further clarification with a particular question please ask.

Thank you for agreeing to be a participant in this study. You are vital to our research project and we appreciate you giving up your time to participate. An appointment has been made for you to register for the study at the Faculty of Health Sciences Lab. If you are unable to attend for any reason please let us know by contacting us as soon as possible. You will have the chance to ask any further questions before you are registered into the study. Please complete the questions below prior to attending for registration. All answers will be kept strictly confidential. If there are any sections you are not sure how to answer, leave that question blank and inform the person who registers you at your appointment.

**Identification number:** _____

**If you answer YES to any questions please give some details including dates where possible.**

1. Are you currently enrolled in any other research study? YES / NO
If yes, unable to participate in this study.

2. Have you any history of heart trouble? (such as heart attack, angina, valve disease, palpations, pains in chest, dizzy spells)

3. Have you any history of problems with blood vessels?
(such as thrombosis, embolus, claudication, aneurysm, dizzy spells, stroke, blood clots)

4. Have you any history of chest problems? (Bronchitis, asthma or wheezy chest)

5. Have you ever smoked? (If YES please state whether you are a current or ex-smoker and how many packets)

6. Do you suffer from diabetes?(if YES please state if insulin dependent)

7. Have you any history of major illness now or in the last 2 years? (such as rheumatoid arthritis, blood disorders, cancer)

8. Have you any history of emotional, memory, or psychiatric problems?

9. Do you suffer from osteoarthritis or rheumatoid arthritis? (if YES please state joints affected and indicate mild, moderate or severe and any medications regularly taken)

10. Have you broken or fractured any bones? (If so, which bones and when)

11. Do you have any problems with your bones?(Diagnosed osteoporosis, loss of height)

12. Have you any history of back problems?

13. Have you had any surgery on your joints?

14. Do you suffer from high blood pressure?

15. Have you had any acute illness in the last two months? (such as influenza, recurrent sore throat, bronchitis)

16. Please state any medication regularly taken for any condition?

17. Have you been in hospital in the last 2 years and if so, for how long?

18. Do you have any physical disabilities? (such as visual or hearing problems)

19. Do you suffer from Multiple Sclerosis or Parkinson's Disease?

20. Is there any other illness or condition that affects your general health or interferes with your mobility?

21. Have you fallen in the past 2 months? (If yes approximately how many times and why)

22. Approximately how tall are you?

23. Approximately how much do you weigh?

## Appendix 11 Recruitment poster/ leaflet for Study A


**Figure A- 1 Recruitment poster/leaflet for Study A**

# Appendix 12 Centres/ Clubs/ Societies approached as recruitment locations for Study A

| | | |
|---|---|---|
| Freemantle Comm. Centre | soton.gov.uk | Randolph St, SO15 3HF |
| St. Denys Comm. Centre | soton.gov.uk | Priory Rd, SO17 2JZ |
| Third age Centre | e.volve.org.uk | Cranberry Terrace, SO14 0LH |
| RHS | soton.gov.uk | Lodge Rd., Southampton |
| WI | soton.gov.uk | St. James' Rd Methodist Church, Shirley |
| Woolston Friendship Luncheon Club | e.volve.org.uk | Woolston Methodist Church, Manor Rd North, Woolston, S019 2JB |
| Botley Over 60s lunch club | e.volve.org.uk | The Botley Centre High St, Botley, SO30 0PJ |
| Swathling Neighbourhood Centre | soton.gov.uk | Off Broadlands Rd, SO16 3AY |
| Bitterne Manor Comm. Centre | soton.gov.uk | Vespasian Rd, SO18 1AX |
| Harefield Comm. Centre | soton.gov.uk | Yeovil Chase, SO18 5NZ |
| Kingsland Comm. Centre | soton.gov.uk | Winton St, SO14 1LF |
| Lordshill Community Centre | soton.gov.uk | Andromeda Rd, SO16 8BB |
| Lordswood Comm. Centre | soton.gov.uk | Sandpiper Rd, SO16 8FD |
| Moorlands Comm. Centre | soton.gov.uk | Townhill Way, SO18 3NN |
| Merryoak Comm. Centre | soton.gov.uk | Acacia Rd, SO19 7JY |
| Northam Comm. Centre | soton.gov.uk | Kent St, SO14 5SP |
| Regents Park Comm. Centre | soton.gov.uk | Tanners Brook School, Elmes Drive, Millbrook, SO15 4PF |
| Sholing Comm. Centre | soton.gov.uk | Butts Rd, SO19 1EF |
| Woolston Comm. Centre | soton.gov.uk | Church Rd, SO19 9FU |
| New Century Bingo | yell.com | 309 Shirley Rd, SO15 3HW |
| Mecca Bingo | yell.com | Portswood Centre, Portswood Rd, SO17 2NH |
| University of the Third Age | Google | various meeting place |
| Brendon Care Thursday Club | e.volve.org.uk | Guardian Ct. |
| Brendon care Coffee shop club | e.volve.org.uk | Kerrigan Ct. |
| Golden Hour Club | e.volve.org.uk | Eastleigh |
| Southampton Bridge Club | Google | Cranbury Terrace, Cranberry Place, SO14 0LH. |

# Appendix 13 Participant Information Sheet text for Study A

Printed on University headed paper.

Measures of strength and physical activity in healthy people aged 65 years and over

Researcher: Nicola Barnes Ethics number:FoHS-ETHICS-2011-045

You are being invited to take part in a research study by the University of Southampton. Please read this information carefully before deciding to take part in this research. If you are happy to participate you will be asked to sign a consent form. Please ask us if there is anything that is not clear or if you would like more information.

**What is the research about?**

This is a study examining measures of strength and physical activity.

We want to find out how easy and pleasant some different measures are to use, and whether they can be measured accurately a number of times by the researchers.

A later study will be looking at whether the measures can be used to predict declining health in frail patients. Before this can happen we need to know whether the tests are easy and quick to use and produce reliable results in healthy individuals, which is the reason for this study.

**Why have I been chosen?**

You have responded to an advert asking for healthy volunteers. Thank-you.

**What will happen to me if I take part?**

You will be asked to come to the Faculty of Health Sciences (Building 45), Highfield Campus, University of Southampton, SO17 1BJ. The visit will last between 1-1 ½ hours.

You will be invited back for a short visit (20 - 30 minutes) one week later to allow us to re-take the strength measurements only (tests 2-5 overleaf). This second visit is not compulsory.

At the start of your visit we will check that there is no reason for you not to take part in the study.

Before each test, time will be taken to explain what each test is and how it is done. There will also be an opportunity for you to ask any questions.

The following tests will be carried out (tests 2 -5 below will happen in a random order):

Questionnaires: we will also ask you to complete five short questionnaires with us, about your daily activities.

Grip strength: you will be asked to squeeze a hand held measuring device as hard as you can. You will be asked to do this three times in each hand, and then repeat with a second researcher.

Peak expiratory flow: you will be asked to breathe out in a short sharp breath into a small hand-held device. This helps measure the strength of muscles used when breathing out. You will be asked to do this three times, and then repeat with a second researcher.

Sniff test: we will ask you to place a small probe comfortably at the entrance of one nostril and then sniff as hard as possible. This helps measure the strength of muscles used in breathing. You will be asked to do this five times each nostril, and then repeat with a second researcher. A short break will be offered between switching nostrils.

Peak inspiratory flow: you will be asked to take a short sharp breath in using a small handheld device. This helps measure the strength of the muscles used when breathing in. You will be asked to do this three times, and repeat with a second researcher.

Feedback: We would then like to ask you some questions about your experience of completing the tests.

After you have completed four measures of strength (test 2-5 above), you will be invited to take a short break before continuing. Refreshments will be provided.

**Are there any benefits in my taking part?**

The information we get will help design the study to look at whether these measures can be used to predict declining health.

**Are there any risks involved?**

There are no known or expected serious side effects or risks in taking part. The peak flow tests may cause some mild coughing immediately after the test.

**Will my participation be kept confidential?**

Yes. All the information about your participation in this study will be kept confidential. We will ask for your permission to contact your GP should any information come to light during the study which we feel needs to be shared with them.

**What happens if I change my mind?**

You are free to withdraw at any time and without giving a reason.

**What happens if something goes wrong?**

If you have a concern or a complaint about this study you should contact Susan Rogers, Head of Research & Enterprise Services, at the Faculty of Health Sciences (Address: University of Southampton, Building 67, Highfield, Southampton, SO17 1BJ ; Tel: +44 (0)23 8059 7942; Email: S.J.S.Rogers@soton.ac.uk). If you remain unhappy and wish to complain formally Susan Rogers can provide you with details of the University of Southampton Complaints Procedure.

**Expenses and payments**

We will reimburse travel expenses. You will need to complete a short form on the day for this, and a cheque will be sent to you.

**Where can I get further information?**

If you would like to ask any further questions please contact Nicola Barnes, Postgraduate Research Students, Faculty of Health Sciences (Address: University of Southampton, Building 45, Highfield, Southampton, SO17 1BJ;

Tel: +44 (0)23 80 59 7970; Email: n.j.barnes@soton.ac.uk).

**What now?**

If you are happy to voluntarily take part please complete the tear off slip at the bottom of the enclosed letter and return in the pre-paid envelope, alternatively telephone or email us to let us know you would like to take part. We will then call you to ensure there are no reasons for you not to take part. You will asked to sign a consent form when you visit, and given a copy of this information sheet and signed consent form to keep.

***Thank you for considering taking part and taking time to read this sheet.***

# Appendix 14 Standard operating procedures for measures of strength

**Mini Wright Standard Range Peak Flow Meter**

1. Before starting the test researcher to examine the meter for any signs of damage or wear, and if so to replace the meter.

2. Insert a new disposable cardboard mouthpiece into the meter. Ensure the pointer is set at zero (L/min position).

3. Ask the participant to hold the Peak Flow Meter so that their fingers are clear of the scale and slot. Researcher to ensure the holes at the end of the Peak Flow Meter are not obstructed.

4. Ask the participant to sit as upright as possible, then to take a deep breath, place the Peak Flow Meter in the mouth and hold horizontally, closing the lips around the mouthpiece, then blow as hard and as fast as they can.

5. Note the number on the scale indicated by the pointer.

6. Return the pointer to zero (L/MIN position) and repeat the procedure twice more to obtain three readings. Record highest reading for analysis.

7. Dispose of cardboard mouthpiece.

Peak flow meter to be cleaned on a weekly basis as per manufacturers cleaning instructions, using manufacturer recommended detergent and disinfectant.

The technical specifications for the Mini-Wright Standard Peak Flow Meter are below:

| | |
|---|---|
| Measurement Range | 60-880 L/min (ATS scale), 20-880 l/min (EU scale), 60-800 (Wright-McKerrow) |
| Accuracy | +/- 10% or 10 L/min |
| Repeatability | < 5 L/min |

**In-Check Oral Inspiratory Flow Meter**

1. Researcher to visually check for loose foreign objects before the device is used. Do not use if any loose objects detected.

2. Researcher to attach a new disposable one-way mouthpiece to the In-Check Oral meter.

3. Researcher to reset the device by returning the red cursor to the start position.

4. To reset the In-Check Oral:

Hold the instrument in a vertical position (with the mouthpiece uppermost) so that the rounded end of the meter can be tapped against the other hand or a horizontal surface, such as a table. A firm tap will dislodge the magnetic resetting weight, which will return the red cursor to a start position. It is then important to invert the In-Check Oral (turn through 180 degrees) to allow the weight to travel back to the magnetic holder.

5. Ask the participant to sit upright and to exhale fully.

6. Ask the participant to hold the In-Check Oral horizontally, and place the disposable mouthpiece in the mouth, closing the lips around completely and comfortably. Care should be taken to ensure that the participant's lips are sealed completely around the mouthpiece.

7. Instruct the participant to inhale forcefully through their mouth. The peak inspiratory manoeuvre should be a short, sharp inspiratory action of about one-second in duration

8. Record the peak inspiratory flow from the position of the red cursor against the scale.

9. Repeat steps 2 to 6 to obtain three readings, record and use the highest reading for analysis.

10. Dispose of the cardboard mouthpiece.

In-Check Meter to be cleaned on a weekly basis as per manufacturers cleaning recommendations, using manufacturer recommended detergent and disinfectant.

Performance accuracy: +/- 10% or 10 L/min (whichever is greater) and repeatability of +/- 5 L/min.

**JAMAR Manual Hand Dynamometer**

Have the participant sit with their shoulder adducted and neutrally rotated, elbow flexed at 90º, forearm in neutral position, and wrist between 0º and 30º dorsiflexion and between 0º and 15º ulnar deviation.

Set the JAMAR® Hand Dynamometer to the second handle position from the inside (note that the handle clip is located at the lower post (furthest from the gauge). Lightly hold around the readout dial to prevent inadvertent dropping.

Rotate the red peak-hold needle counter-clockwise to 0.

Let the participant comfortably arrange the instrument in his/her hand.

Once the participant is positioned properly have them squeeze with their maximum strength, say, "Squeeze as hard as you can...harder!...harder!...relax."

Record the reading and reset the peak-hold needle to zero.

Repeat the test three times using each hand (first visit only), recording all readings. Use the highest reading for analysis. (Follow-up visits dominant hand only).

Clean using a disinfectant wipe between participants.

**MicroRPM Sniff Nasal Inspiratory Pressure Meter**

1. Researcher to fit the nasal probe adaptor

2. Participant and researcher to choose an appropriate size clean nasal probe.

3. Researcher to fit the nasal probe

4. Researcher to switch the Micro RPM to SNIP (auto zero function)

5. Ask the participant while sitting, to insert the nasal probe so that it is in a comfortable position. Meter to be placed on table in front of participant.

6. When ready, ask participant at the bottom of the tidal breathing cycle, close mouth and perform a forceful, maximal inspiratory sniff in through nose.

7. Repeat 5 times, record the results.

Remove the nasal probe, researcher to offer a tissue and drink before switching to the alternative nostril. Once test complete, place used nasal probes in separate marked container ready for disinfection. Tissues to be available and offered before and after the test using each nostril.

Performance accuracy: ±3%

Nasal probes to be used for a single patient and then disinfected using manufacturer recommended product PeraSafe mixed as directed with warm water, and nasal probe allowed to soak for 10 minutes.

# Appendix 15 Grip Strength Normal Values

Adapted from Mathiowetz *et al.* (1985). Grip and Pinch Strength: Normative data for Adults. *Archives of Physical Medicine and Rehabilitation,* 66(2) 69-74.

**Table A- 2 Normative grip strength values**

| Age | Hand | Males mean kg | Males SD kg | Females mean kg | Females SD kg |
|---|---|---|---|---|---|
| **65-69** | R | 41.3 | 9.3 | 22.5 | 4.4 |
| **65-69** | L | 34.8 | 9 | 18.6 | 3.7 |
| **70-74** | R | 34.2 | 9.8 | 22.5 | 5.3 |
| **70-74** | L | 29.4 | 8.2 | 18.8 | 4.6 |
| **75+** | R | 29.8 | 9.5 | 19.3 | 5 |
| **75+** | L | 24.9 | 7.7 | 17.1 | 4 |

# Appendix 16 Published normal values for Peak Expiratory Flow Rate

For use with EU/EN13826 scale PEF meters only
Adapted by Clement Clarke for use with EN13826 / EU scale peak flow meters
from Nunn AJ Gregg I, Br Med J 1989:298;1068-70
In men, readings up to 100 L/min lower than predicted are within normal limits. For women, the equivalent figure is 85 L/min. Values are derived from Caucasian populations.

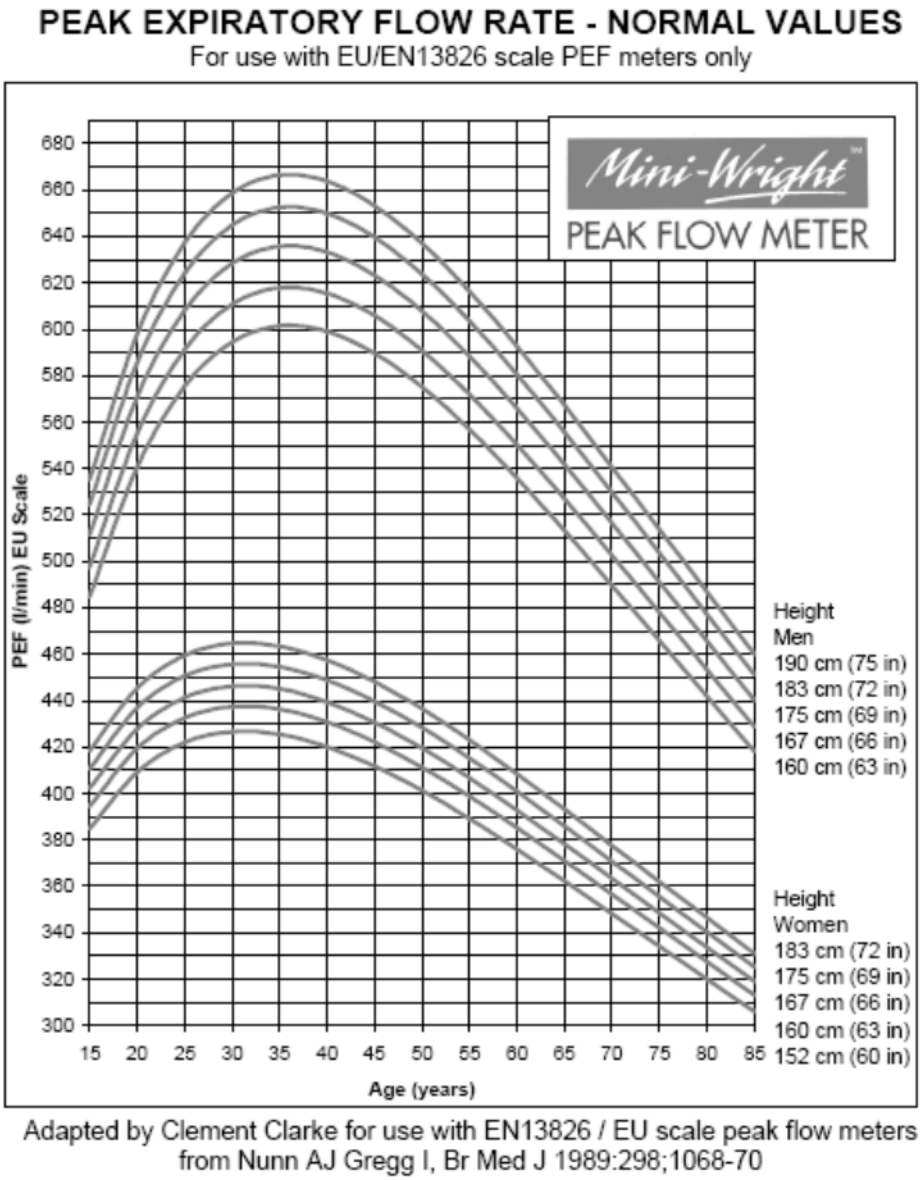



**Figure A- 2 PEF normative values**

# Appendix 17 PIF Normal Values

Normal range published by Clement Clarke 100-300l/min.

## Appendix 18 Data collection form Study A

Data Collection Form

A feasibility and reliability study investigating measures of strength in healthy people aged 65 years and over.

| | | | | | | |
|---|---|---|---|---|---|---|
| **Participant ID number:** | | **Gender:** | | **Age:** | | |
| | | **Height:** | | **Weight** | | |
| **Ethic origin:** | **White:** | *British* | *Irish* | *Any other White background* | | |
| | **Mixed:** | *White & Black Carribean* | *White & Black African* | *White & Asian* | *Any other mixed background* | |
| | **Asian or Asian British:** | *Indian* | *Pakistani* | *Bangladeshi* | *Any other Asian background* | |
| | **Black or Black British:** | *Carribean* | *African* | *Any other Black background* | | |
| | **Chinese or other ethnic gi** | *Chinese* | *Any other ethnic group* | | | |
| | **Not stated** | | | | | |
| | | | | | | |
| **Researcher initials** | ***Reading 1*** | ***Reading 2*** | ***Reading 3*** | ***Reading 4*** | ***Reading 5*** | ***Start time/End time*** |
| **PEF** | | | | x | x | |
| **PIF** | | | | x | x | |
| **SNIP right** | | | | | | |
| **SNIP left** | | | | | | |
| **Handgrip right** | | | | x | x | |
| **Handgrip left** | | | | x | x | |
| **BI score** | | x | x | x | x | |
| **YES-13 score** | | x | x | x | x | |
| **PASE** | | x | x | x | x | |
| | | | | | | |
| **Researcher initials** | ***Reading 1*** | ***Reading 2*** | ***Reading 3*** | ***Reading 4*** | ***Reading 5*** | ***Start time/ End time*** |
| **PEF** | | | | x | x | |
| **PIF** | | | | x | x | |
| **SNIP right** | | | | | | |
| **SNIP left** | | | | | | |
| **Handgrip right** | | | | x | x | |
| **Handgrip left** | | | | x | x | |
| **SF-36** | | x | x | x | x | |
| **Rivermead** | | x | x | x | x | |
| | | | | | | |
| | | | | | | |
| Researcher: Please detail any side effects/ problems? | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |

## Appendix 19 Participant consent form for Study A

UNIVERSITY OF Southampton
School of Health Sciences

**CONSENT FORM**

**Study title: Measures of strength and physical activity in healthy people aged 65 years and over**

Researcher name: Nicola Barnes
Ethics reference: FoHS-ETHICS-2011-045
Participant Identification Number for this study:

***Please initial the boxes if you agree with the statement(s):***

1. I have read and understood the information sheet (Dated ....., version ....) and have had the opportunity to ask questions about the study. ☐
2. I agree to take part in this research project and agree for my data to be used for the purpose of this study. ☐
3. I understand my participation is voluntary and I may withdraw at any time without consequence. ☐
4. I agree that information from the study be shared with my GP. (Please complete GP: .....
Practice address: .....) ☐

Name of participant (print name).....

Signature of participant.....

Name of researcher (print name).....

Signature of researcher.....

Date.....

Version 2 10/05/2011

Building 45
School of Health Sciences, University of Southampton, Highfield Campus, Southampton SO17 1BJ United Kingdom
Tel: +44 (0)23 8059 5830 n.barnes@soton.ac.uk www.southampton.ac.uk/healthsciences

# Appendix 20 Stata output for sample size estimations

```
. ************************************************************************
. * Simulation to compute required sample size for within group comparisons
.

. ************************************************************************
. * 250 simulations, participants 10 or 8, original 5% stepwise reduction in means,
original st devs, correlation 0.9 throughout

For p<0.05, group size 10, means in range 28.10 to 15.46 and correlations in range
0.90 to  0.90
Power of GG test is 1.000, power of HF test is 1.000 and power of Box test is 1.000
For p<0.05, group size  8, means in range 28.10 to 15.46 and correlations in range
0.90 to  0.90
Power of GG test is 1.000, power of HF test is 1.000 and power of Box test is 1.000

Conclusion:  10 adequate

. ************************************************************************
. * 250 simulations, participants 12, 10, revised stepwise reduction in means,
original st devs, correlation 0.9 throughout

For p<0.05, group size 12, means in range 28.10 to 18.27 and correlations in range
0.90 to  0.90
Power of GG test is 1.000, power of HF test is 1.000 and power of Box test is 1.000
For p<0.05, group size 10, means in range 28.10 to 18.27 and correlations in range
0.90 to  0.90
Power of GG test is 1.000, power of HF test is 1.000 and power of Box test is 1.000

Conclusion: 10 adequate


 ************************************************************************

. * 250 simulations, participants 15, 12, 10, further revised stepwise reduction in
means, original st devs, correlation 0.9 throughout

For p<0.05, group size 15, means in range 28.10 to 21.07 and correlations in range
0.90 to  0.90
Power of GG test is 1.000, power of HF test is 1.000 and power of Box test is 0.972
For p<0.05, group size 12, means in range 28.10 to 21.07 and correlations in range
0.90 to  0.90
Power of GG test is 1.000, power of HF test is 1.000 and power of Box test is 0.872
For p<0.05, group size 10, means in range 28.10 to 21.07 and correlations in range
0.90 to  0.90
Power of GG test is 1.000, power of HF test is 1.000 and power of Box test is 0.668

Conclusion: 12 adequate
```

## Appendix 21 Six item cognitive impairment test

The 6CIT Dementia Test

---

# How the test works

| Question | Score range | Weighting | Weighted score |
|---|---|---|---|
| | | | |
| What Year is it | 0-1 | x4 | |
| What month is it | 0-1 | x3 | |
| *Give the memory phrase e.g. (John/Smith/42/West Street/Bedford)* | | | |
| About what time is it | 0-1 | x3 | |
| Count back from 20-1 | 0-2 | x2 | |
| Say months in reverse | 0-2 | x2 | |
| Repeat the memory phrase | 0-5 | x2 | |
| Total score for 6CIT | 0-28 | | |

# Advanced Information

<u>How to perform and score the test</u>

Try to perform the test in a quiet place with no obvious clock or calendar visible to the patient.

Ask the patient what year it is?

If they get it correct then they score zero (no errors), if they get it wrong then score 1

What month is it?

If correct score zero and if wrong then score 1

Tell the patient that you are going to tell them a fictional address which you would like them to try and memorise and then repeat back to you afterwards.

Say "John / Brown / 42 / West Street / Bedford" (or devise a similar address relevant to your country with 5 main elements (eg. Richard Buerks 42 Sandton Road Durban might be more relevant for South Africa). Make sure that the patient is able to repeat the address correctly before moving on and warn them to try and memorise it as you are going to ask them to repeat it again in a few minutes. No score is made at this stage.

Ask the patient the time

If they get to within 60 minutes or an hour of the correct time then they score zero, if not score 1

Ask the patient to count backwards from 20 to 1.

If they do this correctly they score zero, if they make one error then score 1 and for 2 or more errors score 2 (note they can not score more than 2 for this question).

Ask the patient to say the months of the year backwards starting at December.

I tend to give them plenty of time for this and it doesn't matter if they have to keep saying the months of the year forwards in order to get the answer. Inevitably they sometimes forget where they were, and I sometimes prompt them or offer encouragement that they're doing well. Again if they get it all correct then score zero, one error – score one, 2 or more errors score 2.

Finally ask them to repeat the address back to you.

The address is broken into 5 segments and is scored for each error they make in remembering it up to a score of 5. I.e. All correct = zero, one bit wrong = 1, 2 parts wrong = 2 , 3 parts wrong = 3, 4 parts wrong = 4 and all wrong = 5 Finally to complete the scoring multiply the score for each question by the weight in the neighbouring column and then add up all the weighted scores which should give you a score of between 0 – 28.

0-7 probably normal

8-9 mild cognitive impairment

10 + probably significant moderate to severe cognitive impairment

# Appendix 22 Patient invitation pack contents: Study B

All contents printed with University and NHS Trust headings.

Dear Sir or Madam,

**Re: Improving monitoring of patients receiving case management**

Thank-you for showing an interest in our study.

Please find enclosed a Patient Information Sheet that tells you more about the study, and what it involves. If you have any questions after reading it please contact me by telephone or email and I will be happy to discuss them.

If after reading the leaflet you would like to take part, please complete and return the slip below in the pre-paid envelope enclosed, alternatively you can email or call me, via the contact information below.

Thank-you once again for taking time to read the enclosed leaflet and considering volunteering.

Yours faithfully,

Nicola Barnes

Post-graduate Research Student

Tel: 02380 595834

Email: n.j.barnes@soton.ac.uk

*Ethics number:12/SC/0313*

……✂……✂……✂……✂

**Improving monitoring of patients receiving case management**

Yes, I would like to volunteer to take part in this study (please tick) ☐

Signed……

Name (print name)……Date……

Contact telephone number……

If you would like to volunteer for this study, the next step is for me to call you to ask you some questions about your health to ensure you are able to take part. Please provide a contact number above. Please let me know if there are any times more convenient for me to call.

**Participant Information Sheet** (Font size reduced)

**Improving monitoring of patients receiving case management**

Researcher: Nicola Barnes Ethics number: 12/SC/0313

**You are being invited to take part in a study run by the Faculty of Health Sciences, University of Southampton. Please read this information carefully before deciding to take part in this study. If you are happy to participate you will be asked to sign a consent form. Please ask us if there is anything that is not clear or if you would like more information.**

**What is the study about?**

This study looks at how strength changes over the short term in older people who have on-going health problems, and whether changes in strength are linked to symptoms or worsening of an illness. This study is part of a student research project.

**Why have I been chosen?**

You are receiving support from the community care and nursing team.

**Do I have to take part?**

No, your care will continue as normal whether you take part or not.

**What will happen to me if I take part?**

A researcher will arrange to visit you at home three times in the first week, then once every two weeks for a further 12 weeks. Your usual care will not be affected and will continue as normal.

The first visit will last around 1-1 ½ hours. Further visits will last around 20-30 minutes.

At each visit we will be collecting information on your health and well-being, including a measure of your physical strength. We will use three measures of your strength. Before each measure, time will be taken to explain what each measure is and how it is done. There will also be an opportunity for you to ask any questions.

The following measures will be carried out:

**Questionnaires**: we will ask you to complete some questionnaires with us, about your health, daily activities and symptoms.

**Grip strength**: you will be asked to squeeze a hand held measuring device as hard as you can. You will be asked to do this three times in your favoured hand.

**Peak expiratory flow**: you will be asked to do a short sharp breath out into a small hand-held device. This helps measure the strength of muscles used when breathing out. You will be asked to do this three times.

**Peak inspiratory flow**: you will be asked to take a short sharp breath in using a small handheld device. This helps measure the strength of the muscles used when breathing in. You will be asked to do this three times.

**Feedback:** At the final visit we would like to ask you some questions about your experience of completing the tests.

**Are there any benefits in my taking part?**

No, this is an initial study to see whether we should look at these measures further.

**Are there any risks involved?**

There are no known or expected serious side effects or risks in taking part. The peak flow tests may cause some mild coughing immediately after the test.

**Will my participation be kept confidential?**

Yes. All the information about your participation in this study will be kept confidential. We will ask for your permission to contact your GP or community care and nursing team to share any information that comes to light during the study which we feel needs to be shared with them.

**What happens if I change my mind?**

You are free to withdraw at any time and without giving a reason.

**What happens to the results?**

The results from the study will be analysed for use in a PhD research study. They will help tell us if measuring strength could be useful in patient monitoring. Anonymised results will be presented at conferences and in journals.

**Who has approved this study?**

The study has been reviewed and approved by Southampton B Research Ethics Committee. The Research Ethics Committee reference number for the study is 12/SC/0313.

**What happens if something goes wrong?**

If you have a concern or a complaint about this study you should contact Martina Prude, Head of Research Governance. Room 4005, Building 37, University of Southampton, Highfield, Southampton, SO17 1BJ; Tel: 02380 595058; Fax: 02380 595781; Email mad4@soton.ac.uk. If you remain unhappy and wish to complain formally Martina Prude can provide you with details of the University of Southampton Complaints Procedure.

**Where can I get further information?**

If you would like to ask any further questions please contact Nicola Barnes, Postgraduate Research Students, Faculty of Health Sciences (Address: University of Southampton, Building 45, Highfield, Southampton, SO17 1BJ;

Tel: +44 (0)23 80 59 5834 ; Email: n.j.barnes@soton.ac.uk).

**What now?**

If you are happy to voluntarily take part please complete the slip attached to the enclosed letter and return in the pre-paid envelope, alternatively telephone or email us to let us know you would

like to take part. We will then call you to ensure there is no reason for you not to take part and arrange our first visit. You will be asked to sign a consent form when we visit for the first time, and given a copy of this information sheet and signed consent form to keep.

***Thank you for considering taking part and taking time to read this sheet.***

# Appendix 23 Health Screening Questionnaire (Study B)

**Health Screening Questionnaire**

**Identification number: _____** **Gender:** Male / Female (please circle).

**Surname: _____First Name:_____**

**Date of birth: _____ Telephone No: _____**

*N.B. To be completed by researcher with participant over the telephone, prior to first visit.*

**If YES to any questions, please give some details including dates where possible.**

1. Are you currently enrolled in any other research study? YES / NO
   If YES, unable to participate in this study.

2. Have you any history of emotional, memory, or psychiatric problems in the last 6 months?

3. Do you have any sensory impairment or condition that makes it difficult for you to communicate e.g. severe hearing loss not helped by the use of a hearing aid?

4. Do you have any conditions affecting your joints?
   (If YES please state joints affected and indicate mild, moderate or severe)

5. Have you broken or fractured any upper limb bones? (If so, which bones and when)

6. Have you any history of chest problems? (If yes, are you currently experiencing an exacerbation of symptoms) (e.g. Bronchitis, COPD, asthma or wheezy chest)

7. Have you had any acute illness in the last two weeks? (such as influenza)

8. Are you receiving any nursing care from another team? (If yes, please state which teams)

# Appendix 24 Data collection forms (Study B)

First/final visit data collection form

| | | | | | |
|---|---|---|---|---|---|
| **Participant ID number:** | | **Gender:** | **Age:** | **Postcode (1st half only):** | |
| **Height:** | **Weight (1st visit):** | **Weight (final visit):** | | **Occupation/previous occupation:** | |
| **Ethic origin:** | **White:** | *British* | *Irish* | *Any other White background* | |
| | **Mixed:** | *White & Black Carribean* | *White & Black African* | *White & Asian* | *Any other mixed background* |
| | **Asian or Asian British:** | *Indian* | *Pakistani* | *Bangladeshi* | *Any other Asian background* |
| | **Black or Black British:** | *Carribean* | *African* | *Any other Black background* | |
| | **Chinese or other ethnic group:** | *Chinese* | *Any other ethnic group* | | |
| | **Not stated** | | | | |
| Current medical conditions: | (Inc. physical disabilities, any condition/ illness that affects general health/ mobility) | | | | |
| | | | | | |
| Past medical history: | (Inc. hospital admissions in last 6 months, falls in last 2 months, smoking history, surgery to joints) | | | | |
| | | | | | |
| Regular medication: | | | | | |
| | | | | | |
| **Visit 1** | ***Reading 1*** | ***Reading 2*** | ***Reading 3*** | ***Start time*** | ***End time*** |
| **PEF** | | | | | |
| **PIF** | | | | | |
| **Handgrip right** | | | | | |
| **Handgrip left** | | | | | |
| **BI score** | | x | x | | |
| **VES-13 score** | | x | x | | |
| **PASE** | | x | x | | |
| **MMSE (1st visit only)** | | x | x | | |
| **Sickness Behaviour Scale** | | x | x | | |
| **Visit 9** | | | | | |
| **PEF** | | | | | |
| **PIF** | | | | | |
| **Handgrip right** | | | | | |
| **Handgrip left** | | | | | |
| **BI score** | | x | x | | |
| **VES-13 score** | | x | x | | |
| **PASE** | | x | x | | |
| **MMSE (1st visit only)** | | x | x | | |
| **Sickness Behaviour Scale** | | x | x | | |
| Researcher: Please detail any side effects/ problems? | | | | | |

Follow-up visits data collection form

| **Participant ID number:** | | | | | |
|---|---|---|---|---|---|
| **Visit no.** | ***Reading 1*** | ***Reading 2*** | ***Reading 3*** | ***Start time*** | ***End time*** |
| **PEF** | | | | | |
| **PIF** | | | | | |
| **Handgrip** | | | | | |

**Sickness Behaviour Scale** x x

**Changes to medical history inc. medication and unplanned access to primary/ secondary care:**

# Appendix 25 Patient consent (Study B)

Printed on University and NHS Trust headed paper. N.B. Font size reduced.

**CONSENT FORM**

**Study title: Improving monitoring of patients receiving case management**

Researcher's name: Nicola Barnes Ethics reference: 12/SC/0313
Participant Identification Number for this study:

If you agree to take part in this study you will be given a copy of this form to keep, a copy will be sent to your GP to place in your medical records, and the original copy will be kept by the researcher.

***Please initial the boxes if you agree with the statement(s):***

1. I have read and understood the information sheet (Dated ……., version ....) and have had the opportunity to ask questions about the study. ☐

2. I agree to take part in this research project and agree for my data to be used for the purpose of this study. ☐

3. I understand my participation is voluntary and I may withdraw at any time without consequence. ☐

4. I agree that information from the study be shared with my GP and/or Community Healthcare Team if necessary. ☐
(Please complete GP:……

Practice address:……)

Name of participant (print name)…..

Signature of participant…….

Name of researcher (print name)…….....

Signature of researcher……..

Date……

## Appendix 26 Letter to GP informing study participation: Study B

UNIVERSITY OF Southampton

12/SC/0313
*Date*

Dear Dr……,

***For your information only – no action required.***

**Patient participation in research study** – "Improved targeting of admission avoidance interventions in older people with long-term conditions: evaluation of routine monitoring of measures of strength to identify patients at risk of decline."

*[Patient's name]* *[Patient's D.O.B ]* *[Patient's address]*

*[Patient's name]* has agreed to participate in the above research study (REC approval number). There will be no change to the care he/she receives and we do not require any action on your part. This patient has been recruited for this study because they are currently receiving community case management.

The study aims to evaluate whether routine measurement of muscle strength could be used to detect a patient's declining health or functional status, to allow changes to be made to their care to prevent a crisis. The study will also describe the physical and functional status of the patient group receiving Case Management.

The study will involve the assessment of symptoms over 7 weeks, including depression and memory. *[Patient's name]* has consented for us to share any information that should come to light during the study that we feel needs to be shared with yourself or their community care team.

If you would like any further information or would like to be informed of the results of the study when complete, please contact me via the email/ postal address or telephone number below.

Yours faithfully,

Nicola Barnes MPharm
Post-graduate Research Student
Faculty of Health Sciences
Direct tel: +44 (0)23 8059 5834
email: n.j.barnes@soton.ac.uk
This study has received Ethical approval from ……Ethics Committee ref. no. ……

# Appendix 27 Participant Information Sheet for Clinicians (Study B)

Participant Information Sheet for case management teams

## Improving monitoring of patients receiving case management

## Feedback on simple measures of strength

Researcher: Nicola Barnes Ethics number: 12/SC/0313

**You are being invited to take part in a study run by the Faculty of Health Sciences, University of Southampton. Please read this information carefully before deciding to take part in this study. If you are happy to participate you will be asked to sign a consent form. Please ask us if there is anything that is not clear or if you would like more information.**

**What is the study about?**

The study looks at how strength changes over the short term in older people who have on-going health problems, and whether changes in strength are linked to symptoms or worsening of an illness. You are being invited to take part in a short interview to get your views on the measuring equipment and how practical they are to use in your role. This study is being undertaken as a student research project.

**Why have I been chosen?**

You are part of the team providing care to patients receiving case management.

**Do I have to take part?**

No, it is up to you whether you wish to take part or not.

**What will happen to me if I take part?**

A researcher will arrange to visit you at your place of work on one occasion to show you the equipment, allow you to use it if you wish to and ask for your opinions on it. The visit will last around 20 minutes.

The pieces of equipment we are looking at are:

**Jamar grip strength meter**: a handheld device that is squeezed.

**Mini-wright peak expiratory flow meter**: a handheld device that a short, sharp breath out is made through.

**In-check oral peak inspiratory meter**: a handheld device that a short, sharp intake of breath is made through.

**Are there any risks involved?**

There are no known or expected serious side effects or risks when using the equipment. The peak flow tests may cause some mild coughing immediately after the test.

**Are there any benefits in my taking part?**

No, this is an initial study to see whether we should look at these measures further.

**Will my participation be kept confidential?**

Yes. All the information about your participation in this study and your views will be kept confidential.

**Do I have to take part?**

No, you can choose to take part or not.

**What happens if I change my mind?**

You are free to withdraw at any time and without giving a reason.

**What happens to the results?**

The results from the study will be analysed for use in a PhD research study. They will help tell us if measuring strength is feasible and could be useful in patient monitoring. Anonymised results will be presented at conferences and in journals.

**What happens if something goes wrong?**

If you have a concern or a complaint about this study you should contact

Martina Prude, Head of Research Governance. Room 4005, Building 37, University of Southampton, Highfield, Southampton, SO17 1BJ; Tel: 02380 595058; Fax: 02380 595781; Email mad4@soton.ac.uk. If you remain unhappy and wish to complain formally Martina Prude can provide you with details of the University of Southampton Complaints Procedure.

**Where can I get further information?**

If you would like to ask any further questions please contact Nicola Barnes, Postgraduate Research Students, Faculty of Health Sciences (Address: University of Southampton, Building 45, Highfield, Southampton, SO17 1BJ;

Tel: +44 (0)23 80 59 5834 ; Email: n.j.barnes@soton.ac.uk).

**What now?**

If you are happy to voluntarily take part please telephone or email us to let us know you would like to take part. We will then call you to arrange the visit. You will be asked to sign a consent form when we visit and given a copy of this information sheet and signed consent form to keep.

***Thank you for considering taking part and taking time to read this sheet.***

# Appendix 28 Consent form for clinicians (Study B)

On University & NHS Trust headed paper.

**CONSENT FORM**

**For case management team members**

**Study title: Improving monitoring of patients receiving case management – feedback interviews only**

Researcher's name: Nicola Barnes Ethics reference: 12/SC/0313

Participant Identification Number for this study:

If you agree to take part in this study you will be given a copy of this consent form to keep, and a copy will be kept by the researcher.

***Please initial the boxes if you agree with the statement(s):***

1. I have read and understood the information sheet (Dated ……, version ....) and have had the opportunity to ask questions about the study. ☐

2. I agree to take part in this research project and agree for my data to be used for the purpose of this study. ☐

3. I understand my participation is voluntary and I may withdraw at any time without consequence. ☐

Name of participant (print name)…..

Signature of participant……

Name of researcher (print name)……..

Signature of researcher……

Date……

# Appendix 29 Wilcoxon signed-rank tests (Study C)

A Wilcoxon signed-rank test suggested that a statistically significant reduction in A&E admissions following virtual ward admission occurred (z=-2.245, p=0.025), in non-elective length of stay (z=-3.739, p=0.000), in number of non-elective admissions (z=-3.281, p=0.001), and in the number of outpatient attendances following virtual ward admission occurred (z=-2.064, p=0.039). However this is likely to be due to regression to the mean.

A Wilcoxon signed-rank test suggested that no statistically significant reduction in elective length of stay occurred (z=-1.515, p=0.130), or number of elective admissions (z=-1.084, p=0.278).

A Wilcoxon signed-rank test suggested that a statistically significant reduction in A&E admissions following virtual ward admission occurred (z=-2.245, p=0.025), in non-elective length of stay (z=-3.739, p=0.000), in number of non-elective admissions (z=-3.281, p=0.001), and in the number of outpatient attendances following virtual ward admission occurred (z=-2.064, p=0.039).

A Wilcoxon signed-rank test suggested that no statistically significant reduction in elective length of stay occurred (z=-1.515, p=0.130), or number of elective admissions (z=-1.084, p=0.278).

# Appendix 30 Chi square tests (Study C)

Chi square tests were performed and no relationship found between the number of long term conditions and A&E admissions both prior to virtual ward admission, $X^2$ (14, N=101) = 0.41, p>0.95, or after $X^2$ (14, N=101) = 0.07, p>0.95.

Chi square tests were performed and no relationship found between gender and A&E admissions both prior to virtual ward admission, $X^2$ (2, N=101) = 0.72, p>0.50, or after $X^2$ (2, N=101) = 0.12, p>0.90.

Chi square tests were performed and no relationship found between IMD and A&E admissions both prior to virtual ward admission, $X^2$ (14, N=101) = 0.34, p>0.95, or after $X^2$ (14, N=101) = 0.55, p>0.95.

Chi square tests were performed and no relationship found between age and A&E admissions both prior to virtual ward admission, $X^2$ (12, N=101) = 0.52, p>0.90, or after $X^2$ (12, N=101) = 0.08, p>0.95.

Chi square tests were performed and no relationship found between number of falls and A&E admissions both prior to virtual ward admission, $X^2$ (2, N=101) = 0.32, p>0.80, or after $X^2$ (2, N=101) = 0.00, p>0.95.

Chi square tests were performed and no relationship found between age and A&E admissions both prior to virtual ward admission, $X^2$ (12, N=101) = 0.52, p>0.90, or after $X^2$ (12, N=101) = 0.08, p>0.95.

Chi square tests were performed and no relationship found between all type admissions and A&E admissions both prior to virtual ward admission, $X^2$ (8, N=101) = 0.00, p>0.95, or after $X^2$ (8, N=101) = 0.00, p>0.95.

Chi square tests were performed and no relationship found between frequency of case management team visits and A&E admissions after virtual ward admission $X^2$ (4, N=101) = 0.30, p>0.95, or number of long term conditions and frequency of case management team visits $X^2$ (14, N=101) = 0.27, p>0.95.

# Appendix 31 Kruskal-Wallis tests (Study C)

**Hypothesis Test Summary**

| | Null Hypothesis | Test | Sig. | Decision |
|---|---|---|---|---|
| 1 | The distribution of CM is the same across categories of Tertile. | Independent-Samples Kruskal-Wallis Test | .065 | Retain the null hypothesis. |

Asymptotic significances are displayed. The significance level is .05.

**Figure A- 3 Kruskal–Wallis test summary recorded case management contact by FI tertile**

**Hypothesis Test Summary**

| | Null Hypothesis | Test | Sig. | Decision |
|---|---|---|---|---|
| 1 | The distribution of OPD is the same across categories of Tertile. | Independent-Samples Kruskal-Wallis Test | .089 | Retain the null hypothesis. |

Asymptotic significances are displayed. The significance level is .05.

**Figure A- 4 Kruskal-Wallis test summary recorded outpatient department visits by FI tertile**

# Appendix 32 Publications

**Barnes, Nicola , Agyapong-Badu, Sandra , Walsh, Bronagh , Stokes, Maria and Samuel, Dinesh (2013) Reliability and acceptability of measuring sniff nasal inspiratory pressure (SNIP) and peak inspiratory flow (PIF) to assess respiratory muscle strength in older adults: a preliminary study.** ***Aging Clinical and Experimental Research*****.**


**Abstract**

**Background**

Sniff nasal inspiratory pressure (SNIP) and peak oral inspiratory flow (PIF) are portable, relatively new methods for indirect measurement of respiratory muscle strength. The reliability and acceptability of these measures were investigated in older adults.

**Methods**

Twenty one self-reported healthy adults, aged 65-84 years (Mean 73.5; SD 6.4 years). Participants were tested in a sitting position on two occasions, one week apart. The best of three attempts for PIF measured through the mouth, and five for each nostril for SNIP were recorded. Reliability was tested using intra-class correlation coefficient (ICC), standard error of measurement (SEM), minimal detectable change (MDC) and Bland and Altman analysis. Feedback on the measures in relation to ease of completion and preference was obtained using a semi-structured interview.

**Results**

Between-day reliability of SNIP and PIF were $ICC_{3,1}$ 0.76 (95% CI 0.49-0.9) and 0.92 (0.81-0.97) respectively. Standard error of measurement for SNIP (11.94 $cmH_2O$) and MDC (33.10 $cmH_2O$) were at the least 61% higher than for PIF. The participants reported difficulties in performing SNIP, rating it as being less easy and uncomfortable to perform than PIF, with a higher rate of missing data for SNIP due to participants' dislike of test.

**Conclusions**

The wide range of SNIP readings, lower ICC value and negative user feedback is suggestive of a less robust and unacceptable clinical measure. PIF showed excellent reliability and acceptability and is therefore recommended for assessing inspiratory muscle strength in older people without known obstructive lung disease.



*Keywords*: respiratory muscle strength, inspiratory flow, inspiratory pressure, acceptability.

**Introduction**

Muscle strength has been shown to be a good predictor of future health and function in older people (Bassey 1998; Newman et al., 2006). However, simple portable measures of strength have yet to be embraced as part of routine general clinical practice in the community setting, suggesting the need for inexpensive clinically acceptable measures. The most commonly investigated measures of strength in older people are grip and quadriceps, however respiratory muscles are also important. Hand grip strength is a simple, reliable and inexpensive surrogate of overall muscle strength and has been shown to be a valid predictor of physical disability and mobility limitation in older people (Rantanen et al., 2002; Shinkai et al., 2000). However, due to pain or underlying upper limb injury, older people may find it difficult to perform this test and good grip strength may not necessarily be indicative of good general muscle strength. Respiratory muscle function is important for whole body functional performance and it may be useful to assess the changes in this specific function as one ages.

Previous research has demonstrated reduced respiratory function with ageing, with lower levels of pulmonary function and respiratory muscle strength associated with restricted mobility, declining health and mortality (Buchman et al., 2009; Watsford et al., 2007, Vaz Fragoso et al., 2007). These results demonstrate the potential for using respiratory muscle function assessment in regular physical performance tests for older adults in research, as well as routine clinical practice. However, there is insufficient evidence on the reliability and acceptability of these measures in older people.

Portable respiratory measures such as sniff nasal inspiratory pressure (SNIP) and peak oral inspiratory flow (PIF), have recently become commercially available. SNIP has been found to be a good indicator of respiratory muscle strength with emphasis on diaphragm strength (Colville et al., 2007; Fitting 2006). Whilst normal peak nasal inspiratory flow values have been widely reported (Ottaviano et al., 2008; Ottaviano et al., 2012), few published normative data for SNIP and PIF exist, leading to a lack of published reliability studies in healthy older individuals, using commercially available unadapted equipment. Excellent reliability of SNIP in healthy mixed age populations has been reported in the literature; with within-day reliability intraclass correlation coefficient (ICC) 0.93 and between-day ICC of 0.93 (n=20) (Jones et al., 2009) and test-retest reliability with an ICC of 0.92 (n=223) (Kamide et al., 2009). The authors reported a gender effect on reliability in their population aged 18-69 years, with men demonstrating a higher ICC of 0.93 (95%CI 0.91-0.95) compared to women with 0.88 (95%CI 0.84-0.91) (Kamide et al., 2009). Nairn et al. (1963) reported a coefficient of variation for PIF twice that observed with PEF, which was thought to reflect the greater difficulty in PIF technique.

A clinically useful device for monitoring and evaluation should be acceptable to the users and have the potential to provide results that are easily reproducible and sensitive to clinically important change (Graham 2000; Hughes et al., 2011). The present study did not aim to directly compare the measures in regard to their effectiveness in measuring respiratory muscle strength, given their involvement of different anatomical parts of the respiratory tract. Rather, the study aimed to investigate the reliability and acceptability of SNIP and PIF in older adults, in order to assess their potential clinical usefulness.

**Materials and methods**

Twenty-one self-reported healthy adults from 65-84 years, with a mean age of 73.5 (SD 6.3) years were recruited from the local community using posters, leaflets and through luncheon clubs, across 27 locations. Whilst the target sample size of 40 (20 males and 20 females) was not achieved, due to lower than expected response rate, the minimum sufficient sample size (n=19) for calculating inter- and intra-rater reliability (Walter et al., 1998) was achieved. Participants with any serious, active or unstable illness, or conditions that precluded completion of the measures or unable to provide informed consent were excluded. Respiratory muscle strength was measured using SNIP (MicroRPM) and oral PIF (In-Check Oral). Activity level was assessed using the validated physical activity scale for the elderly (Washburn et al., 1993). Participants were tested in a sitting position on two occasions, one week apart by two raters. Following an initial trial attempt, the best of three maximal efforts for PIF through the mouth and five from each nostril for SNIP were recorded. The number of repetitions was decided following consideration of manufacturer's guidelines (PIF 3 attempts recommended; SNIP between 5-10 attempts recommended), published research and concern for participant burden (Colville et al., 2007; Fitting 2006; Kamide et al., 2009; Uldry et al., 1997). PIF took less than two minutes to perform all repetitions, whilst SNIP took about four minutes to complete. A semi-structured interview obtained feedback on the tests in relation to ease of completion and participant preference. Reliability was estimated using intra-class correlation coefficient ($ICC_{3,1}$), standard error of measurement (SEM), minimal detectable change (MDC) and Bland and Altman plots. The number of participants included in the study did not allow for separate gender-based analysis. Data were recorded in Microsoft Excel and analysed using SPSS 18 (SPSS Inc, Chicago, IL).The data were examined for normality using the Shapiro-Wilk test and found to be normally distributed. Descriptive statistics were used to summarise the data as means and standard deviations (SD).

All participants gave their written informed consent. The study was approved by the Faculty of Health Sciences Ethics Committee, University of Southampton.

## Results

### Participant characteristics

The baseline characteristics of the sample are shown in Table 1. Males and females were of similar age, with BMI of both groups falling within the overweight category. The number of diagnosed chronic medical conditions was similar in both groups, with only one participant having no diagnosed chronic condition (male participants on average were diagnosed with 2.1 chronic conditions each; females 1.8 condition). A similar trend was recorded for the number of participants taking regular prescription medication, with only two participants taking no regular prescribed medication (male participants were taking on average 2.8 medicines each; females 1.7 medicines). The baseline PIF values in Table 1 were within expected normal ranges for male and female participants (Depledge 1985). However, SNIP values appeared slightly below published norms (Uldry and Fitting 1995).

*[Insert Table 1 near here]*

### Reliability of measures of inspiratory muscle strength

Intra-rater reliability of tests performed on two days, estimated using intraclass correlation coefficient ($ICC_{3,1}$), showed that the PIF ($ICC_{3,1}$ 0.92) test was more reliable than SNIP($ICC_{3,1}$ 0.76). PIF demonstrated excellent inter-rater reliability ($ICC_{3,1}$ 0.97) as well. Bland and Altman plots showed good agreement between values on both days for PIF (Figure 1).

*[Insert Figures 1,2,3& 4 and Tables 2 & 3 near here]*

### Acceptability of PIF and SNIP measurements

Incomplete SNIP readings were obtained on four occasions, due to incorrect technique, displacement of the nasal probe, dislike of test, and submaximal effort. PIF was however completed on all occasions. No other unexpected side effects or problems were observed. Participants rated SNIP as the least preferred to complete (Table 4).

## Discussion

The present study demonstrated good reliability for measuring both PIF and SNIP in a healthy group of adults over 65 years, although PIF measurements were more robust and appeared to be more acceptable to participants. These findings may be worth considering when assessing respiratory muscle in patient groups especially the use of SNIP, since the healthy older participants in the current study found the technique unacceptable.

It is worth noting, however, that the two tests involved different anatomical parts of the upper respiratory tracts with different resistances which could have accounted for the differences in results obtained. While SNIP has been validated as a test of inspiratory muscle strength, this is not the case for PIF, which was developed as an alternative test of airway obstruction (Depledge 1985). PIF is largely influenced by the calibre of the airway and could reflect inspiratory muscle strength only after exclusion of obstructive lung disease, which was not screened for in the current study. Variations in absolute values for inspiratory strength measurements between the two groups indicated an influence of gender which has been highlighted in the literature but the small numbers involved in the present study cannot allow definitive conclusions to be drawn.
In the current study, reliability estimates for PIF ($ICC_{3,1}$ between-day 0.92, between-rater 0.97) showed it could be measured consistently and accurately in people aged 65 years and over by the rater and remained stable over the one-week testing period. Although the ICC for SNIP was good ($ICC_{3,1}$ between-day 0.76, between-rater 0.88), it fell below the recommended 0.90 to ensure reliability for clinical measurements (Portney and Watkins 2000). The Bland-Altman plot for SNIP also demonstrated proportionally wide limits of agreement when compared to PIF; and showed SNIP's apparent increasing error at lower values, which may limit its clinical use. The reliability estimates for SNIP, however, were below previously published work (Kamide et al., 2009; Maillard et al., 1998). The lower reliability observed with SNIP may be due to a number of limitations of the study including a potential learning effect that may have meant that with further repetitions the reliability may have increased. The protocol adopted in the study may also have accounted for the reliability results obtained. It has been reported that the best SNIP involving a true maximal inspiration was 6% higher in sniffs 11-20 than in 1-10 (Lofaso et al., 2006). The number of sniffs in the current study was set at 5 as reported in recent literature (Colville et al., 2007; Kamide et al., 2009) compared to 10 (Uldry and Fitting 1995). A compromise between scientific rigour and practical considerations had to be reached in the current study, which may account for the lower reliability observed. Five sniffs were chosen as this was clinically feasible, had been used before and also to prevent fatigue before performing PIF (Fitting 2006). Moreover, it has been proposed that ten and more sniffs should be performed when SNIP is used to monitor functional decline over time, which was not the case in the current study (Lofaso et al., 2006; Stell et al., 2001).

Practically, performing ten or more sniffs during routine clinical assessment may not be feasible, limiting the clinical utility of the measure. In the current study, maximum effort from functional residual capacity was not monitored on a computer screen, as this would have been useful for participants to observe their effort. SNIP values demonstrated a wider variability and this may be because participants were allowed to perform only one trial test before recording strength values.

Other studies allowed several sniffs to take into account a learning effect (Kamide et al., 2009). Increasing error at lower values, as demonstrated in Bland-Altman plots for SNIP, may limit the clinical usefulness of the measure as a monitoring aid. This is because as a patient's strength declines towards lower values, the measure can no longer be relied upon to provide accurate values. Further repetitions may be required which may not be feasible as a patient's condition worsens, or meaning the measure will no longer be suitable.

Regarding acceptability, neither the participants nor investigators found the SNIP device easy to use, with incorrect technique, displacement of the nasal probe and perceived sub-maximal effort observed as possible limitations. Following interviews with participants, the acceptability of PIF was repeatedly rated higher than SNIP for ease of use and preference. As regards acceptability, the difficulty in obtaining desired number of repetitions for SNIP is indicative of a lower acceptability than indicated by the Likert scales alone. Participants reported their dislike of performing the manoeuvre when asked open questions during the semi-structured interview. Lack of acceptability is likely to impact on the potential usefulness of SNIP in routine general clinical practice, if patients repeatedly either refuse to perform the test or they perform sub-maximally. Following the feedback obtained on the SNIP technique in the current study, future studies could explore the potential of maximal inspiratory pressure test for assessing inspiratory muscle strength in older adults who may find the SNIP technique uncomfortable. A priority for future research is to explore reliability and acceptability of PIF in clinical groups, including frail older people, both in community and hospital settings and this is currently being conducted by the research group.

**Conclusions**

In conclusion, the results from the reliability and acceptability study indicate that PIF is both reliable and acceptable for assessing respiratory muscle strength in healthy older adults aged 65 years and over, without known obstructive lung disease. Its performance in clinical populations now needs to be assessed. The SNIP test fell below the reliability threshold recommended for clinical measures, and was less acceptable to participants.

**Conflict of interest**

No conflict of interest noted. Funding is acknowledged from the University of Southampton and Ghana Education Trust Fund.

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**Figure legends**

**Figure 1**

Bland and Altman plot showing agreement between days for PIF. The difference in values between days is plotted against mean values for each day. The middle line shows the mean difference. The 95% upper and lower limits of agreement represent 2 standard deviations above and below the mean difference.

**Figure 2**

Bland and Altman plot showing agreement between days for SNIP. The difference in values between days is plotted against mean values for each day. The middle line shows the mean difference. The 95% upper and lower limits of agreement represent 2 standard deviations above and below the mean difference.

**Figure 3**

Bland and Altman plot showing agreement between raters for SNIP. The difference in values between raters is plotted against mean values for each rater. The middle line shows the mean difference. The 95% upper and lower limits of agreement represent 2 standard deviations above and below the mean difference.

**Figure 4**

Bland and Altman plot showing agreement between raters for PIF. The difference in values between raters is plotted against mean values for each rater. The middle line shows the mean difference. The 95% upper and lower limits of agreement represent 2 standard deviations above and below the mean difference.

Table 1. Summary demographic and baseline characteristics of participants

| | Males (n=8) Mean ± SD[a] | Median | Females (n=13) Mean ± SD[a] | Median |
|---|---|---|---|---|
| Age (years) | 72.6 ± 4.3 | 74.5 | 74.0 ± 7.4 | 77 |
| BMI[b] ($kg/m^2$) | 26.3 ± 3.4 | 26.2 | 28.6 ± 5.7 | 26.6 |
| Maximal PIF[c] (l/min) | 303.8 ± 59.6 | 312.5 | 225.4 ± 56.6 | 225 |
| Maximal SNIP[d] ($cmH_2O$) | 72.8 ± 19.9 | 70 | 60.8 ± 19.1 | 55 |

[a]Standard Deviation, [b]Body Mass Index, [c]Peak Inspiratory Flow, [d]Sniff Nasal Inspiratory Pressure

Table 2. Between day reliability for PIF and SNIP

| Strength Measure | Mean ± SD[a] Day 1 | Day2 | $ICC_{3,1}$(95%CI[b]) | SEM[c] | MDD[d] |
|---|---|---|---|---|---|
| PIF[e] (l/min) | | | | | |
| Males (n=8) | 280.0 ± 75.8 | 282.5 ± 57.0 | 0.92(0.81-0.97) | 20.39 | 56.52 |
| Median | 300 | 305 | | | |
| Females (n=13) | 200.4 ± 66.3 | 213.5 ± 65.8 | | | |
| Median | 200 | 225 | | | |
| SNIP[f]($cmH_2O$) | | | | | |
| Males (n=8) | 66.7 ± 21.8 | 56.5 ± 30.3 | 0.76 (0.49-0.9) | 11.94 | 33.10 |
| Median | 64 | 48 | | | |
| Females (n=13) | 44.8 ± 22.1 | 53.3 ± 25.1 | | | |
| Median | 42 | 51 | | | |

*Measurements based on maximum of three readings for PIF and 10 (5 per nostril) readings for SNIP

[a]Standard Deviation, [b]Confidence Interval, [c]Standard Error of Measurement, [d]Minimal Detectable Difference, [e]Peak Inspiratory Flow, [f]Sniff Nasal Inspiratory Pressure

Table 3. Inter-rater reliability for PIF and SNIP

| Strength Measure | $ICC_{3,1}$(95%CI[a]) | SEM[b] | MDD[c] |
|---|---|---|---|
| PIF[d] (l/min) | 0.97(0.92-0.99) | 12.80 | 35.48 |
| SNIP[e]($cmH_2O$) | 0.88(0.70-0.95) | 8.47 | 23.48 |

*Measurements based on readings from day 1; maximum of three readings for PIF and 10 (5 per nostril) readings for SNIP

[a]Confidence Interval, [b]Standard Error of Measurement, [c]Minimal Detectable Difference, [d]Peak Inspiratory Flow, [e]Sniff Nasal Inspiratory Pressure

Table 4. Acceptability of respiratory strength measures

| *Questions 1-4 based on a Likert scale of 1-5, where 1 is strongly disagree, to 5 strongly agree (mean score)* | PIF[a] | SNIP[b] |
|---|---|---|
| 1."It was easy to understand what I had to do" | 4.7 | 4.7 |
| 2."It was easy to do" | 4.6 | 4.5 |
| 3."It was comfortable to do" | 4.7 | 4.4 |
| 4."I would recommend the test to anyone" | 5.0 | 4.8 |
| 5.Tests' ranking in order of preference ( where 1 is most preferred and 2 is least preferred): | | |
| Most common ranking | 1 | 2 |
| Time taken, in minutes, to complete 3 repetitions for PIF, and 10 for SNIP (5 each nostril) | 1.5 | 4.0 |

[a]Peak Inspiratory Flow
[b]Sniff Nasal Inspiratory Pressure

**Barnes N, Agyapong-Badu S, Walsh B, Samuel D, and Stokes M (2012) Reliability and acceptability of sniff nasal inspiratory pressure and peak inspiratory flow measurement in adults over 65. *Age & Ageing* 41, (S2), supplement Communications to the British Geriatrics Society Spring Meeting 16-18th May 2012, Llandudno, ii83**

**Introduction**

Sniff nasal inspiratory pressure (SNIP) and peak inspiratory flow (PIF) are portable, relatively new methods of measuring respiratory muscle strength. We aimed to investigate their reliability and acceptability in older participants.

**Methods**

Twenty-one self-reported healthy adults (65-84 years, 13 females) were studied. Respiratory muscle strength was measured using SNIP (MicroRPM), PIF (In-Check Oral), and peak expiratory flow (PEF) (Mini-Wright Standard) for comparison. Participants were tested in a sitting position on two occasions, one week apart. The best of three attempts for PIF and PEF, and five for SNIP were recorded. A semi-structured interview obtained feedback on the tests in relation to ease of completion and preference ranking. Reliability was tested by intra-class correlation coefficient (ICC), standard error of measurement (SEM), minimal detectable change (MDC) and Bland and Altman plots.

**Results**

For between-day reliability of SNIP, PIF and PEF, the ICCs were 0.76, 0.92 and 0.95 respectively. SNIP's SEM (11.94 $cmH_2O$) and MDC (33.10 $cmH_2O$) were at the least 61% higher than for PIF or PEF.

Not all five SNIP readings were obtained on four occasions, due to dislike of test, nasal congestion and inability to perform the manoeuvre correctly. Participants rated SNIP as the least easy and comfortable test to perform, and the least preferred test to complete, followed by PIF. Neither the participants nor operators found the SNIP easy to perform, with incorrect technique, displacement of the nasal probe and submaximal effort observed.

**Conclusions**

SNIP was the least preferred and least reliable measure; ICC falling below the recommended 0.90 to ensure validity for clinical measurements. The PIF and PEF showed excellent reliability, with participants finding PEF the most acceptable.

# Glossary

| | |
|---|---|
| **Inflammatory markers** | Agents involved in the inflammatory response. |
| **Middle old** | 75-84 years of age |
| **Older old** | 85 years of age and older |
| **Red flag** | A symptom that acts as a warning of danger. |
| **Read code** | A standardised medical code used to record health conditions and events. |
| **Younger old** | 65-74 years of age |

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