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Progressive Resistance Training in a Post-acute, Older, Inpatient Population

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A thesis submitted to the School of Postgraduate Studies, Faculty of Medicine and Health Sciences, Royal College of Surgeons in Ireland, in fulfillment of a Masters Degree of Science by Research

Supervisor(s): Professor Frances Horgan
Professor Conal Cunningham
Ms Niamh Murphy

May 2019

DECLARATION

Candidate Thesis Declaration

I declare that this thesis, which I submit to RCSI for examination in consideration of the award of a higher degree MSc in Research is my own personal effort. Where any of the content presented is the result of input or data from a related collaborative research programme this is duly acknowledged in the text such that it is possible to ascertain how much of the work is my own. I have not already obtained a degree in RCSI or elsewhere on the basis of this work. Furthermore, I took reasonable care to ensure that the work is original, and, to the best of my knowledge, does not breach copyright law, and has not been taken from other sources except where such work has been cited and acknowledged within the text.

Signed Sinéad Coleman

Student Number 14103010

Date 30th April 2019

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LIST OF ABBREVIATIONS

1RM	1-Repetition Maximum
5TSTS	5 Time Sit to Stand
ACSM	American College of Sports Medicine
AD	ankle dorsiflexion
ADL	Activities of Daily Living
AP	ankle plantarflexion
BI	Barthel Index
BIA	Bioelectrical Impedance Analysis
BMI	Body Mass Index
BMD	Bone Mineral Density
CC	Conal Cunningham (Supervisor/Statistics Guidance)
CFS	Clinical Frailty Scale
CGA	Comprehensive Geriatric Assessment
CM	Claire Murtagh (Assessor – Physiotherapist)
CN	Clinical Nutrition
CPNG	Chartered Physiotherapists in Neurology and Gerontology
DXA	Dual-energy X-ray absorptiometry
EE	elbow extension
EQ-5D	EuroQol-5D
EQ-5D AD	EuroQol 5D Anxiety/Depression
EQ-5D PD	EuroQol 5D Pain/Discomfort
EQ-5D Mobility	EuroQol 5D Mobility
EQ-5D SC	EuroQol 5D Self-Care
EQ-5D UA	EuroQol 5D Usual Activities
EQ-5D VAS	EuroQol 5D Visual Analogue Scale
EWGSOP	European Working Group on Sarcopenia in Older People
FH	Frances Horgan
g	grams
GC	Gareth Clifford (Gatekeeper)
HA	hip abduction

HE	hip extension
HF	hip flexion
I	Interview
IADL	Instrumental Activities of Daily Living
ICD_10_CM	International Classification of Diseases, Tenth Revision, Clinical Modification
ICF	International Classification of Functioning, Disability and Health
IWGS	The International Working Group on Sarcopenia
JG	Jenny Gannon (External Validator in Qualitative Study)
KE	knee extension
kg	kilograms
L	Left
LHA	left hip abduction
LHF	left hip flexion
LL	lower limb
LOS	Length of Stay
MDT	Multidisciplinary team
MM	Marie Monaghon (Assessor – Clinical Nutrition)
MN	motor neurons
MTP	metatarsophalangeal
PAC	Postacute Care
PF&S	Physical Frailty & Sarcopenia
PRT	Progressive Resistance Training
QD	Qualitative Description
QoL	Quality of Life
R	Right
RCT	Randomised Controlled Trial
RHA	right hip abduction
RHF	right hip flexion
RJ	Rachel Joy (Assessor – Clinical Nutrition)

RT	Resistance Training
SC	Sinead Coleman (Lead researcher)
SD	Standard Deviation
SL	Sophie Lang (Assessor – Physiotherapist)
SNT	Stair Negotiation Test
SPPB	Short Physical Performance Battery
STS	sit to stand
T1	Time of entry to the study
T2	Six weeks after T1
TUG	Timed Up and Go
UL	upper limb

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SUMMARY

Introduction

Many older adults are at risk of functional decline following an acute hospital admission. Many of these older adults are pre-sarcopenic or sarcopenic and are extremely vulnerable to a further deterioration of function and dependence in Activities of Daily Living ability. Progressive Resistance Training (PRT) is an intervention that involves exercising a muscle against a load that is progressively increased as the muscle strengthens. PRT has been shown to successfully target both functional decline and sarcopenia in older adults. However, the majority of this research has been performed with a healthy older community-dwelling population.

Aims and Objectives

The aim of this study was to evaluate the feasibility of using PRT in an older, postacute, inpatient population and to explore the perceptions and experiences of physiotherapists in the use of PRT in this population.

Methods

This was a mixed-methods research design. A randomised controlled feasibility study recruited appropriate older inpatients undergoing postacute rehabilitation. Feasibility measures examined were safety, recruitment, outcome measurement, adherence and retention rates and satisfaction. A range of clinical measures were used to capture changes in body structure and function, activity and participation. Assessments were performed on admission to the study and six weeks later.

The study employed a qualitative description design using semi-structured interviews with thirteen Physiotherapists from three hospitals. An interview schedule was developed, interviews were recorded and later transcribed. Key themes emerged from analysing the data using thematic analysis.

Results

Feasibility study - there were no serious adverse events, adherence rates were 63% and retention rates were 82%. Clinical measures – there were no significant differences between the two groups.

Qualitative study – Physiotherapists do not routinely use PRT with this population due to concerns of injury and reduced motivation for this intervention. Prescription and progression are usually subjective.

Conclusion

This study demonstrated that PRT is safe to use with this population. It also demonstrates that physiotherapists do not routinely use PRT as a rehabilitation intervention for this population.

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DEDICATION

To my husband Ollie and gorgeous daughters Molly, Izzy and Rosie for their patience, love and support throughout the last three years and always.

INTRODUCTION

Although Ireland has one of the youngest populations in Europe, the proportion of the population aged 65 and over is projected to increase, by 59% between 2016 and 2031, while the number of people aged 85 and over is projected to increase by 97% (Central Statistics Office, 2016). Older age cohorts are the highest users of most health and social care services, therefore reducing age-related disability is an essential public goal.

The process of ageing can cause a deterioration in cardiovascular fitness, strength, postural stability, flexibility and psychological function which can lead to a decline in functional performance in this population (Mazzeo et al, 1998). A further decline in function is common following an acute hospital admission, with the prevalence varying from 38-80% depending on the study. This is due to a combination of factors – the presence of an acute medical condition, the vulnerability of older patients to polypharmacy and nutritional deficiencies (Stott and Quinn, 2013) and low physical activity and bedrest which are common in hospitalised older patients (Smith et al, 2008). This inactivity can have detrimental effects on muscle mass, strength and physical function.

Postacute rehabilitation is a combination of recovery, recuperation and rehabilitation whose function is to further the goals of acute care (Kane, 2007). It aims to provides continuing interdisciplinary care which helps to prevent premature institutionalisations and reduce unnecessary hospital readmissions (Lee et al, 2012). Designated multidisciplinary rehabilitation units for older inpatients have been shown to provide several benefits, including a shorter length of stay (LOS) in hospital (Zelada et al, 2009), an improvement in physical function, a decreased risk of nursing home placement and a reduction in mortality (Kosse et al, 2013), an improvement in the ability to perform activities of daily living (ADL) (Landefeld et al, 1995), improved self-efficacy (McCloskey, 2004), a significant reduction in functional decline with no increase in costs (Cohen et al, 2002) and a greater likelihood of returning home and remaining at home for longer (McCloskey, 2004). Previous research carried out in this postacute rehabilitation unit examined outcomes following six weeks of inpatient rehabilitation. Results of this study showed that frail older inpatients in the rehabilitation unit improved in aspects of functional mobility, balance, exercise tolerance, health-related quality of life, frailty

and ability to perform ADLs. However, lower limb strength was shown not to improve significantly in this study (Coleman et al, 2012).

Sarcopenia is “a syndrome characterised by progressive and generalised loss of skeletal muscle mass and strength with a risk of adverse outcomes such as physical disability, poor quality of life and death” (Cruz-Jentoft et al, 2010, p413). Sarcopenia is an age-related reduction in muscle mass and quality which may contribute to several frailty symptoms, for example, weakness, low walking speed, reduced physical activity and energy expenditure, which may further lead to impaired balance, mobility and falls, thereby increasing the risk of frailty (Fried et al, 2001; Ahmed et al, 2007; Topinkova, 2008). Frailty is a syndrome which describes an older person who has existing health problems, has lost functional abilities and is likely to deteriorate further (Fairhall et al, 2008). Both of these geriatric syndromes result from incompletely understood interactions of disease and age on multiple systems and result in a variety of signs and symptoms. Other consequences of sarcopenia include a higher risk of fractures, an impaired ability to regulate body temperature, slower metabolism and a deficiency in glucose regulation (Mazzeo et al, 1998). Sarcopenia is mediated by multiple mechanisms including a sedentary lifestyle, malnutrition, alpha-motor neuron death, altered hormone concentrations and increased inflammation (Sundell, 2011). Sarcopenia is an important independent predictor of disability linked to poor balance, gait speed, falls, and fractures (Sundell, 2011), impaired ADLs (Morandi et al, 2015), the need for institutional care (Tang et al, 2018), it is also associated with a higher mortality rate (Gariballa et al, 2013).

Progressive resistance training (PRT) is a type of exercise where “participants exercise their muscles against some type of resistance that is progressively increased as their strength improves. Common equipment used for PRT includes exercise machines, free weights or elastic bands” (Liu and Latham, 2009, p2). The American College of Sports Medicine (ACSM) have recommended resistance training (RT) for older adults at a frequency of 2-4 days per week, 20-45 minutes per session and an intensity of 65-75% of maximum to significantly increase muscle strength (Mazzeo et al, 1998). The adaptations induced by RT include muscle hypertrophy, an increase in the motor unit recruitment capacity and motor unit firing rate. These neuromuscular adaptations result in improved muscle

strength and power development and is an effective intervention known to target and improve sarcopenia, as well as reducing physical disability and improving functional performance (Johnston et al, 2008; Aagaard et al, 2010; Mayer et al, 2011; Stewart et al, 2014).

Older adults can achieve similar gains to younger adults with RT (Mazzeo et al, 1998) and have demonstrated substantial adaptive plasticity both in skeletal muscle and the neuromuscular system in response to RT (Bean et al, 2004; Seynnes et al, 2004; Mickle et al, 2016; Daly et al, 2017), which can compensate for age-related declines in muscle function and lead to improved functional performance even in the oldest old (Aagard et al, 2010). Resistance training is currently the most effective intervention in slowing down this decline in muscle mass and strength, and has been shown to increase muscle mass and strength even in a frail older population (Rolland et al, 2011). Progressive resistance training has been widely used in clinical trials in healthy community-dwelling older adults and has been shown to be well tolerated and have many benefits, including an increase in muscle mass and strength (Damas et al, 2015) and functional performance (Papa et al, 2017). However, there is currently a shortage of available evidence investigating the feasibility and effects of using PRT as a rehabilitation intervention in an older, postacute, inpatient population. Liu and Latham, (2009) recommended that frail or recently medically unwell older people should be closely monitored for adverse responses to PRT, such as musculoskeletal complaints, as this has not been well documented in previous research. Examining the feasibility of tailored exercise programmes is critical in the safe implementation of these programmes in a postacute, inpatient setting. Interestingly, at the time of writing this review, the author could not find any research investigating the views and experiences of physiotherapists working in this clinical area, on the use of PRT with this population.

As older people make up the biggest segment of the population participating in rehabilitation, meeting their needs adequately is a challenge for rehabilitation services. It is vital that safe and effective interventions are being employed to optimise the rehabilitation outcomes of this population. The purpose of this research project was to evaluate the feasibility of using PRT in an older, postacute, inpatient population and to explore the perceptions and experiences of physiotherapists in the use of PRT in an older, postacute, inpatient population.

CHAPTER 1 - LITERATURE REVIEW

Introduction

The purpose of this chapter is to give an overview of the current evidence regarding functional decline following acute hospitalisation in older adults, effects of postacute rehabilitation of older adults, sarcopenia and PRT in older adults.

1.1 Acute Hospitalisation and Postacute Rehabilitation of Older Adults

1.1.1 Causes of Functional Decline during Acute Hospitalisation

Hospitalisation has been shown to result in functional decline for many older people (Creditor, 1993; Callen et al, 2004). This functional decline during an acute hospital admission is multifactorial in nature; contributing factors include lack of activity and immobility, the effects of acute illness in the context of chronic diseases, and the vulnerability of older patients to polypharmacy and nutritional deficiencies (Stott and Quinn, 2013). Volpato et al (2007) reported that pre-existing characteristics associated with the frailty syndrome are important predictors of functional decline in hospitalised older patients. These characteristics include physical and cognitive function, co-morbidity, inflammatory markers and body composition. Kortebein (2008) reported that acute hospitalisation can result in a significant decline in functional ability that is often unrelated to the medical reason for admission to hospital, for example, a neurological or orthopaedic insult. The author termed this functional decline ‘hospital-associated deconditioning ’and reported that many older adults are unable to return to independent living because of this decline.

Low physical activity and bedrest are common in hospitalised older patients (Brown et al, 2004; Smith et al, 2008, Pederson et al, 2013; Villumen et al, 2015) and can have detrimental effects on muscle mass, strength and physical function. A significant percentage of older adults may be either sarcopenic or severely sarcopenic. It has been suggested that some of these sarcopenic older adults may be close to a threshold whereby they might not recover from unanticipated and prolonged bed rest (Hirsch et al, 1990). Brown et al (2004) reported that low levels of mobility during hospitalisation is an independent predictor of poor hospital outcomes at discharge, particularly a decline in ADL function, new institutionalisation and death. Coker et al (2015) reported a reduction of 12% of 1-Repetition Maximum (1RM) knee extension as well as significant reductions in

lean muscle mass and physical function in a cohort of 19 healthy older adults, mean age 66 years, following 10 days of bedrest. Tanner et al (2015) observed age-dependent effects of five days of bedrest in their study of nine healthy older adults, mean age 66 years, and 14 healthy younger adults, mean age 22 years. The older participants lost 4% of lower limb muscle mass and 16% of knee extensor strength, while the younger participants were resistant to the effects of bed rest. The period of bedrest was followed by eight weeks of high-intensity resistance training, during which time the older participants bedrest-induced deficits were fully restored. While these results may not be generalisable to a frailer, older population with multiple comorbidities, one could assume that that effects of bedrest on this population would indeed have more pronounced detrimental results.

Hospitalisation of older people can lead to a number of adverse outcomes, including a reduction in muscle strength and aerobic capacity, vasomotor instability, a reduction in respiratory function, demineralisation of bone, urinary incontinence, loss of skin integrity and nutritional problems, such as malnutrition and dehydration. The researchers attributed these outcomes to bedrest (Creditor, 1993). Contrary to these findings, Bodilsen et al (2013) found that knee extension strength and handgrip strength remained unchanged during acute hospitalisation as a result of medical disease and the first 30 days after discharge in 46 acutely admitted older medical patients, mean age 82.7 years. In contrast, functional performance, quantified with the Timed Up and Go (TUG), improved significantly from admission to discharge and remained at the discharge level during the first 30 days after discharge. This was despite a very low level of physical activity while in hospital. Accelerometers were used to measure 24-hour activity on 30 of these participants. The mean time spent lying down was 17.4 hours, sitting 4.8 hours and walking or standing 0.8 hours.

1.1.2 Effects of Functional Decline following Acute Hospitalisation

Sager et al (1996) carried out a prospective study of 1,279 community-dwelling older patients who had been admitted to hospital with an acute illness. At discharge, 31% of the study population reported a decline in ADL function when compared with preadmission baseline. At three-month follow-up, 19% of the surviving study population reported a new ADL disability and 40% reported a new

disability in their instrumental activities of daily living (IADL). They reported that patients at greatest risk of adverse outcomes at the three-month follow-up stage were older, had difficulties with IADL pre-admission, lower mental status scores on admission and that many of these patients had subsequently been re-hospitalised. Palese et al (2016) performed a longitudinal study of 1,464 older patients who were admitted to 12 acute medical wards. Of these participants, 17.1% (n = 251) demonstrated functional decline, which was defined as a decrease of at least five points in the Barthel Index (BI). Zisberg et al (2011) performed a prospective study of 525 acutely hospitalised older adults. Forty-six percent of participants had declined in ADLs at discharge and 49% at 1-month follow-up, while 57% had declined in IADLs at follow-up. Low levels of mobility in hospital was associated with worse basic functional status at discharge and at follow-up and worse IADLs at follow-up, when compared with high levels of mobility. Covinsky et al (2003) performed a prospective, observational study of 2,293 patients aged 70 and older. They found that 35% of patients declined in ADL function between baseline and discharge, with patients over 90 years at a particularly high risk of poor functional outcomes. This included 23% of the sample who declined between baseline and admission to hospital and failed to recover to baseline function between admission and discharge and 12% of the sample who declined between hospital admission and discharge.

Sleiman et al (2009) carried out a retrospective cohort study on 1,119 acutely ill older patients admitted to an acute geriatric ward. They found that 33.8% of patients did not achieve functional recovery at discharge which was associated with higher rates of three-month mortality. Boyd et al (2008) performed a 12-month observational study of 2,279 patients who had been discharged from hospital. Of their sample, 70% had been discharged with similar or better functional status than at 2-weeks before admission. Of the remaining 799 older people who had been discharged from hospital with worse functional status than at two weeks preadmission, 41.3% had died, 28.6% had not recovered to baseline function and 30.1% were at baseline function. This was in sharp contrast to the 1,480 who had been discharged at baseline function, 17.8% had died, 15.2% had a reduced baseline function and 67% remained at their baseline function. Zisberg et al (2015) performed a prospective cohort study of 684 older adults admitted to an acute medical ward. Two hundred and eighty-two participants (41.2%) reported

functional decline at discharge and 317 (46.3%) at one month after discharge. Further analysis indicated that in-hospital mobility, continence care and length of stay were directly related to functional decline at discharge, while nutrition consumption was significantly related to functional decline at one month after discharge.

Iwata et al (2006) reported variables associated with one-year mortality were a score of two or more in the Charlson Co-morbidity Index, six or more prescribed medications at discharge, the presence of a pressure sore and a history of delirium. Functional impairment was only weakly associated with mortality at one year in patients aged 85 years and older. Baztan et al (2009) reported higher one-year mortality rates in patients who were male, had a worse preadmission functional status and a higher functional loss at admission, while a greater functional gain following rehabilitation was associated with a lower mortality. Covinsky et al (1997) reported that ADL function on admission to hospital was an important predictor of mortality and higher resource use. They found a 17.5% one-year mortality and 3% nursing home use in patients who were independent in ADL on admission to hospital, compared to a 54.9% one-year mortality and 33% nursing home use in those patients who were dependent in all ADL on admission to hospital. They also reported a 53% variance in hospital costs in this group of inpatients aged 70 years or older.

Campbell et al (2005) carried out a prospective cohort study of 1,626 older patients discharged following an acute hospital admission. They found that physical function and cognition on day 3 of hospitalisation were the best predictors of mortality, discharge destination and LOS. Inouye et al (1998) identified IADL impairment, cognitive impairment and depressive symptoms as independent predictors of 90-day and 2-year mortality in older hospitalised patients. Rozzini et al (2005) found a relationship between a loss in function prior to hospital admission for an acute illness and 6-month mortality.

1.1.3 Rehabilitation of Older Adults

People in Ireland are living longer as can be seen in the changes in the population aged over 65 which has increased by 19.1 per cent since 2011. There are approximately 705,000 people over the age of 65, with approximately 67,500 of

these over the age of 85 (Central Statistics Office, 2016). While this can be seen as a success story for public health policies and for socioeconomic development, it also presents a challenge to society to adapt, in order to maximise the health and functional capacity of older people as well as their social participation and security (World Health Organisation, 2018). Providing safe and effective patient-centred rehabilitation for our ageing population is an essential aspect of Irish healthcare. Wells et al (2003, p890) have defined rehabilitation of older people as "evaluative, diagnostic, and therapeutic interventions whose purpose is to restore functional ability or enhance residual functional capability in elderly people with disabling impairments". Mas et al (2009) reported that an important goal of inpatient rehabilitation for older adults is the achievement of maximal functional recovery following acute admission to hospital and the subsequent return of patients to their own home. The recovery process in older adults is often complex and frequently requires a longer period of time than that of younger adults. Postacute rehabilitation is a combination of recovery, recuperation and rehabilitation whose function is to further the goals of acute care (Kane, 2007). It provides continuing interdisciplinary care which helps to prevent premature institutionalisations and reduce unnecessary hospital readmissions (Lee et al, 2012).

The rehabilitation of older adults is distinguishable from that of younger adults. Older adults often present with a higher burden of co-morbid disease as well as multi-causal disabilities which require input from several specialties and disciplines to investigate and manage their medical issues and rehabilitation needs (Wells et al, 2003). The current model for medical care for older patients is based on the comprehensive geriatric assessment (CGA), which restores function through collaborative work by multi-disciplinary teams using a variety of interventions (McKelvie et al, 2018). CGA has many benefits and has been shown to reduce the rates of institutionalisation (Ellis et al, 2017) and mortality (Bachmann et al, 2010). Targeted CGA-based rehabilitation can improve function, reduce mortality and the risk of institutionalisation compared with usual care (Kosse et al, 2013). Most older people with a significant disability of recent onset have the potential to benefit from rehabilitation (Cameron and Kurrie, 2002). Mazzeo et al (1998) reported that the capacity to adapt to increased levels of physical activity is preserved in older people and regular exercise results in a number of positive changes in this population. These include physiological, metabolic, psychological and functional

adaptations which can even be elicited in the frail and very old. Participation in regular exercise is an effective modality in the reduction and prevention of several functional declines associated with ageing. Kortebein (2009) stated that physiotherapy is the most important aspect of a rehabilitation programme for deconditioned patients as the most significant deficits include lower limb muscle strength and endurance as well as basic mobility and aerobic capacity.

1.1.4 Evidence for the Effectiveness of Postacute Rehabilitation of Older Adults

Postacute care (PAC), in which rehabilitative therapy plays a key role, is essential in the promotion of functional recovery of older patients and should be provided by the interdisciplinary team (Lee et al, 2012). These authors performed a comparative study to explore the optimal intensity for rehabilitative therapy in PAC. Between July 2007 and December 2010, all patients with functional decline after acute illness hospitalisation admitted to the PAC unit of a community hospital in Taiwan were enrolled. The usual rehabilitation program, 40 minutes of moderate-intensity physiotherapy per day, was provided to all patients five days per week before April 2009. After April 2009, physiotherapy was increased to 80 minutes per day. Functional improvement was measured using CGA at admission and four weeks after admissions to the PAC unit. Overall, 458 patients (mean age: 83.4±5.5 years, all males) completed PAC services. Patients who received the higher dosage of rehabilitative therapy showed significantly better improvement in daily living activities (BI: 28.8±18.4 compared to 20.0±14.6, $p<0.001$), depressive mood (geriatric depression score short form: -0.5±1.0 compared to -0.1±0.5, $p<0.001$), and pain reduction (numerical rating scale: -2.0±2.2 compared to -0.9±2.1, $p=0.01$); but not in cognitive function (mini-mental status examination: 2.9±3.3 compared to 3.3.±5.2, $p=0.305$), or nutritional status (body mass index (BMI): 0.3±0.9 compared to 0.3±2.5, $p=0.9$). Due to the extra staffing cost that this additional physiotherapy input would involve, it would have been interesting to see if the higher-intensity group had a shorter LOS. However, LOS was not reported in this study.

Seematter-Bagnoud et al (2013) reported that those most likely to achieve improved functional outcomes following postacute rehabilitation were younger, female, lived alone and had no formal supports prior to admission, had fewer

chronic diseases and better cognition and BI scores on admission. Coleman et al (2012) reported significant improvements in balance, functional mobility, exercise capacity, ADLs, quality of life (QoL) and frailty measures in patients, mean age 82.9 years, undergoing postacute rehabilitation. However, significant gains were not found in measures of lower limb strength. Verweij et al (2018) performed a systematic review and meta-analysis of studies which provided postacute rehabilitation for older adults in out-of-hospital settings, for example, outpatient rehabilitation clinics. They reported an improvement in mobility at three months post discharge, with an average increase of 23 metres in the six-minute walk test. Bornet et al (2017) examined QoL in 167 older patients undergoing postacute rehabilitation. They reported that a greater QoL was significantly associated with higher functional status, better cognitive status and greater satisfaction with care. While poorer QoL was significantly associated with comorbidities, greater depressive symptoms and unmet spiritual needs. Multivariate linear regression indicated that depressive symptoms significantly predicted quality of life in this patient cohort.

Elphick et al (2007) performed a retrospective analysis of 230 hospitalised patients aged 90 years or over who were admitted to inpatient older person rehabilitation. They reported that 76% of those admitted from their own homes were discharged back to their own homes and almost half of the study population required no increase in social supports. They found that the BI and the number of co-morbidities present at time of admission were the best predictors of success following inpatient rehabilitation. Jones et al (2006) performed a randomised controlled trial (RCT) of 180 older inpatients. The control group received usual physiotherapy care, while the intervention group received an additional 30 minutes of individually tailored exercises, consisting mainly of strengthening and mobility exercises. They reported a significant improvement in functional abilities in those with poor functional ability at admission. They also reported a trend for the intervention to be associated with a reduction in LOS. Gosselin et al (2008) compared outcomes between adults <65 years of age and older adults during and after inpatient rehabilitation. They reported significant improvements in functional independence, balance, walking performance, pain, grip strength and psychosocial aspects in both groups. Similar benefits were derived from rehabilitation in both groups. While the older adults had maintained these

improvements at three months follow-up, the younger adults had continued to improve. The older adults in this study had a mean age of 78 years and an average LOS of 59 days.

1.1.5 Summary

Acute hospitalisation can result in a significant decline in functional ability in older adults and is associated with higher rates of mortality and institutionalisation. The capacity to adapt to increased levels of physical activity is preserved in this population. While older adults have been shown to make functional gains during postacute inpatient rehabilitation, there is a scarcity of good quality evidence in this area.

1.2 Sarcopenia

1.2.1 Defining Sarcopenia

Dr Irwin Rosenberg (1984, p1232) stated ‘‘no decline with age is more dramatic or potentially more functionally significant than the decline in lean body mass...Why have we not given it more attention? Perhaps it needs a name derived from the Greek. I’ll suggest a couple: sarcomalacia or sarcopenia’’. Sarcopenia was of course the term chosen to describe this age-related loss of muscle mass. However, until recently, there has been no widely accepted definition of sarcopenia that was suitable for use in research and clinical practice. In fact, sarcopenia has only recently been recognised as a disease entity and was given a dedicated International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) code in September 2016 (Cao et al, 2016). The International Working Group on Sarcopenia (IWGS) provided a consensus definition of sarcopenia in 2009 as “age-associated loss of skeletal muscle mass and function” (Fielding et al, 2011, p250). A practical clinical definition with consensus diagnostic criteria was then developed in 2010 and reported by the European Working Group on Sarcopenia in Older People (EWGSOP) (Cruz-Jentoft et al, 2010, p413). This new working definition of sarcopenia was reported as “a syndrome characterised by progressive and generalised loss of skeletal muscle mass and strength with a risk of adverse outcomes such as physical disability, poor quality of life and death”. Sarcopenic obesity is another recently

identified condition where both sarcopenia and obesity or increased fat mass are present, and is highly prevalent among the older population (Akishita et al, 2018). Cruz-Jentoft et al (2010) suggested that it would be useful to recognise sarcopenia as a geriatric syndrome, because similar to other geriatric syndromes such as delirium, falls and incontinence, sarcopenia also results from incompletely understood interactions of disease and age on multiple systems and result in a variety of signs and symptoms.

Sarcopenia is a condition with many causes and varying outcomes. While it is mainly observed in older people, it can also develop in younger adults. In some cases, a clear and single cause of sarcopenia can be identified. In other cases, there is no evident cause which can be isolated. The categories of primary sarcopenia and secondary sarcopenia were suggested by the EWGSOP to assist the clinician during clinical practice (Cruz-Jentoft et al, 2010). Primary sarcopenia, otherwise known as age-related sarcopenia, has no other evident cause except for ageing. Secondary sarcopenia is present when more than one cause is evident. Other causes may be i) activity-related, for example, bed rest, sedentary lifestyle or deconditioning; ii) disease-related, for example, advanced organ failure, inflammatory disease or malignancy; iii) nutrition-related, for example, inadequate dietary intake of energy and/or protein which can occur with malabsorption or gastrintestinal disorders. It may be difficult to determine if many older adults have a primary or seconadry sarcopenia as the aetiology is often multi-factorial.

The EWGSOP also suggested a conceptual staging of sarcopenia as ‘presarcopenia’, ‘sarcopenia’ and ‘severe sarcopenia’. Presarcopenia is characterised by low muscle mass without impact on muscle strength or physical performance. Sarcopenia is characterised by low muscle mass, plus low muscle strength or low physical performance. Severe sarcopenia’ is characterised by low muscle mass, low muscle strength and low physical performance. Recognising the stages of sarcopenia may help in the selection treatments and the setting of appropriate recovery goals.

1.2.2 Diagnosing Sarcopenia

Based on this working definition, the EWGSOP recommended using measurements of both low muscle mass and low muscle function (strength or

performance) in the diagnosis of sarcopenia. This is because, even though muscle mass and muscle strength are related, their trajectories of decline during ageing are different. Goodpaster et al (2006) reported that the decline in muscle strength is far greater than that predicted by the decrease in muscle mass. Also, muscle strength is a stronger predictor of adverse outcomes than muscle mass (Kim et al, 2015). Therefore, defining sarcopenia only in terms of muscle mass would be of limited clinical value (Marzetti et al, 2017). Cruz-Jentoft et al (2010) included a useful summary of measurable variables and cut-off points in their report on sarcopenia which can be used in the diagnosis of sarcopenia both clinically and in research studies under the criterion of muscle mass (Dual-energy X-ray absorptiometry (DXA), Bioelectrical Impedance Analysis (BIA)), muscle strength (handgrip strength) and physical performance (Short Physical Performance Battery (SPPB) and gait speed). They also suggested an algorithm for sarcopenia case finding in older adults, which included a cut-off point of 0.8m/s in gait speed.

1.2.3 Prevalence of Sarcopenia

The prevalence of sarcopenia has been widely reported in the literature. The EWGSOP reported a prevalence of sarcopenia of 1-29% in community-dwelling populations, 14-33% in long-term care populations and 10% in the acute hospital-care population, in a review article which selected well-defined populations >50 years (Cruz-Jentoft et al, 2014). Sanchez-Rodriguez et al (2014) reported a prevalence of sarcopenia of 46% in a sample of 99 older patients, mean age 84.6 years, undergoing rehabilitation in a subacute geriatric unit. A review performed by Sanchez-Rodriguez et al (2016) reported a rate of sarcopenia of 50% in older adults undergoing postacute care and rehabilitation. The majority of studies included in their review used the EWGSOP criteria for diagnosis of sarcopenia and used BIA to measure muscle mass, handgrip to measure muscle strength and gait speed to measure physical performance. Ages ranged from 61.5 ±6 to 84.6±6.6 years.

Previous researchers have suggested that the prevalence of sarcopenia increased with age. In a sample of 730 community-dwelling older adults, Volpato et al (2014) reported a prevalence of sarcopenia of 2.6% and 1.2 % respectively in women and men aged 70-74 years. This increased to 31.6% and 17.4% respectively in women and men aged over 80 years. Other studies have reported the prevalence of

sarcopenia in relation to gender. Landi et al (2012) reported that sarcopenia appeared to be related to gender in a sample of 146 nursing home residents, with males more commonly affected than females. While Patel et al (2013) showed a higher prevalence of sarcopenia and severe sarcopenia in women than in men, in a study of 1,784 community-dwelling older adults. Other studies that reported gender found no significant association with sarcopenia prevalence (Landi et al, 2013; Lee et al, 2013). Higher rates of sarcopenia have been reported in several patient groups with varying disease states. Srikanthan et al (2010) reported a higher prevalence of sarcopenia in patients with Type 2 Diabetes Mellitus in an analysis of 14,528 adult Americans. Yoshimura et al (2017) reported a prevalence of sarcopenia of 8.2% and determined that 57.3% of these were complicated by osteoporosis, in a study investigating mineral bone density (BMD) of 1,099 community-dwelling older adults. The authors also reported that the prevalence of osteoporosis in this cohort was correlated with the future onset of sarcopenia, with an odds ratio of 2.99. While Di Monaco et al (2011) also reported a strong association between sarcopenia and osteoporosis with an odds ratio of 1.8 in a large sample of older women post hip fracture.

1.2.4 Causes of Sarcopenia

Skeletal muscle accounts for approximately 40% of bodyweight and is therefore the largest organ in the body (Perkisas et al, 2016). Normal ageing is associated with a progressive loss of muscle mass from approximately 40 years of age, at about 8% per decade until the age of 70 years, after which the loss increases to 15% per decade (Grimby et al, 1983). Therefore, between 40 and 70 years, healthy adults lose an average of 24% of muscle. A 10-15% loss of leg strength per decade is seen until 70 years of age, after which a faster loss, ranging from 25% to 40% by decade, occurs (Nyun Kim and Mook Choi, 2013). Many factors, including low physical activity, chronic illness, inadequate nutrition and the process of ageing itself have been associated with this loss of muscle strength and mass.

Perkisas et al (2016) described specific changes in muscle mass and muscle architecture, neuronal and hormonal changes as the four cornerstones of the complex relationship between muscle mass and muscle strength in the sarcopenic elderly. Changes in muscle architecture includes muscle fibre atrophy due to age-related modifications, denervation of Type II muscle fibres, an impairment of

protein function which causes a reduction in force generation, shorter muscle fibre length in older people which alters the muscle-specific length-tension and force-velocity relationships, a reduction in muscle quality with age, elevated adipose tissue deposition, tendon stiffness, an overall reduction in blood flow and oxygen delivery to muscle and a reduction in mitochondrial turnover. Age-related neuronal changes include cortical atrophy, altered neurochemistry, reduced motor cortical excitability and altered agonist-antagonist co-activation strategies, a reduction in spinal excitability and a reduction in the number and firing rate of motor units, all of which are linked with reductions in motor performance. Age-related hormonal changes include a reduction in the number of oestrogen receptors in postmenopausal women, a decline in testosterone in older men and low levels of Vitamin D in both older women and men (Perkisas et al, 2016).

There are several risks factors which may contribute to the development of sarcopenia. All conditions related to reduced muscle activity predispose to sarcopenia, for example, a sedentary lifestyle, hospitalisation, immobilisation and prolonged bed rest. Certain diseases can also promote the development of sarcopenia through chronic inflammation and metabolic abnormalities, such as endocrine disorders, malignancies, chronic inflammatory diseases, and advanced organ failure (Marzetti et al, 2017). Nutrition has a great impact on muscle health by influencing myocyte homeostasis and energy metabolism. An inadequate intake of energy and/or proteins due to malabsorption, gastrointestinal disorders or the use of anorexigenic drugs has been linked to sarcopenia (Landi et al, 2016).

1.2.5 Relationship of Sarcopenia to Disability and Co-morbidity

Sarcopenia is associated with many negative health-related events in older people. Mazzeo et al (1998) reported that consequences of sarcopenia included a reduction in muscle strength, a higher risk of falls and fractures, an impaired ability to regulate body temperature, slower metabolism, a possible deficiency in glucose regulation and an overall reduction in functional capacity. Muscle mass decrease is directly responsible for functional impairment with loss of strength, increased likelihood of falls and loss of autonomy (Janssen et al, 2002). Arango-Lopera et al (2013) discussed the impact of sarcopenia on several physiological and psycho-social systems i) inability to independently perform tasks of daily living, ii) frailty and increased risks of falls, iii) loss of independent living and related

depression/social isolation, iv) physical inactivity (sedentarism), v) increased risk of chronic diseases, vi) increased risk of all-cause mortality. Kilavuz et al (2018) reported that sarcopenia was significantly associated with depressive symptoms and functional disability in 861 ambulatory community-dwelling elderly.

Several studies have found an association between the presence of sarcopenia with an increased risk of falls and fractures. Marzetti et al (2017) linked sarcopenia to falls, physical frailty and disability. In a study conducted in a community population, sarcopenic participants were over three times more likely to fall during a followup of two years than those without sarcopenia, regardless of age, gender and other possible confounding factors (Landi et al, 2012). Sarcopenia has long been considered to confer a high risk for falls, hospitalisation and mortality and to be synonymous with disability and co-morbidity (Lang et al, 2009). Zhang et al (2018) reported a significant association between sarcopenia and fractures among community-dwelling older people but only for males.

1.2.6 Sarcopenia as a Predictor of Dependency, Hospitalisation, Mortality and Institulisation

Sanchez-Rodriguez et al (2014) performed an observational study on 99 older patients, mean age 84.6 years, undergoing inpatient rehabilitation in a subacute geriatric unit. They reported a prevalence of sarcopenia in 46% of their sample. They found that the sarcopenic group had a worse baseline functional status but achieved similar functional improvements during the period of inpatient rehabilitation when compared to the non-sarcopenic group. All participants underwent a further period of three months of rehabilitation at home, and the non-sarcopenic group demonstrated higher functional gains during this time. There was no difference between groups in mortality rates at three months. Morandi et al (2015) observed a sample of 280 older inpatients receiving rehabilitation. Patients were mainly female (66%) with a mean age of 82±7 years. The mean probability of sarcopenia overall was 60%. The probability of sarcopenia was significantly associated with an overall worse functional status at discharge based on total BI score and the ability to walk at discharge as measured with the BI walking mobility subitem.

Gariballa et al (2013) assessed 432 acutely ill hospitalised older patients for sarcopenia using the EWGSOP diagnostic criteria. Compared with patients without sarcopenia, those diagnosed with sarcopenia 44 (10%) were more likely to be older, have more depression symptoms and lower serum albumin concentration. The length of hospital stay was significantly longer in patients diagnosed with sarcopenia (13.4±8.8 days) compared with patients without sarcopenia (9.4±7 days). The risk of non-elective readmission in the six months follow up period was significantly lower in patients without sarcopenia compared with those diagnosed with sarcopenia (55% versus 32%). The death rate was also lower in patients without sarcopenia compared with those with sarcopenia (10% versus 27%). Results from the Health, Aging and Body Composition Study (Health ABC Study) demonstrated that low muscle strength, low muscle density and low physical performance, but not muscle size or lean muscle mass, increased the risk of hospital admission in a sample of 3,011 older adults (Cawthorn et al, 2009). Legrand et al (2014) also demonstrated that physical performance and muscle strength are strong predictors of mortality, hospitalisation and disability in people aged 80 years or older, in a sample of 560 older adults, mean age 84 years.

Cerri et al (2015) reported a high prevalence (21.4%) of sarcopenia in a sample of 103 acutely ill hospitalised older patients (mean age 84.2 years) which was associated with an increased risk of mortality in the three months post-discharge period. The ilSIRENTE prospective cohort study of 364 community-dwelling older adults (median age 84.2 years) found that low physical performance, as measured by the SPPB, and not multimorbidity was predictive of mortality over a 10-year follow-up period (Landi et al, 2016). The InCHIANTI study reported reported a 10.2% prevalence of sarcopenia in a sample of 538 community-dwelling older adults, mean age 77.1 years. The presence of sarcopenia was assessed using the EWGSOP phenotype and was associated disability, hospitalisation and mortality (Bianchi et al, 2016). Jang et al (2018) conducted comprehensive geriatric assessments for 1,379 community-dwelling older adults, mean age 76 years. Sarcopenia was diagnosed using the Asian Working Group consensus algorithm, which combined grip strength, gait speed and muscle mass. They found that the presence of sarcopenia could predict death or institutionalisation, having adjusted for age and gender. Tang et al (2018) reported a prevalence of sarcopenia of 9.5% among 728 older community-dwelling adults in Taiwan, mean age 73.4 years.

Those with a diagnosis of sarcopenia were older, frailer, more obese and demonstrated poorer physical performance. They also had a significantly higher risk of all-cause mortality, falls, emergency department visits, institutionalisation, and hospitalisation.

1.2.7 Sarcopenia, Frailty and Ageing

The incidence of sarcopenia increases with age and will become more prevalent as our population ages (Klein et al, 2005). Many authors believe that sarcopenia is a critical factor in the cause of frailty (Ahmed et al, 2007; Fried et al, 2001; Topinkova, 2008; Watson, 2008). Frailty is a geriatric syndrome which describes an older person who has existing health problems, has lost functional abilities and is likely to deteriorate further (Fairhall et al, 2008). Several attributes of frailty also apply to the ageing process. As people age, they accumulate impairments in multiple physiological systems, therefore becoming increasingly vulnerable to adverse outcomes, making this process complexly linked to the ageing process (Bergman et al, 2007). These accumulated effects lead to a loss of reserve capacity in skeletal muscle mass which results in an increased sense of effort for a given exercise intensity (Lang et al, 2009). This causes older adults to avoid exercise as the perception of exercise effort increases. This, in turn, creates a vicious cycle which results in a decline in exercise performance, a decrease in resting metabolism and a reduction of total energy expenditure.

The majority of frailty scales point to physical function impairment as the central determinant of vulnerable health status. This emphasis on physical function and performance shows significant overlap with sarcopenia which has lead to the concept of muscle wasting as the biological substrate for the development of physical frailty. The two conditions, physical frailty and sarcopenia have recently been merged into a new entity, physical frailty and sarcopenia (PF&S) and have been defined by the following parameters – low muscle mass, low physical performance and an absence of major mobility disability (Cesari et al, 2017). Calvani et al (2018) have recently published a study protocol aiming to identify specific biomarkers which will assist in the assessment of PF&S in clinical and research settings.

1.2.8 Treatment Strategies for Sarcopenia

Kuzuya et al (2018) have recently developed guidelines based on previous research into interventions which could be used to prevent or delay the onset of sarcopenia. They recommended a diverse diet with an appropriate daily protein intake of at least 1.0g/kg and an active lifestyle with regular exercise. Muhlberg and Sieber (2004), Rolland et al (2011) and Arai et al (2018) have discussed the treatment strategies for sarcopenia under three distinct headings – nutrition, pharmacological and exercise.

i) Nutrition – reduced food intake, particularly protein intake, has been shown to result in weight loss and a decrease in muscle mass synthesis (Vanitallie, 2003). As a result, the dietary requirements of protein and amino acids may be higher in older people than in young adults (Walrand and Boirie, 2005). It has been recommended that healthy adults require 0.83grams(g) of protein/kilogram(kg)/day (Rand et al, 2003), older people require 0.89g of protein/kg/day (Campbell et al, 1996) and 1.3g of protein/kg/day in acute conditions, for example, hospitalisation (Gaillard et al, 2008). A review carried out by Arai et al (2018) reported that nutritional interventions, which ranged from 3g of essential amino acids twice daily to 12g of protein plus 7g of essential amino acids daily, extending for at least three months might contribute to increases in muscle strength and recommended further research to determine it's effect on muscle mass and physical performance.

ii) Pharmacological - previous studies have reported an increase in muscle mass (Wang et al, 2004) plus strength (Dobs et al, 2002) as a result of androgen supplementation therapy in men with decreased gonadal function and postmenopausal women. However, neither of these cohorts were diagnosed with sarcopenia. A review by Yoshimura et al (2017) found only one study that examined the effects of drug therapy on older people with sarcopenia. This RCT found that older women who were given 50mg of selective androgen receptor modulator for six months showed a greater increase in lean body mass at three and six months but there was no significant difference in muscle strength and physical

performance than the placebo group in the study (Papanicolaou et al, 2013).

iii) Exercise therapy – there is an abundance of evidence to support the use of exercise therapy, particularly PRT, in the treatment of sarcopenia. This will be discussed in more detail in the Section 3.

1.2.9 Summary

Sarcopenia is an age-related loss of skeletal muscle mass and strength and is associated with physical disability, poor quality of life, death and institutionalisation. It has been shown to be highly prevalent in older adults in both acute and community-dwelling populations. Sarcopenia is accelerated by many factors including low physical activity, chronic illness and inadequate nutrition. The principle treatment strategies for sarcopenia therefore are exercise, pharmacological management and nutrition.

1.3 Progressive Resistance Training (PRT)

1.3.1 Defining Progressive Resistance Training

Resistance training is an essential intervention for improving physical function and preventing acute sarcopenia in older adults (Cadore et al, 2014). Continual improvements in muscle strength require a progressively increasing resistance as the individual becomes stronger, regardless of age or health status (Kraemer et al, 2002). Progressive resistance training is a “type of exercise where participants exercise their muscles against some type of resistance that is progressively increased as their strength improves. The exercise is usually conducted two to three times per week at moderate to high intensity by using exercise machines, free weights or elastic bands” (Liu and Latham, 2009, p2). Muscle strength has been shown to increase after only a few days of RT, while it can take six to eight weeks for muscle mass to increase (Rolland et al, 2011). Clark and Manini (2008) explained this disassociation between muscle mass and strength. They reported that the increased strength observed during the early phases of RT occurs before the exercise stimulus can elicit gross morphological changes in muscle, which suggests that short-term gains in strength are not related to factors associated with the intrinsic capacity of the muscle itself. They suggested that RT improves the excitatory drive from the motor cortex, excitation-contraction uncoupling, motor unit recruitment, neuromuscular transmission, muscle morphology and

architecture. They recommended that muscle mass should not be used as an intermediate endpoint in interventions designed to improve functional or physical capacity. Martinez-Velilla et al (2016) performed a systematic review of early rehabilitation in older hospitalised patients. They recommended that RT programs should be performed starting with light loads (i.e., 20-30% of patients' maximal load) and progressing to moderate to heavier loads (60-80% of patients' maximal load). They also recommended that RT prescription should include explosive mode contractions into the strength training program, as skeletal muscle power has been strongly associated with the functional capacity in elderly populations and should include exercises in which daily activities are simulated, such as the sit-to-stand exercise to optimise the functional capacity of this cohort.

1.3.2 Benefits of PRT for Older Adults

Ageing is characterised by a gradual loss of spinal motor neurons (MN) due to apoptosis, which leads to a decline in the number and size of muscle fibres. This results in impaired muscle performance which in turn leads to a reduced functional capacity in everyday tasks (Aagard et al, 2010). While this decline in spinal MNs is not preventable, RT can induce adaptive changes in muscle and central nervous system function that can largely compensate for the age-related loss of MNs. Resistance training promotes hypertrophy through an increase in muscle protein synthesis (Damas et al, 2015), inducing substantial gains in muscle mass and strength, while also providing a protective effect against many of the cellular and molecular changes associated with muscle wasting (Reeves et al, 2006). A recent systematic examined the effects of RT on frail older adults (Lopez et al, 2018). They included 16 studies in their review. Resistance training was performed on it's own or in combination with other exercise modalities, including balance, endurance or flexibility. Frequency of interventions ranged from 1–6 sessions per week, with a training volume of 1–3 sets of 6–15 repetitions and intensity ranging from 30–70%1RM. They reported significant enhancements of muscle strength (6.6-37%), muscle mass (3.4-7.5%) and functional outcomes (4.7-58.1%). Papa et al (2017) concluded following a systematic review that older adults should be encouraged to participate in PRT because of the large number of benefits, including improvements in gait speed, static and dynamic balance and fall risk reduction. Liu and Latham (2009) performed a systematic review of 123 trials. They concluded that older people would benefit from doing PRT two to three times

per week. Gains would include a reduction in physical disability, and improvements in function and muscle strength. They also recommended that frail or recently medically unwell older people should be closely monitored for adverse responses to PRT, such as musculoskeletal complaints, as this has not been well documented in previous research. Johnston et al (2008), Aagaard et al (2010), Mayer et al (2011) and Stewart et al (2014) have reported that RT is an effective intervention known to target and improve sarcopenia and functional capacity by stimulating muscle hypertrophy and increasing strength. Caserotti et al (2008) performed a study on untrained old (60-65 years) and very old (80-89 years) women who had significant deficits in rapid force capacity at baseline. The subjects participated in a 12-week programme of explosive-type heavy RT. Both groups made significant improvements in rapid muscle force capacity, with the very old group making up to twice the improvements of the old group. While there have been many studies performed which have investigated the effect of RT in relation to improvements in muscle strength and function, their feasibility in the practical clinical context requires further investigation (Valenzuela et al, 2018).

Benefits of RT have also been demonstrated in subjects over 90 years of age. Fiatarone and Evans (1990) performed a study investigating the effects of an 8-week high-intensity RT intervention in frail, institutionalised older adults, mean age 90 years. Quadriceps strength gains averaged 174% ± 31% (mean ± SEM), while mean tandem gait speed improved 48% after training in the 9 subjects who completed training. RT has been shown to provide benefits to different clinical groups, from female patients with fibromyalgia (Kingsley et al, 2010), patients with a neck of femur fracture (Mangione et al, 2010) and arthritis (Latham and Liu, 2010). Li et al (2018) performed a systematic review examining the effect of RT on cognitive function in older adults. They reported that RT had a positive effect on executive function and global cognitive function but minimal positive effects on memory and attention.

1.3.3 Benefits of PRT for Hospitalised Older Adults

There has been extensive research performed in the use of PRT in a healthy, community-dwelling older population (Marques et al, 2017; LaStayo et al, 2017; Villanueva et al, 2015). However, there have been very few studies performed in the postacute, frail, older inpatient population, which included PRT as an

intervention to improve muscle strength and function. Mallery et al (2003) investigated the feasibility of RT performed in bed by older, acutely ill, hospitalised patients. This intervention was found to be both feasible in terms of participation and adherence. Other authors have shown that RT performed in bed could be beneficial in preventing loss of muscle mass and strength during periods of disuse (Akima et al, 2000; Kawakami et al, 2001).

Latham et al (2001) completed a two-phase study of older people recruited from a geriatric rehabilitation unit. The first phase comprised five participants who completed daily knee extension strengthening exercises at 50-80% of 1RM for the duration of their hospital stay. Three sets of eight repetitions were performed with three seconds of rest between each extension and one minute of rest between each set. This was in addition to routine physiotherapy, including gait re-education, balance retraining and functional retraining. All five participants, mean age 86 years, had a high level of compliance with the exercise programme and reported it to be an acceptable intervention. Phase two involved a RCT of 20 patients from the same unit, mean age 81 years and mean length of stay was 1.7 weeks. The same exercise protocol was used for the intervention group as in Phase One. The control group received ongoing physiotherapy during their hospital admission. This study had some limitations: it was not powered to detect effect changes, however the intervention group demonstrated a large improvement in knee extensor strength compared to the control group and a larger mean improvement in all of the performance measures. Also, neither the assessors or participants were blinded during the study which could have affected bias. There were no adverse events reported in either phase of the study. The authors recommended further research to determine if PRT is safe and effective in improving health outcomes in frail older inpatients.

Suetta et al (2004) performed a RCT comparing the effects of 12 weeks of standard home-based rehabilitation, unilateral neuromuscular electrical stimulation and unilateral RT of the operated side in the early postoperative stage of patients with a unilateral hip replacement due to primary hip osteoarthrosis. The RT group performed leg press and seated knee extension exercises, 10 repetitions, three sets, progressing intensity from 50 to 80% of 1RM during the course of the study. The RT group had a shorter LOS (37%) than the standard rehabilitation group,

and an increase in muscle mass and functional measures of gait speed, stair climb and chair rise, while the standard rehabilitation group showed no improvements in these measures.

Tibaek et al (2014) carried out a single-blind RCT investigating the effects of routine rehabilitation with/without additional RT in older hospitalised patients, mean age 79 years. Participants in the RT group performed an additional RT four times per week, 12-15 repetitions, three sets at 60-70% of 1RM. Intensity and progression was assessed using the participant's perceptions of difficulty using the Modified Borg Scale. Exercises included hip and knee extension, sit to stand (STS), walking sideways, heel raise, resistance was provided using ankle weights, elastic bands or weighted vest. Significant improvements in the 10-m walk test ($P < 0.01$) and BI (walking) ($P = 0.01$) were demonstrated within the treatment group but not in the control group. Both groups had significant improvements in the TUG, 30-second chair-stand (modified) and BI (transfer and walking). However, no significant difference was found between groups except for the BI (stairs) ($P = 0.05$). Analysis by the mixed-effects model showed that the treatment group improved more than the control group in all outcome variables. Study limitations included: missing data due to dropouts and the inability to complete some of the outcome measures; the practicalities of the acute clinical setting – the authors felt that high intensity training was not appropriate for this cohort, the use of elastic bands may not have provided sufficient resistance, the authors also felt that the expected LOS for this cohort may not be sufficient to achieve the positive effects of RT. Donald et al (2000) performed an RCT on 54 older patients in a geriatric rehabilitation unit. Patients received either conventional care only or conventional care and additional RT. This was performed on the hip flexors and ankle dorsiflexors, using the maximum weight that the patient could lift, three sets of 10 repetitions twice daily for the duration of their hospital stay. The authors reported that the additional RT was tolerated by 73% of the participants. They did not find any significant difference in the number of falls, LOS or discharge destination between the two groups.

There are currently two interesting RCTs awaiting completion and publication in the clinical area of RT older medical patients. Martinez-Velilla et al (2015) published an RCT protocol, which will investigate the functional and cognitive

effects of early physical activity for older hospitalised patients. Patients will be randomised to a control group of usual care or an intervention group who will participate in a multicomponent exercise training programme. Exercises will consist of supervised PRT, balance training and walking for 5-7 consecutive days for 20 minutes twice per day. PRT will be performed using weight machines, 2-3 sets of 8-10 repetitions at an intensity of 30-60% of 1RM. Pederson et al (2013) are comparing the effects of PRT on a control group (usual care) and an intervention group who will receive PRT during their hospital stay which will continue following discharge home for four weeks. The intervention group will receive daily supervised PRT, on weekdays, while in hospital and three times per week for four weeks after discharge. Seated lower limb strengthening exercises will be performed at an intensity of 60-70% of 1RM, three sets of 12 repetitions with a 2-minute rest in between sets. These will progress to STS and standing heel raises using a weighted vest. Outcome measures have been chosen to assess mobility, knee extension strength, STS, gait speed, grip strength and ADLs.

1.3.4 Multimodal Exercise Programmes

Cadore et al (2014) performed a 12-week RCT of frail institutionalised nonagenarians. The intervention group performed twice weekly muscle power training (8-10 reps at 40-60% of 1RM) in combination with balance and gait retraining. The control group participated in 30 minutes of mobility exercises four days per week. While this was a small sample size (n=24), the intervention group demonstrated significant improvements in the TUG, balance, chair rise, muscle mass and a lower incidence of falls. Similar results have been reported by Lord et al (2003) and Binder et al (2002). Freiberger et al (2012) performed an RCT of 280 community-dwelling older adults, mean age 76.1 years, using a control group (no intervention) and three different intervention groups: strength and balance group (SB), fitness group (SB and endurance training) and multifaceted group (SB and fall risk education). Interventions lasted 16 weeks and included two 1-hour sessions per week. Resistance training consisted of progressive exercises for upper and lower body strength using dumbbells and body weight. Exercises were progressed using the self-perceived exertion scale. Approximately 84% of each group attended at least 24 of the planned 32 sessions. No significant adverse events were reported during the study. Improvements in physical performance

(walking speed, balance and mobility) were reported in the SB and fitness groups with gains lasting up to two years after the intervention. However, there was no significant difference in the number of falls and fall-related psychological outcomes compared to the control group.

Gianoudis et al (2014) performed a 12-month community-based RCT in 162 older adults, mean age 67 years, with risk factors for falls and/or low BMD. The intervention group underwent high-velocity PRT combined with weight-bearing impact exercises and challenging balance/mobility training three times per week. Significant gains in femoral neck and lumbar spine BMD, muscle strength, functional muscle power (timed stair climb) and dynamic balance (four square step test, sit-to-stand) were reported when compared to usual care controls. Silva et al (2013) performed a meta-analysis of 12 RCTs investigating multimodal exercise programmes in older adults residing in long-term care facilities. Findings revealed that combined resistance and balance training programs were effective at preventing falls (RR 0.71; 95% CI 0.55–0.90), with the strongest effects observed with long-term (>6 months) programs with a frequency of at least two to three sessions per week.

1.3.5 Prescription of PRT

It is recommended that all older adults achieve 150 minutes of moderate-intensity aerobic activity plus muscle-strengthening activities for at least two days per week (Chodzko-Zajko et al, 2009). The intensity and duration of physical activity should be low for deconditioned older adults or those with physical function limitations and increased slowly as tolerated (US Department of Health and Human Services, 2008). Frail individuals may need to commence with muscle strengthening and balance exercises prior to performing aerobic training activities (Lee et al, 2017). A meta-analysis performed by Peterson et al (2010) investigating the prescription of RT programmes for older adults found a large range of prescription properties. Length of training ranged from six to 52 weeks (mean duration = 17.6 ± 8.6 weeks). Frequency from one to three times per week (mean = 2.7 ± 0.5 days/week). Intensity from 40% to 85% of 1RM (mean = 70 % ± 12.7 1RM). The number of sets per exercise session ranged from one to six sets for each individual muscle (mean = 2.5 ± 1.0 sets). The number of exercises performed ranged from five to 16 (mean = 8.3 ± 2.1 resistance exercises). The rest period

between sets ranged from 60 to 360 seconds (mean = 110 ± 25 seconds). Compliance, defined as the percentage of exercise sessions attended, ranged from 85 to 100%.

Fiatarone et al (1994) performed a randomised, placebo-controlled trial comparing PRT, multinutrient supplementation, both interventions, and neither in 100 frail nursing home residents, mean age 87 years, over a 10-week period. Progressive resistance training sessions lasting 45 minutes were performed three days per week, with a rest day between each session, on hip and knee extensors at an intensity of 80% of 1RM. Strength testing was repeated every two weeks to establish a new baseline. Each repetition lasted six to nine seconds, with a one- to two-second rest between repetitions and a two-minute rest between the three sets of eight lifts. Muscle strength increased significantly by 113 ±8 % in the subjects who underwent exercise training, as compared with 3 ±9 % in the non-exercising subjects. Gait velocity increased by 11.8 ±3.8 % in the exercisers but declined by 1.0 ±3.8 % in the non-exercising subjects. Stair-climbing power also improved in the exercisers as compared with the non-exercisers (by 28.4 ±6.6 % versus 3.6 ±6.7 %). Cross-sectional thigh-muscle area increased by 2.7 ±1.8 % in the exercisers but declined by 1.8 ±2.0 % in the non-exercisers. The nutritional supplement had no effect on any primary outcome measure. Seynnes et al (2004) performed an RCT investigating the dose-response effect of a 10-week knee extensor RT programme on institutionalised older adults, mean age 81.5 years. Subjects were in one of three groups – high intensity 80% of 1RM, low-moderate intensity 40% of 1RM and weight-free placebo group. Exercises were performed three times per week. Knee extensor strength and endurance, stairclimbing power and chair-rise time improved significantly in the high and low-moderate intensity groups compared with the placebo group. Knee extensor strength and endurance and the 6-Minute Walk Test were significantly better in the high intensity group compared to the low-moderate group.

In an RCT of healthy community-dwelling older women, De Vreede et al (2005) prescribed RT exercises for all major upper and lower limb muscle groups. Three sets of ten repetitions of exercises were performed using three different resistances of elastic bands or dumbbells 0.5-8kg or ankle weights 0.25-10kg or weighted vest with 1-10kg. Intensity of the load was prescribed using a perceived

exertion rating scale with exercises programmes set initially at 7-8 on a 10-point scale (1=very, very light; 10=very, very hard), and progressed subjectively by the participants subjectively by the participants if the exercise was rated as only “somewhat hard”. In this RCT, there were three groups, RT group, a functional-task exercise group and a control group. Exercises were performed three times per week for 12 weeks. Functional task performance, knee extensor strength, handgrip strength, elbow flexor strength and knee extension were measured at baseline, at end of training and six months after training. Functional task performance increased significantly more in the functional-task exercise group than the RT group, these improvements were maintained six months after training. Knee extension and elbow flexor strength increased significantly more in the RT group than the functional-task exercise group. This study demonstrated an improvement at impairment level in the RT group, however this did not translate to improvements in functional performance.

Singh et al (2005) compared the effects of a high-intensity RT programme (80% of IRM) to a low-intensity RT programme (20% or 1RM) in older community-dwellers. Training occurred three times per week for eight weeks. The high-intensity group performed significantly better with an increase in muscle strength of 37%±3, while the low-intensity group demonstrated a 6%±1 increase in muscle strength. Stec et al (2017) performed a randomised, four-arm efficacy trial using exercise prescriptions varying in intensity, frequency, and contraction mode/rate. The four groups were: 1) a high-resistance concentric-eccentric (H) training three days per week (HHH); (2) H training two days per week (HH); (3) three days per week mixed model consisting of H training two days per week separated by 1 bout of low-resistance, high-velocity, concentric only (L) training (HLH); and (4) two days per week mixed model consisting of H training one day per week and L training one day per week (HL). Sixty-four subjects (65.5±3.6 years) completed the trial. All participants completed four weeks of pre-training consisting of three days per week followed by three weeks of randomised RT. The HLH prescription provided the maximum gains in thigh muscle mass, knee extension strength and total body lean mass. The HL prescription induced minimal muscle regrowth and generally lesser gains in muscle performance when compared with the other prescriptions. The authors concluded that older adults benefit greatly from two days per week

high-intensity RT, and may further benefit from inserting an additional weekly bout of low-load, explosive RT.

In a systematic review, Cadore et al (2014) found that moderate to high (65-80% of 1RM) training intensities lead to greater strength gains, while lower intensities (40-60% of 1RM) combined with high velocity movements will optimise the power output in older adults. They also recommended two to three training sessions per week as this leads to greater strength gains when compared to just one session per week. Sullivan et al (2007) performed a double-blind RCT which examined the effects of RT in a frail older community-dwelling population who participated in a 12-week PRT programme, of varying intensities. While this study was limited by a small sample size, greater gains in muscle strength were found in the group who progressed from 20% to 80% of 1RM compared to the group who remained at 20% of 1RM throughout the study. No adverse events were noted during the study.

1.3.6 PRT and Nutrition

Rosendahl et al (2006) carried out an RCT of 191 institutionalised older adults, who were dependent in ADLs, to investigate the effects of a high-intensity functional exercise program on balance, gait ability, and lower-limb strength. Participants in the exercise group were also given a protein-enriched energy supplement immediately after the exercises to investigate the impact on the effects of the training. The high-intensity functional exercise program consisted of 29 sessions over three months, with exercises performed at 8-12 repetition maximum. The exercise group had improved significantly in self-paced gait speed compared with the control group (mean difference 0.04 metres/second, $p = 0.02$) at three months. At six months, there were significant improvements in the exercise group in balance (1.9 points, $p = 0.05$), self-paced gait speed (0.05 metres/second, $p = 0.009$), and lower-limb strength (10.8 kg, $p = 0.03$). No interaction effects were seen between the exercise and nutrition interventions.

Thomas et al (2016) and Daly et al (2016) have performed systematic reviews to investigate the effects of protein supplementation on RT in older adults. While RT has been shown to provide significant effects on muscle strength and functional performance, protein supplementation does not significantly enhance the effects of

PRT in older adults. Similarly, it appears that the amount of protein intake does not augment the effects of RT in older people. In a 12-week trial of older adults participating in RT three times per week plus daily protein intake of 0.9g/kg/day or 1.3g/kg/day, there were no differences found between the two groups in body composition, muscle mass or serum lipid-lipoprotein profiles (Sullivan et al, 2007).

1.3.7 Summary

Progressive resistance training is an exercise intervention where participants exercise against resistance which is progressively increased as strength improves. The optimal intensity and frequency of PRT has not yet been determined in older populations. Older adults have been shown to make significant gains in muscle strength and physical function following PRT. However, the majority of this research has been carried out in healthy community-dwellers.

1.4 Summary of Literature Review

Many older people who present to hospital for an acute medical condition are sarcopenic, frail and at risk of functional decline both during and following this period of hospitalisation. Postacute inpatient rehabilitation has been shown to provide many functional benefits for this patient cohort. PRT has been shown to deliver many benefits in older people, including an increase in muscle mass, strength and functional performance. However, most of this research has been performed in older healthy community-dwelling populations. There is also a lack of research in the area of physiotherapist's experiences and perceptions of prescribing and including PRT as part of their routine rehabilitation for older postacute inpatients. The aim of this research study was:

i. to evaluate the feasibility of using PRT in an older, postacute, inpatient population
ii. to explore the perceptions and experiences of physiotherapists in the use of PRT in an older, postacute, inpatient population.

To meet the first objective, a randomised controlled feasibility trial was carried out in a postacute inpatient geriatric rehabilitation unit. The control group received routine inpatient rehabilitation only. The intervention group received routine

inpatient rehabilitation, as well as, twice weekly PRT for a period of six weeks. Primary outcome variables used were measures of clinical trial feasibility: safety, recruitment, properties of outcome measures used, adherence rates, retention rates and satisfaction rates. Secondary outcome measures used were upper and lower limb dynamometry, the Timed Up and Go (TUG), the Stair Negotiation Test (SNT), the Clinical Frailty Scale (CFS) and the EuroQol-5D (EQ-5D). To meet the second objective, a series of qualitative semi-structured interviews were performed which examined the perceptions and experiences of physiotherapists, working with older people in postacute rehabilitation, in relation to PRT.

CHAPTER 2 – RANDOMISED CONTROLLED FEASIBILITY STUDY IN THE USE OF PROGRESSIVE RESISTANCE TRAINING IN A POSTACUTE OLDER INPATIENT POPULATION

The purpose of this chapter is to describe the methodology and to present the results of the quantitative component of this study - Randomised controlled feasibility study in the use of progressive resistance training (PRT) in a postacute older inpatient population.

METHODOLOGY

2.1 Aims and Objectives

2.1.1 Research Aims

- The primary aim of this study was to determine the feasibility of using a six-week PRT programme in a postacute older inpatient population;
- The secondary aim was to evaluate changes in strength, function and quality of life (QoL) following six weeks of PRT in a postacute older inpatient population.

2.1.2 Research Objectives

- To evaluate the feasibility (including safety, recruitment, outcome measurement, adherence rates, retention rates and satisfaction) of the design and intervention of this randomised controlled feasibility study;
- To evaluate changes in strength, functional mobility, frailty and QoL following a six-week PRT programme.

2.2 Study Design

This was a prospective, single-blinded, randomised controlled feasibility study. According to Eldridge et al (2016), a feasibility study asks whether something can be done, should we proceed with it, and if so, how. Many methodological issues can be satisfactorily investigated in the context of a randomised controlled feasibility trial. Key objectives are: to test the integrity of the study protocol for a future trial (which gives a valid reason for randomisation), to gain initial estimates for sample size calculation, to test data collection forms or questionnaires, to test

randomisation procedures, to estimate rates of recruitment and consent, to determine the acceptability of the intervention, to select the most appropriate primary outcome measures (Lancaster et al, 2004), to determine the percentage consenting to randomisation, to test retention in intervention and control groups, to determine if blinding can be maintained, and if all components of the protocol work together (Shanyinde et al, 2011),

The protocol for this study was registered with Clinical Trials NCT02141126. The authors had initially performed a power calculation (n=100) which would enable to study to give results regarding the efficacy of the intervention. A previous study of 32 older rehabilitation inpatients in the rehabilitation unit was used to inform the power calculation (Coleman et al, 2012). A sample size of 100 (50 per group) would have a power of 80% to detect a difference in muscle strength of 0.5kg at the hip, knee and ankle with an alpha of 5%. However, due to a longer than predicted recruitment rate, changes to patient flow through the rehabilitation unit and a reduction in LOS, it was felt that this study would need to make a number of changes to its methodology and become a multi-centre trial in order to achieve this sample size. Following much consideration, the authors agreed that this trial would still provide useful information regarding the feasibility of performing PRT with this much under-researched cohort.

There were two arms (i) exercise intervention and (ii) control. It was not possible to blind the treating physiotherapist or the patient to the exercise intervention; hence the single (assessor) blinded design. The study was designed incorporating recommendations of the CONSORT 2010 statement: extension to randomised pilot and feasibility trials (Sandra et al, 2016) (Appendix 1).

All participants received routine physiotherapy care. Routine physiotherapy care included balance and gait training and endurance exercise but did not routinely include lower limb (LL) PRT. Assessments were completed at entry to the study (T1) and again at six weeks (T2).

2.3 Setting

The study was based in the Medicine for the Elderly Rehabilitation Unit in a large teaching hospital, St James's Hospital, Dublin. The rehabilitation unit provides postacute care (PAC) to older inpatients. PAC is a combination of recovery,

recuperation and rehabilitation whose function is to further the goals of acute care (Kane, 2007). Patients are referred to the rehabilitation service from other hospital wards when their acute medical or surgical problems have been treated. At this time, the patient's main requirement is input from the multidisciplinary rehabilitation team (MDT) which is specialised in the care of the older person. The MDT consists of five consultant-led medical teams, nursing staff, physiotherapists, occupational therapists, speech and language therapists, medical social workers and clinical nutritionists (CN).

Routine physiotherapy was provided five days per week, from Monday to Friday, and patients were expected to participate fully. Routine physiotherapy consisted of a variety of interventions aimed at improving balance, functional exercise capacity, upper limb (UL) and LL strength, mobility and transfers. The frequency and intensity of routine physiotherapy input was recorded as the number of sessions that the patient received. The interventions that each patient received during their routine physiotherapy session was also recorded (Appendix 2). Patients were discharged from the unit when their full rehabilitation potential had been reached or when they could continue their rehabilitation as an outpatient or in the Primary Care setting.

2.4 Participants

Consecutive admissions to the rehabilitation service of St. James's Hospital, Dublin were considered eligible for admission, representing a sample of heterogeneous older adults with multiple co-morbidities. Patients admitted to three 18-bedded rehabilitation wards between July 2013 and June 2014 were invited to participate in the study. A sample of convenience was utilised. Participant recruitment occurred within 72 hours of admission to the rehabilitation service. Participants were identified from a daily medical ward list and eligibility for participation was confirmed through communication with physiotherapists working on these wards. Appropriate patients were approached by a gatekeeper (GC), and the intervention explained to them. Patients were then given an information leaflet and 48 hours to consider involvement in the study. A detailed verbal explanation was provided by GC and any questions were answered. If the patients were happy to participate, they were asked to sign a consent form. Recruitment occurred between the dates 28th of July 2013 and 15th of June 2014.

2.5 Inclusion and Exclusion Criteria

2.5.1 Inclusion Criteria

- Patients admitted for rehabilitation to the Medicine for the Elderly Rehabilitation Unit in St James's Hospital, Dublin
- Patients had an expected LOS of six weeks in the rehabilitation unit
- Patients >65 years of age
- Patients must be able to achieve a STS transfer independently and be able to stand independently with the use of the parallel bars in the physiotherapy gym
- Patients must be medically stable (as determined by their treating consultant)
- Patients must be able to give informed consent

2.5.2 Exclusion criteria

- Patients unable to follow one-stage commands
- Patients with acute pain or fracture
- Patients unable to stand or requiring > assistance of one to transfer
- Patients admitted with a recent diagnosis of stroke, due to their varying patterns of recovery

2.6 Ethical Considerations

An application for ethical approval was submitted to the St James's Hospital/Adelaide and Meath Hospital, incorporating the National's Children Hospital Research Ethics Committee (Appendix 3). Ethical approval was granted on the 15th May 2013 (Appendix 4). Recruitment commenced following approval by the ethics committee. All participants were provided with a Participant Information Leaflet (Appendix 5) at which time the research aims and objectives were explained. Participants were given 48 hours to consider their participation in the study. Any questions or queries were answered and participants were informed that their participation was voluntary. Participants were advised that they could withdraw from the study at any time and that it would not affect their rehabilitation. Signed, informed consent (Appendix 6) was obtained from each participant.

There was no identifiable personal information noted on the data collection form (Appendix 7). Patient identification number, name and medical record number were kept on a master copy which only the lead researcher (SC) had access to. All written documentation was kept in a locked filing cabinet which only SC had access to. Data was stored on a hard drive which was password protected. The collection, storage and use of participant data was carried out in accordance with the Data Protection Act (1998). Permission was obtained from the treating hospital consultants prior to commencement of the study.

2.7 Procedure

All assessments and the delivery of the exercise intervention took place in the Physiotherapy gym in the Rehabilitation Unit. During the course of the study, there were two blinded Physiotherapy assessors – (CM) and (SL) – and two blinded CN assessors – (RJ) and (MM). On admission or transfer to the rehabilitation service, patients identified as eligible to participate were provided with an information leaflet (Appendix 5) and asked to sign a consent form (Appendix 6).

Following this, patients underwent a comprehensive baseline assessment by one of the blinded Physiotherapy assessors (SL or CM) evaluating their level of ability across several aspects of body function, activity and participation, including LL and grip strength, functional mobility, stair climb ability, as well as completing a self-reported measure of ability in ADL and health status. This information was then employed along with the assessor's clinical judgement to provide a frailty score using the Canadian Study of Health and Ageing CFS (Rockwood et al, 2005) (Appendix 8).

Following the Physiotherapy assessment, one of the blinded CNs (RJ or MM) performed measurements of participant height, weight, BMI and skeletal muscle mass. Equipment used by the Physiotherapy assessors were present in the gym, such as, stopwatch, dynamometers, plinth, chair. Equipment used by the CN assessors, such as, body composition scales, was brought to the Physiotherapy gym when needed. All assessors received comprehensive testing of the assessment procedures and equipment prior to commencement of the study. Completed assessments and data were stored in a lockable filling cabinet in the Physiotherapy Gym in the Medicine for the Elderly Rehabilitation Unit, St James's

Hospital. The exercise intervention was delivered by the lead researcher (SC) with routine rehabilitation interventions being carried out by existing Physiotherapy staff members.

2.7.1 Outcome Measurement and Timing of Assessments

Participants eligible for inclusion in the study were assessed on admission to the rehabilitation service (T1) and at six weeks after admission (T2). This timeframe was chosen based on the median LOS of patients (excluding stroke patients) in the rehabilitation unit (Coleman et al, 2012). Depending on functional status and level of assistance needed, assessments took between 45 and 60 minutes to complete.

2.7.2 Demographic Data

Quantitative demographic and baseline information was obtained from the participant's medical chart on entry to the study. This included age, gender, presenting complaint, number of co-morbidities, current medications and details of living situation prior to admission. Participants were asked to provide details of their baseline mobility and transfer status. This information was recorded in a data collection form (Appendix 7). Information was recorded regarding the participant's medications, mobility and transfer status and discharge destination at T2 (Appendix 9).

2.8 Outcome Measurements

The primary outcome measures used were measures of feasibility:

2.8.1 Feasibility Outcome Measures

A feasibility study is a small study used for helping to design a further confirmatory study (Arnold et al, 2009). Thabane et al (2010) recommend that the outcome measures cited below are utilised when conducting feasibility studies.

The feasibility outcomes measures of interest were:

1) Safety: This was monitored using adverse events forms in the physiotherapy gym following the PRT interventions (Appendix 10).
2) Recruitment: Identified using the number of patients transferred to the rehabilitation unit during the recruitment period (Appendix 11).
3) Outcome Measurement: suitability, appropriateness, timeliness.
4) Adherence Rates: Evaluated using weekly attendance records (Appendix 12).
5) Retention Rates: Evaluated using the proportion of participants who attended for post assessment against the proportion who attended for baseline assessment.
6) Satisfaction: Evaluated using a non-validated satisfaction questionnaire, designed specifically for use in this study (Appendix 13). This questionnaire was added after the study commenced and was completed by the final nine participants recruited to the study.

Feasibility outcome measures 1-5 were recorded by SC. Feasibility outcome measure 6 was recorded by the blinded Physiotherapy assessor (SL or CM) at T2 assessment.

Secondary outcome variables were chosen to capture impairments of body functions, limitation of activities and restriction in participation, consistent with these domains described in the International Classification of Functioning, Disability and Health (ICF) (World Health Organisation, 2001). These were performed by Physiotherapists (SL, CM) and CNs (RJ, MM) and recorded on an assessment form at T1 and T2 (Appendix 14).

2.8.2 Measures of Impairment

2.8.2.1 Dynamometry (Bohannon, 1986) was measured using the MICROFET 2 Handheld Dynamometer (Hoggan Health Industries) (Appendix 15). Bilateral elbow extension, hip extension, hip flexion, hip abduction, knee extension, ankle dorsiflexion and plantarflexion were measured. The procedure employed for measuring muscle strength is shown in Table 2.1 and was previously utilised by Bohannon (1986). For the purpose of this study, the ‘Make Test’ was used which is an isometric

contraction held for three to five seconds. Test-retest reliability has been proven in an older population (Abizanda et al, 2012). Inter-rater reliability has been proven in an older population (Bandinelli et al, 1999).

Table 2.1: Dynamometry Protocol for measuring Muscle Strength

Muscle Group	Patient Position	Limb Positions	Manually Stabilised Body Part	Dynamometer Placement
Elbow Extensors	Supine	Arm beside trunk, elbow flexed 90°, forearm in neutral supination, wrist in neutral flexion	Arm	Just proximal to wrist joint on ulnar surface of forearm
Hip Flexors	Supine	Hip flexed 90°, knee relaxed	Trunk	Just proximal to knee on extensor surface of thigh
Hip Extensors	Supine	As hip flexors	Trunk	Just proximal to knee on flexor surface of thigh
Hip Abduction	Supine	Hip in neutral position	Trunk	Just proximal to knee on lateral surface of thigh
Knee Extensors	Sitting	Hip and knee flexed 90°	Thigh	Just proximal to ankle on anterior surface of leg
Ankle Dorsiflexors	Sitting	Hip and knee extended	Lower limb proximal to ankle	Just proximal to MTP joints on dorsal surface of foot
Ankle Plantarflexors	Sitting	As ankle dorsiflexors	As ankle dorsiflexors	Just proximal to MTP joints on plantar surface of foot

MTP=metatarsophalangeal

Following commencement of the recruitment phase, inter-rater reliability testing was carried out on the dynamometry protocol. This was due to a noticeable variation in results of dynamometry testing between the two Physiotherapy assessors (SL and CM). This involved a small sample size of participants (n=13) who were currently inpatients in the Rehabilitation Unit and was covered under the initial REC application. Participants were invited to participate and were provided with a Participant Information Leaflet (Appendix 16) at which time the research aims and objectives were explained. Participants were given 48 hours to consider their participation in the study. Any questions or queries were answered and participants were informed that their participation was voluntary. Participants were advised that they could withdraw from the study at any time and that it would not affect their rehabilitation. Signed, informed consent (Appendix 17) was obtained from each participant. Both Physiotherapy assessors (SL and CM) performed the assessments. To allow for the most reliable procedure, participants were alternated between morning and afternoons on two consecutive days. To further improve testing, the order of muscle groups tested was reversed at T2 and the assessment was blinded. Results are presented below in Table 2.2.

Table 2.2: Inter-rater Reliability testing of Dynamometry Protocol (n=13)

Muscle Group	Interclass Correlation
Elbow extension	0.675
Hip flexion	0.792
Hip extension	0.339
Hip abduction	0.802
Knee extension	0.245
Ankle dorsiflexion	0.219
Ankle plantarflexion	0.006

As shown in Table 2.2, elbow extension, hip flexion and hip abduction were shown to have good inter-rater reliability. During the randomised controlled feasibility study, each participant's T1 and T2 assessments were carried out by the same assessor which should ensure maximum reliability of UL and LL dynamometry assessments.

Testing was also carried out on the 5 Times Sit to Stand Test (5TSTS) to determine if this measure of LL muscle strength could be used as part of this study. In this test, participants are asked to stand up and sit down five times as quickly as possible without the use of their upper limbs. Alcazar et al (2018) have reported that this outcome measure is an easy, inexpensive and portable way of assessing muscle power in older people (Appendix 18). Ten patients from the Rehabilitation Unit participated in this small study. The procedure for performing the test was explained and demonstrated to the patient. Only two patients, who would have fit the inclusion criteria for the randomised controlled feasibility study, were successfully able to complete this outcome measure. For this reason, this outcome measure was not included in the feasibility study.

2.8.2.2 Grip strength was measured using a dynamometer (SAEHAN Hydraulic Hand Dynamometer, model SH5001) (Appendix 19). Participants were in a seated position, with their elbow flexed to 90 degrees and held by their side. Participants were asked to squeeze the hand dynamometer to the maximum of their ability. The average of three attempts was used which has been shown to be the most reliable method of measurement (Mathiowetz et al, 1984). Reliability (Tager et al, 1998) and validity (Bohannon, 2008) have been proven in an older population. Grip strength is often used as a proxy for overall body strength and research has shown that lower grip strength is associated with an increased risk of future fractures, cognitive decline and mortality. Kenny et al (2013) have published normative data for an older population.

2.8.2.3 Height was measured from ulna length (BAPEN, 2004) (Appendix 20), *weight* was measured using body composition scales (Tanita SC-331S Total Body Composition Analyser) (Appendix 21), and BMI calculated using these measures. *Skeletal muscle mass* was calculated using a validated equation based on BIA from the body composition scales. Participants were required to stand on the body composition scales in their bare feet, without holding onto any support, for 30 seconds (Janssen et al, 2000). These assessments were performed by the CNs (RJ and MM).

2.8.3 Measures of Activity

2.8.3.1 Timed Up and Go (TUG) – this is a test of basic functional mobility for frail older people (Podsiadlo and Richardson, 1991) that is often used in clinical practice to assess an individual's risk of having a fall (Kenny et al, 2013). Participants were asked to stand up from a chair 45cm in height, using the armrests if required, walk three metres at a comfortable pace, turn around and return to the chair, while being timed using a stopwatch (Appendix 22). The patient was allowed to use a walking aid if they were using it at the time of assessment. The TUG was measured to the hundredth of a second with one trial given prior to recording the score. The validity (Shumway-Cook et al, 2000; Shimada et al, 2010) and reliability (Lin et al, 2004) have been proven in older people participating in inpatient rehabilitation (Brooks et al, 2006). The TUG has good inter-rater and intra-rater reliability (ICC 0.99) and is a valid measure of functional mobility (Shumway-Cook et al, 2000).

2.8.3.2 Stair Negotiation Test (SNT) – this test is a strong predictor of declining ADL ability and mobility in older adults (Oh-Park et al, 2012) and is a clinically relevant measure of LL strength (Cruz-Jentoft et al, 2010). Participants were instructed to climb three steps on a set of stairs which is used for assessment purposes in the Physiotherapy Gym. The dimensions of the steps were 18 centimetres (cm) in height, 26cm in depth, and 62cm in width. Stair ascent timing was started once the participant began lifting their leading foot from the floor after the tester said "go." Subjects could use handrails to steady themselves. The Physiotherapy assessor noted use of handrails or any other difficulty while performing the task. When the participant placed both feet flat on the third step, the timing was stopped. After a brief rest, participants were requested to walk down. The stair descent timing started from the time when the leading foot began lifting from the third step and stopped when both feet were placed flat on the base of the stairs. The SNT was measured to the hundredth of a second with one trial for stair ascent and descent. The test–retest reliability for this measure is excellent (Pearson's r = .94 for ascent time, r = .93 for descent time) and this measure has also shown predictive validity for functional decline (Oh-Park et al, 2011) (Appendix 23).

2.8.3.3 Canadian Study of Health and Ageing - Clinical Frailty Scale (CFS) – this is a measure of frailty based on clinical judgement. It is a seven-point ordinal scale, with one meaning very fit with robust health and seven meaning severely frail with complete functional dependence on others (Appendix 8). Reliability and validity have been established in an older population (Rockwood et al, 2005).

2.8.4 Measures of Participation

2.8.4.1 EuroQol-5D (EQ-5D) - measures health related quality of life (Anonymous, 1990), it contains a visual analogue scale (0 to 100, representing dead to excellent health state) and five items: mobility, self-care, usual activities, pain/discomfort and anxiety/depression (Appendix 24). Validity and reliability of the EQ-5D have been proven in the older population and it has been recommended in situations where a succinct assessment of health status is required, particularly for patients in whom a substantial change in health is expected (Haywood et al, 2005).

Other data gathered at discharge were discharge destination and LOS. This was collected using hospital administration data.

2.9 Randomisation

Following completion of the T1 assessments, patients were randomised into two groups. Patient allocation was stratified based on age, gender and muscle strength (knee extension) using the technique of minimisation, which was performed using Microsoft Excel® 2003 software. The randomisation schedule was developed by the clinical supervisor (CC). Randomisation was performed by CC.

2.10 Description of Intervention

The **intervention group** received usual physiotherapy care as well as twice weekly tailored PRT for the LLs and elbow extensors. PRT sessions were delivered by SC in a supervised class (usually with 2-3 patients) with a circuit-type setting, lasting approximately 45 minutes and included a warm-up and cool-down

period. Exercises were tailored to each patient. Four exercises were included in the PRT; bilateral hip flexion and abduction using ankle weights (Appendix 25) and STS and heel raises using a weighted vest (Appendix 26).

Ankle weights: moderate-intensity 65% (Steib et al, 2009) of participant's 1-Repetition Maximum (1RM) (this is the heaviest weight that can be lifted only once) was used. The 1RM was determined using submaximal strength testing at the beginning of Week 1 and calculated using the Oddvar Holten diagram (Appendix 27). Pollock et al (1991) previously reported that 1RM testing was not appropriate for older adults. The intervention group was re-assessed using submaximal strength testing at the beginning of Week 3 and Week 5 to progress the intensity of exercise for each patient.

Weighted vest: this was calculated at 5-10% of body weight as used in previous research (Greendale et al, 2000). The weight prescribed in the weighted vest was calculated at 5% of body weight at the beginning of Week 1 and increased to 7% at the beginning of Week 4. The intervention lasted for 6 weeks.

Hip flexion and abduction exercises were performed in standing, holding onto the parallel bars. Participants were encouraged to maintain good posture throughout the exercises to ensure specific muscle group activation. STS was performed from a chair 45cm in height. Participants were instructed to stand up from the chair, using the armrests if required, to come to a full standing position and to return to a seated position in a controlled manner. Heel raises were performed holding onto the parallel bars. Participants were encouraged to maintain good posture throughout the exercise and were instructed to lift their heels off the ground as high as possible. All exercises were performed in a slow and controlled manner to ensure the correct technique. PRT sessions occurred twice per week, meaning four PRT sessions over a two-week period. Repetitions and sets were progressed over a two-week period as follows (Table 2.3):

Table 2.3 Progression of Repetitions and Sets over a Two-Week Period

	Repetitions	Sets
Session 1	15	2
Session 2	15	3
Session 3	20	2
Session 4	20	3

Following reassessment of their 1RM at two and four weeks and progression of the load being used, repetitions and sets were reduced and built up again over the next two-week period. A rest period of one minute was given between each set. There was at least one day of rest between PRT sessions. A record of repetitions, sets and intensity was kept for each participant (Appendix 28).

2.11 Statistical Methods

Data was coded and collated in a Microsoft Excel® Version 22 spreadsheet and Stata 12 was used for statistical analysis. Demographic characteristics and baseline data were summarised using descriptive statistics and baseline comparability of the groups was examined. The distribution of the data was assessed and, where appropriate, parametric methods were used in analysis. Two sample t-tests were used to compare groups and paired t-tests were used for within group comparisons. The non-parametric equivalent was used where data was not normally distributed. A significance level of $p<0.05$ was set. Due to the small sample size, only those who had a value for T2 were included in data analysis. The data from the outcome variables was quantitative and consisted of a combination of nominal, ordinal, ratio and interval data. Data was tested for normality using the Shapiro-Wilk test. The independent t-test or Mann-Whitney test, where appropriate, was used to test for differences between treatment groups. Multivariate logistic regression analysis was performed to measure the association between baseline factors and changes in outcome measures. Further details of statistical tests used can be found in Appendix 29.

RESULTS

2.12 Introduction

The aim of this study was to determine the feasibility of using a six-week PRT programme in a postacute older inpatient population.

Primary outcome variables used were measures of clinical trial feasibility:

1) Safety: Monitored using adverse events forms in hospital.
2) Recruitment: Identified using the number of patients transferred to the rehabilitation unit during the recruitment period.
3) Outcome Measures: Reliability and suitability of outcome measures were analysed.
4) Adherence Rates: Evaluated weekly attendance records for the intervention sessions.
5) Retention Rates: Evaluated the proportion of participants who attended for post assessment against the proportion who attended for baseline assessment.
6) Satisfaction: Evaluated using a non-validated satisfaction questionnaire (n=9), designed specifically for use in this study.

Secondary outcome measures used were UL and LL dynamometry, skeletal muscle mass, the TUG, the SNT, the CFS and the EQ-5D.

One hundred and thirty-four patients were admitted to the Medicine for the Elderly Rehabilitation Unit, St James's Hospital between July 2013 and June 2014. Ninety-seven patients did not meet the inclusion criteria. From the remaining 37 patients who were invited to participate, 33 patients gave informed consent. Figure 2.1 provides a detailed description of the recruitment process and flow of patients through the study.

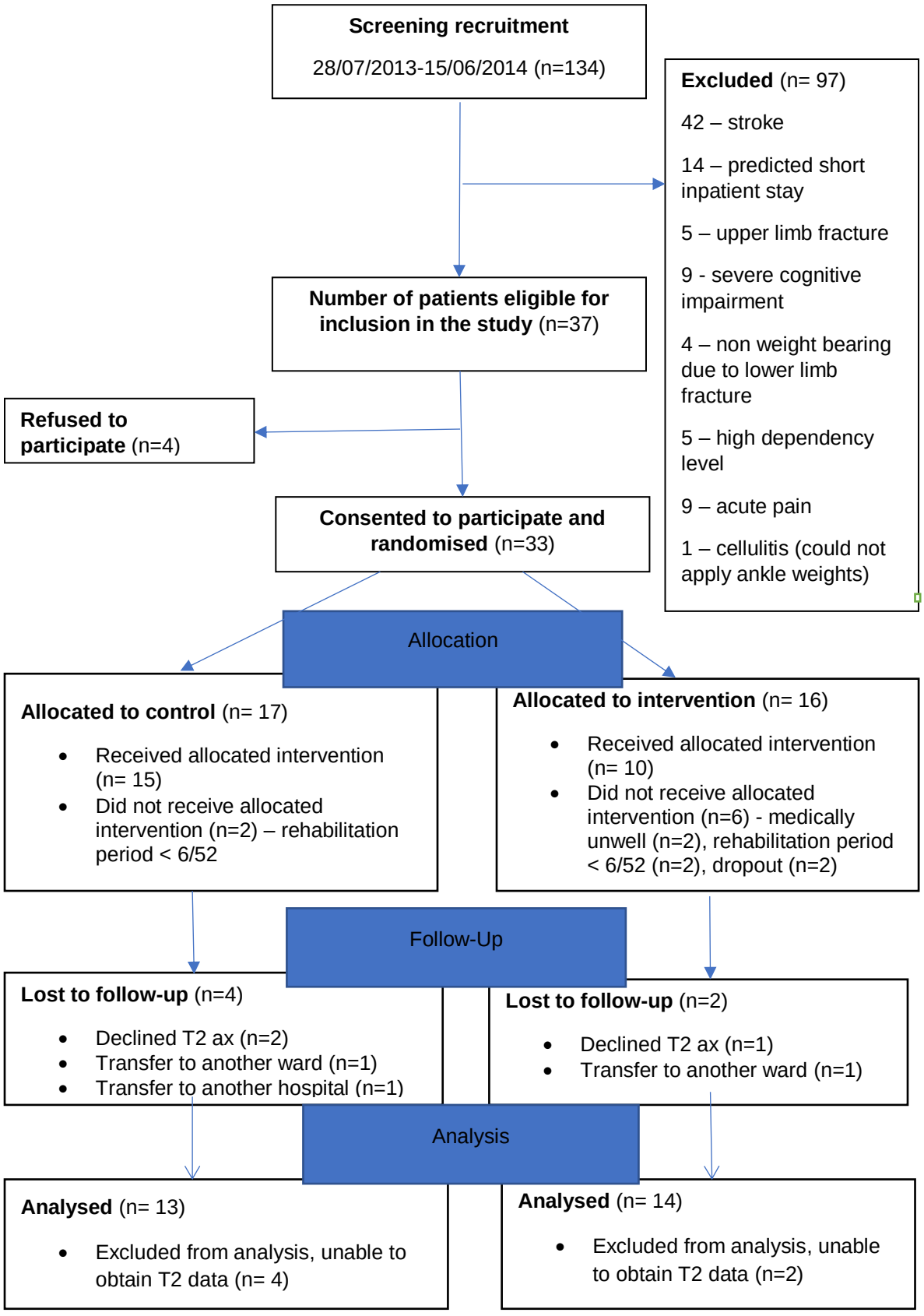


Figure 2.1: CONSORT diagram demonstrating patient flow through the study

2.13 Baseline Demographic Data

The mean age of the whole sample was 82.88 years with a standard deviation (SD) of 6.1 years. The mean age of the control group was 82.7 years (SD = 6.3). The mean age of the intervention group was 83.1 years (SD = 6.1). There was an equal distribution of male and female patients across both groups. Baseline demographic data is presented in Table 2.4 for the 33 subjects who had T1 assessments completed. As demonstrated by Table 2.4, baseline demographics were comparable in both the control and the intervention groups, apart from the number of comorbidities which was statistically significantly higher in the control group (Figure 2.2).

Table 2.4: Baseline Demographic Data of Participants (n=33)

Characteristic		Control Group (n=17) Value N / (%)	Intervention Group (n=16) Value N/ (%)	p-value
Gender	Male	8 (47.1)	8 (50.0)	0.866*
Age	Median age	82.7 (6.3)	83.1 (6.1)	0.826+
Presenting diagnosis	Falls Hip fracture Pubic ramus fracture Other (vertebral fracture, gastrointestinal, cardiac, oncology)	5 (29) 1 (6) 3 (18) 8 (47)	10 (62) 2 (13) 0 (0) 4 (25)	
No. of Comorbidities		5.4 (2.1)	3.3 (1.5)	0.003+
Mobility on admission to rehabilitation	Independent Independent with walking stick Independent with walking frame Supervision Assistance	0 (0) 1 (6) 4 (23) 9 (53) 3 (18)	0 (0) 1 (6) 4 (25) 5 (31) 6 (38)	
Transfers on admission to rehabilitation	Independent Supervision Assistance	7 (41) 4 (23) 6 (34)	4 (25) 7 (44) 5 (31)	
Social History	Lives alone Lives with family Other	10 (58.8) 5 (29.4) 2 (11.8)	10 (62.5) 6 (37.5) 0 (0)	

Values are mean (SD) or n (%). *Chi-square test. +Independent t-test

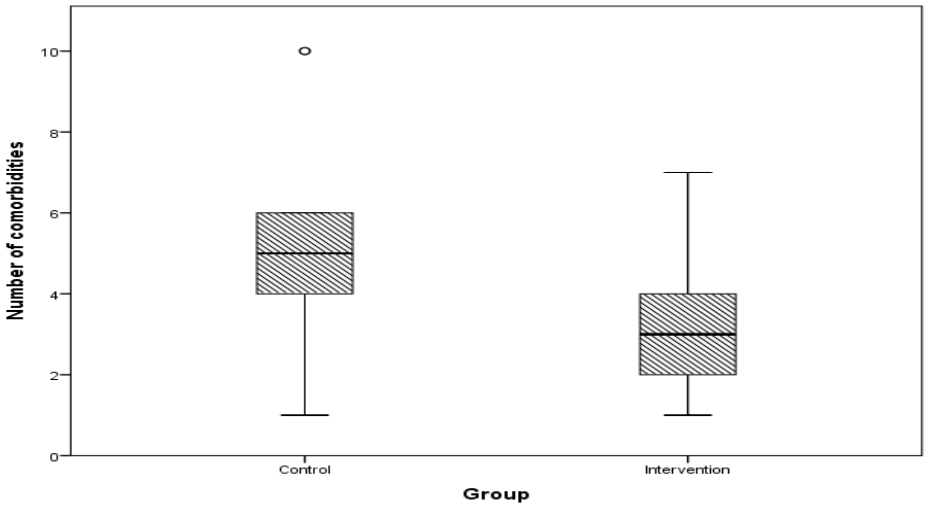


Figure 2.2: Baseline number of comorbidities by treatment group (Control n=17, Intervention n=16)

2.14 Time Awaiting Admission to Rehabilitation and LOS

The mean length of time in the acute hospital setting before transfer to the inpatient rehabilitation unit was 33.9 days (SD 27.5) for the control group and 32.8 days (SD 28.4) for the intervention group. See Table 2.5 for details related to length of stay in the acute and rehabilitation setting. None of these values were statistically significant.

Table 2.5: Number of Days awaiting transfer to the Rehabilitation Unit, Entire Inpatient LOS and LOS in the Rehabilitation Unit

Variable	Control (n=17) Mean (SD)	Intervention (n=16) Mean (SD)	p-value
Number of Days awaiting Transfer to Rehabilitation	33.9 (27.5)	32.8 (28.4)	0.908+
LOS – Acute + Rehabilitation	119.2 (95.5)	100.3 (42.9)	0.466+
LOS in Rehabilitation	85.4 (80.2)	67.6 (30.9)	0.405+

LOS = length of stay +Independent t-test

2.15 Physiotherapy Assessments and Interventions

The mean number of routine physiotherapy visits received by the control group was 21.5 ± SD 7.4, while the mean number of routine physiotherapy visits received by the intervention group was 21.6 ± SD 6.9. The mean number of PRT interventions received by the intervention group was 7.6 ± 3.63. Please see Table 2.6 for further details.

Table 2.6: Number of Routine Physiotherapy and PRT sessions delivered

Variable	Control (n=17) Mean (SD)	Intervention (n=16) Mean (SD)	p-value
Routine Physiotherapy Sessions	21.5 (7.4)	21.6 (6.9)	0.970[+]
PRT Sessions	-	7.6 (3.63)	-

[+]Independent t-test

The mean number of days between the T1 assessment and T2 assessment for the control group (n=13) was 43.38 ± SD 5.38. The mean number of days between the T1 assessment and T2 assessment for the intervention group (n=14) was 40 ± SD 8.09. The T2 assessment was not completed for four participants of the control group and two participants of the intervention group. Of the six participants who did not receive a T2 assessment, one had been transferred to another hospital to continue their rehabilitation, three had been discharged home and declined to come back for reassessment and two had been transferred to another ward as they had become medically unwell.

2.16 Discharge Destination

Eleven participants in the control group and 12 participants in the intervention group were still receiving inpatient rehabilitation at the time of the T2 assessment. Discharge destination was recorded for each participant who completed the T1 assessment. Please see Table 2.7 for further details.

Table 2.7: Discharge Destination of Participants

Discharge Destination	Control (n=17) N (%)	Intervention (n=16) N (%)
Home	5 (29.4)	3 (18.8)
Home with follow-up in Primary Care	5 (29.4)	6 (37.5)
Long Term Care	2 (11.8)	5 (31.3)
Other hospital	2 (11.8)	0 (0)
Deceased	3 (17.6)	2 (12.5)

2.17 Baseline Outcome Measures

The baseline outcome measures were administered by two physiotherapists and two dieticians who were blinded to group allocation. All outcome measures were administered in the physiotherapy gym using a standard protocol and battery of assessments. All outcome measures were similar at baseline for both groups. Please see Tables 2.8, 2.9 and 2.10 for further details.

Table 2.8 Baseline Outcome Measures (TUG, SNT, CFS, EQ-5D)

Outcome Measure	Control (n=17)			Intervention (n=16)		
	Mean	SD	Range	Mean	SD	Range
TUG (seconds)	46.03	29.35	17.13-129	57.18	29.22	22.2-125
SNT Ascent (seconds)	16.04	16.3	3.1-70	13.13	5.14	6.1-25.93
SNT Descent (seconds)	18.11	16.71	4.9-7.5	15.74	6.09	7-32.2
CFS (/7)	5.35	1.27	3-7	5.62	1.09	4-7
EQ-5D VAS (/100)	50	22.64	0-90	61.87	20.89	30-100
EQ-5D Mobility (/3)	2	0.5	1-3	1.95	0.25	1-2
EQ-5D SC (/3)	1.59	0.51	1-2	1.875	0.62	1-3
EQ-5D UA (/3)	2	0.79	1-3	2.125	0.72	1-3
EQ-5D PD (/3)	1.76	0.75	1-3	1.81	0.65	1-3
EQ-5D AD (/3)	1.65	0.7	1-3	1.87	0.72	1-3

SD = Standard Deviation, TUG = Timed Up and Go; SNT = Stair Negotiation Test; CFS = Clinical Frailty Scale; EQ-5D VAS = EuroQol 5D Visual Analogue Scale; EQ-5D Mobility = EuroQol 5D Mobility; EQ-5D SC = EuroQol 5D Self-Care, EQ-5D UA = EuroQol 5D Usual Activities;EQ-5D PD = EuroQol 5D Pain/Discomfort; EQ-5D AD = EuroQol 5D Anxiety/Depression

Table 2.9 Baseline Outcome Measures (Grip Strength and Lower Limb Strength)

Outcome Measure (kgs)	Control (n=17)			Intervention (n=16)		
	Mean	SD	Range	Mean	SD	Range
Grip (R)	12.69	7.37	3.5-29.3	13.87	6.56	2-22.7
Grip (L)	11.29	7.15	2-25.7	11.2	5.58	1.7-23.3
HA (R)	5.77	2.35	2.5-9.9	4.97	2.44	1.6-9.7
HA (L)	5.25	1.45	2.8-7.5	4.92	2.29	1.4-9.1
HF (R)	5.48	2.63	2.3-12.3	4.54	1.66	1.9-8.4
HF (L)	4.89	1.41	2.8-7.4	4.71	1.93	2.2-9.5
HE (R)	6.12	2.08	3.5-10.6	6.19	2.65	2-10.6
HE (L)	6.24	2.08	3.1-10.5	6.19	2.39	2-10.8
KE (R)	5.55	2.34	2-9.5	5.2	2.15	1.9-9.9
KE (L)	5.35	1.99	1.6-8.2	5.33	2.31	1.8-10.6
AP (R)	6.09	3.36	2.1-15.4	4.77	2.21	2-9.4
AP (L)	5.36	2.26	2.9-10.7	4.64	2.38	1.6-10.7
AD (R)	4.33	2.48	1.8-10.6	3.52	1.67	1.9-7.3
AD (L)	4.04	1.75	1.8-8.1	3.11	1.54	1.6-7.1
EE (R)	5.56	2.71	2.1-11.6	5.31	2.94	2.1-13.3
EE (L)	5.71	2.38	2.9-10.3	5.27	2.98	2.6-12.6

(R) = Right, (L) = left, SD = standard deviation, kgs= kilograms, HA = hip abduction, HF = hip flexion, HE = hip extension, KE = knee extension, AP = ankle plantarflexion, AD = ankle dorsiflexion, EE = elbow extension

Table 2.10 Baseline Outcome Measures (Height, Weight, Body Mass Index (BMI), Muscle Mass)

Outcome Measure	Control (n=17)			Intervention (n=16)		
	Mean	SD	Range	Mean	SD	Range
Height (cm)	159.58	8.96	148-181	162.93	6.66	153-177
Weight (kgs)	61.05	11.84	46.6-84	65.36	9.41	47.5-79
BMI	23.19	3.31	17.98-30.27	24.65	3.61	19.39-31.3
Muscle Mass(kgs)	42.19	8.85	31.7-60.7	46.97	6.71	35.6-55.4

SD=Standard Deviation, cm=centimetres, kgs=kilograms

2.18 Post Intervention Primary Outcome Measures – Feasibility

The primary outcome variables used were measures of clinical trial feasibility. These included safety, recruitment, suitability of outcome measures, adherence rates, retention rates and satisfaction.

1) Safety: This was monitored using adverse events forms in the physiotherapy gym during and following PRT interventions (Appendix 10). Adverse event records were only kept for those in the intervention group. There were no serious adverse events for those participating in the intervention group. Three mild to moderate musculoskeletal adverse events were reported by three different participants. Two participants each reported one episode of back pain and one participant reported one episode of thigh pain on one episode. One of these participants chose to discontinue the intervention due to the aggravation of already present back pain. The other two participants were happy to continue in the study.

2) Recruitment: Recruitment rates were identified by the clinical trial gatekeeper (GC) using the number of patients transferred to the rehabilitation unit during the recruitment period of 28/07/2013 until 15/06/2014. One hundred and thirty-four patients were admitted to the

rehabilitation unit during the recruitment period. Ninety-seven patients did not fit the inclusion criteria. From the remaining 37 patients who were invited to participate, 33 patients gave informed consent. Please refer to Figure 3.1 for further details. The number of suitable patients who agreed to participate in the study was high (89%). Of the four participants who declined to participate, two of these were related to family members who were concerned about their older relative undertaking resistance training exercises. The other two patients who declined simply did not want to participate.

3) Validity and Reliability of Outcome Measures used: Inter-rater reliability testing was carried out on the Hand-Held Dynamometry test. Having carried out a literature review on this outcome measure, it was felt that this would be an appropriate measure to use in the study (Bohannon 1986). During the course of the recruitment phase, a second blinded physiotherapy assessor joined the study. There were noticeably higher T1 values during this time. It was decided to perform inter-rater reliability testing between the two blinded physiotherapy assessors using the Hand-Held Dynamometer. Reliability was poor between most of the muscle groups. Results can be seen in Table 2.2. To ensure maximum intra-rater reliability, the same assessor performed both the T1 and T2 assessments on the participants that they tested.

   The TUG, CFS, SNT and EQ-5D proved to be quick and easy to use in this patient cohort.

   Skeletal muscle mass was only measured on 23 participants at T1. This was due to a variety of reasons:

   - Participants with pacemakers were contra-indicated from using the bio impedance scales.
   - Participants were required to stand completely unaided for approximately 30 seconds to allow the equipment to perform its calculations. Some of the participants were unable to do this.
   - Participants were required to stand in their bare feet, however some of the participants were wearing lower limb dressings which covered part of their feet.

4) Adherence Rates: This was evaluated using weekly attendance records for the study. The mean number of PRT interventions received by the intervention group was 7.6 ± 3.63. The planned number of intervention sessions per participant was 12, made up of twice weekly PRT sessions over a period of six weeks. Therefore, this equates to the delivery of 63% of the possible total number of intervention sessions. The remainder of the intervention sessions were not delivered for a variety of reasons:
    - Two patients became medically unwell and were transferred to another ward for medical management.
    - Two patients had achieved their optimal rehabilitation potential earlier than six weeks and had been discharged home early.
    - Two patients dropped out of the study.

5) Retention Rates: This evaluated the proportion of participants who attended for T2 assessment against the proportion who attended for baseline assessment. The T2 assessment was not completed for four participants (23%) of the control group and two participants (12%) of the intervention group. Of the six participants who did not receive a T2 assessment, one had been transferred to another hospital to continue their rehabilitation, three had been discharged home and declined to come back for reassessment and two had been transferred to another ward as they had become medically unwell.

6) Satisfaction: This was evaluated using a non-validated satisfaction questionnaire (Appendix 13) with nine participants. Only one of these said that they would not participate in the study again, as the participant felt that he did not benefit from being in the study. Participants reported that they were very satisfied with their overall involvement in the research process and those that were in the intervention group reported benefits in strength and balance following the intervention, including an improved ability to perform their daily activities.

2.19 Post Intervention Secondary Outcome Measures

2.19.1 Measures of Impairment

a) Dynamometry and Grip strength

Mann-Whitney testing was performed on grip strength and lower limb strength to determine if there was a significant difference in the change in median scores from T1 to T2 in the two groups. There was no significant difference in the change in median scores from T1 to T2 in the two groups in grip strength. As demonstrated by Table 2.11, the only significant change in lower limb strength between the two groups was left ankle dorsiflexion strength. Please see Figure 2.3 for further details.

Table 2.11: Changes in grip strength and lower limb dynamometry from initial to final assessment (n=27). Control (n=13) Intervention (n=14).

Muscle Group (kgs)		T1 Median (Min, Max)	T2 Median (Min, Max)	T2-T1 Median (Min, Max)	p value
Grip (R)	**Control**	9.8 (3.5, 29.3)	12 (5, 29)	1.40 (-6.00, 4.70)	0.681
	Intervention	15.7 (2, 22.7)	14.3 (2, 25.7)	0.70 (-7.70, 7.30)	
Grip (L)	**Control**	10.7 (2, 25.7)	9.7 (3.3, 25.7)	1.30 (-5.30, 6.70)	0.472
	Intervention	12.7 (1.7, 23.3)	14.3 (3.3, 17)	0.30 (-9.00, 8.00)	
HA (R)	**Control**	6.1 (2.5, 9.9)	4.5 (3.1, 12.1)	0.90 (-2.70, 5.10)	0.234
	Intervention	4.55 (1.6, 9.7)	6.35 (2.5, 11.8)	1.45 (-1.40, 7.30)	
HA (L)	**Control**	5.1 (2.8, 7.5)	4.1 (2.3, 9.3)	0.20 (-2.60, 3.40)	0.382
	Intervention	4.7 (1.4, 9.1)	5.4 (2.5, 10.8)	0.40 (-2.50, 5.50)	

Muscle Group (kgs)		T1 Median (Min, Max)	T2 Median (Min, Max)	T2-T1 Median (Min, Max)	p value
HF (R)	**Control**	4.5 (2.3, 12.3)	4.4 (2.7, 11)	0.40 (-9.10, 3.40)	0.645
	Intervention	4.3 (1.9, 8.4)	4.95 (2.7, 9.9)	0.7 (-3.8, 2.7)	
HF (L)	**Control**	4.3 (2.8, 7.4)	4.6 (2.5, 8.2)	0.1 (-1.3, 2.6)	0.645
	Intervention	4.5 (2.2, 9.5)	5.05 (3.1, 7.8)	0.8 (-3.4, 3.4)	
HE (R)	**Control**	5.7 (3.5, 10.6)	6.4 (4.4, 10.6)	0.6 (-3.6, 4.8)	0.512
	Intervention	6 (2, 10.6)	7.05 (2.5, 11)	1.3 (-5.8, 5.4)	
HE (L)	**Control**	5.5 (3.1, 10.5)	5.8 (4.2, 10.3)	-0.6 (-3.4, 3.5)	0.099
	Intervention	6.2 (2, 10.8)	7.05 (3.4, 11.3)	0.3 (-2.1, 4.9)	
KE (R)	**Control**	5.6 (2, 9.5)	5.7 (2.3, 11.7)	0.5 (-2.8, 4.2)	0.752
	Intervention	5.35 (1.9, 9.9)	5.7 (2.7, 10.5)	0.2 (-3.1, 3.8)	
KE (L)	**Control**	5 (1.6, 8.2)	5.3 (3, 11.1)	0.2 (-1.6, 3.5)	0.789
	Intervention	5.5 (1.8, 10.6)	5.7 (2.5, 10.5)	0.2 (-3.2, 3.5)	
AP (R)	**Control**	4.7 (2.1, 15.4)	4 (1.9, 10.9)	-0.9 (-4.5, 2.6)	0.207
	Intervention	3.9 (2, 9.4)	5 (1.7,11)	-0.3 (-21, 4.3)	

Muscle Group (kgs)		T1 Median (Min, Max)	T2 Median (Min, Max)	T2-T1 Median (Min, Max)	p value
AP (L)	**Control**	4.2 (2.9, 10.7)	5 (1.9, 10.5)	-0.2 (-3.7, 4.4)	0.544
	Intervention	4 (1.6, 10.7)	4.3 (2.5, 10)	-0.2 (-2.3, 3.8)	
AD (R)	**Control**	3.4 (1.8, 10.6)	3.8 (2.1, 9.4)	-0.3 (-1.9, 1.9)	0.697
	Intervention	3 (1.9, 7.3)	3.7 (1.8, 6.8)	-0.1 (-3.8, 3.9)	
AD (L)	**Control**	3.6 (1.8, 8.1)	3.6 (2, 7.6)	-0.3 (-3.6, 1.6)	0.027*
	Intervention	2.65 (1.6, 7.1)	4.1 (2, 7)	0.7 (-1.2, 3.3)	
EE (R)	**Control**	5 (2.1, 11.6)	4.8 (2.2, 10.8)	-0.7 (-1.6, 0.9)	0.152
	Intervention	4.95 (2.1, 13.3)	5.8 (2.1, 11.1)	0.3 (-4.7, 3.6)	
EE (L)	**Control**	4.95 (2.9, 10.3)	3.9 (2.5, 10.5)	-0.7 (-3.8, 1.6)	0.120
	Intervention	4.45 (2.6, 12.6)	5 (2.2, 11)	0.3 (-3.7, 2.8)	

Values are median (range) and p-values from Mann-Whitney U test.

Change values calculated as T2 minus T1. *Significant at the p ≤ 0.05 level

T1 = Assessments at entry to the study, T2 = Assessment at six weeks

(R) = Right, (L) = left, kgs=kilograms, HA = hip abduction, HF = hip flexion, HE = hip extension, KE = knee extension, AP = ankle plantarflexion, AD = ankle dorsiflexion, EE = elbow extension

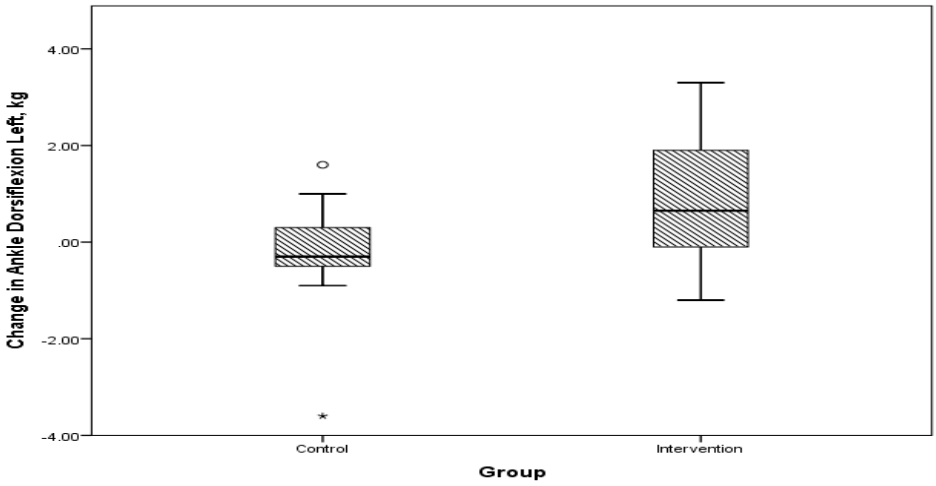


Figure 2.3. Change from T1 to T2 in Left Ankle Dorsiflexion (kg) by treatment group.

b) Weight and Muscle Mass

Mann-Whitney testing was performed on weight and skeletal muscle mass to determine if there was a significant difference in the change in median scores from T1 to T2 in the two groups. There was no significant difference in the change in median scores from T1 to T2 in the two groups in weight or skeletal muscle mass. Please see Table 2.12 for further details.

Table 2.12 Changes in Weight and Skeletal Muscle Mass from initial to final assessment (n=27). Control (n=13) Intervention (n=14)

Outcome Measure (kgs)		N	T1 Median (Min, Max)	N	T2 Median (Min, Max)	T2-T1 Median (Min, Max)	p value
Weight	**Control**	8	61.7 (46.6, 84)	10	57.9 (40.3, 67.3)	-0.65 (-6.8, 8.0)	0.534
	Intervention		66.8 (47.5, 79)		63.2 (48.1, 80.5)	0.85 (-4.5, 3.4)	
Muscle Mass	**Control**	7	39.9 (31.7, 60.7)	7	38.8 (31.9, 48)	0 (-11.5, 14.1)	0.655
	Intervention		45.5 (35.6, 55.4)		44.1 (38.5, 54.6)	0.4 (-3.9, 2.9)	

*Significant at the $p \leq 0.05$ level, T1 = Assessments at entry to the study, T2 = Assessment at six weeks, kgs=kilograms

2.19.2 Measures of Activity

a) Timed Up and Go (TUG)

The median TUG score for the control group at T2 was 32 seconds (Min, Max = 17.2, 104). The median TUG score for the intervention group at T2 was 31.42 seconds (Min, Max = 18.95, 136).

b) Stair Negotiation Test (SNT)

The median SNT Ascent score for the control group at T2 was 7.7 seconds (Min, Max = 4, 22.6). The median SNT Ascent score for the intervention group at T2 was 7.16 seconds (Min, Max = 4.15, 20.62).

The median SNT Descent score for the control group at T2 was 10.2 seconds (Min, Max = 3.58, 25). The median SNT Descent score for the intervention group at T2 was 8.45 seconds (Min, Max = 5.3, 42.7).

c) Canadian Study of Health and Ageing - Clinical Frailty Scale (CFS)

The median CFS score for the control group at T2 was 5 (Min, Max = 3, 7). The median CFS score for the intervention group at T2 was 5 (Min, max = 4, 6).

Mann-Whitney testing was performed on these outcome measures to determine if there was a significant difference in the change in median scores from T1 to T2 in the two groups. There was no significant difference in the change in median scores from T1 to T2 in the two groups in any of the outcome measures. Please see Table 2.13 for further details on the changes in measures of activity.

Table 2.13: Changes in Outcome Measures from initial to final assessment (n=27). Control (n=13) Intervention (n=14).

Outcome Measure		T1 Median (Min, Max)	T2 Median (Min, Max)	(T2-T1) Median (Min, Max)	p value
TUG (seconds)	**Control**	37.96 (17.13, 129)	32 (17.2, 104)	-12.4 (-60.8, 51.6)	0.923
	Intervention	49.82 (22.2, 125)	31.42 (18.95, 136)	-12.8 (-74.3, 59.0)	
SNT Ascent (seconds)	**Control**	13 (3.1, 70)	7.7 (4, 22.6)	-2.7 (-62.1, 6.3)	0.734
	Intervention	11.6 (6.1, 25.93)	7.16 (4.15, 20.62)	-4.9 (-11.6, 4.7)	
SNT Descent (seconds)	**Control**	13.45 (4.9, 75)	10.2 (3.58, 25)	-2.7 (-64.8, 16.1)	0.961
	Intervention	15.11 (7, 32.2)	8.45 (5.3, 42.7)	-4.8 (-15.5, 22.7)	
CFS (/7)	**Control**	6 (3, 7)	5 (3, 7)	0 (-1, 0)	0.550
	Intervention	6 (4, 7)	5 (4, 6)	0 (-2, 1)	

*Significant at the p ≤ 0.05 level, T1 = Assessments at entry to the study, T2 = Assessment at six weeks, TUG = Timed Up and Go, SNT = Stair Negotiation Test, CFS = Clinical Frailty Scale

2.19.3 Measures of Participation

EuroQol-5D (EQ-5D)

The maximum score for the EQ-5D – VAS is 100. The median EQ-5D - VAS score for the control group at T2 was 60 (Min, Max = 50, 90). The median EQ-5D – VAS score for the intervention group at T2 was 70 (Min, Max = 40, 100).

The maximum score for the EQ-5D – Mobility is 3. The median EQ-5D - Mobility score for the control group at T2 was 2 (Min, max = 1, 2). The median EQ-5D - Mobility score for the intervention group at T2 was 1.5 (Min, Max = 1, 3).

The maximum score for the EQ-5D – Self Care is 3. The median EQ-5D – Self Care score for the control group at T2 was 1 (Min, Max = 1, 2). The median EQ-5D – Self Care score for the intervention group at T2 was 1.5 (Min, Max = 1, 3).

The maximum score for the EQ-5D – Usual Activities is 3. The median EQ-5D – Usual Activities score for the control group at T2 was 2 (Min, Max = 1, 3). The median EQ-5D – Usual Activities score for the intervention group at T2 was 2 (Min, Max = 1, 3).

The maximum score for the EQ-5D – Pain/Discomfort is 3. The median EQ-5D – Pain/Discomfort score for the control group at T2 was 1 (Min, Max = 1, 3). The median EQ-5D – Pain/Discomfort score for the intervention group at T2 was 2 (Min, Max = 1, 2).

The maximum score for the EQ-5D – Anxiety/Depression is 3. The median EQ-5D – Anxiety/Depression score for the control group at T2 was 1 (Min, Max = 1, 3). The median EQ-5D – Anxiety/Depression score for the intervention group at T2 was 1.5 (Min, Max = 1, 2).

Mann-Whitney testing was performed on these outcome measures to determine if there was a significant difference in the change in median scores from T1 to T2 in the two groups. There was no significant difference in the change in median scores from T1 to T2 in the two groups in any of the outcome measures. Please see Table 2.14 for further details on the changes in measures of participation.

Table 2.14: Changes in EQ-5D from initial to final assessment (n=27). Control (n=13) Intervention (n=14).

Outcome Measure		T1 Median (Min, Max)	T2 Median (Min, Max)	(T2-T1) Median (Min,Max)	p value
EQ-5D VAS (/100)	Control	50 (0, 90)	60 (50, 90)	10(-20,60)	0.156
	Intervention	60 (30, 100)	70 (40, 100)	0 (-25, 55)	
EQ-5D Mobility (/3)	Control	2 (1, 3)	2 (1, 2)	-1 (-1, 0)	0.474
	Intervention	2 (1, 2)	1.5 (1, 3)	0 (-1, 1)	
EQ-5D SC (/3)	Control	2 (1, 2)	1 (1, 2)	0 (-1, 1)	0.826
	Intervention	2 (1, 3)	1.5 (1, 3)	0 (-1, 1)	
EQ-5D UA (/3)	Control	2 (1, 3)	2 (1, 3)	0 (-1, 1)	0.727
	Intervention	2 (1, 3)	2 (1, 3)	0 (-1, 1)	
EQ-5D PD (/3)	Control	2 (1, 3)	1 (1, 3)	0 (-2, 1)	0.501
	Intervention	2 (1, 3)	2 (1, 2)	0 (-1, 1)	
EQ-5D AD (/3)	Control	2 (1, 3)	1 (1, 3)	0 (-1, 0)	0.891
	Intervention	2 (1, 3)	1.5 (1, 2)	0 (-2, 1)	

*Significant at the p ≤ 0.05 level, T1 = Assessments at entry to the study, T2 = Assessment at six weeks,

EQ-5D VAS = EuroQol 5D Visual Analogue Scale; EQ-5D Mobility = EuroQol 5D Mobility;

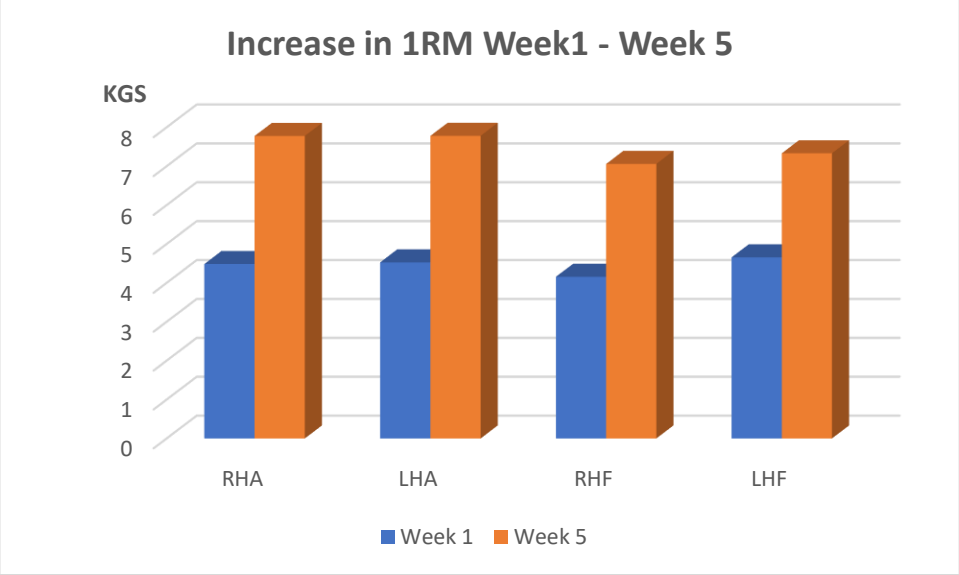
EQ-5D SC = EuroQol 5D Self-Care; EQ-5D UA = EuroQol 5D Usual Activities;

EQ-5D PD = EuroQol 5D Pain/Discomfort; EQ-5D AD = EuroQol 5D Anxiety/Depression

2.20 Progression of PRT in the Intervention Group

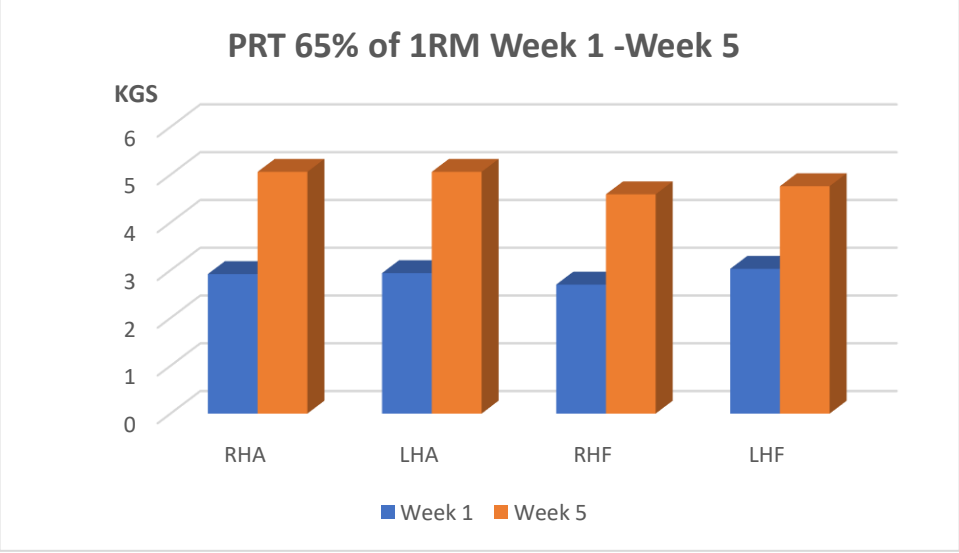
As previously described in the methods section, participants in the intervention group participated in up to six weeks of PRT. Two of the exercises utilised ankle weights, these were bilateral hip abduction and hip flexion exercises in standing. The other two exercises used a weighted vest to provide resistance, these were sit-to-stand and heel raises. The prescription and progression of resistance used in hip abduction and hip flexion was determined using submaximal testing. This was initially tested following T1 assessment (Week 1) and repeated at Week 3 and Week 5. During the course of the study, participants in the intervention group (n=16) demonstrated a mean increase in their 1RM in right hip abduction of 73%, left hip abduction of 72%, right hip flexion of 70% and left hip flexion of 57%. This

in turn lead to an equivalent increase in the prescription of the load used in the ankle weights. Please see figures 2.4 and 2.5 for further details regarding the mean increase demonstrated by the intervention group in 1RM and the progression of ankle weights used in bilateral hip abduction and hip flexion during the course of the study. Training weights used varied greatly which reflected the diverse range of muscle strength of the participants.



1RM = 1 Repetition Maximum, KGS = kilograms, RHA = right hip abduction, LHA = left hip abduction, RHF = right hip flexion, LHF = left hip flexion

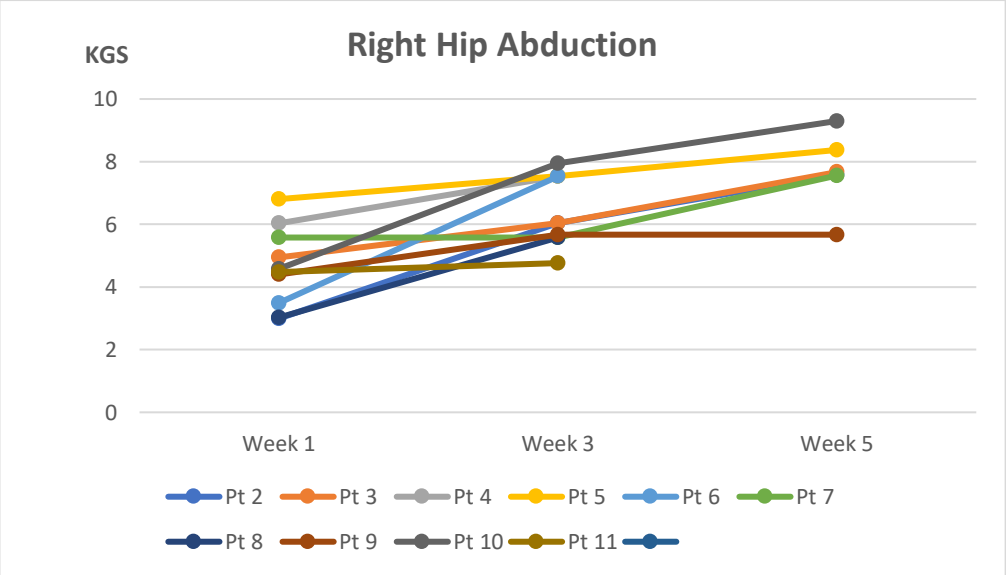
Figure 2.4: Increase in 1RM from Week 1 to Week 5



PRT = Progressive Resistance Training, 1RM = 1 Repetition Maximum, KGS = kilograms, RHA = right hip abduction, LHA = left hip abduction, RHF = right hip flexion, LHF = left hip flexion

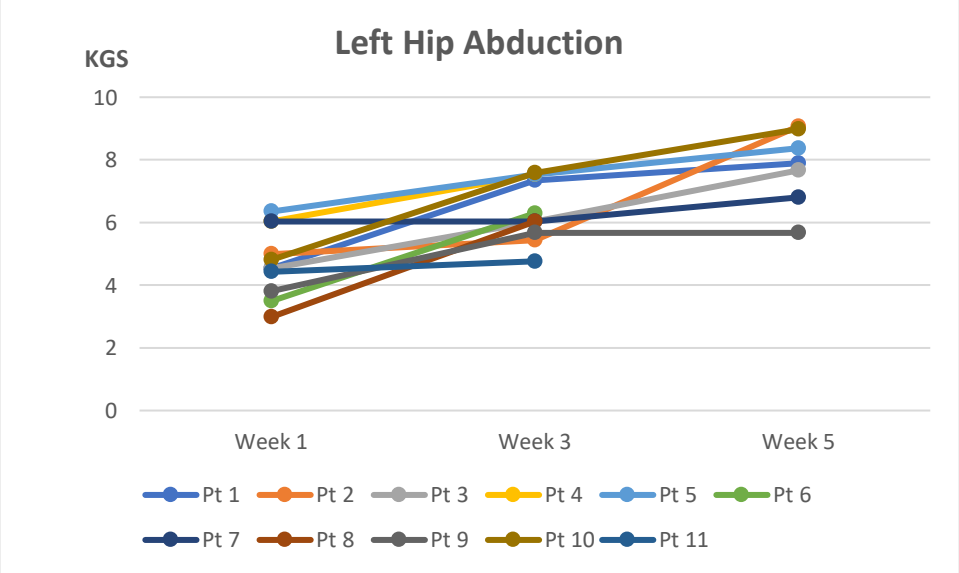
Figure 2.5: Progression of 65% of 1RM from Week 1 to Week 5

Further analysis was performed on individual participants which demonstrates increases in 1RM in right hip abduction, left hip abduction, right hip flexion and left hip flexion. This analysis was performed on the 11 participants who had submaximal testing carried out more than once. Please see Figures 2.6, 2.7, 2.8 and 2.9 for further details. Five participants received submaximal testing only once, this was for a variety of reasons including participants transferring out of the rehabilitation unit, please see Figure 3.1 for further details.



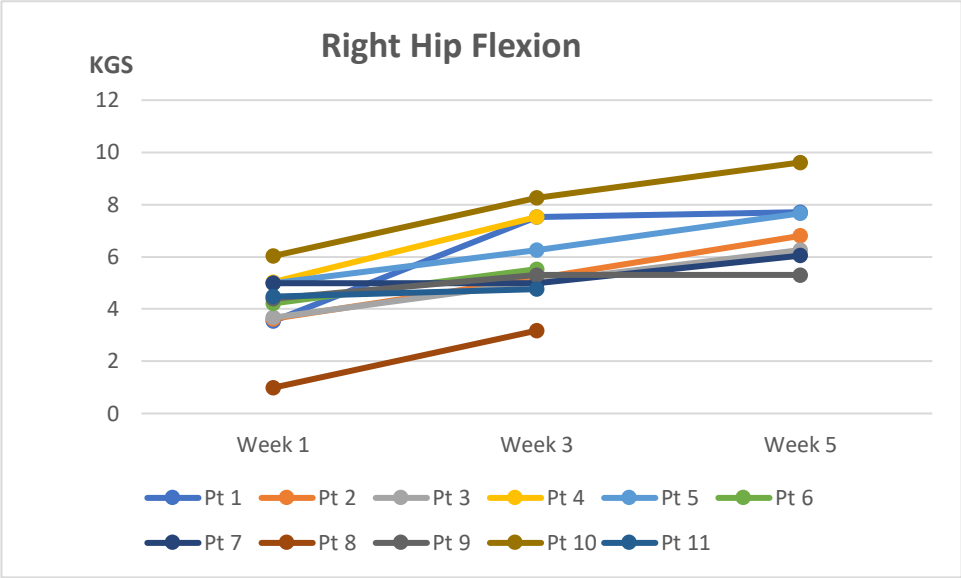
KGS= kilograms, Pt = participant

Figure 2.6: Increase in 1RM in Right Hip Abduction



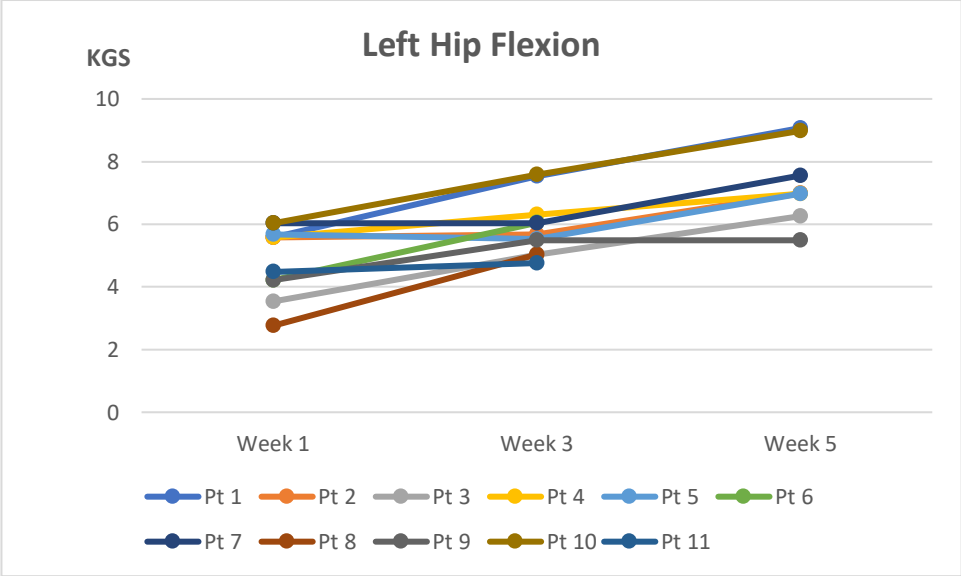
KGS= kilograms, Pt = participant

Figure 2.7: Increase in 1RM in Left Hip Abduction



KGS= kilograms, Pt = participant

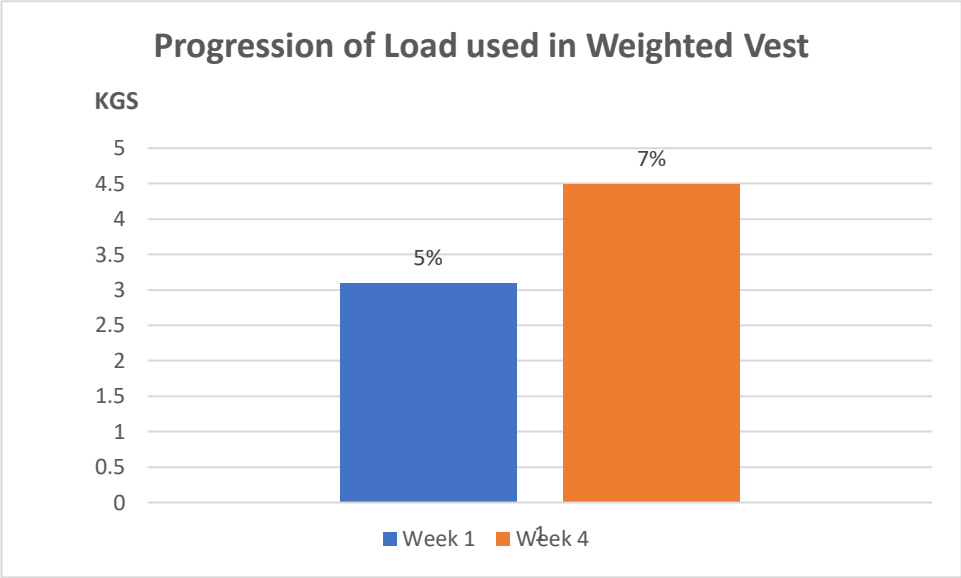
Figure 2.8: Increase in 1RM in Right Hip Flexion



KGS= kilograms, Pt = participant

Figure 2.9: Increase in 1RM in Left Hip Flexion

The prescription and progression of resistance used in the weighted vest was calculated as a percentage of body weight. The starting weight used at Week 1 was 5% of body weight, this was progressed to 7% of body weight at Week 4. The mean load in the weighted vest increase from 3.1 kgs to 4.49 kgs. Please refer to Figure 2.10 for further details.



KGS=kilograms

Figure 2.10 Progression of Load used in Weighted Vest calculated as a percentage of body weight

2.21 Conclusion

A randomised controlled feasibility study was carried out to determine the feasibility of using PRT in an older postacute inpatient population. This study demonstrated that PRT was a safe and well-tolerated intervention in this population. Due to the nature of the patient cohort, a postacute inpatient group, adherence and retention rates were sub optimal. The sample size used was not sufficient to determine the efficacy of the intervention. However, participants in the intervention group demonstrated a considerable increase in the 1RM of bilateral hip abduction and hip flexion.

CHAPTER 3 – PERCEPTIONS AND EXPERIENCES OF PHYSIOTHERAPISTS IN THE USE OF PROGRESSIVE RESISTANCE TRAINING IN A POSTACUTE OLDER INPATIENT POPULATION

The purpose of this chapter is to describe the methodology and to present the results of the qualitative component of this study – Perceptions and experiences of physiotherapist in the use of progressive resistance training (PRT) in a postacute older inpatient population.

METHODOLOGY

3.1 Aims and Objectives

3.1.1 Research Aims

- The primary aim of this qualitative research study was to explore the perceptions and experiences of physiotherapists in the use of PRT in a postacute, older inpatient population

3.1.2 Research Objectives

- To determine physiotherapists understanding of PRT and it's clinical application with an older inpatient population using semi-structured interviews.
- To ascertain the outcome measures and assessments used by physiotherapists when measuring strength and prescribing resistance exercises using semi-structured interviews.
- To explore the challenges experienced by physiotherapists in the use of PRT with an older inpatient population using semi-structured interviews.

3.2 Study Design

The Consolidated Criteria for Reporting Qualitative Research (COREQ) guidelines (Appendix 30) were used throughout the design and analysis of this study (Tong et al 2007). The research methodology guiding this study was Qualitative Description (QD) as described by Sandelowski (2000). QD is a useful method for many research questions in health care because it can help to focus on the perceptions and experiences of patients, relatives and health professionals. It answers the

questions *"why"*, "*how"* and "*what"* about human behaviour, motives, views and barriers. (Neergaard et al 2009). Semi-structured interviews are used to engage participants and involve the interviewer and participants engaging in a formal interview. The interview guide used in QD is based on expert knowledge and is a list of questions and topics that need to be covered during the conversation, usually in a particular order. The interviewer follows the guide but is able to follow topical trajectories in the conversation that may stray from the guide when he or she feels this is appropriate. Qualitative description involves low-inference interpretation meaning that even though description is the aim of QD interpretation is always present (Giorgi, 1992). Qualitative description aims to describe patterns in data based on specific factors which assists in providing clear information on ways to improve care provision (Sullivan-Bolyai et al, 2005). For these reasons, QD was considered a suitable methodology for this study exploring physiotherapists perceptions and experiences in the use of PRT in a postacute older inpatient population.

3.3 Setting

Semi-structured interviews took place in three hospitals which offer postacute rehabilitation to older inpatients - St James's Hospital, Dublin; Tallaght University Hospital, Dublin; Cappagh National Orthopaedic Hospital, Dublin. The interviews took place between June and December 2017.

3.4 Participants

The study used purposeful sampling which entails deliberate, non-random sampling of a group of people with a specific characteristic (Carter and Henderson 2005) who are willing to participate and communicate experiences and opinions in an articulate, expressive, and reflective manner (Bernard, 2002). The participants were physiotherapists currently working in, or had worked in the past six months, in the clinical area of older person inpatient rehabilitation. Physiotherapy grades ranged from staff grade physiotherapists to clinical specialist physiotherapists. An initial sample size of 20 physiotherapists was chosen in order to achieve data saturation. However, having completed three focus groups, with a total of 13 physiotherapists, it was believed that data saturation had been achieved. Qualitative methods place primary emphasis on data saturation, which occurs when data informs existing findings but does not offer anything new and which can

help to guide qualitative sample size (Miles & Huberman, 1994). A smaller sample size may be used in qualitative studies as this type of research does not require a representative sample (Stanley and Nayar, 2014) and is advised when the scope of the study is more focused (Hansen, 2006). As this study focused on a specific cohort of physiotherapists and a specific physiotherapy intervention, it was felt that this smaller sample size adequately explored all themes and achieved data saturation.

3.5 Inclusion and Exclusion Criteria

The inclusion criterion was any physiotherapist working in Ireland with at least one year's clinical experience. The physiotherapist must have experience working in the clinical area of older person inpatient rehabilitation, either currently or in the previous six months. Therefore, the exclusion criterion was any physiotherapist with less than one year's clinical experience who had not worked in this clinical area.

3.6 Recruitment

Purposive sampling was used. Physiotherapists were approached in several different ways. Firstly, colleagues working in the inpatient rehabilitation unit in Mercer's Institute for Successful Ageing (MISA), St James's Hospital were invited to participate. Following this, an invitation to participate was emailed to the Secretary of the Irish Society of Chartered Physiotherapists' Special Interest Group, Chartered Physiotherapists in Neurology and Gerontology (CPNG) (Appendix 31). This was then sent to all CPNG members. Those who wished to take part in the study contacted SC. SC also approached peers from the National Clinical Programme for Older People.

3.7 Data Collection Methods

An interview schedule (Appendix 32) of open-ended questions and prompts was devised in accordance with the aims and objectives of the study, following a preliminary literature search and in collaboration with the study supervisors. Participants were asked to complete a data collection form with the following characteristics: location of current employment, number of years of experience, staff/senior grade post and current client profile (Appendix 33). This allows potential readers to consider the relevance of the findings to their own situation

(Tong et al 2007). Participants were sent a participant information leaflet (Appendix 34) by email or post 48 hours before the interview. The participant information leaflet explained the rationale for the study and contained the contact details of the lead researcher, supervisor and co-supervisor should anyone have any further questions. Participants were asked to sign a consent form (Appendix 35) prior to conducting the interviews. Throughout the semi-structured interviews, there were several prompts to ensure adequate exploration of each topic and inclusion of all participants.

Semi-structured interviews took place at a location of the participant's choice which was in the hospital in which the participants were currently employed: St James's Hospital, Dublin; Tallaght University Hospital, Dublin; Cappagh National Orthopaedic Hospital, Dublin and ranged from 35-45 minutes in duration. The interviews were conducted by SC, with supervision and guidance from study supervisor FH during the first interview to ensure the correct interviewing technique. The interviews were recorded using a dictaphone to ensure all salient pieces of information were captured. The interviews were transcribed verbatim by a company called Audiotrans. Each participant was sent a copy of their transcript for member checking which provided the participants with an opportunity to review the data and ensure it was an accurate reflection of their opinions (Creswell and Miller, 2010).

3.8 Data Analysis

Thematic Analysis was used to analyse data in this study. Thematic Analysis is a method used in qualitative research for identifying, analysing and reporting patterns or themes within data. The six stages of Thematic Analysis as described by Braun and Clarke (2006) were completed by SC. **Stage one** involved becoming familiar with the data through line by line reading of each transcript and noting down initial ideas. SC had conducted each of the focus groups and had listened to the recordings of each focus group and therefore was very familiar with the data. **Stage two** involved generating initial codes which involved labelling portions of the data in a systematic manner, collating data relevant to each code. **Stage three** involved collating into potential themes. **Stage four** involved reviewing and refinement of the themes; SC reviewed the coded data by reading the data set for each theme and ensuring that the data set accurately reflected each theme. **Stage**

five involved defining and naming the themes using ongoing analysis to refine the specifics of each theme and generating clear definitions and names for each theme. **Stage six** involved the final analysis and production of the completed report which consists of a concise and logical account of the identified themes.

To optimise the rigor of the study, an external validator completed stages one to three of data analysis with a sample of transcripts. This process is referred to as triangulation analysis, which is a process where the same material is investigated from different perspectives to enhance validity (Farmer et al, 2006) and is a powerful method for enhancing credibility (Krefting, 1991). A meeting took place between SC and the external validator (JG) where all codes and themes were compared, discussed and reviewed. Miles and Huberman (1994) suggest that an inter-rater reliability of 80% agreement between coders on 95% of the codes is sufficient agreement when there is more than one coder, which was achieved in this study. The external validator was not directly involved in the study and is a physiotherapist (JG) who has previous experience with qualitative research following her own PhD work.

3.9 Ethical Considerations

An amendment to the ethics application (Appendix 36) of the Randomised Controlled Feasibility Study (as described in Chapter 2) was submitted and approved by the the St James's Hospital/Adelaide and Meath Hospital, incorporating the National's Children Hospital Research Ethics Committee on the 31st of May 2017 (Appendix 37).

The dictaphone recordings were deleted after the interviews were transcribed. All transcripts were coded I (Interview) 1, I2 and I3 with one master document that detailed which codes related to each participant's details should any participant later wish to withdraw their information from the study. All transcripts, signed consent forms and any study documentation was scanned, encrypted and stored in a password protected file. All information will be stored for five years accordance with the St James's Hospital/Adelaide and Meath Hospital, incorporating the National's Children Hospital Research Ethics Committee policy. For the purpose of secondary analysis, the external validator had access to three transcripts but not the audio recordings. To facilitate this analysis, the external

validator was supplied with an encrypted USB device from the lead researcher which was returned once thematic analysis was completed.

RESULTS

3.10 Introduction

The primary aim of this qualitative research study was to explore the perceptions and experiences of physiotherapists in the use of PRT in a postacute older inpatient population. Thematic analysis identified three major themes which are outlined in Figure 3.1. This section will provide a broad overview of these themes and sub themes in relation to the research question: 'What are the perceptions and experiences of physiotherapists in the use of PRT in a postacute older inpatient population?'

3.11 Demographic Information

Three semi-structured interviews were completed with thirteen physiotherapists working in the clinical area of postacute older person rehabilitation in Ireland. Data saturation was reached at the third interview, as no new themes emerged. Interviews took place between the dates of 30th June 2017 and 7th December 2017. The mean duration of the interviews was 34.6 minutes (range was from 29 minutes to 45 minutes). Twelve of the participants were female and one was male. They worked in three acute hospital sites which had onsite rehabilitation units for postacute older inpatients. The interviews took place in the workplace of the participants. The mean number of years since qualification was 7.65 years. The mean number of years spent working with older people was 5.15 years. The first interview was made up of participants numbered one to four, the second interview was made up of participants numbered five to eight and the third interview was made up of participants numbered nine to thirteen. Please refer to Table 3.1 for further details.

Table 3.1: Participant Demographics

Participant	Gender	Work Location	Grade	Context of Practice	Years working with older people
1	F	Dublin	Senior	Older Person Rehabilitation	16
2	F	Dublin	Staff	Older Person Rehabilitation	1
3	F	Dublin	Clinical Specialist	Older Person Rehabilitation	10
4	M	Dublin	Staff	Older Person Rehabilitation	2
5	F	Dublin	Senior	Older Person Rehabilitation	4
6	F	Dublin	Staff	Older Person Rehabilitation	1
7	F	Dublin	Senior	Older Person Rehabilitation and ESD	6
8	F	Dublin	Senior	Older Person Rehabilitation	7
9	F	Dublin	Senior	Older Person Rehabilitation	6
10	F	Dublin	Senior	Older Person Rehabilitation	6
11	F	Dublin	Staff	Older Person Rehabilitation	1
12	F	Dublin	Staff	Older Person Rehabilitation	3
13	F	Dublin	Staff	Older Person Rehabilitation	4

F = Female M = Male ESD = Early Supported Discharge

3.12 Themes and Sub-Themes derived from Semi-Structured Interviews

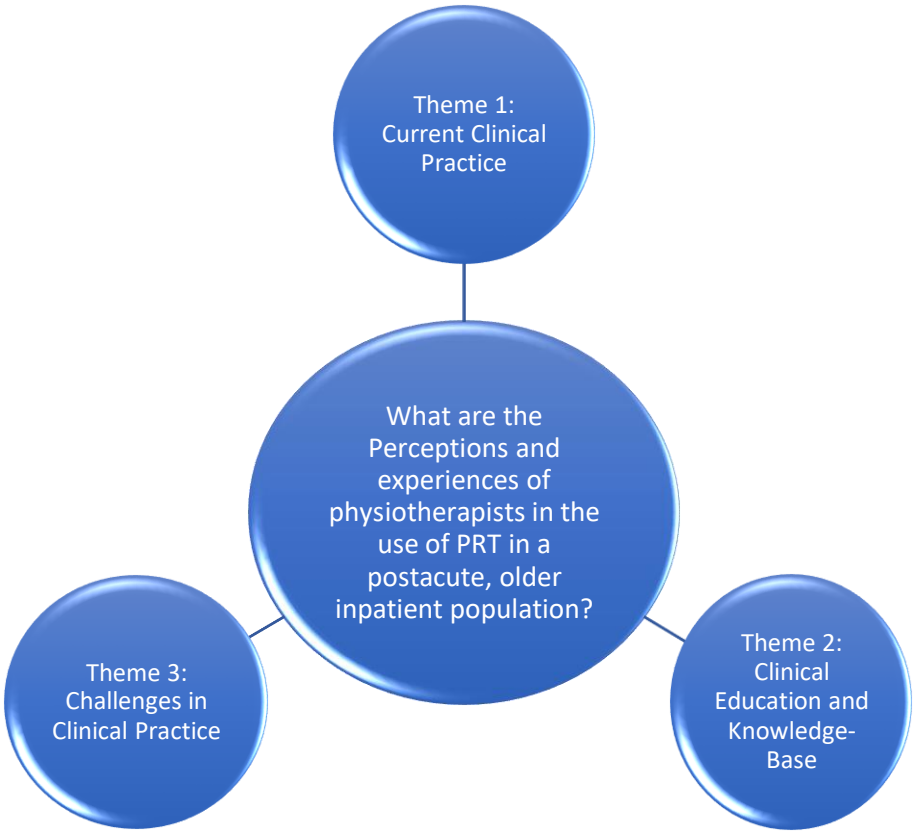


Figure 3.1: Graphical Representation of Themes and Sub-Themes

<u>Theme 1 Current Clinical Practice</u>

Subtheme 1 Clinical caseload

Subtheme 2 Emphasis on functional rehabilitation

Subtheme 3 Clinical assessment

Subtheme 4 Exercise prescription

Subtheme 5 Progression of resistance exercise

Subtheme 6 Under-prescription / underutilized

<u>Theme 2 Clinical Education and Knowledge base</u>

Subtheme 1 Clinical guidelines used to guide clinical practice

Subtheme 2 Benefits of PRT in an older patient population

Subtheme 3 Education and CPD

Theme 3 Challenges in Clinical Practice

Subtheme 1 Resources

Subtheme 2 Patient factors

Subtheme 3 Therapist factors

Subtheme 4 Family and other staff factors

Subtheme 5 Clinical setting

3.12.1 Theme 1: Current Clinical Practice

3.12.1.1 Clinical caseload

Eleven of the participants reported that older patients make up 80% or more of their clinical caseload. The remaining two participants' clinical caseloads contain 40-60% of older patients. All participants reported that the majority of their patients were frail.

3.12.1.2 Emphasis on Functional Rehabilitation

All of the participants reported that there is an emphasis on interventions to address functional limitations, for example, sit to stand, functional transfers, stairs practice, gait training.

P 7 "*I would often look at a person much more through the eyes of function."*

P 13 "*Routinely probably standing, functional strength exercises and mobility, motomed, some upper limb weights."*

P 5 "*I work with inpatients so we are trying to rehab people to get, for a specific function of getting them home."*

P 8 "*I would be the same, functional transfer practice, gait re-education, balance re-education."*

P 7 *"But I would be looking for what are your functional limitations probably first and what can't you do so do you struggle in the kitchen to squat down to get your dishes well let's practice that activity. And let's make it meaningful to the patient."*

The majority of participants reported that PRT would not be their first treatment of choice for this population.

P 2 "*With these patients, it (PRT) is not the first thing I think of doing."*

However, participants did report that resistance training would be considered a key component of a patient's rehabilitation if muscle weakness was deemed to be the main contributing factor to a patient's functional limitations.

P 6 "*If I think that their primary problem is really strength related then there might be a bit more evidence base to my approach."*

3.12.1.3 Clinical Assessment

Participants reported using mainly activity-related outcome measures in their everyday clinical practice. Outcome measures included Timed Up and Go, Elderly Mobility Scale, Tinetti, Clinical Frailty Scale, with outcomes being performed on admission and at discharge.

P10 *"We use a collection of outcome measures, the main ones we use are probably more functional ones, like the TUG or the Tinnetti. We use the Elderly Mobility Scale on admission and discharge."*

When assessing strength specifically, most participants reported using the Oxford Scale and dynamometer for grip strength.

P12 "*For upper limb strength we use the handgrip dynamometer."*

Most of the participants did not have access to a hand-held dynamometer to test upper and lower limb strength.

3.12.1.4 Exercise Prescription

Several of the participants regularly use the Motomed to provide resistance exercise for their patients. This piece of equipment is seen as a very useful adjunct to physiotherapy in rehabilitation gyms. The resistance can be graded and the time spent can be easily progressed. The most common prescription using the Motomed was reported as Gear 3-6 for 10-15 minutes and up to 5 times per week.

P 10 “T*he motomed is probably what we would consider most important when it comes to resistance training. Again, I suppose it’s a case of resource management as well because we can, its time well spent I think using the motor-med and then our one-on-one sessions are maybe based around other things like the balance re-ed and stuff like that, depending on the level the patient is at.”*

Other equipment used for resistance exercises are ankle weights and graded exercise bands. Body weight is also regularly used.

Participants routinely use their own clinical reasoning to determine the most appropriate interventions for their patients.

P 12 “*I think the type of strengthening that we do might depend then on the level of the patient’s balance. So the higher-level patients you might use some resistance bands, or ankle weights as well and then for the lower level patients it would be just the standing functional exercises using the parallel bars or using the step-ups and things like that.”*

P 11 “*In general in a one-to-one session if they are finding it very easy, their body weight it’s too easy then. You would add a weight then.”*

The participants of one of the focus groups reported considering using the 1RM method for the prescription of resistance exercises but felt that it was not appropriate for their patient cohort.

P 8 “F*or a very brief time we kind of toyed around with doing the one repetition maximum but it just was completely not practical for all, for the caseload.”*

When prescribing resistance exercises using ankle weights, graded exercise bands and body weight, the number of repetitions and sets and frequency were varied but appeared to be influenced by international guidelines.

P 9 *“I suppose it varies person to person, but yeah probably be about 10 to 15 reps and then they would be doing three sets of those.”*

P 1 "*Maybe 2-3 sets and 8-10 repetitions."*

P 8 "*I would recommend them to take a rest day in between because I think that's something that can get missed a bit, so try and do it on alternate days."*

Resistance exercises can take place either in a gym setting or on the ward. They are generally supervised by a physiotherapist or physiotherapy assistant. Occasionally, the exercises are supervised by a family member in the home.

Several of the participants reported using resistance exercises in a class setting. However, difficulties were reported around tailoring the intensity to each patient. This was mainly due to staffing and time resources. Even though exercise prescription was not specific to each patient in the class, it was felt that this was still a beneficial intervention for the patients.

P 10 "*No, like I say it isn't individual, it's definitely not individual in the class. We tried to get people that are of a reasonably similar level. On the same day they might do another strengthening session with resistance training where they are not doing as much resistance maybe in the class. But it still has good benefits, it definitely does.*"

Participants reported treating a smaller proportion of young-old patients (65-75 years old). There was a definite likelihood of challenging this patient group more when it came to resistance training. It was felt that these patients were generally more motivated and willing to accept a more challenging exercise programme.

P 10 *I think motivation is a factor in that group as well, whereby if you are that younger person we've had people here that are still working. They might be 65 or 66 but they still have a job or do something part-time or they are very active in the community. Those people the motivation for them is very different so they want to do more.*

3.12.1.5 Progression of Resistance Training

Most of the participants reported using resistance exercises as part of their rehabilitation for their older patients. However, progression of these exercises is often guided by the subjective response of the patient, with patient comfort, fatigue and quality of movement being the most utilised indicators. Progression is generally not specific or measured.

P 9 "*1 or 2kg and build up just doing the 12 reps and see if they are fatiguing with that weight. And then you increase that if they are not fatiguing with it."*

P 13 *"Subjectively how they are feeling if they feel it's quite easy, not that challenging we could add some weights."*

P 5 *"It's not officially progressed in that we might be doing sit to stand as a strengthening exercise and get them to go to a lower seat. Or you know that kind of thing, but we are not putting weights on and progressing it very often."*

P 6 "*There's no kind of set routine way that we decide its more what the patient can tolerate for the length of their class."*

Other participants reported using the American College of Sports Medicine (ACSM) Guidelines (Ref) to determine progression of resistance exercises.

P 3 "*I would usually refer to the ACSM Guidelines for this."*

3.12.1.6 Under-prescription and Underutilisation of PRT

Overall, participants acknowledged that resistance training is generally an under-utilised intervention in their daily clinical practice in the management of the older inpatient.

P 10 "*But for that frail elderly population the number that I see that I feel are really, really able to progress a lot with that is probably quite low. That's probably the wrong way to see it because I know we probably should be doing more."*

P 10 "*I think we are a wee bit risk averse."*

P11 "*We probably don't use the leg weights as much as we could be with some of the patients. A lot of the progression would be just more so in terms of reps and things like that that we do with patients.*"

Many of the participants reported using lower limb weights for patients but acknowledged that their prescription and progression was not specific or guided using objective measurement.

P 6 *And they would be progressed throughout the course of the class, it's usually about six to eight weeks that they are in the class. But it's probably not progressed enough. There's no kind of set routine way that we decide its more what the patient can tolerate for the length of their class."*

P8 *"They keep that weight no matter what muscle group they are exercising. So we don't vary it based on whether we are doing hip exercises or knee exercises. So it's not very specific that way.*"

One participant reported that PRT may be underutilized even though muscle weakness is likely a contributing factor in the patient's functional limitations.

P 6 *"Usually strength is one of the factors that you are looking at or one of the problems that you are looking at but more than likely there's maybe something that is taking priority over that. So generally might try and aim your treatment towards that particular issue as opposed to progressive, although it's probably contributing to the main problem anyway."*

3.12.2 Theme 2: Clinical Education and Knowledge-Base

3.12.2.1 Clinical Guidelines Used to guide Clinical Practice

All participants were familiar with the ACSM Guidelines and refer to these when looking for information regarding assessment and prescription of resistance exercises for older people. The participants of one of the focus groups acknowledged that they don't apply these guidelines to their clinical practice as they feel that it would not be appropriate for their patient cohort.

P 8 "*The ACSM guidelines are the ones we'd love to follow…. And we were finding that I suppose if you do give people too heavy a weight they are just not going to comply with it…So that's one of the reasons why we don't follow the guidelines as well."*

The participants of one of the other focus groups reported using the 10RM or 1RM method for prescription purposes as per the ACSM Guidelines.
P 3 "*We use the ACSM Guidelines to determine the weights used for resistance exercises."*

3.12.2.2 Benefits of PRT in an Older Patient Population

All participants were aware of the benefits which could be achieved using PRT in an older population. These included managing sarcopenia, increasing muscle strength which would translate to better functional performance, reducing falls risk, improving gait patterns, improving balance, improving bone health, improving mobility which would lead to an increase in physical activity and psychological benefits, including an increase in confidence with mobility.
P2 "*PRT is useful in the management of sarcopenia, which can translate to better functional performance"*

P7 "*There's loads of evidence to show it reduces falls risk, it improves gait, it improves their function."*

3.12.2.3 Education and Continuous Professional Development

The majority of participants reported not receiving any formal training on PRT since undergraduate level, which focused more in the area of sports medicine. Most reported using independent reading of research papers and guidelines as the most prevalent method to further their knowledge of this topic. Some participants felt that PRT in an older population was a neglected area of CPD.
P 10 *"There's not a lot of choice for CPD for the frail elderly population, especially in progressive resistance training."*

However, participants were optimistic that this would improve soon due to the fact the there has been an increase in the number of formal courses in the area of frailty.

P 10 "*There is probably a bit more now in frailty and things like that and it might be mentioned and there might be conversation about it."*

While another participant felt that any currently available formal courses on PRT focus more on theory than the clinical application of PRT.

P 12 *"But a lot of it is theoretical, it's all theory based, as opposed to actual practical skills."*

Two of the participants discussed recent formal courses that they attended which delivered training in the area of PRT in an older population. These included the ParkinsonNet and MDS Summer School for Physiotherapists and Chartered Physiotherapists in Neurology and Gerontology Falls Study Day. Both of these courses discussed the fact that physiotherapists are generally under prescribing resistance exercises in older patients. Reference was also made to the fact that 1RM was impractical in the clinical setting and some guidance was given about prescribing resistance training.

P 8 "*But one of the things that they did say was just about looking at being able to perform the say the ten or twelve good quality movements whatever the number is at the last good quality movement against resistance is and set it at that. And then gradually progress it on, either with adding more resistance or by increasing your number of repetitions."*

3.12.3 Theme 3: Challenges in Clinical Practice

3.12.3.1 Resources

Many participants reported a lack of equipment as a limiting factor in their clinical practice. This included equipment for both assessment, for example, dynamometers and for treatment purposes, for example, access to adequate ankle weights. Participants tended not to offer ankle weights to their patients for use on the ward as they had gone missing in the past. Several participants were unaware of the potential clinical application of

weighted vests for PRT but felt that it would be a useful piece of equipment to have in their facility.

P 9 "*So it is something that I was thinking about trying to just have it [weighted vest] set up, I was asking them what their average weight they used was and even just have it set up with that to try and start people doing that for something as simple as stands."*

Busy clinical caseloads and organizational pressures to expedite discharges were expressed as everyday limitations to the routine clinical application of PRT in the hospital setting.

P 5 *"It depends on our case load at the time and how much time we have to do one to one with them*."

P 4 "*I usually take a functional approach because there is pressure to shorten length of stay and facilitate discharge from the hospital."*

The availability of a physiotherapy assistant and their level of experience was also reported as a factor that may assist or limit the progression of resistance exercises

P 8 "*Since we've got a bit more allocation of physiotherapy assistant that it's something that I prescribe a lot more."*

P 8 *"We have one very experienced physio assistant so he does progress it…..*

…and then the newer person isn't so experienced so we would kind of go through that with him. And it would be through upping the weights, the resistance of the weight or just increasing the reps"

3.12.3.2 Patient Factors

Patient motivation, personality and baseline activity levels were described as a potential limiting factor in the provision of PRT in a patient's physiotherapy programme.

P 6 *"Some people if you push them too hard they just won't come back with you so it's looking at their personality and getting that balance between getting them to keep coming."*

P 7 *"And their baseline activity levels as well, I think if you know that someone was very inactive before you are going to be slightly more gradual with them."*

Patient ability and tolerance was expressed as a major limiting factor for using PRT in this population, with most of the participants reporting that this population would find PRT too challenging.

P 10 *"Sometimes they are challenged enough without, like in those functional moves they are challenged enough without adding weight to them, like say in a squat or a sit to stand or things like that. They probably, the challenge is probably big enough already."*

Patients can have difficulty applying the ankle weights themselves which will impact on their ability to perform these exercises at home or unsupervised.

P 8 *"I wouldn't tend to give people weights to do without supervision. And a lot of that is because a lot of the population have trouble putting them on."*

Participants engage with family members, where possible, to overcome this restriction.

P 5 *"If they have a family member we try and link in with them as much as possible but then if you pick a patient who's very safe and cognitively aware and then they are happy to perform them at home independently."*

Participants also expressed concern about the prescription of resistance training for their cognitively impaired patients mainly due to the amount of direction that they tend to require.

P 10 *"We do get a lot of cognitively impaired, mildly enough so that it might be just small memory deficits. But others then who really need a lot of instruction and a lot of demonstration."*

Several of the participants raised concerns about skin fragility in this population and the potential risk involved with the application of ankle weights.

P 2 *"I worry about their fragile skin and putting on ankle weights in case the skin tears."*
Weighted vests were mentioned as a potential solution for this issue.

Infection control risk was also discussed as a limiting factor in the hospital setting.
P 12 *"The other thing that would limit us from an equipment point of view is hygiene. And the fact that like a lot of things have to be wipe-able, you can't have cross-contamination between patients."*

One participant expressed concern about using PRT for their frail patients, with particular concern to deterring the patient from continuing with their physiotherapy intervention.
P 7 *"The thought of loading a lot of weight probably on a frail looking (patient)… you would have some apprehension around that. Concern maybe about the next day they might be very sore and that would put them off coming back and so you're balancing on that fine line of how far do I push this individual because I want them to continue because overall if they do a little and often with me it's better than doing a lot one day and not coming back to me again."*

3.12.3.3 Therapist Factors
Participants acknowledged that their clinical experience will often determine clinical practice and report this as a reason for focusing more on functional limitations than specific muscle strengthening.
P 7 *"I think as well definitely your background…probably impacts….when I'm working with the stroke population I would never really pick up ankle weights for example, it would be all through functional strengthening so then when I come and work with the day hospital my mind doesn't go there either."*

P 5 *"You tend to consider PRT more when treating younger patients with musculoskeletal injuries rather than your frail older patients."*

3.12.3.4 Family and Other Staff Factors

The attitudes and perceptions of family members and other staff was provided as another limiting factor in the clinical application and progression of resistance training in this population.

P 5 *"In some families they are horrified by their elderly relative being pushed. And other staff members as well…Nursing mainly. Yeah there's still an attitude of god they are old!"*

Staff and family education was suggested as a way to promote resistance exercises in the hospital setting.

P 9 *"Some of it could come down to like family and staff training as well. If we did more of that we probably could leave weights by the bedside and get the staff and family members to supervise the exercise programs there. Because we do give out exercise programs for the families to perform but I suppose we rarely give out the weights."*

However, some participants reported that they seek guidance from their Dietetics colleagues if they were concerned about nutrition and weight management.

3.12.3.5 Clinical Setting

Several participants felt that the hospital setting was not the most appropriate clinical setting for using PRT, and that it would be more suited to community-dwelling older people.

P 5 *"I would be more likely to use resistance exercises with patients in the community or attending the day hospital."*

3.13 Conclusion

Thirteen Physiotherapists from a variety of clinical settings with varying levels of experience participated in this qualitative research study. These physiotherapists routinely use a variety of equipment to provide resistance training as part of their routine intervention for older inpatients, in both class and one-to-one treatments. However, the prescription and progression of this resistance training is not specific and often appears to be under-prescribed. The participants appeared to have a good knowledge-base of current guidelines but reported a scarcity in formal

training since undergraduate level. Challenges in the use of PRT in an older population included patient factors, perceptions of family members and other staff members as well as their own clinical experience and routine practice. Participants reported an increased tendency to use PRT when treating younger patients. The next chapter will discuss the key implications of these findings, as well as the findings from the randomised controlled feasibility study from Chapter 2 and make recommendations for future research.

CHAPTER 4 – DISCUSSION

4.1 Introduction

This mixed methods study was undertaken to explore the topic of progressive resistance training (PRT) in a postacute older inpatient population. The research study was divided into two sections. The first section was of a quantitative nature and explored the feasibility of using PRT as an intervention in this cohort, while the second section consisted of qualitative research methodology and explored the perceptions and experiences of physiotherapists currently working in the clinical area of older person rehabilitation. Mixed method designs can often be superior to a single methodological approach in implementation research (Proctor et al, 2009; Palinkas et al, 2011). This is due to the complex challenges of implementing evidence-based and other innovative practices, treatments, interventions and programs. Mixed method designs are viewed as preferable in implementation research because they provide a better understanding of research issues than either qualitative or quantitative approaches alone (Palinkas et al, 2011). In such designs, qualitative methods are used to explore and obtain an understanding as to the reasons for success or failure in the implementation of evidence-based practice or to identify strategies for facilitating implementation while quantitative methods are used to test and confirm hypotheses based on an existing models and can help to guide successful implementation (Teddlie & Tashakkori, 2003).

The sample in the feasibility study was a heterogenous group of mildly frail, older inpatients referred for rehabilitation following an acute admission to the hospital. The mean age was 82.88 years and there was an equal distribution of male and female across the entire sample. The sample was dependent in relation to mobility and transfers on admission to the rehabilitation service, while many had a history of hip fracture, immobility and falls. The majority of the sample lived alone prior to admission to the rehabilitation service. Based on this baseline demographic data, the sample in this study was comparable to patients in other geriatric rehabilitation services described by previous authors (Landi et al, 2002; Gosselin et al, 2008; Johansen et al, 2012).

Tanner et al (2015) and Coker et al (2015) have previously reported losses of lean muscle mass, reductions in gait speed and aerobic capacity in healthy older adults after as little as five to ten days of bedrest. There is also an abundance of

evidence which confirms the negative effect that acute hospitalisation can have on older adults (Creditor, 1993; Sager et al, 1996; Boyd et al, 2008), with an increased LOS being directly related to functional decline (Zisberg et al, 2015). The patient cohort in this feasibility study had a median length of stay of 33.9 days (SD27.5) for the control group and 32.8 (SD 28.4) for the intervention group, before transfer to the inpatient rehabilitation unit. This would make this sample a typical cohort of frail, older patients, with multiple co-morbidities, who have been admitted to the acute hospital for an acute condition and who have likely undergone further functional decline following this prolonged acute hospital admission.

Sarcopenia is a condition characterised by an age-related loss of muscle mass, muscle strength and physical performance (Fielding et al, 2011). Cruz-Jentoft et al (2014) reported a prevalence of 1-29% in community-dwelling older adults. While Sanchez-Rodriguez et al (2016) have reported a prevalence of 50% in older adults undergoing postacute care and rehabilitation. Consequences of sarcopenia include an inability to perform ADLs, an increase risk of falls, loss of independence, an increased risk of chronic disease and all-cause mortality (Arango-Lopera et al, 2013) and is associated with an increased acute hospital length of stay and hospital readmission (Gariballa et al, 2013) and institutionalisation (Tang et al, 2018). The participants in the feasibility study possessed many of these characteristics. Falls were the most common reason for admission to hospital, with 70% presenting with a fall or a fall-related injury. Also, following an extended period of rehabilitation, TUG scores indicated that participants were still at a high risk of falling with median scores of 32 and 31 seconds for the control and intervention groups respectively. Both groups had an extended LOS in hospital. The control group had an acute hospital LOS of 33.9 days and a total LOS of 119.2 days. The intervention group had an acute hospital LOS of 32.8 days and a total LOS of 100.3 days. Twenty-one per cent of the entire sample were discharged to institutionalised care.

Resistance training is an essential intervention for improving physical function and preventing acute sarcopenia in older adults (Cadore et al, 2014). Benefits of PRT include gains in muscle mass and strength (Damas et al, 2015) and improvements in gait speed and balance (Papa et al, 2017). There is a scarcity of research

examining the use of PRT in an older postacute inpatient population. This pragmatic study aimed to examine the feasibility of employing PRT as an intervention in this patient cohort.

Participants in the qualitative study were qualified Physiotherapists who currently work in the clinical area of older person rehabilitation. The mean number of years since qualification was 7.65 years. The mean number of years spent working with older people was 5.15 years.

As previously discussed, there is a scarcity of research performed which explores PRT as an intervention in an older postacute inpatient population. The results of the qualitative study in this Research Masters demonstrated that physiotherapists working with this cohort do not routinely use PRT with their patients. Is this lack of current clinical research influencing the perceptions of physiotherapists who treat these patients? Are their concerns about feasibility measures, such as, the safety and tolerability of this intervention correct? This chapter will aim to answer these questions by discussing both the quantitative and qualitative findings of this research. Findings will be discussed under the themes derived from the semi-structured interviews.

4.2 Current Clinical Practice

4.2.1 Emphasis on Functional Rehabilitation

Eleven of the participants from the semi-structured interviews reported that older patients make up 80% or more of their clinical caseload. All participants reported that the majority of their patients were frail. All of these physiotherapists discussed their focus on functional rehabilitation, which is vital for this patient population. However, the emphasis of their rehabilitation interventions were targeted at limitations of activity, for example, transfers and mobility. Interventions targeted at body function or structure (impairment) level were less commonly used in their daily clinical practice. It was reported that this was due to increasing in-hospital pressures to expedite patient discharge and it was felt that targeting the patient's functional limitations was the best approach. This was reported by all physiotherapists, independent of their level of clinical experience. Holistic rehabilitation of older people should include interventions which target body

function and structure, as these factors are associated with and predictive of older adults' independence in measures of activity and participation (Seaton and Brown, 2018). Clinical trials investigating the effects of PRT in an older population generally include outcome measures which measure body function (muscle strength) and structure (muscle mass), functional activity measures (TUG, SPPB, gait speed) and participation measures (quality of life) to determine the outcome of this intervention, demonstrating that this intervention which is generally targeted at an impairment level will often lead to gains in activity and participation.

However, it is important to tailor PRT to the participant cohort. For example, the cohort in this study were mildly frail, deconditioned and demonstrated limitations in mobility and balance. Therefore, in order to enable participation and ensure patient safety, the exercises were performed either standing from a chair or holding onto the parallel bars in the physiotherapy gym. Gains in muscle strength and function in older inpatient cohorts have been reported following a series of bed-based (Akima et al, 2000; Kawakami et al, 2001; Mallery et al, 2003) and chair-based PRT (Latham et al, 2001; Suetta et al, 2004), indicating that this intervention can be tailored to suit all levels of mobility, balance and dependency. Similarly, if this patient group achieved independent mobility and were followed up in a community setting, the exercises could be progressed to include more functional tasks, for example, using the weighted vests while practicing stairs or including ankle weights during gait re-education, as seen in previous research (LaStayo et al, 2017; Villanueva et al, 2015).

4.2.2 Clinical Assessment

The selection of the most appropriate outcome measures is vital in a clinical trial. A range of outcome measures were used in the feasibility study to capture impairments of body functions, limitation of activities and restriction in participation, consistent with these domains described in the ICF (World Health Organisation). Hand-held dynamometry was used to assess elbow extensor and lower limb muscle strength. This outcome measure has previously been shown to be reliable in an older population (Bohannon, 1998; Abizanda et al, 2012) and the author found this outcome measure to have good intra-rater reliability in a previous study (Coleman et al, 2012). However, following the addition of a second blinded Physiotherapy assessor, there were noticeable variations in measurements and it

was felt necessary to perform an inter-rater reliability study between the two assessors. Inter-rater reliability was poor for the majority of muscle groups tested. Stone et al (2011) previously reported that tester strength is as important a determinant of reliability as the characteristics of the sample being tested, which was a potential factor in the poor inter-rater reliability results. The author would recommend a single assessor to ensure optimal reliability when using the hand-held dynamometer in future studies. This outcome measure was also time consuming, taking 15-20 minutes per participant. The 5TSTS is a reliable test of lower limb strength (Alcazar et al, 2018) and would have been quicker to administer. However, a small study involving ten patients in the rehabilitation service determined that this would not be a valid outcome measure that could be used in this patient group due to the inability to stand without using the armrests of the chair. Tibaek et al (2014) reported similar difficulties when using the 30-Second Chair-Stand test with their older inpatient cohort, as many of their participants (39%) were unable to perform this test without the use of the armrests. Skeletal muscle mass testing, using the bio impedance scales, could only be performed on 70% of participants at T1, the main reason for not being able to perform the test was the participants inability to stand unaided on the scales. Other outcome measures used; TUG, SNT, CFS and EQ-5D have previously been shown to have good reliability and validity in older populations. They were found to be quick and easy to use for the purpose of this feasibility study.

4.2.3 Prescription and Progression of Progressive Resistance Training

Chodzko-Zajko et al (2009) recommended a prescription of progressive resistance training for older adults of at least two days per week, between moderate to vigorous intensity. This feasibility study employed PRT of twice-weekly, moderate intensity (65% of 1RM) exercise in addition to routine physiotherapy, up to five days per week. Submaximal testing performed at Weeks 1, 3 and 5 ensured that the load was progressed every two weeks, while the number of repetitions and sets was also progressed. This prescription was shown to be safe and well tolerated by the older inpatients in this feasibility study. Physiotherapists in the semi-structured interviews reported a range of prescription of resistance training, from once per week to five times per week, and using a range of equipment or body weight. However, intensity of exercise was often subjective and influenced by the age-profile of the patients being treated.

Physiotherapists spoke about including resistance training in their routine rehabilitation with these patients but admitted to generally under-prescribing and using quite a conservative approach to their prescription. Many of the physiotherapists reported that they would start by using 1 or 2 kg (2.2 - 4.4 pounds) in ankle weights for this patient group. None of the participants reported using weighted vests during their routine clinical practice. Due to the lack of research looking specifically at a postacute older inpatient population, it is evident why physiotherapists would have concerns about using the recommended prescriptions for this cohort, particularly in relation to patient safety and tolerability.

As discussed in the methodology chapter, submaximal testing was performed for the intervention group on admission to the study and after two and four weeks. The average load prescribed (65% of 1RM) in Week 1 for right hip abduction was 2.86kg, left hip abduction 2.94kg, right hip flexion 2.7kg and left hip flexion 3.03kg. These loads had progressed to 5.06kg, 5.06kg, 4.59kg and 4.76kg respectively by Week 5. The average T1 load used in the weighted vest was 3.25 kg (7.16 pounds). This would indicate that participants of the interviews are under-prescribing when it comes to resistance training in this population.

4.3 Clinical Education and Knowledge-Base

Participants in the semi-structured interviews demonstrated a good knowledge of current clinical guidelines which can be employed to guide prescription and progression of PRT in this patient population. They also demonstrated a comprehensive understanding of the benefits which can be derived from using PRT for this cohort. However, the physiotherapists expressed a lack in confidence in the prescription of resistance training in this population. A lack of formal education, both at undergraduate and postgraduate level, was viewed as partly responsible for this. However, the physiotherapists felt that the accessibility of continuous professional development in recent times in the area of frailty and PRT has improved.

As mentioned previously, there is a lack of good quality evidence in the optimum prescription of PRT in this patient cohort. However, this study has shown that PRT was well-tolerated by this patient group, with no serious adverse events.

Physiotherapists, with the relevant education and training can feel confident that PRT could be safely included as part of their routine intervention for this group. There are plenty of good resources in the form of guidelines and systematic reviews which would help to guide practice. Local inservice training could be delivered to educate Physiotherapy staff in a rehabilitation unit, including Physiotherapy assistants who play a crucial role in the delivery of both one-to-one and class interventions.

4.4 Challenges in Clinical Practice

4.4.1 Resources

Physiotherapists in the focus groups attributed their busy clinical caseloads and pressures to expedite patient discharge as part of the reason for not routinely including PRT in the management of this patient cohort. Both the control and intervention groups received an average of 21 routine physiotherapy sessions. The intervention group also received an average number of 7.6 PRT sessions. Further studies are required to determine the optimum number of PRT sessions that would be needed to lead to a functional improvement in this population. In the busy clinical setting, it is vital to target interventions to achieve the best outcomes without putting extra demands on already stretched resources. An interesting study would be to introduce PRT in a class setting 2-3 days per week, with the remaining days being spent delivering routine rehabilitation and comparing this to the current practice of daily routine rehabilitation.

Other resource issues reported were lack of weights. Most rehabilitation units should have access to this equipment. If not, a business case could be submitted, for example, for three pairs of ankle weights, preferably with a single strap to allow for ease of application, and three weighted vests. This would be sufficient to run a class with six participants, and the equipment could also be used individually.

4.4.2 Patient Factors

Many of the physiotherapists involved in the semi-structured interviews expressed concerns regarding potential injury to patients. These included skin lacerations and musculoskeletal injuries. During the course of the feasibility study, there were no incidents of skin lacerations following the application of leg weights. While there were no serious adverse events for those participating in the intervention group,

three mild to moderate musculoskeletal adverse events were reported by three different participants. Only, one of these participants chose to discontinue the intervention due to the aggravation of already present back pain. The other two participants were happy to continue in the study. Previous studies examining early rehabilitation programmes in the acute hospital setting, but not specifically PRT, reported few adverse events in the intervention groups and there were no significant differences when compared to the control groups (Mallery et al, 2003; Courtney et al, 2012; Laver et al, 2012). In a systematic review by Lopez et al (2018), which examined the feasibility of using PRT with frail older community-dwelling adults, seven of the studies discussed adverse events, with there being no adverse events reported in any of the studies. Tibaek et al (2014) performed an RCT looking at PRT in an older inpatient population and reported no adverse events during the intervention.

There also appeared to be a perception among the physiotherapists involved in the interviews that this older postacute inpatient population would not want to participate in PRT and that it would discourage the patient from continuing in rehabilitation. However, 89% of patients who were invited to be included in the study agreed to participate, even though it had been explained to them that if chosen for the intervention group, that they would be engaging in PRT. This is much higher than the 54% of participants who consented to participate in a similar study (Tibaek et al, 2014) Also, the satisfaction survey demonstrated that only 1 participant would not engage in the study again. Previous research by Broderick et al (2015) explored the perceptions of frail older inpatients around exercise activity. They reported that this population saw exercise as an important activity with potentially positive outcomes. Participants who had experience with structured exercise or rehabilitation programmes indicated strong positive perceptions, likely associated with positive physical outcomes achieved during these programmes. Perceived barriers included lack of social support, presence of an underlying medical condition, fear, age and limited ability. Lenze et al (2012) found that patient motivation can be influenced by principles of engagement used by the physiotherapist, for example, clearly stating the benefits and goals of interventions and by providing regular feedback. Outcome expectations are based on a belief that the completion of a planned action will result in the achievement of a planned goal (Hall et al, 2012). Self-efficacy refers to a person’s belief in their ability to

effectively carry out a specific behaviour (Bandura et al, 1997) and is a significant predictor of exercise activity among older adults (Warner et al, 2011; Neupert et al, 2009). Therefore, if a patient is given adequate education around the benefits of an intervention and assurances that it is safe, they will likely be motivated to participate in PRT and work towards clearly defined and mutually developed functional goals.

The feasibility study was not powered to comment on the efficacy of the intervention. The intervention group demonstrated median gains in the majority of measures of grip, elbow extensor and LL strength. While the control group demonstrated a decline or minimal improvements in these measures. However, the only muscle group which showed a statistically significant improvement in the intervention group was left ankle dorsiflexion. There was a decline in muscle mass and body weight in both groups with no statistically significant difference between the groups. Both groups demonstrated improvements in their measures of activity – TUG, SNT, CFS. However, there was no statistically significant differences between the two groups. Both groups also demonstrated an improvement in their EQ-VAS measure of participation. However, there was no statistically significant difference between the two groups. The control group had a longer LOS in the rehabilitation unit, an average of 85.4 days when compared to 67.6 days spent in the unit by the intervention group. This was not statistically significant. Following their inpatient rehabilitation, the sample remained a frail group with lower functional mobility and grip strength scores when compared with their age-matched community-dwelling peers (Kenny et al, 2013). This study demonstrates that PRT is a safe and feasible intervention even for this cohort.

4.4.3 Therapist Factors

Participants of the focus groups acknowledged that their clinical experience will often determine clinical practice and report this as a reason for focusing more on functional limitations than specific muscle strengthening. Many of the physiotherapists have worked with this cohort for a number of years and don't appear to routinely consider this intervention for this patient group. Although, many of the physiotherapists reported that they would consider using PRT for younger patients particularly in a musculoskeletal clinical setting.

4.4.4 Clinical Setting

Many of the physiotherapists who took part in the focus groups felt that the postacute inpatient setting was not the most appropriate clinical setting to include PRT in the rehabilitation of this population. It was felt that the outpatient setting, either in a day hospital or in primary care was more appropriate. As already reported, this study demonstrated that PRT was well tolerated by this patient group and the class format was easily incorporated into routine clinical practice.

Due to the setting of the clinical trial, a postcute rehabilitation unit, patient turnover was lower than in an acute ward. Due to this lower patient turnover, only thirty-seven suitable patients were identified, with thirty-three agreeing to participate. In the four years since this study was completed, there is a much stronger emphasis on reducing length of stay and performing this postacute rehabilitation phase in the Primary Care setting. A six-week period of rehabilitation in the current hospital setting would hugely limit the available number of patients that could potentially be recruited if the same timepoint was adhered to in a future study. Future research would need to have collaboration between the acute and primary care settings, with the participants continuing with their PRT after discharge from the hospital setting. Just over a quarter of patients (28%) who transferred to the rehabilitation unit were eligible for inclusion in this feasibility study and 89% of these agreed to participate in the study. Kosse et al (2013), in a systematic review of early rehabilitation programmes, found that between the 14% and 48% of the admitted patients met the inclusion to be enrolled in the programs, and between 3% and 19% of the patients were not willing to participate. However, most of these studies were trying to recruit patients within 1-2 days of acute hospital admission. Brown et al (2006) found that trying to recruit from the acute hospital setting was not feasible, with only 2% of their sample recruited from this setting, the remainder were recruited post discharge.

Both adherence and retention rates were affected by the postacute nature of the patient cohort in the feasibility study. Patients became medically unwell and were transferred to another ward for medical management, patients had achieved their optimal rehabilitation potential earlier than six weeks and had been discharged home early and two patients in the intervention group (12%) dropped out of the study. Adherence rates were evaluated using weekly attendance records for the

study. The mean number of PRT interventions received by the intervention group was 7.6 ± 3.63. The planned number of intervention sessions per participant was 12, made up of twice weekly PRT sessions over a period of six weeks. Therefore, this equates to the delivery of 63% of the possible total number of intervention sessions. Mallery et al (2003) reported the same adherence rate of 63%, while Laver et al (2012) reported a much higher adherence rate of 90%. Similar reasons were given for reduced adherence rates. Retention rates examined the number of participants who attended for T2 assessment compared with those who attended for baseline assessment. The T2 assessment was not completed for four participants (23%) of the control group and two participants (12%) of the intervention group.

These adherence and retention rates should not discourage physiotherapists from including PRT in their management of these patients. Physiotherapists could include details of a patient's exercise prescription, including number of sets, repetitions and load in their referrals to their colleagues in Primary Care or Day Hospital settings. Higher level patients could be advised to attend their local gym and continue their PRT under the supervision of a trained gym instructor. Patients can find extremely useful resources on the Get Ireland Active website (www.getirelandactive.ie) and the Go for Life initiative which runs in partnership with the Local Sports Partnerships and the Health Services Executive Heath Promotion Units (www.ageandopportunity.ie).

4.5 Strengths of the Study

- This was a mixed-methods design which provided valuable information both on the feasibility of delivering PRT to a postacute older inpatient population and about the current practice of physiotherapists who work with this population.
- The feasibility study demonstrated that the majority of the eligible patients were happy to be approached and included in a trial which delivered PRT.
- The feasibility study demonstrated that PRT was a safe intervention with only three mild to moderate adverse events reported throughout the course of the study.

- The feasibility study highlighted issues around outcome measures that were chosen to measure muscle mass and muscle strength. This could be useful for future studies.
- The feasibility study was not powered to comment on the efficacy of the intervention. However, participants in the intervention group demonstrated substantial increases in the 1-RM of both hip abductors and hip flexors.
- Baseline demographics were similar for both the control and intervention groups. The number of days between T1 and T2 assessments was similar for both groups – 43 days for the control group and 40 days for the intervention group. Both groups received the same number of routine physiotherapy sessions – 21 sessions. This demonstrates a high level of treatment fidelity throughout the course of the study.

4.6 Limitations of the Study

- There was missing data at both T1 and T2. This was due to the inability of approximately one third of participants to complete the assessment for muscle mass on the bio impedance scales. The nature of the patient cohort, medical instability, early discharge and dropouts, were the main causes of missing data at T2.
- Due to the small sample size, conclusions can not be made about the efficacy of the intervention. A larger multi-centre RCT is recommended to determine efficacy and optimal exercise dosage.
- The three semi-structured interviews took place in acute hospitals in Dublin. While it had been planned to visit other national hospitals, the achievement of data saturation at this point meant that the researchers felt that there was no further information to be gained from further interviews.

4.7 Recommendations for Future Research

- Due to the issues regarding inter-rater reliability of handheld dynamometry testing, it is recommended that a single assessor is used to ensure optimal reliability of this outcome measure.
- The feasibility study was undertaken as a pragmatic piece of research in a busy clinical setting. Recruitment was slow with only 33 participants recruited in one year. The authors would recommend a grant-funded multi-

centre RCT to examine the optimum frequency and intensity required to provide functional gains in this population.

- The focus of postacute rehabilitation is changing, with the emphasis being placed on providing rehabilitation in the community. The authors would recommend a change in methodology, for example a shorter length of hospital stay, followed by continued PRT after hospital discharge provided by physiotherapy colleagues in primary care.

4.8 Conclusion

Functional decline is highly prevalent among older people following an acute hospital admission. This functional decline is multifactorial in nature, one of these factors being extended bedrest and low levels of physical activity while in hospital. This can have a detrimental effect on an older adult's muscle mass, muscle strength and physical performance. Many of these older adults are pre-sarcopenic or sarcopenic and are extremely vulnerable to a further deterioration of function and dependence in ADL ability. PRT has been shown to successfully target both functional decline and sarcopenia. However, the majority of this research has been performed with a healthy older community-dwelling population.

This mixed-methods research study aimed to examine the feasibility of using PRT in an older postacute inpatient population while also examining the current clinical practice and perceptions of physiotherapists who work with this cohort.

The feasibility study involved a sample that was frail, older, dependent in mobility and transfers, with multiple co-morbidities and polypharmacy. PRT was shown to be safe in this population with no serious adverse events reported. While just over one quarter of patients admitted for rehabilitation were suitable for inclusion in the study, most of those consented to participate. Adherence and retention rates were affected by the nature of the cohort, as some participants were discharged home early and others were transferred to another ward after becoming medically unwell. Satisfaction rates were high and the participants reported perceived benefits in strength and ADL ability following the study. The authors found some issues with the psychometric properties of some of the outcome measures employed.

The semi-structured interviews with physiotherapists who treat this patient cohort provided information about current clinical practice. Physiotherapists regularly use resistance training with their patients but usually without objective prescription and progression. Many of the participants felt that frail older adults would not tolerate resistance training and are often reluctant to use it as an intervention in their rehabilitation. All of the physiotherapists were aware of current clinical guidelines but felt that there is currently a lack of continuous professional development aimed at this intervention for this particular cohort.

This study has demonstrated that PRT is safe to use with this population. It also demonstrates that physiotherapists do not routinely use PRT as a rehabilitation intervention for this population and when they do, it is often under-prescribed and inadequately progressed. A larger trial, in collaboration with Primary Care colleagues, to confirm the optimal frequency and intensity in order to prove the efficacy of this intervention with this population is recommended.

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Appendix 1 – CONSORT Checklist

CONSORT 2010 checklist of information to include when reporting a pilot or feasibility trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a pilot or feasibility randomised trial in the title	1
	1b	Structured summary of pilot trial design, methods, results, and conclusions (for specific guidance see CONSORT abstract extension for pilot trials)	14
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale for future definitive trial, and reasons for randomised pilot trial	49
	2b	Specific objectives or research questions for pilot trial	48
Methods			
Trial design	3a	Description of pilot trial design (such as parallel, factorial) including allocation ratio	n/a
	3b	Important changes to methods after pilot trial commencement (such as eligibility criteria), with reasons	n/a
Participants	4a	Eligibility criteria for participants	51
	4b	Settings and locations where the data were collected	49
	4c	How participants were identified and consented	50
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	59
Outcomes	6a	Completely defined prespecified assessments or measurements to address each pilot trial objective specified in 2b, including how and when they were assessed	53-59
	6b	Any changes to pilot trial assessments or measurements after the pilot trial commenced, with reasons	56
	6c	If applicable, prespecified criteria used to judge whether, or how, to proceed with future definitive trial	n/a
Sample size	7a	Rationale for numbers in the pilot trial	n/a
	7b	When applicable, explanation of any interim analyses and stopping guidelines	n/a.
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	59
	8b	Type of randomisation(s); details of any restriction (such as blocking and block size)	59
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	59

Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	59
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	52
	11b	If relevant, description of the similarity of interventions	n/a
Statistical methods	12	Methods used to address each pilot trial objective whether qualitative or quantitative	61
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were approached and/or assessed for eligibility, randomly assigned, received intended treatment, and were assessed for each objective	63
	13b	For each group, losses and exclusions after randomisation, together with reasons	63
Recruitment	14a	Dates defining the periods of recruitment and follow-up	62
	14b	Why the pilot trial ended or was stopped	n/a
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	65
Numbers analysed	16	For each objective, number of participants (denominator) included in each analysis. If relevant, these numbers should be by randomised group	74-80
Outcomes and estimation	17	For each objective, results including expressions of uncertainty (such as 95% confidence interval) for any estimates. If relevant, these results should be by randomised group	n/a
Ancillary analyses	18	Results of any other analyses performed that could be used to inform the future definitive trial	81-84
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	71
	19a	If relevant, other important unintended consequences	n/a
Discussion			
Limitations	20	Pilot trial limitations, addressing sources of potential bias and remaining uncertainty about feasibility	116
Generalisability	21	Generalisability (applicability) of pilot trial methods and findings to future definitive trial and other studies	117
Interpretation	22	Interpretation consistent with pilot trial objectives and findings, balancing potential benefits and harms, and considering other relevant evidence	117
	22a	Implications for progression from pilot to future definitive trial, including any proposed amendments	n/a
Other information			
Registration	23	Registration number for pilot trial and name of trial registry	49
Protocol	24	Where the pilot trial protocol can be accessed, if available	n/a
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	15
	26	Ethical approval or approval by research review committee, confirmed with reference number	51

Appendix 2 - Record of Routine Physiotherapy Sessions

ID: _____

Date of 1st session / /	One tick per session	Number of minutes per session	Treatment Type
Week 1	M _____ T _____ W _____ T _____ F_____		Gait: Balance: Strength: Flexibility: Other:
Week 2	M _____ T _____ W _____ T _____ F_____		Gait: Balance: Strength: Flexibility: Other:
Week 3	M _____ T _____ W _____ T _____ F_____		Gait: Balance: Strength: Flexibility: Other:
Week 4	M _____ T _____ W _____ T _____ F_____		Gait: Balance: Strength: Flexibility: Other:
Week 5	M _____ T _____ W _____ T _____ F_____		Gait: Balance: Strength: Flexibility: Other:
Week 6	M _____ T _____ W _____ T _____ F_____		Gait: Balance: Strength: Flexibility: Other:

STANDARD APPLICATION FORM

For the Ethical Review of Health-Related Research Studies

which are not

Clinical Trials of Medicinal Products For Human Use as defined in S.I. 190/2004

DO NOT COMPLETE THIS APPLICATION FORM
IF YOUR STUDY IS A CLINICAL TRIAL OF A MEDICINAL PRODUCT

This Application Form is divided into Sections.

Sections A, B, C, D, E, J, K, L are Mandatory

Sections F, G, H, and I are optional. Please delete Sections F, G, H, and I if these sections do not apply to the application being submitted for review.

IMPORTANT NOTE: It is imperative that the Standard Application Form is not completed if there is any possibility that the study for review is a clinical trial of medicinal product as defined by Statutory Instrument 190/2004.

IMPORTANT NOTE: Please refer to **Section I** within the form before any attempt to complete the Standard Application Form. **Section I** is designed to assist applicants in ascertaining if their research study is in fact a clinical trial of a medicinal product.

IMPORTANT NOTE: This application form permits the applicant to delete individual questions within each section depending on their response to the preceding questions. Please respond to each question carefully and refer to the accompanying *Guidance Manual* for more in-depth advice prior to deleting any question.

SECTION A GENERAL INFORMATION

SECTION A IS MANDATORY

IMPORTANT NOTE: This application form permits the applicant to delete individual questions within each section depending on their response to the preceding questions. Please respond to each question carefully and refer to the accompanying *Guidance Manual* for more in-depth advice prior to deleting any question.

A1 Title of the Research Study:
Can lower limb resistance training improve strength, muscle mass and functional outcomes in older inpatients in a post-acute rehabilitation unit? A randomised control trial.

A2 Principal Investigator(s):
Title: Ms. **Name:** Sinead Coleman(SC)
Qualifications: BSc Physiotherapy, MSc Neurology and Gerontology
Position: Senior Physiotherapist
Dept: Physiotherapy
Organisation: St James's Hospital
Tel: 01 4162149
E-mail: scoleman@stjames.ie

A3 (a) Is this a multi-site study? No

A3 (b) Please name each site where this study is proposed to take place and state the lead investigator for each site:

Site:	Lead Investigator:
ST JAMES'S HOSPITAL	SINEAD COLEMAN

A3 (c) For any of the sites listed above, have you got an outcome from the research ethics committee (where applicable)? N/A

A4. Co-Investigators:

Name of site St James's Hospital

Title: Dr. **Name:** Conal Cunningham
Qualifications: MD FRCPI
Position: Geriatric consultant
Organisation: St James's Hospital
Role in Research: Statistician and advisory supervisor

Title: Dr. **Name:** Frances Horgan
Qualifications: PhD
Position: Senior Lecturer in Physiotherapy
Organisation: RCSI
Role in Research: Supervisor

Title: Ms. **Name:** Niamh Murphy
Qualifications: MSc
Position: Physiotherapy Manager
Organisation: St James's Hospital
Role in Research: Supervisor

Title: Mr. **Name:** Gareth T Clifford
Qualifications: MSc Neurology and Gerontology
Position: Physiotherapist
Organisation: St James's Hospital
Role in Research: Researcher

Title: Dr. **Name:** David Robinson
Qualifications: MD FRCPI
Position: Geriatric Consultant
Organisation: St James's Hospital
Role in Research: Supervisor

Title: Ms. **Name:** Rachel Joy
Qualifications: BSc
Position: Clinical Nutritionist in Geriatrics
Organisation: St James's Hospital
Role in Research: Researcher

A5. Overall contact person who is to receive correspondence in relation to this application / who is to be contacted if a query arises in relation to this application.

Title: Ms. **Name:** Sinead Coleman
Address: **Physiotherapy Department, St James's Hospital, James's St, Dublin 8**
Tel (work): 014162149 **Tel (mobile):** 0863779143
E-mail: scoleman@stjames.ie

A6. Please provide a lay description of the study.
We would like to carry out a randomised control trial to determine if lower limb strengthening improves functional performance and increases muscle mass in an older population in a post-acute inpatient rehabilitation unit. Patients will be asked to participate in a circuit-type exercise class two times per week. The class will consist of exercises to specifically target and strengthen the muscles in the legs. Resistance will be provided with ankle weights or weighted vests. This will be in addition to their usual care.

A7 (a) Is this study being undertaken as part of an academic qualification?
No

A7 (b) If yes, please complete the following:
Student Name: Course:
Institution: Academic Supervisor:

SECTION B STUDY DESCRIPTORS

SECTION B IS MANDATORY

B1. Provide information on the study background.
Due to the increasing older population in Ireland, reducing age-related disability is an essential public goal. Currently 11% of the population are aged 65 years or older. This

proportion will have increased to 18% (>1,000,000) by 2031, with the biggest increase of people aged 80 years or older (National Steering Group on the Prevention of Falls in Older People and the Prevention and Management of Osteoporosis throughout Life, 2008). Mazzeo et al (1998) reported that the process of ageing can cause a deterioration in cardiovascular fitness, strength, postural stability, flexibility and psychological function which can lead to a decline in functional performance in this population. Regarding the impairment of reduced strength, the body's muscle mass decreases (sarcopenia) with increasing age. This gradually leads to a reduction in muscle strength (ACSM). Consequences of sarcopenia include a higher risk of falls and fractures, an impaired ability to regulate body temperature, slower metabolism, a possible deficiency in glucose regulation and an overall reduction in functional capacity. Older people have been shown to make significant gains in strength with an adequate training stimulus (Bean et al, 2004; Seynnes et al, 2004). Strength training can have beneficial effects on bone density, physical activity and functional status in the older adult. The ACSM have recommended a frequency of 2-4 days per week, 20-45 minutes per session and an intensity of 65-75% of maximum to significantly increase muscle strength. Previous research carried out in this post-acute rehabilitation unit looking at the effects of rehabilitation for older people demonstrated significant gains in balance, exercise tolerance, functional mobility, frailty and quality of life but not in lower limb strength (Coleman et al, 2010).We would like to carry out a randomised control trial to determine if an appropriate individually-tailored resistance-training programme can improve lower limb strength and physical function in an older inpatient population. A pilot study has been carried out which has determined the most appropriate types of exercises, and ensured us that this is a tolerable type of exercise for a frail older population.

B2. List the study aims and objectives.

Aim: The primary aim of this research is to evaluate changes in lower limb strength and physical function following six weeks of resistance training and routine physiotherapy versus a contol group of routine physiotherapy only in an older inpatient population.

Objectives: To evaluate changes in lower limb strength, mobility, functional exercise capacity, quality of life and frailty following six-weeks of routine physiotherapy and twice weekly resistance training.

B3. List the study endpoints (if applicable).

At the end of the study, we will be able to describe changes in lower limb strength, muscle mass and physical function following six weeks of resistance training and routine physiotherapy versus a control group of routine physiotherapy only in an older inpatient population.

B4. Provide information on the study design.

This will be a randomised control trial, recruiting consecutive appropriate patients in this post-acute rehabilitation unit.

B5. Provide information on the study methodology.

Inclusion and exclusion criteria will be set. Appropriate patients will be approached, and the intervention explained to them. The patient will be given an information leaflet and 48-hours to consider involvement in the study. If the patient is happy to participate, they will sign a consent form. A full initial assessment will be carried out, to include;

1. Patient demographics

2. Lower limb dynamometry (Bohannon, 1986) will be measured using the Power Track II Commander by JTech Medical. A previous study in this rehabilitation unit has determined that this is a reliable measure of lower limb strength in this population. The primary outcome measurement will be quadriceps muscle strength. Secondary outcome measures will be hip and ankle strength as well as the following outcome measures 3-7.

3. Functional mobility using the Timed Up and Go (TUG) – this is a test of basic functional mobility for frail elderly people (Podsiadlo and Richardson, 1991). The patient is asked to stand up from a chair, walk three metres, turn around and return to the chair, while being timed by the assessor.

4. Six Minute Walk Test (6MWT) – this is a performance-based test (Butland et al, 1982). The distance walked in six minutes is measured and reported in metres or feet and is an indication of exercise tolerance.

5. EuroQol-5D (EQ-5D) - measures health related quality of life (Anonymous, 1990), it contains a visual analogue scale (0 to 100, representing dead to excellent health state) and five items: mobility, self-care, usual activities, pain/discomfort and anxiety/depression.

6. Canadian Study of Health and Ageing Clinical Frailty Scale (CFS) – this is a measure of frailty based on clinical judgement. It is an ordinal scale which ranges from 1 to 7. Reliability and validity have been proven in an older population (Rockwood et al, 2005).

7. Height will be measured from ulna length (BAPEN, 2004), weight will be measured using body composition scales (Tanita), and body mass index (BMI) calculated using these measures. Skeletal muscle mass will be calculated using a validated equation based on measured bioimpedance from the body composition scales (Janssen J Appl Phil 2000). Grip strength will be measured using a handgrip dynamometer on the non-dominant arm (Clinifeed/Roussel dynamometer). Data on gait speed, grip strength and muscle mass will be will be interpreted using the EWGSOP algorithm to identify cases of sarcopenia (Cruz-Jentoft, Age and Ageing). Patients will be identified according to sarcopenic status and will receive Clinical Nutrition input in the usual way.

A blinded assessor, who has been fully trained, will perform the assessments. Patients will then be randomised into two groups. Patient allocation will be stratified based on age, gender

and muscle strength using the technique of minimisation. The intervention group will receive usual physiotherapy care as well as twice weekly tailored and progressive resistance exercises for the lower limbs. The control group will receive usual physiotherapy and will be provided with a leaflet outlining the benefits of exercise. The intervention group will participate in a resistance training class with a circuit-type setting twice weekly, sessions will last approx 35 minutes and will include a warm-up and cool-down period. The intervention will be carried out by SC and a research assistant. Exercises will be tailored to each patient. Some of the exercises will use ankle weights as the resistance, using 65-75% of their 1-Repetition Maximum (this is the heaviest weight that can be lifted only once). The 1-RM will be determined using the Oddvar Holten diagram. Some of the exercises will use weighted vests as the resistance. This will be calculated at 5-10% of body weight as used in previous research (Salem et al, 2004; Greendale et al, 2000). The intervention will last for 6 weeks. The intervention group will be reassessed using dynamometry at 2 and 4 weeks in order to progress the intensity of exercise for each patient.

Outcome measurement will occur again when the intervention has been completed.

Anonymous. (1990) EuroQol – a new facility for the measurement of health-related quality of life. The EuroQol Group. *Health Policy,* 16:199-208.

Bean JF, Herman S, Kiely DK, Frey IC, Leveille SG, Fielding RA, Frontera WR (2004) Increased velocity exercise specific to task (invest) training: a pilot study exploring effects on leg power, balance and mobility in community-dwelling older women. *J Am Geriatr Soc,* 52(5), 799-804.

Bohannon R.W. (1986) Test-retest reliability of hand-held dynamometry during a single session of strength assessment. *Physical Therapy,* 66(2):206-209.

Butland R.J.A., Pang J., Gross E.R., Woodcock A.A., Geddes D.M. (1982) Two, six and twelve minute walking tests in respiratory disease. *British Medical Journal,* 284:1607-1608.

Coleman S, Cunningham C, Walsh JB, Coakley D, Harbison J, Casey M, Murphy N, Horgan F (2012) Outcomes among older people in a postacute inpatient rehabilitation unit. *Disability and Rehabilitation,* 34:15,1333-1338

Cruz-Jentoft AJ, Baeyens JP, Bauer JM, Boirie Y, Cederholm T, Landi F, Martin FC, Michel JP, Rolland Y, Schneider SM, Topinková E, Vandewoude M, Zamboni M; European Working Group

on Sarcopenia in Older People. Sarcopenia: European consensus on definition and diagnosis: Report of the European Working Group on Sarcopenia in Older People. *Age Ageing.* 2010 Jul;39(4):412-23

Haywood K.L., Garratt A.M., Fitzpatrick R. (2005) Quality of life in older people: a structured review of generic self-assessed health instruments. *Quality of Life Research,* 14(7):1651-1668.

Janssen I, Heymsfield SB, Baumgartner RN, Ross R. Estimation of skeletal muscle mass by bioelectrical impedance analysis. *J Appl Physiol*. 2000 Aug;89(2):465-71

Mazzeo R.S., Cavanagh P., Evans W.J., Fiatarone M., Hagberg J., McAuley E., Startzell J. (1998) Exercise and physical activity for older adults. *Medicine and Science in Sports and Exercise,* 30(6):992-1008.

National Steering Group on the Prevention of Falls in Older People and the Prevention and Management of Osteoporosis throughout Life (2008) Strategy to Prevent Falls and Fractures in Ireland's Ageing Population. www.hse.ie (accessed 05 January 2010).

Podsiadlo D., Richardson S. (1991) The Timed 'Up and Go': a test of basic functional mobility in frail elderly persons. *Journal of the American Geriatrics Society,* 39:142-148.

Rockwood K., Song X., MacKnight C., Bergman H., Hogan D.B., McDowell I., Mitnitski A. (2005) A global clinical measure of fitness and frailty in elderly people. *Canadian Medical Association Journal,* 173(5):489-495.

Seynnes O, Fiatarone Singh MA, Hue O, Pras P, Legros P, Bernard PL (2004) Physiological and functional responses to low-moderate versus high-intensity progressive resistance training in frail elders. *J Gerontol A Biol Sci Med Sci,* 59(5), 503-509

B6. What is the anticipated start date of this study?
June 2013

B7. What is the anticipated duration of this study?
12-18 months

B8 (a) How many research participants are to be recruited in total?
100 participants

B8 (b) How many research participants are to be recruited per treatment group (if applicable)? 50 per group

B8 (c) Provide information on the statistical approach to be used (if appropriate) / source of any statistical advice. Statistical advice is provided by Mercer's Institute for Research In Ageing (MIRA). A study of 32 elderly rehabilitation inpatients from hospital 2 was used to inform the power calculation (Coleman et al 2012). A sample size of 100 (50 per group) would have a power of 80% to detect a difference in muscle strength of 0.5kg at the hip, knee and ankle with an alpha of 5%.

B8 (d) Please give a brief justification of sample size and details of the sample size calculation (including minimum clinically important difference).
A study of 32 elderly rehabilitation inpatients from hospital 2 was used to inform the power calculation (Coleman et al 2012). A sample size of 100 (50 per group) would have a power of 80% to detect a difference in muscle strength of 0.5kg at the hip, knee and ankle with an alpha of 5%.

B8 (e) Where sample size calculation is impossible (e.g. It is a pilot study and no previous studies can be used to provide the required estimates) then please explain why the sample size to be used has been chosen.
N/A

SECTION C STUDY PARTICIPANTS

SECTION C IS MANDATORY

IMPORTANT NOTE: This application form permits the applicant to delete individual questions within each section depending on their response to the preceding questions. Please respond to each question carefully and refer to the accompanying *Guidance Manual* for more in-depth advice prior to deleting any question.

SECTION C1 PARTICIPANTS – SELECTION AND RECRUITMENT

C1. 1 How many research participants are to be recruited? At each site (if applicable)? And in each arm of the study (if applicable)?

Name of site:	**Names of arms (if applicable)**		
	Insert name of arm (if applicable):	**Insert name of arm (if applicable):**	**Insert name of arm (if applicable):**
ST JAMES HOSPITAL	N/A	N/A	N/A

C1.2 How will the participants in the study be selected?
Consecutive admissions to the rehabilitation unit will be screened for suitability and if appropriate, their consent will be requested by SC. They will then be randomised into the intervention or control group.

C1.3 How will the participants in the study be recruited?
Suitable patients will be approached by SC.

C1.4 What are the main inclusion criteria for research participants? (please justify)
Patients admitted to the unit for rehabilitation.
Patients >65 years of age.

Patients must be medically stable.

Patients who are able to follow one-stage commands.

Patients must be able to give informed consent.

C1.5 What are the main exclusion criteria for research participants? (please justify)
Patients who are unable to follow one-stage commands.

Acute pain or fracture

Patients who are unable to stand or require more than assistance of two staff to mobilise/transfer.

Patients who have been admitted with a recent diagnosis of stroke, due to their varying patterns of recovery.

C1.6 Will any participants recruited to this research study be simultaneously involved in any other research project?
Not to my knowledge

SECTION C2 PARTICIPANTS – INFORMED CONSENT

C2.1 (a) Will informed consent be obtained? Yes

C2.1 (b) If no, please justify.

C2.1 (c) If yes, how will informed consent be obtained and by whom?
Suitable patients will be provided with an information leaflet. SC will approach these patients 24 hours later and ask them to give written informed consent.

C2.1 (d) If yes, will participants be informed of their right to refuse to participate and their right to withdraw from this research study? Please elaborate.
Participants will be advised that they are free to withdraw at any stage without prejudice and they will be assured that all data obtained will be handled in strict confidentiality.

C2.1 (e) Will there be a time interval between giving information and seeking consent?
Yes

C2.1 (f) If yes, please elaborate.
24-48 hours

C2.1 (g) If no, please justify.

SECTION C3 ADULT PARTICIPANTS - CAPACITY

C3.1 (a) Will all adult research participants have the capacity to give informed consent? Yes

C3.1 (b) If no, please elaborate.

C3.1 (c) If no, is this research of such a nature that it can only be carried out on adults without capacity? N/A

SECTION C4 PARTICIPANTS UNDER THE AGE OF 18

C4.1 (a) Will any research participants be under the age of 18 i.e. Children?
No

C4.1 (b) If yes, please specify:
Persons < 16 Yes / No
Persons aged 16 – 18 Yes / No
Children in care Yes / No

C4.2 Is this research of such a nature that it can only be carried out on children?
No

C4.3 Please comment on what will occur if the researcher discovers that a child is at risk during the course of this study?
N/A

C4.4 Will each child receive information according to his/her capacity of understanding regarding the risks and benefits of the study? Please elaborate.
N/A

C4.5 Will the explicit wish of the child who is capable of forming an opinion and assessing information to refuse to participate or to be withdrawn from the study be considered by the lead investigators, co-investigators and principal investigator? Please elaborate.
N/A

C4.6 Please comment on the involvement (if any) of parents / legal guardians of the child in the consent process.
N/A

SECTION C5 PARTICIPANTS - CHECKLIST

Please confirm if any of the following groups will participate in this study. This is a quick checklist for research ethics committee members and it is recognised that not all groups in this listing will automatically be vulnerable or lacking in capacity.

C5.1 Patients Yes
C5.2 Unconscious patients No
C5.3 Current psychiatric in-patients No
C5.4 Patients in an emergency medical setting No
C5.5 Relatives / Carers of patients No
C5.6 Healthy Volunteers No
C5.7 Students No
C5.8 Employees / staff members No
C5.9 Prisoners No
C5.10 Residents of nursing homes No
C5.11 Pregnant women No

C5.12 Women of child bearing potential No
C5.13 Breastfeeding mothers No
C5.14 Persons with an acquired brain injury No
C5.15 Intellectually impaired persons No
C5.16 Elderly / aged persons > 65 Yes

C5.17 If yes to any of the above, what special arrangements have been made to deal with issues of consent and assent (if any)?
An information leaflet will be provided to the patient. Informed consent will be sought 24 hours later. If necessary, a witness may sign the consent form in the presence of the patient if there are any issues due to visual deficits or functional deficits of the hand or arm which would lead to the patient being unable to sign the consent form themselves.

SECTION D RESEARCH PROCEDURES

SECTION D IS MANDATORY

IMPORTANT NOTE: This application form permits the applicant to delete individual questions within each section depending on their response to the preceding questions. Please respond to each question carefully and refer to the accompanying *Guidance Manual* for more in-depth advice prior to deleting any question.

D1. What research procedures or interventions (over and above those clinically indicated and/or over and above those which are part of routine care) will research participants undergo whilst participating in this study?
Patients will be assessed as described above. The intervention, as described above, will consist of a twice weekly exercise class in addition to their usual care.

D2. If there are any potential harms resulting from any of the above listed procedures, provide details below:
There is a theoretical risk that an individual could lose their balance during the assessment procedure as many of the outcome measures are assessed in standing/walking. However, this is very unlikely as the subject will be supervised very closely at all times by an experienced clinician. This risk is the same for all patients attending physiotherapy. There is also a theoretical risk that a patient may experience muscle soreness after the exercise class. To reduce this risk, there will be at least one rest day between exercise sessions. Patients will be under the supervision of a medical team and nursing staff at all times.

D3. What is the potential benefit that may occur as a result of this study?
Patients may experience an improvement in lower limb strength which will lead to an improvement in function as assessed using the outcome measures described above.
D4 (a) Will the study involve the withholding of treatment?
No

D4 (b) Will there be any harms that could result from withholding treatment?
N/A

D4 (c) If yes, please elaborate. N/A

D5. How will the health of participants be monitored during and after the study?
Patients admitted to the rehabilitation unit are assessed by the medical team on admission to the rehabilitation unit and thereafter are under constant medical supervision.

D6 (a) Will the interventions provided during the study be available if needed after the termination of the study?
No but the patients will continue to receive standard physiotherapy intervention based on need. If the results of this trial are favourable, this intervention will be introduced as part of routine physiotherapy in this rehabilitation unit.

D6 (b) If yes, please state the intervention you are referring to and state who will bear the cost of provision of this intervention?
N/A

D7. Please comment on how individual results will be managed.
All data will be coded on an Excel spreadsheet and analysed using an SPSS package. All other written data will be stored in a secure cabinet, which the SC only has access to. Electronic data will be secured by using password protected spreadsheets.

D8. Please comment on how aggregated study results will be made available.
Results of the follow-up RCT will be disseminated at a local, national and international level through conferences and possible publications.

D9. Will the research participant's general practitioner be informed the research participant is taking part in the study (if appropriate)? Non-applicable

D10. Will the research participant's hospital consultant be informed the research participant is taking part in the study (if appropriate)? Yes

SECTION E DATA PROTECTION

SECTION E IS MANDATORY

IMPORTANT NOTE: This application form permits the applicant to delete individual questions within each section depending on their response to the preceding questions. Please respond to each question carefully and refer to the accompanying *Guidance Manual* for more in-depth advice prior to deleting any question.

SECTION E1 DATA PROCESSING - CONSENT

E1.1 (a) Will consent be sought for the processing of data? Yes

E1.1 (b) If no, please elaborate.

SECTION E2 DATA PROCESSING - GENERAL

E2.1 Who will have access to the data which is collected?
SC and co-investigators.

E2.2 What media of data will be collected?
Data will be collected on paper and then input onto spreadsheets and statistical packages.

E2.3 (a) Would you class the data collected in this study as anonymous, irrevocably anonymised, pseudonymised, coded or identifiable data? Coded

E2.3 (b) If 'coded', please confirm who will retain the 'key' to re-identify the data? SC

E2.4 Where will data which is collected be stored?
Data will be stored in a secure cabinet locked with a key and in a password protected spreadsheet on a password protected and encrypted computer that will not be available to anyone outside the study team

E2.5 Please comment on security measures which have been put in place to ensure the security of collected data.
Data will be stored in a secure cabinet locked with a key and in a password protected spreadsheet on a password protected and encrypted computer that will not be available to anyone outside the study team

E2.6 (a) Will data collected be at any stage leaving the site of origin? No

E2.6 (b) If yes, please elaborate.

E2.7 Where will data analysis take place and who will perform data analysis (if known)?
Data analysis will be performed on site by the investigators.

E2.8 (a) After data analysis has taken place, will data be destroyed or retained?
Retained

E2.8 (b) Please elaborate.
As per data protection guidelines, data will be retained for five years

E2.8 (c) If destroyed, how, when and by whom will it be destroyed?
N/A

E2.8 (d) If retained, for how long, for what purpose, and where will it be retained?
Data will be retained for five years, as raw data, on disc format, within the Physiotherapy and Medicine for the Elderly departments, to act as a resource if the results of the study need to be verified and to inform decisions regarding future research in this population.

E2.9 Please comment on the confidentiality of collected data.
All data will be stored confidentially in a secure cabinet or password protected spreadsheet.

E2.10 (a) Will any of the data collected consist of audio recordings / video recordings?
No

E2.10 (b) If yes, will participants be given the opportunity to review and amend transcripts of the tapes?

E2.11 (a) Will any of the data collected consist of photographs / video recordings?
Yes

E2.11 (b) If yes, please elaborate. Photographs will be taken of participants taking part in the exercise class. Consent will be obtained from the relevant patients. These photographs will be used in future presentations to demonstrate the intervention used.

SECTION E3 ACCESS TO HEALTH CARE RECORDS

E3.1 (a) Does the study involve access to healthcare records (hard copy / electronic)?
Yes

E3.1 (b) If yes, please elaborate.
The patients medical chart will be accessed to identify demographic information

E3.1 (c) Who will access these healthcare records?
SC, the patient's medical chart will be accessed to identify demographic information

E3.1 (d) Will consent be sought from patients for research team members to access their healthcare records? No

E3.2 (a) Who or what legal entity is the data controller in respect of the healthcare records?
The data controller (SC) is a qualified chartered physiotherapist who accepts referrals from the geriatricians for rehabilitation.

E3.2 (b) What measures have been put in place by the data controller which may make access to healthcare records permissible without consent?
The data controller (SC) is a qualified chartered physiotherapist who accepts referrals from the geriatricians for rehabilitation. This request from the medical team to assess and treat the patient confers the ability to access healthcare records without consent. However, the patient retains the right to refuse participation in the study.

SECTION J INDEMNITY

SECTION J IS MANDATORY

IMPORTANT NOTE: This application form permits the applicant to delete individual questions within each section depending on their response to the preceding questions. Please respond to each question carefully and refer to the accompanying *Guidance Manual* for more in-depth advice prior to deleting any question.

J1 (a) Is each site in which this study is to take place covered by the Clinical Indemnity Scheme (CIS)? Yes

J1 (b) If the answer is 'no' for any site, what other arrangements are in place in terms of indemnity / insurance?

J2 (a) Is each member of the investigative team covered by the Clinical Indemnity Scheme (CIS)? Yes

J2 (b) If no, do members of the investigative team not covered by the Clinical Indemnity Scheme (CIS) have either current individual medical malpractice insurance (applies to medical practitioners) or current professional liability insurance either individually or as provided by their hosting/employing institution (generally applies to allied healthcare professionals, university employees, scientists engineers etc.)?

J3 (a) Who or what legal entity is the sponsor of this research study?
N/A

J3 (b) What additional indemnity arrangements has the sponsor put in place for this research study in case of harm being caused to a research participant (if any)?
N/A

SECTION K COST AND RESOURCE IMPLICATIONS AND FUNDING

SECTION K IS MANDATORY

IMPORTANT NOTE: This application form permits the applicant to delete individual questions within each section depending on their response to the preceding questions. Please respond to each question carefully and refer to the accompanying *Guidance Manual* for more in-depth advice prior to deleting any question.

K1 (a) Are there any cost / resource implications related to this study? Yes
K1 (b) If yes, please elaborate.
Existing staff, as well as additional research assistants will carry out the assessments and intervention.

K2 (a) Is funding in place to conduct this study? No
K2 (b) If no, has funding been sought to conduct this study? No

K2 (c) Please state the source of funding (industry, grant or other) and the amount of funding.
N/A

K2 (d) Is the study being funded by an external agency? N/A
K2 (e) Is the external agency a 'for profit' organisation? N/A

K2 (f) Do any conflicts of interest exist in relation to funding? Please elaborate.
N/A

K2 (g) Please provide additional details in relation to management of funds.
N/A

K3. Please provide details of any payments (monetary or otherwise) to investigators.
N/A

K4. Please provide details of any payments (monetary or otherwise) to participants.
N/A

SECTION L ETHICAL ISSUES

SECTION L IS MANDATORY

L1. Please identify any ethical issues which this project raises and discuss how you have addressed these issues.
After screening, suitable candidates will be given a patient information leaflet in the first 72 hours after admission outlining the procedures, risks and benefits of the trial and requesting their voluntary participation. Written informed consent will be sought after a cooling-off period of 24 hours. Participants will be advised that they are free to withdraw at any stage without prejudice and they will be assured that all data obtained will be handled in strict confidentiality. A coded list of patient names and identifiers will be locked in a secure

cabinet, which only the lead investigator may access. All other written data will be stored in the secure cabinet. Electronic data will be secured by using password protected spreadsheets.

Participants may be under the care of numerous consultants. Permission will be sought from each consultant to allow subjects participate in this study. Formal ethical approval will be sought by the St James's Hospital/Adelaide, Meath and National Children's Hospital Research Ethics Committee prior to commencement of the trial

Appendix 4 – Ethics Approval – Feasibility Study

THIS NOTEPAPER MUST NOT BE USED FOR PRESCRIPTIONS OR INVOICING PURPOSES

THE ADELAIDE & MEATH HOSPITAL, DUBLIN
INCORPORATING
THE NATIONAL CHILDREN'S HOSPITAL

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SJH/AMNCH Research Ethics Committee Secretariat
Ursula Ryan Ph: 4142342 email: Ursula.Ryan@amnch.ie
Secretariat Fax 4142371

Ms. Sinead Coleman
Senior Physiotherapist
Department of Physiotherapy
St. James's Hospital
James Street
Dublin 8

May 15th 2013

Re: Can Lower Limb Resistance Training Improve Strength, Muscle Mass and Functional Outcomes in Older Inpatients in a Post Acute Rehabilitation Unit? A Randomised Control Trial.

Please quote this reference in any follow up to this letter: 2013/05/04 Chairman's Action

Dear Sinead,

Thank you for your recent submission of the above proposal to the SJH/AMNCH Research Ethics Committee.

The Chairman, having reviewed the proposal on behalf of the SJH/AMNCH Research Ethics Committee has given ethical approval to this proposed study.

Yours sincerely

Ms. Ursula Ryan
Secretary,
SJH/AMNCH Research Ethics Committee

Appendix 5

Participant Information Leaflet

1. Title

Can lower limb progressive resistance training improve strength and functional outcomes in older inpatients in a post-acute rehabilitation unit? A randomised controlled trial.

2. Introduction

The body's muscle size reduces as we get older. This can lead to a higher risk of falls and fractures, difficulty in regulating body temperature, slower metabolism, a possible deficiency in glucose regulation and an overall reduction in function. Older people have been shown to make significant gains in strength when performing resistance exercises. We would like to carry out a study to determine if twice weekly strengthening exercises, as well as your usual physiotherapy will improve strength in your leg muscles, your walking and your quality of life. This will be compared to usual physiotherapy.

3. Procedures

You will be asked to complete a number of physical tests on two separate occasions, once prior to commencing the strengthening exercise and once after 6 weeks of the strengthening exercises. These tests will look at your ability to perform some everyday tasks, such as standing up from a chair, walking, your ability to perform stairs, the strength in your leg muscles and quality of life. We will also assess the size of your leg muscles. The tests should take no longer than 50 minutes to complete. If you have been discharged from the hospital before the final assessment, you may need to return to the hospital for an out-patient appointment to complete the study.

Following this initial assessment, you will be randomly assigned into one of two groups. One group will receive an extra 2 sessions of physiotherapy per week, in addition to their usual physiotherapy, consisting of strengthening exercises for your legs. The other group will receive information regarding the benefits of exercise and physical activity recommendations. They will also continue to receive their usual physiotherapy.

4. Benefits

Participants in the exercise group may experience an improvement in the strength in your leg muscles. This may improve your ability to walk and to perform stairs, as well as your quality of life. The information gathered from this study will help focus physiotherapy treatments aimed at improving strength in the leg muscles and functional performance in other patients.

5. Risks
There is a theoretical risk that you could lose your balance during the assessment procedure as many of the outcome measures are assessed in standing/walking. However, this is very unlikely as you will be supervised very closely at all times by an experienced clinician. This risk is the same for all patients attending regular physiotherapy. There is also a theoretical risk that a patient may experience muscle soreness after the exercise class. To reduce this risk, there will be at least one rest day between exercise sessions. You will be under the supervision of a medical team and nursing staff at all times.

6. Exclusion from Participation
You may not participate in this study if you have any medical condition that may limit your ability to participate in the study; if you are medically unwell; or if you are unable to give informed consent.

7. Alternative Treatment
This study will not interfere with your hospital treatment in any way. You will continue to receive your usual physiotherapy during and after the study.

8. Confidentiality
Your identity will remain strictly confidential at all times. Your name or personal details will not be published or given to anyone outside of this study.

9. Compensation
Participation in this study is covered by an approved insurance policy. All of the researchers involved, are covered by standard malpractice and professional indemnity insurance.

10. Voluntary Participation

It is up to you to decide if you would like to participate in this study. If you do not to take part, this will not affect you personally and will not affect your treatment. If you do decide to take part, you will be asked to sign a consent form. If you are unable to sign, due to visual deficits or functional deficits of the hand or arm which would lead to the patient being unable to sign the consent form themselves, a witness may sign on your behalf. This may be a family member or another staff member. You may withdraw from this study at any time. Withdrawing from the study will not affect you personally or affect your treatment.

11. Stopping the study
Your doctor or physiotherapist may stop you participating in the study at any time without your consent.

12. Permission
Ethical approval for this project has been granted by the SJH/AMNCH Research Ethics Committee

13. Further Information

If you have any further questions about this study please do not hesitate to contact me directly or by asking the nursing staff to contact me on your behalf. Contact details for the project supervisor are also available if you have any other concerns.

Principal Investigator:
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Project Supervisor
Dr Conal Cunningham
Consultant Geriatrician,
MedEl Directorate
St. James's Hospital,
Dublin 8

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Appendix 6

Consent Form

Title of Research Study: Can lower limb progressive resistance training improve strength and functional outcomes in older inpatients in a post-acute rehabilitation unit? A randomised control trial.

Procedures

I acknowledge that I will be asked to complete a number of physical tests on two separate occasions. These tests will assess the performance of my leg and elbow strength, walking and quality of life. I acknowledge that I may be assigned to an exercise group or given written information regarding benefits of exercise and physical activity recommendations.

Declaration

- This study and the consent form have been explained to me…….Yes/No
- I have read, or have had read to me, this consent form……...Yes/No
- I have had the opportunity to ask questions and the investigator has answered all of my questions to my satisfaction……..Yes/No
- I believe I understand what will happen if I agree to be a part of this study…Yes/No
- I understand that my participation is voluntary……..Yes/No

- I understand I may withdraw at any time and this will not affect my treatment……Yes/No
- I have received a copy of this agreement……Yes/No
- I agree to take part in this study……Yes/No

Participant's Name: _____

Participant's Signature: _____Date: _____

I have explained the nature, purpose, procedures, benefits, risks of, or alternatives to, this research study. I have offered to answer any questions and fully answered such questions. I believe that the participant understands my explanation and has freely given informed consent.

Physiotherapist: _____

Where the participant is capable of comprehending the nature, significance and scope of the consent required, but is physically unable to sign written consent, the signatures of two witnesses is required when consent given to the principal investigator

1. Witness's Name: _____ Date: _____
Witness's Signature: _____
Relationship to participant: _____

2. Witness's Name: _____ Date: _____
Witness's Signature: _____
Relationship to participant: _____

ID _____ **Date** _____

Appendix 7

Demographic Data Collection Form T1

ID _____

1. Age ____

2. DOB ____/ ____/ ____ **Barthel: _____**

3. Gender – Male □ Female □ **MMSE: _____**

4. Current Diagnosis _____

5. Co morbidities _____ _____
_____ _____
_____ _____

6. Medications (number of meds and details)

_____ _____
_____ _____
_____ _____

7. Mobility and Transfers

	Baseline		T1 Ax	
	Mobility	Transfers	Mobility	Transfers
Independent				
Independent + w/stick				
Independent + z/frame				
Supervision				
Assistance of therapist				

8. Social Support - Lives alone □ Lives with family □ Other □ Details _____

9. History of current inpatient admission

Admission to SJH	Admission to rehab	Assessment (initial)	Assessment (final)
/ /	/ /	/ /	/ /

D/C Date (from SJH)	Length of Stay (days)
/ /	

Appendix 8

CSHA Clinical Frailty Scale (standardised instructions)

Instructions to rater – use your clinical judgement to assign a score to the subject

1 Very fit – robust, active, energetic, well motivated and fit; these people commonly exercise regularly and are in the most fit group for their age
2 Well – without active disease, but less fit than people in category 1
3 Well, with treated comorbid disease – disease symptoms are well controlled compared with those in category 4
4 Apparently vulnerable – although not frankly dependent, these people commonly complain of being 'slowed up' or have disease symptoms
5 Mildly frail – with limited dependence on others for instrumental activities of daily living
6 Moderately frail – help is needed with both instrumental and non-instrumental activities of daily living
7 Severely frail – completely dependent on others for the activities of daily living, or terminally ill

Appendix 9

Demographic Data Collection Form T2

ID _____

1. Medications (number of meds and details)

_____ _____
_____ _____
_____ _____

2. Mobility and Transfers

	T2 Ax	
	Mobility	Transfers
Independent		
Independent + w/stick		
Independent + z/frame		
Supervision		
Assistance of therapist		

3. Discharge Destination **Barthel: _____**

Home
Home with follow-up
LTC

Still an inpatient at T2 Ax?
If so, d/c to Home
Home with follow-up
LTC

Appendix 10 - Adverse Events Log

ID: _____

	Session 1 (Specify mild/mod/severe)	Session 2 (Specify mild/mod/severe)
Week 1		
Week 2		
Week 3		
Week 4		
Week 5		
Week 6		

Appendix 11 – Recruitment Record

Patients transferred to Rehabilitation Unit

MRN	Fits inclusion criteria	Consent: Y/ N	Reason for refusal/exclusion

Week beginning: __/__/__

Appendix 12 – Weekly Attendance Record

Week	Session 1	Session 2
0-1	Able to attend: Unable to attend: If not, reason: Session completed:	Able to attend: Unable to attend: If not, reason: Session completed:
1-2	Able to attend: Unable to attend: If not, reason: Session completed:	Able to attend: Unable to attend: If not, reason: Session completed:
2-3	Able to attend: Unable to attend: If not, reason: Session completed:	Able to attend: Unable to attend: If not, reason: Session completed:
3-4	Able to attend: Unable to attend: If not, reason: Session completed:	Able to attend: Unable to attend: If not, reason: Session completed:
4-5	Able to attend: Unable to attend: If not, reason: Session completed:	Able to attend: Unable to attend: If not, reason: Session completed:
5-6	Able to attend: Unable to attend: If not, reason: Session completed:	Able to attend: Unable to attend: If not, reason: Session completed:

Appendix 13

Progressive Resistance Training Programme

Exit Questionnaire

This questionnaire aims to give you the opportunity to let us know about your experience during the research study. Please answer all questions honestly and elaborate where you feel is relevant. The more information you provide the more we can evaluate your outcome.

1. Were you part of the

   Control Group: Routine physiotherapy ☐

   Intervention Group: Routine physiotherapy + Weight training programme ☐

2. Were you satisfied overall with the care you received during this study?
   - □ Very satisfied
   - □ Somewhat satisfied
   - □ Neither satisfied or dissatisfied
   - □ Somewhat dissatisfied
   - □ Very dissatisfied

Why?_____
_____
_____

3. Were you satisified with the way you were approached to take part in this study?
   - □ Very satisfied
   - □ Somewhat satisfied
   - □ Neither satisfied or dissatisfied
   - □ Somewhat dissatisfied
   - □ Very dissatisfied

Why?_____
_____
_____

4. Were you satisfied with your assessments in the physiotherapy department?
   - □ Very satisfied
   - □ Somewhat satisfied
   - □ Neither satisfied or dissatisfied
   - □ Somewhat dissatisfied
   - □ Very dissatisfied

Why?_____
_____
_____

5. Were you satisfied with the way the exercise programme was provided to you?
    - □ Very satisfied
    - □ Somewhat satisfied
    - □ Neither satisfied or dissatisfied
    - □ Somewhat dissatisfied
    - □ Very dissatisfied

Why?_____
_____
_____

6. How easy or difficult was it for you to stick to your exercise programme?
    - □ Very difficult
    - □ Somewhat difficult
    - □ Neither difficult or easy
    - □ Somewhat easy
    - □ Very easy

Why?_____
_____
_____

7. Do you feel that taking part in this exercise programme has been of benefit to you?
    - □ No benefit at all
    - □ Some benefit
    - □ great benefit
    - □ Not sure

Why?_____
_____
_____

8. Would you once again participate in the study?
    - □ Yes
    - □ No
    - □ Don't know

Why?_____
_____
_____

9. Would you recommend the exercise programme to a friend?
    - □ Yes
    - □ No

Why?_____
_____
_____

Do you have any ideas or proposals for programme improvements?

_____

_____

Do you have any other comments regarding your experience during the research study?

_____
_____
_____

THANK YOU FOR TAKING THE TIME TO FILL OUT THIS QUESTIONNAIRE

Appendix 14 – Assessment Form

ID _____ Assessor Initial: _____ Date _____

TUG (seconds)	Able __ Unable __ Time:							
Stairs (seconds)	**Ascent** Able __ Unable__ Time:				**Descent** Able __ Unable __ Time:			
Strength	**Right**				**Left**			
	1	2	3	Mean	1	2	3	Mean
Hip Abduction lbs								
Kgs								
Hip Flexion lbs								
kgs								
Hip Extension lbs								
kgs								
Knee Extension lbs								
kgs								
Ankle Plantarflexion lbs								
kgs								
Ankle Dorsiflexion lbs								
kgs								
Elbow Extension lbs								
kgs								
Grip Strength kgs								

EuroQol (attach copy)	
Clinical Frailty Scale	

Appendix 15 – Handheld Dynamometer

Appendix 16 - Participant Information Leaflet for Dynamometry Reliability study

Participant Information Leaflet

1. Title
Inter-rater reliability of hand-held dynamometry in the measurement of lower limb and elbow extension strength in older people.

2. Introduction
We are currently performing a study here in the rehabilitation unit to determine if twice weekly strengthening exercises, as well as your usual physiotherapy will improve strength in your leg muscles, your walking and your quality of life. As part of this research, we need to determine the reliability of the equipment we are using to measure the strength of the muscles in the leg and elbow.

3. Procedures
You will be asked to complete a physical test which measures the strength in your leg and elbow muscles. You will be asked to complete this test on two consecutive days. Two different assessors will perform the test. Both of these assessors are qualified physiotherapists. The test should take no longer than 20 minutes.

4. Benefits
The information gathered from this study will help focus physiotherapy treatments aimed at improving strength in the leg muscles and functional performance in patients in the rehabilitation unit.

5. Risks
There is a theoretical risk that a patient may experience muscle soreness after the test. To reduce this risk, the second assessment will take place on the following day. You will be under the supervision of a medical team and nursing staff at all times.

7. Exclusion from Participation
You may not participate in this study if you have any medical condition that may limit your ability to participate in the study; if you are medically unwell; or if you are unable to give informed consent.

8. Alternative Treatment
This study will not interfere with your hospital treatment in any way. You will continue to receive your usual physiotherapy during and after the study.

8. Confidentiality
Your identity will remain strictly confidential at all times. Your name or personal details will not be published or given to anyone outside of this study.

10. Compensation
Participation in this study is covered by an approved insurance policy. All of the researchers involved, are covered by standard malpractice and professional indemnity insurance.

10. Voluntary Participation
It is up to you to decide if you would like to participate in this study. If you do not to take part, this will not affect you personally and will not affect your treatment. If you do decide to take part, you will be asked to sign a consent form. If you are unable to sign, due to visual deficits or functional deficits of the hand or arm which would lead to the patient being unable to sign the consent form themselves, a witness may sign on your behalf. This may be a family member or another staff member. You may withdraw from this study at any time. Withdrawing from the study will not affect you personally or affect your treatment.

11. Stopping the study
Your doctor or physiotherapist may stop you participating in the study at any time without your consent.

12. Permission
Ethical approval for this project has been granted by the SJH/AMNCH Research Ethics Committee

13. Further Information
If you have any further questions about this study please do not hesitate to contact me directly or by asking the nursing staff to contact me on your behalf. Contact details for the project supervisor are also available if you have any other concerns.

Principal Investigator:
Ms Sinead Coleman, M.Sc.
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Project Supervisor
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Consultant Geriatrician,
MedEl Directorate
St. James's Hospital,
Dublin 8

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01 - 4162603

Appendix 17 - Consent Form for Dynamometry Reliability study

Consent Form

Title of Research Study: Inter-rater reliability of hand-held dynamometry in the measurement of lower limb and elbow extension strength in older people.

Procedures

I acknowledge that I will be asked to complete a physical test which measures the strength of my leg and elbow on two separate occasions.

Declaration

- This study and the consent form have been explained to me…….Yes/No
- I have read, or have had read to me, this consent form……...Yes/No
- I have had the opportunity to ask questions and the investigator has answered all of my questions to my satisfaction……..Yes/No
- I believe I understand what will happen if I agree to be a part of this study…Yes/No
- I understand that my participation is voluntary……..……..Yes/No
- I understand I may withdraw at any time and this will not affect my treatment……Yes/No
- I have received a copy of this agreement……Yes/No
- I agree to take part in this study……Yes/No

Participant's Name: _____

Participant's Signature: _____Date: _____

I have explained the nature, purpose, procedures, benefits, risks of, or alternatives to, this research study. I have offered to answer any questions and fully answered such questions. I

believe that the participant understands my explanation and has freely given informed consent.

Physiotherapist: _____

Where the participant is capable of comprehending the nature, significance and scope of the consent required, but is physically unable to sign written consent, the signatures of two witnesses is required when consent given to the principal investigator

1. Witness's Name: _____ Date: _____
Witness's Signature: _____
Relationship to participant: _____

2. Witness's Name: _____ Date: _____
Witness's Signature: _____
Relationship to participant: _____

Appendix 18 - 5TSTS

Five-Times Sit to Stand Test (standardised instructions):

Method: Use a straight back chair with a solid seat that is 16” high. Ask the participant to sit on the chair with arms folded across their chest.

Instructions: “Stand up and sit down as quickly as possible five times keeping your arms folded across your chest”.

Measurement: Stop timing when the participant sits down the fifth time.

Appendix 19 – Handgrip Dynamometer

Appendix 20 – Estimating Height from Ulna length

Nutrition Screening Week NSW11

BAPEN

'Malnutrition Universal Screening Tool' ('MUST')

MAG

Estimating height from ulna length: instructions and tables

If height cannot be obtained, measure length of forearm (ulna) (cm) as described below, and calculate height (m) using the conversion table.

Estimating height from ulna length

Measure between the point of the elbow (olecranon process) and the midpoint of the prominent bone of the wrist (styloid process) (left side if possible).

HEIGHT (m)	Men (<65 years)	1.94	1.93	1.91	1.89	1.87	1.85	1.84	1.82	1.80	1.78	1.76	1.75	1.73	1.71
	Men (>65 years)	1.87	1.86	1.84	1.82	1.81	1.79	1.78	1.76	1.75	1.73	1.71	1.70	1.68	1.67
	Ulna length (cm)	32.0	31. 5	31.0	30. 5	30.0	29. 5	29.0	28.5	28.0	27.5	27.0	26. 5	26.0	25. 5
HEIGHT (m)	Women (<65 years)	1.84	1.83	1.81	1.80	1.79	1.77	1.76	1.75	1.73	1.72	1.70	1.69	1.68	1.66
	Women (>65 years)	1.84	1.83	1.81	1.79	1.78	1.76	1.75	1.73	1.71	1.70	1.68	1.66	1.65	1.63
HEIGHT (m)	Men (<65 years)	1.69	1.67	1.66	1.64	1.62	1.60	1.58	1.57	1.55	1.53	1.51	1.49	1.48	1.46
	Men (>65 years)	1.65	1.63	1.62	1.60	1.59	1.57	1.56	1.54	1.52	1.51	1.49	1.48	1.46	1.45
	Ulna length (cm)	25.0	24. 5	24.0	23. 5	23.0	22. 5	22.0	21. 5	21.0	20. 5	20.0	19. 5	19.0	18. 5
HEIGHT (m)	Women (<65 years)	1.65	1.63	1.62	1.61	1.59	1.58	1.56	1.55	1.54	1.52	1.51	1.50	1.48	1.47
	Women (>65 years)	1.61	1.60	1.58	1.56	1.55	1.53	1.52	1.50	1.48	1.47	1.45	1.44	1.42	1.40

BAPEN Royal College of Nursing National Patient Safety Agency

BAPEN's Nutrition Screening Weeks are undertaken in collaboration with the British Dietetic Association and the Royal College of Nursing and with the support of the National Patient Safety Agency, Department of Health of England, The Scottish Government, Welsh Assembly Government and the Chief Nursing Officer in Northern Ireland.

Appendix 21 – Bio Impedance Scales

Appendix 22

Timed Up and Go Test (TUG) (standardised instructions)

1. Equipment: Arm chair, tape measure, tape, stopwatch

2. Begin the test when the subject is sitting correctly (hips all of the way back to the back of the seat) in a chair with arm rests. The chair should be stable and positioned such that it will not move when the subject moves from sit to stand. The subject is allowed to use the arm rests during the sit to stand and stand to sit movements.

3. Place a piece of tape or other marker on the floor 3 meters away from the chair so that it is easily seen by the subject.

4. Instructions: 'On the word GO, you will stand up, walk to the line on the floor, turn around and walk back to the chair and sit down. Walk at your regular pace.'

5. Start the timing on the word 'GO' and stop the timing when the subject is back seated again correctly in the chair with their back resting against the back of the chair.

6. The subject wears their regular footwear, may use any gait aid they normally use during ambulation, but may not be assisted by another person. There is no time limit. They may stop and rest (but not sit down) if they need to.

The subject should be given a practice trial that is not timed before testing

Appendix 23

Stair Negotiation Test Protocol (standardised instructions)

1. Prior to the stair test, ask the participant whether they are willing to climb up and down three steps.

2. To assess the stair negotiation times, the participant stands with the tester at the base of a well-lighted, uncarpeted flight of stairs with handrails

3. Each step measures 18 cm in height, 26 cm in depth, and 110 cm in width.

4. Ask the participant about difficulty in stair negotiation before performing the test using (Do you have difficulty climbing stairs? Do you have difficulty coming down stairs?).

5. Start the stair ascent timing using a stopwatch once the participant begins lifting their leading foot from the floor after the tester says “GO”.

6. When the participant places both feet flat on the third step, stop the timing.

7. After a brief rest, request the participant to walk down.

8. Start the stair descent timing from the time when the leading foot begins lifting from the third step and stop when both feet are placed flat on the base of the stairs.

9. Note the use of handrails and objective difficulty.

10. Testers can intervene to assist the participant in case of safety concerns.

Appendix 24

EQ - 5D

Health Questionnaire
(English version for the UK)
(validated for use in Eire)

By placing a tick in one box in each group below, please indicate which statements best describe your own health state today.

Mobility

I have no problems in walking about ❑
I have some problems in walking about ❑
I am confined to bed ❑

Self-Care

I have no problems with self-care ❑
I have some problems washing or dressing myself ❑
I am unable to wash or dress myself ❑

Usual Activities (*e.g. work, study, housework, family or leisure activities)*

I have no problems with performing my usual activities ❑
I have some problems with performing my usual activities ❑
I am unable to perform my usual activities ❑

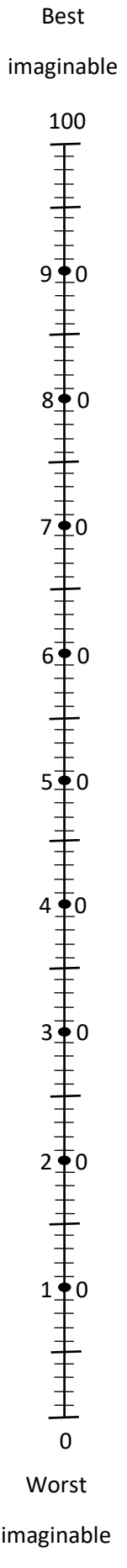
Pain/Discomfort

I have no pain or discomfort ❑
I have moderate pain or discomfort ❑
I have extreme pain or discomfort ❑

Anxiety/Depression

I am not anxious or depressed ❑
I am moderately anxious or depressed ❑
I am extremely anxious or depressed ❑

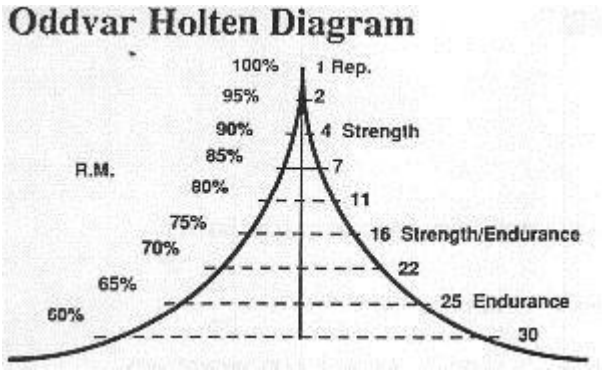
To help people say how good or bad a health state is, we have drawn a scale (rather like a thermometer) on which the best state you can imagine is marked 100 and the worst state you can imagine is marked 0.



Appendix 25 – Ankle Weights

Appendix 26 – Weighted Vest

Appendix 27



Appendix 28 – Record of Progression of PRT over Six Weeks

ID: _____

	R Hip abduction	L Hip abduction	R Hip flexion	L Hip flexion
Week 0 - 1				
Weight – 1RM				
- %				
Reps				
Sets				
Week 1 - 2				
Weight – 1RM				
- %				
Reps				
Sets				
Week 2 - 3				
Weight – 1RM				
- %				
Reps				
Sets				
Week 3 - 4				
Weight – 1RM				
- %				
Reps				
Sets				
Week 4 - 5				

Weight – 1RM				
- %				
Reps				
Sets				
Week 5 - 6				
Weight – 1RM				
- %				
Reps				
Sets				

	STS	Heel Raises
Wk 0-1		
% Body weight		
Reps		
Sets		
Wk 1-2		
% Body weight		
Reps		
Sets		
Wk 2-3		
% Body weight		
Reps		
Sets		
Wk 3-4		
% Body weight		
Reps		
Sets		
Wk 4-5		
% Body weight		
Reps		
Sets		
Wk 5-6		
% Body weight		
Reps		
Sets		

Appendix 29

Group Statistics

	Group	N	Mean	Std. Deviation	Std. Error Mean
Age	Control	17	82.65	6.294	1.527
	Intervention	16	83.13	6.087	1.522
No of comorbidities	Control	17	5.41	2.123	.515
	Intervention	16	3.31	1.493	.373
No of days from admission to rehab ward	Control	17	33.88	27.538	6.679
	Intervention	16	32.75	28.365	7.091
Length of Stay in SJH (W-Q)	Control	17	119.24	95.543	23.173
	Intervention	16	100.31	42.851	10.713
Length of Stay in Rehab (W-R)	Control	17	85.35	80.154	19.440
	Intervention	16	67.56	30.857	7.714
No of routine Physiotherapy sessions	Control	17	21.53	7.392	1.793
	Intervention	16	21.63	6.859	1.715
No of Resistance Training sessions	Control	0[a]	.	.	.
	Intervention	16	7.63	3.631	.908

Independent Samples Test

		Levene's Test for Equality of Variances		t-test for Equality of
		F	Sig.	t
Age	Equal variances assumed	.052	.821	-.222
	Equal variances not assumed			-.222
No of comorbidities	Equal variances assumed	.413	.525	3.266
	Equal variances not assumed			3.301
No of days from admission to rehab ward	Equal variances assumed	.136	.715	.116
	Equal variances not assumed			.116
Length of Stay in SJH (W-Q)	Equal variances assumed	5.665	.024	.726
	Equal variances not assumed			.741

		df	Sig. (2-tailed)	Mean Difference
Age	Equal variances assumed	31	.826	-.478
	Equal variances not assumed	30.974	.826	-.478
No of comorbidities	Equal variances assumed	31	.003	2.099
	Equal variances not assumed	28.762	.003	2.099

No of days from admission to rehab ward	Equal variances assumed	31	.908	1.132
	Equal variances not assumed	30.739	.908	1.132
Length of Stay in SJH (W-Q)	Equal variances assumed	31	.473	18.923
	Equal variances not assumed	22.475	.466	18.923

		Std. Error Difference	95% Confidence ... Lower
Age	Equal variances assumed	2.158	-4.879
	Equal variances not assumed	2.155	-4.874
No of comorbidities	Equal variances assumed	.643	.788
	Equal variances not assumed	.636	.798
No of days from admission to rehab ward	Equal variances assumed	9.732	-18.717
	Equal variances not assumed	9.742	-18.742
Length of Stay in SJH (W-Q)	Equal variances assumed	26.065	-34.238
	Equal variances not assumed	25.529	-33.956

		Levene's Test for Equality of Variances		t-test for Equality of
		F	Sig.	t
Length of Stay in Rehab	Equal variances assumed (W-R)	6.755	.014	.831
	Equal variances not assumed			.851
No of routine Physiotherapy sessions	Equal variances assumed	.038	.847	-.038
	Equal variances not assumed			-.039

		df	Sig. (2-tailed)	Mean Difference
Length of Stay in Rehab (W-R)	Equal variances assumed	31	.412	17.790
	Equal variances not assumed	20.883	.405	17.790
No of routine Physiotherapy sessions	Equal variances assumed	31	.970	-.096
	Equal variances not assumed	30.995	.970	-.096

		Std. Error Difference	95% Confidence ... Lower
Length of Stay in Rehab	Equal variances assumed (W-R)	21.406	-25.867
	Equal variances not assumed	20.915	-25.719
No of routine Physiotherapy sessions	Equal variances assumed	2.487	-5.167
	Equal variances not assumed	2.481	-5.155

Mann-Whitney Test Ranks

	Group	N	Mean Rank	Sum of Ranks
Change in # of Medications	Control	14	11.96	167.50
	Intervention	14	17.04	238.50
	Total	28		
Change in Barthel	Control	5	7.30	36.50
	Intervention	6	4.92	29.50
	Total	11		
Change in Mobility	Control	13	14.38	187.00
	Intervention	14	13.64	191.00
	Total	27		
Change in Transfers	Control	13	13.00	169.00
	Intervention	14	14.93	209.00
	Total	27		
Change in EQ5D Mobility	Control	13	13.00	169.00
	Intervention	14	14.93	209.00
	Total	27		
Change in EQ5D Self Care	Control	13	13.69	178.00
	Intervention	14	14.29	200.00
	Total	27		
Change in EQ5D Usual Activities	Control	13	14.46	188.00
	Intervention	14	13.57	190.00
	Total	27		
Change in EQ5D PD	Control	13	13.04	169.50
	Intervention	14	14.89	208.50
	Total	27		

Change in EQ5D AD	Control	13	14.19	184.50
	Intervention	14	13.82	193.50
	Total	27		
Change in EQ5D VAS	Control	13	16.23	211.00
	Intervention	14	11.93	167.00
	Total	27		
Change in Clinical Frailty	Control	13	13.19	171.50
	Intervention	14	14.75	206.50
	Total	27		
Change in Weight, kg	Control	8	8.63	69.00
	Intervention	10	10.20	102.00
	Total	18		

Ranks

	Group	N	Mean Rank	Sum of Ranks
Change in Muscle Mass, kg	Control	7	8.00	56.00
	Intervention	7	7.00	49.00
	Total	14		
Change in Timed Up & Go, sec	Control	13	14.15	184.00
	Intervention	14	13.86	194.00
	Total	27		
Change in Stairs Ascent, sec	Control	13	14.54	189.00
	Intervention	14	13.50	189.00
	Total	27		
Change in Stairs Descent, sec	Control	13	14.08	183.00
	Intervention	14	13.93	195.00
	Total	27		

Change in Hip Abduction Right, kg	Control	13	12.12	157.50
	Intervention	14	15.75	220.50
	Total	27		
Change in Hip Abduction Left, kg	Control	13	12.62	164.00
	Intervention	14	15.29	214.00
	Total	27		
Change in Hip Flexion Right, kg	Control	13	13.27	172.50
	Intervention	14	14.68	205.50
	Total	27		
Change in Hip Flexion Left, kg	Control	13	13.27	172.50
	Intervention	14	14.68	205.50
	Total	27		
Change in Hip Extension Right, kg	Control	13	12.96	168.50
	Intervention	14	14.96	209.50
	Total	27		
Change in Hip Extension Left, kg	Control	13	11.38	148.00
	Intervention	14	16.43	230.00
	Total	27		
Change in Knee Extension Right, kg	Control	13	14.50	188.50
	Intervention	14	13.54	189.50
	Total	27		
Change in Knee Extension Left, kg	Control	13	14.42	187.50
	Intervention	14	13.61	190.50
	Total	27		

	Change in # of Medications	Change in Barthel	Change in Mobility	Change in Transfers
Mann-Whitney U	62.500	8.500	86.000	78.000
Wilcoxon W	167.500	29.500	191.000	169.000
Z	-1.645	-1.218	-.255	-.666
Asymp. Sig. (2-tailed)	.100	.223	.799	.505
Exact Sig. [2*(1-tailed Sig.)]	.104[b]	.247[b]	.830[b]	.550[b]

Statistics

	Change in EQ5D Mobility	Change in EQ5D Self Care	Change in EQ5D Usual Activities	Change in EQ5D PD
Mann-Whitney U	78.000	87.000	85.000	78.500
Wilcoxon W	169.000	178.000	190.000	169.500
Z	-.715	-.220	-.349	-.673
Asymp. Sig. (2-tailed)	.474	.826	.727	.501
Exact Sig. [2*(1-tailed Sig.)]	.550[b]	.867[b]	.793[b]	.550[b]

	Change in EQ5D AD	Change in EQ5D VAS	Change in Clinical Frailty	Change in Weight, kg
Mann-Whitney U	88.500	62.000	80.500	33.000
Wilcoxon W	193.500	167.000	171.500	69.000
Z	-.137	-1.417	-.598	-.623

Asymp. Sig. (2-tailed)	.891	.156	.550	.534
Exact Sig. [2*(1-tailed Sig.)]	.905[b]	.169[b]	.616[b]	.573[b]

	Change in Muscle Mass, kg	Change in Timed Up & Go, sec	Change in Stairs Ascent, sec	Change in Stairs Descent, sec
Mann-Whitney U	21.000	89.000	84.000	90.000
Wilcoxon W	49.000	194.000	189.000	195.000
Z	-.447	-.097	-.340	-.049
Asymp. Sig. (2-tailed)	.655	.923	.734	.961
Exact Sig. [2*(1-tailed Sig.)]	.710[b]	.943[b]	.756[b]	.981[b]

	Change in Hip Abduction Right, kg	Change in Hip Abduction Left, kg	Change in Hip Flexion Right, kg	Change in Hip Flexion Left, kg
Mann-Whitney U	66.500	73.000	81.500	81.500
Wilcoxon W	157.500	164.000	172.500	172.500
Z	-1.190	-.874	-.461	-.461
Asymp. Sig. (2-tailed)	.234	.382	.645	.645
Exact Sig. [2*(1-tailed Sig.)]	.239[b]	.402[b]	.650[b]	.650[b]

	Change in Hip Extension Right, kg	Change in Hip Extension Left, kg	Change in Knee Extension Right, kg	Change in Knee Extension Left, kg
Mann-Whitney U	77.500	57.000	84.500	85.500
Wilcoxon W	168.500	148.000	189.500	190.500
Z	-.655	-1.652	-.316	-.268
Asymp. Sig. (2-tailed)	.512	.099	.752	.789
Exact Sig. [2*(1-tailed Sig.)]	.519[b]	.105[b]	.756[b]	.793[b]

Test Statistics

	Change in Ankle Plantarflexion Right, kg	Change in Ankle Plantarflexion Left, kg	Change in Ankle Dorsiflexion Right, kg	Change in Ankle Dorsiflexion Left, kg
Mann-Whitney U	65.000	78.500	83.000	45.500
Wilcoxon W	156.000	169.500	174.000	136.500
Z	-1.263	-.607	-.389	-2.212
Asymp. Sig. (2-tailed)	.207	.544	.697	.027
Exact Sig. [2*(1-tailed Sig.)]	.220[b]	.550[b]	.720[b]	.025[b]

	Change in Elbow Extension Right, kg	Change in Elbow Extension Left, kg	Change in Grip Right, kg	Change in Grip Left, kg
Mann-Whitney U	61.500	59.000	76.500	70.500
Wilcoxon W	152.500	150.000	167.500	161.500
Z	-1.432	-1.555	-.411	-.719
Asymp. Sig. (2-tailed)	.152	.120	.681	.472
Exact Sig. [2*(1-tailed Sig.)]	.155[b]	.128[b]	.687[b]	.479[b]

a. Grouping Variable: Group

b. Not corrected for ties.

	Change in # of Medications	Change in Barthel	Change in Mobility	Change in Transfers
Mann-Whitney U	62.500	8.500	86.000	78.000
Wilcoxon W	167.500	29.500	191.000	169.000
Z	-1.645	-1.218	-.255	-.666
Asymp. Sig. (2-tailed)	.100	.223	.799	.505
Exact Sig. [2*(1-tailed Sig.)]	.104[b]	.247[b]	.830[b]	.550[b]

Appendix 30 COREQ Checklist

COREQ (COnsolidated criteria for REporting Qualitative research) Checklist

A checklist of items that should be included in reports of qualitative research. You must report the page number in your manuscript where you consider each of the items listed in this checklist. If you have not included this information, either revise your manuscript accordingly before submitting or note N/A.

Topic	Item No.	Guide Questions/Description	Reported on Page No.
Domain 1: Research team and reflexivity			
Personal characteristics			
Interviewer/facilitator	1	Which author/s conducted the interview or focus group?	88
Credentials	2	What were the researcher's credentials? E.g. PhD, MD	1
Occupation	3	What was their occupation at the time of the study?	1
Gender	4	Was the researcher male or female?	F
Experience and training	5	What experience or training did the researcher have?	88
Relationship with participants			
Relationship established	6	Was a relationship established prior to study commencement?	87
Participant knowledge of the interviewer	7	What did the participants know about the researcher? e.g. personal goals, reasons for doing the research	87
Interviewer characteristics	8	What characteristics were reported about the inter viewer/facilitator? e.g. Bias, assumptions, reasons and interests in the research topic	87
Domain 2: Study design			
Theoretical framework			
Methodological orientation and Theory	9	What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis	86
Participant selection			
Sampling	10	How were participants selected? e.g. purposive, convenience, consecutive, snowball	86
Method of approach	11	How were participants approached? e.g. face-to-face, telephone, mail, email	87
Sample size	12	How many participants were in the study?	86
Non-participation	13	How many people refused to participate or dropped out? Reasons?	N/A
Setting			
Setting of data collection	14	Where was the data collected? e.g. home, clinic, workplace	86
Presence of non-participants	15	Was anyone else present besides the participants and researchers?	88
Description of sample	16	What are the important characteristics of the sample? e.g. demographic data, date	91
Data collection			
Interview guide	17	Were questions, prompts, guides provided by the authors? Was it pilot tested?	88
Repeat interviews	18	Were repeat inter views carried out? If yes, how many?	N/A
Audio/visual recording	19	Did the research use audio or visual recording to collect the data?	88
Field notes	20	Were field notes made during and/or after the inter view or focus group?	N/A
Duration	21	What was the duration of the inter views or focus group?	88
Data saturation	22	Was data saturation discussed?	86
Transcripts returned	23	Were transcripts returned to participants for comment and/or	88

Topic	Item No.	Guide Questions/Description	Reported on Page No.
		correction?	
Domain 3: analysis and findings			
Data analysis			
Number of data coders	24	How many data coders coded the data?	89
Description of the coding tree	25	Did authors provide a description of the coding tree?	88
Derivation of themes	26	Were themes identified in advance or derived from the data?	92
Software	27	What software, if applicable, was used to manage the data?	n/a
Participant checking	28	Did participants provide feedback on the findings?	n/a
Reporting			
Quotations presented	29	Were participant quotations presented to illustrate the themes/findings? Was each quotation identified? e.g. participant number	93-104
Data and findings consistent	30	Was there consistency between the data presented and the findings?	93-104
Clarity of major themes	31	Were major themes clearly presented in the findings?	92
Clarity of minor themes	32	Is there a description of diverse cases or discussion of minor themes?	n/a

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

Once you have completed this checklist, please save a copy and upload it as part of your submission. DO NOT include this checklist as part of the main manuscript document. It must be uploaded as a separate file.

Appendix 31 - Invitation to CPNG

Dear CPNG Member

My name is Sinead Coleman. I am a Clinical Specialist Physiotherapist in Gerontology, working in St James's Hospital.

As part of my PhD, I recently carried out a feasibility study looking at Progressive Resistance Training in frail older inpatients.

I am now interested in getting stakeholder's views on this topic and plan to hold a number of focus groups and interviews over the coming months. If you work in the clinical area of frail older inpatients (currently or in the past 6 months, all physiotherapy grades), I would love to hear from you.

The focus groups and interviews will take place between August and October, in St James's Hospital or in a place convenient for you. These will last approximately 1.5 hours.

If you are interested in taking part or would like more information, please contact me at:

Email: scoleman@stjames.ie

Tel: 01 4103000 (bleep 082)

Thanks in advance

Sinead Coleman

Appendix 32 - Interview Schedule Semi-Structured Interviews

School of Physiotherapy Royal College of Surgeons in Ireland 123

St Stephen's Green, Dublin 2

INTERVIEW SCHEDULE

(Version 2 Date: 08/10/2015) Title of Study: PERCEPTIONS AND EXPERIENCES OF PHYSIOTHERAPISTS IN THE USE OF PROGRESSIVE RESISTANCE TRAINING IN A POSTACUTE OLDER INPATIENT POPULATION

Interviewer: Sinead Coleman, Physiotherapist

Ensure the room is quiet and safe. Welcome participants. Introduce self and study. Discuss the format; dictaphone and time keeping. Turn on dictaphone and record start time.

Begin the interview;

Themes to be explored in the Interviews for Physiotherapists:

1.Interview commences with a definition of progressive resistance training (PRT).

> PRT is a "type of exercise where participants exercise their muscles against some type of resistance that is progressively increased as their strength improves."

Question to the participants – Is that what you understand to be PRT? Is there anything you would add to that?

2.How much of your current clinical caseload is older inpatients?

3.What types of exercise intervention do you routinely use with this patient group?

4.What outcome measures do you use to assess strength in this population?

5.Would you routinely use PRT with this patient group?

6.If yes, what guidelines do you use to guide your practice? How do you assess the most appropriate resistance or weight? How many sets and repetitions do you ask your patient to perform? Do you give rest periods in between the sets? How many times per week do your patients perform resistance training exercises? Do they only perform them under your

supervision or do they also perform them independently? How do you progress the intensity prescribed?

7.If no, why do you not routinely use PRT? Is it a resource issue? Is it a perceived safety/risk issue?

8.What would you perceive to be the benefits of PRT in this patient group?

9.What do you perceive to be the barriers/challenges to prescribing PRT to this patient group?

11. Have you received any formal training or education regarding PRT or it's application in this population?

Appendix 33 – Data Collection Form for Semi-Structured Interviews

Name	Current post	No of years qualified	No of years working with older inpatients

Appendix 34 – Participant Information Leaflet Semi-Structured Interviews

School of Physiotherapy

Royal College of Surgeons in Ireland

123, St Stephen's Green, Dublin 2

And

St James's Hospital

James's Street

Dublin 8

Participant Information Leaflet

(Version 1 Date: 29/6/2017)

Study title: Exploring Physiotherapy perceptions and experiences in the use of progressive resistance training in the older inpatient population.

Principal investigator: **Ms Sinead Coleman, M.Sc., Physiotherapist, St James's Hospital**

Phone number: **01 4103000**

Project Supervisor: **Dr Frances Horgan, School of Physiotherapy, RCSI**

Phone number: **01 4022472**

You are being invited to take part in a research study carried out by Sinead Coleman and Dr Frances Horgan at St James's Hospital.

Before you decide whether or not you wish to take part, you should read the information provided below carefully. Take time to ask the researcher questions. You should clearly understand the risks

and benefits of taking part in this study so that you can make a decision that is right for you. This process is known as 'Informed Consent'.

You do not have to take part in this study. You can change your mind about taking part at any time. Even if the study has started, you can still opt out without giving a reason. You can take plenty of time, up to a week to decide if you wish to be part of the study.

Why is this study being done?

A feasibility study has been carried out, investigating the use of progressive resistance training in the frail, older inpatient population. Now, this study aims to explore the stakeholder's views on this topic and gather information regarding the use of progressive resistance training to aid recovery and functional rehabilitation in the older inpatient.

Who is organising and funding this study?

This research study is being undertaken by researchers in the School of Physiotherapy at RCSI and St James's Hospital.

Am I eligible to take part?

To take part in this study you must have experience in the clinical area of frail older inpatients, either currently or within the past 6 months. Physiotherapy staff of all grades are welcome to participate.

What does this study involve?

<u>Focus group/interview (stakeholders)</u>

You will be given information about the study by the study gatekeeper (study supervisor), if you would like to participate, your details will be forwarded to the researchers Ms Sinead Coleman and Dr Frances Horgan. You will then be asked to attend the research venue (Mercer's Institute of Successful Ageing (MISA), St James's Hospital as appropriate) on one occasion, at a time that suits you for a focus group. You will be asked to sign a consent form, you will have an opportunity to ask the researcher/s questions that you may have about the study.

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

Your participation is entirely voluntary. If you initially decide to take part you can subsequently change your mind without difficulty.

If you agree to participate, you will be required to contact the investigators listed above by phone or email and attend a group discussion. The group discussion will be around your views on

progressive resistance training based on your own experience. This will take place in the MISA building in St James's Hospital on a date and time to be decided based on when would be most appropriate. The focus group will last approximately 1.5 hours. The focus groups will be carried out by a trained physiotherapist. Light refreshments will be provided for the focus group.

Video/and or Audio recordings?

The group discussion will be recorded throughout and you have the right, should you wish, to review and edit any transcripts to which you are involved in. You will be asked at the end of the group discussion if you would like to do this.

What are the benefits?

It is hoped that the information you provide will help in the future development of progressive resistance strengthening for the older inpatient to aid functional and effective rehabilitation.

What are the risks?

There are no physical risks involved in this study.

What if something goes wrong when I'm taking part in this study?

If you feel like leaving the group discussion at any point and for any reason then you are free to do so and you will not be penalised or affected negatively in anyway. You will not have to give a reason for your leaving at any point also.

Will it cost me anything to take part?

You will NOT be expected to pay any additional costs for participating.

Is this study confidential?

Anonymity and confidentiality will be maintained for all participants. All of the study information will be stored on V: drive of an RCSI networked password protected computer, only accessible to the researcher. All of the study documents, along with any other identifiable data, such as the signed consent form will be destroyed after 5 years by Dr Cunningham, in accordance with RCSI and St James's Hospital Data Protection Policy Guidelines. The data collected during the course of this study will be analysed and may be published as part of the study in a scientific journal. However, the collected data will be confidential and participants will not be identifiable.

Where can I get further information?

If you need any further information now or at any time in the future, please contact:

Name: Ms Sinead Coleman

Phone No: 01 410 3000 Bleep 082

Email address: scoleman@stjames.ie

Appendix 35 – Consent Form Semi-Structured Interviews

School of Physiotherapy
Royal College of Surgeons in Ireland
123, St Stephen's Green, Dublin 2
And
St James's Hospital
James's Street
Dublin 8

PARTICIPANT CONSENT FORM

(Version 1 Date: 29/06/2017)

Study title: Exploring Physiotherapy perceptions and experiences in the use of progressive resistance training in the older inpatient population.

Principal investigator: **Ms Sinead Coleman, M.Sc., Physiotherapist, St James's Hospital**

Phone number: **01 4103000**

Project Supervisor: **Dr Frances Horgan, School of Physiotherapy, RCSI**

Phone number: **01 4022472**

Email Address: scoleman@stjames.ie/fhorgan@rcsi.ie

*I have read and understood the **Information Leaflet** about this research project. The information has been fully explained to me and I have been able to ask questions, all of which have been answered to my satisfaction.*	***Yes*** ☐	***No*** ☐
I understand that I don't have to take part in this study and that I can opt out at any time. I understand that I don't have to give a reason for opting out.	***Yes*** ☐	***No*** ☐
I am aware of the potential risks and benefits of participating in this research study.	***Yes*** ☐	***No*** ☐
I have been assured that information about me will be kept private and confidential in a key locked cabinet or password protected external hard drive.	***Yes*** ☐	***No*** ☐
I have been given a copy of the Information Leaflet and this completed consent form for my records.	***Yes*** ☐	***No*** ☐

Storage and future use of information: *I give my permission for information collected about me to be stored or electronically processed for the purpose of scientific research and to be used in related studies or other studies in the future but only if the research is approved by a Research Ethics Committee*	***Yes ☐***	***No ☐***
I have been informed that I have the right, should I wish, to review and edit any transcripts to which I am involved in.	***Yes ☐***	***No ☐***

Participant Name (Block Capitals): _____

Participant Signature: _____ *Date:*_____

To be completed by the Principal Investigator or his nominee.

I the undersigned, have taken the time to fully explain to the above patient the nature and purpose of this study in a manner that they could understand. I have explained the risks involved as well as the possible benefits. I have invited them to ask questions on any aspect of the study that concerned them.

Name (Block Capitals): _____ *Qualifications:* _____

Signature: _____ *Date:* _____

Appendix 36 – Ethics Application Semi-Structured Interviews

25th May 2017

Chairperson,
Tallaght Hospital / St. James's Hospital Joint
Research Ethics Committee,
Tallaght Hospital,
Tallaght,
Dublin 24

Ethics Committee Reference Number: Original: 2013/05/04 Chairman's Action

Principal Investigators: Ms Sinead Coleman, Dr Conal Cunningham, Dr Frances Horgan, Ms Niamh Murphy

Title of Study: Can lower limb resistance training improve strength, muscle mass and functional outcomes in older inpatients in a post-acute rehabilitation unit? A randomised control trial.

Dear Chairperson

I would like to make an amendment to the above-named application.

This amendment would involve adding an in-depth audio-recorded interview with physiotherapists who work in the area of rehabilitation for the frail older patient. This will involve approximately 10 physiotherapists nationally.

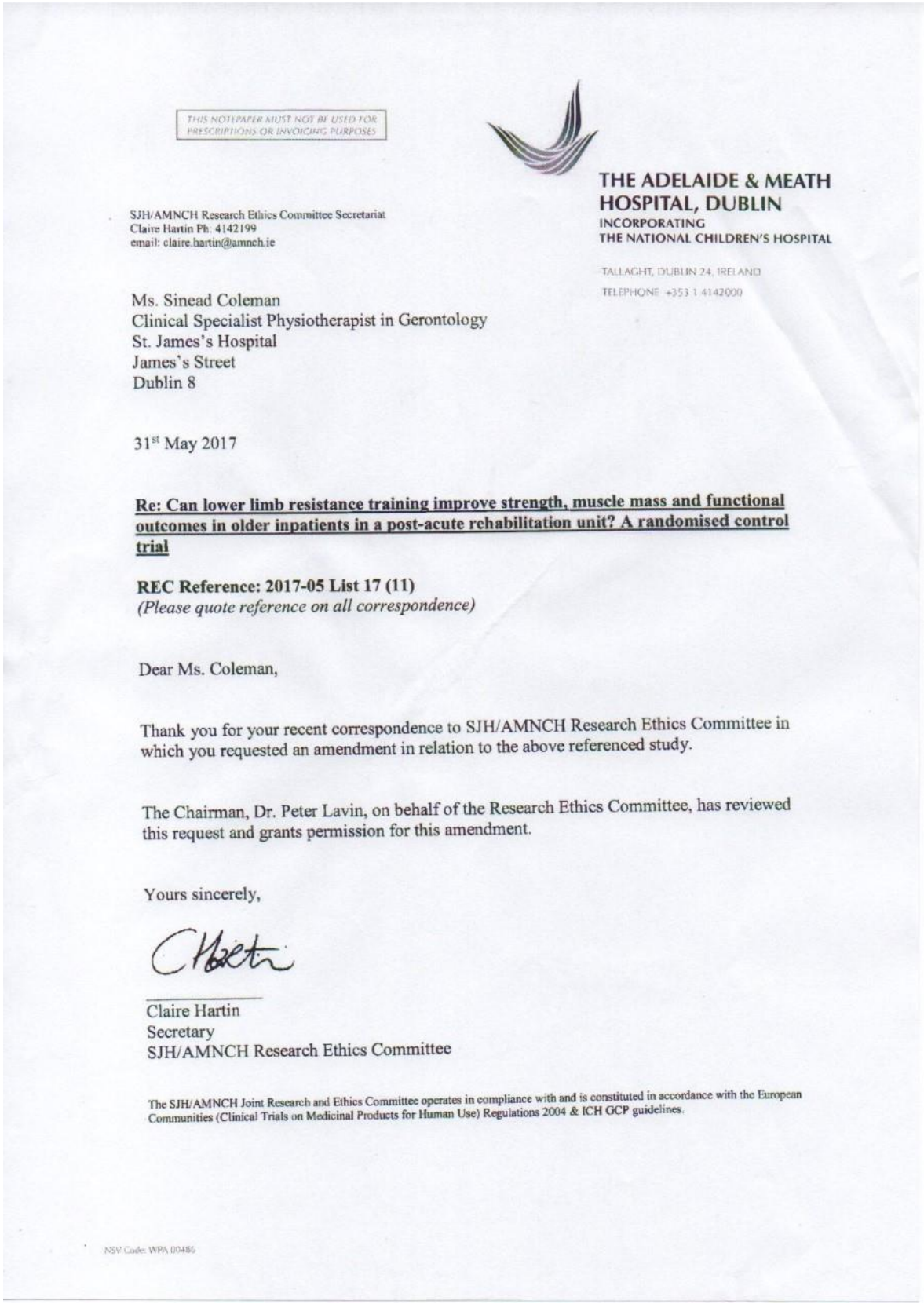
The rationale for this amendment is to gain insight regarding the use of progressive resistance training with frail older patients during the rehabilitation process, as well as benefits and challenges experienced by physiotherapists and patients. Qualitative methodology would allow participants to share their experience in more detail and would give researchers and clinicians a deeper understanding of current practices.

Physiotherapists who work with frail older patients in the area of rehabilitation will be contacted by telephone and invited to be interviewed in-depth about their experiences. These interviews will take place at a time and location convenient to participants. Interviews will be audio-recorded with the permission of participants on a study-specific dictaphone. Audio-recordings of in-depth interviews with be transcribed verbatim and identifying details will be removed. Transcripts will be qualitatively analysed using thematic analysis by two researchers. Participants will be informed that they have the right, should they wish, to review and edit the transcripts in which they are involved.

While the content of interviews will be individual to participants I have enclosed a sample schedule of questions that are likely to be asked by the researcher.
Please don't hesitate to contact me if you require further information.

Yours sincerely,
Sinead Coleman
Clinical Specialist Physiotherapist in Gerontology

Appendix 37 – Ethics Approval



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Ms. Sinead Coleman
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31st May 2017

Re: Can lower limb resistance training improve strength, muscle mass and functional outcomes in older inpatients in a post-acute rehabilitation unit? A randomised control trial

REC Reference: 2017-05 List 17 (11)
(Please quote reference on all correspondence)

Dear Ms. Coleman,

Thank you for your recent correspondence to SJH/AMNCH Research Ethics Committee in which you requested an amendment in relation to the above referenced study.

The Chairman, Dr. Peter Lavin, on behalf of the Research Ethics Committee, has reviewed this request and grants permission for this amendment.

Yours sincerely,

Claire Hartin
Secretary
SJH/AMNCH Research Ethics Committee

The SJH/AMNCH Joint Research and Ethics Committee operates in compliance with and is constituted in accordance with the European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations 2004 & ICH GCP guidelines.

NSV Code: WPA 00486