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Life After Falls prevention Therapy involving ExeRcise (LAFTER)

Susanne Kathleen Finnegan BSc (Hons), MCSP, MSc

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Declaration

This thesis is submitted to the University of Warwick in support of my application for the degree of Doctor of Philosophy. It has been composed by myself and has not been submitted in any previous application for any degree.

The work presented (including data generated and data analysis) was carried out by the author.

The author has published parts of this thesis:

- Finnegan S, Seers K, Bruce J. Long-term follow-up of exercise interventions aimed at preventing falls in older people living in the community: a systematic review and meta-analysis. *Physiotherapy*. 2019; 105: 187-99 (Appendix 1).
- Finnegan S, Bruce J, Seers K. What enables older people to continue with their falls prevention exercises? A qualitative systematic review. *BMJ Open*. 2019;9 (Appendix 2).

Abstract

Background: Exercise programmes addressing problems of gait, balance and lower limb strength, are effective in reducing rate and risk of falls in community-dwelling older people. There is a lack of evidence regarding the long-term effects of falls prevention exercises.

Aim: To investigate whether a falls prevention exercise intervention had any long-term effects on health-related outcomes compared to advice only, in older adults who have participated in a falls prevention clinical trial.

Methods: This study used mixed methods. A cohort study followed-up a subset of 4891/9803 (50%) older people recruited to a larger RCT; The Prevention of Fall Injury Trial (PreFIT). Data on falls, health-related quality of life, frailty, cognition and general health were collected from participants allocated to advice only and advice plus exercise, up to six-years after randomisation. Interviews were undertaken with 23 participants randomised to the exercise intervention to explore their experiences of the trial.

Results: 2980/4891 (61%) participants responded to a postal survey (advice: n=1507; exercise: n=1473). At six years, there were no long-term effects of exercise on falls or other health outcomes. There were no differences by treatment arm or by adherence to exercise. Overall health of the whole cohort gradually declined over time, in multiple domains. Analysis of interviews identified five themes: happy to help; exercise behaviours; “It keeps me going”; “It wasn’t a real fall”; and loss. Participants were no longer undertaking the strength and balance exercises prescribed during their intervention. They preferred walking as their main form of exercise, and no-one reported preventing falls as a motivator to continuing to exercise.

Conclusions: There were no long-term effects of falls prevention exercises in this cohort of older people. This may be because older people stop their specific strength and balance exercises when their supervised intervention comes to an end.

Abbreviations

ACSM	American College of Sports Medicine
ADLs	Activities of Daily Living
AGS	American Geriatric Society
ANOVA	Analysis of Variance
BGS	British Geriatric Society
CASP	Critical Appraisal Skills Programme
CERQual	Confidence in the Evidence from Reviews of Qualitative Research
CI	Confidence Intervals
CMO	Chief Medical Officers
CONSORT	Consolidating Standards of Reporting Clinical Trials
COPD	Chronic Obstructive Pulmonary Disease
DPA	Data Protection Act
EBP	Evidence-Based Practice
EQ-5D-3L	EuroQol-5 dimensions, three-level
GCP	Good Clinical Practice
GP	General Practice
HCP	Health Care Professional
HRQoL	Health-Related Quality of Life
LAFTER	Life After Falls prevention Therapy involving ExeRcise
LER	Lived Experience Research
MFFP	Multifactorial Falls Prevention
NHS	National Health Service
NICE	National Institute for health and Care Excellence
NIHR	National Institute for Health Research

OA	Osteoarthritis
OEP	Otago Exercise Programme
OR	Odds Ratio
PIS	Participant Information Sheet
PPI	Patient and Public Involvement
PreFIT	Prevention of Fall Injury Trial
ProFaNE	Prevention of Falls Network Europe
PHOF	Public Health Outcomes Framework
RaR	Rate Ratio
RCT	Randomised Controlled Trial
REC	Research Ethics Committee
RR	Risk Ratio or Relative Risk
SD	Standard Deviation
SE	Standard Error
UK	United Kingdom

Chapter 1: Introduction

Background

The problem of falls

One in three community-dwelling people aged 65 years and over fall at least once per year and this number rises to one in two among those aged 80 years and over (1). Falls can result in significant injury; fractures affect 5% of those with a history of falling, and falls are the second leading cause of accident-related mortality in older adults (2, 3). Falls are also associated with loss of independence, disability, functional decline, and social isolation, admission to long-term care, increased health and social care utilisation and United Kingdom (UK) National Health Service (NHS) related costs (4, 5).

Aetiology of falls

A fall is an “unexpected event in which the participants come to rest on the ground, floor, or lower level” (6) (p.1619). Falls have a multifactorial aetiology, with up to 400 proposed risk factors (7). The range of risk factors varies; some are unmodifiable i.e. age and previous falls history, but some, including impairments of gait, strength and balance, are potentially modifiable and are the target of falls prevention interventions (8).

Prevention of falls

The implementation of falls prevention services in secondary care across the UK was founded on early clinical trials of assessment and treatment of multiple falls risk factors (1, 9, 10). Currently, supported by the American Geriatric Society (AGS), British Geriatric Society (BGS) and The National Institute for Health and Care Excellence (NICE), multifactorial risk assessment with subsequent targeted referral and treatment of individual risk factors is the primary intervention for falls prevention in the UK (1). In 2007, it was estimated that £34 million per year was being spent on these interventions (11). However, these falls services vary significantly in their structure, design and mode of delivery (12).

Numerous clinical trials and subsequent systematic reviews have investigated the effectiveness of different falls prevention interventions. The most recent (2018) Cochrane systematic review of multifactorial interventions

(interventions consisting of components specific to individuals following an assessment of their risk), and multiple component interventions (interventions with the same components for all participants) for preventing falls in older people living in the community (13) included 62 randomised controlled trials (RCTs) involving 19,935 participants. Based on the results from 43 of these trials, the authors concluded that multifactorial falls prevention (MFFP) interventions, when compared to usual care or attention control, may reduce rate of falls (number of falls per unit of time of falls monitoring i.e. falls per person years), but may have little or no effect on other fall-related outcomes (low quality evidence). Seventeen trials of multiple component interventions versus usual care or attention control, were found, based on moderate quality evidence, to reduce rate of falls as well as risk of falling (proportion of people having one or more falls) (13).

A second recently published Cochrane systematic review (2019) investigating exercise for preventing falls in older people living in the community (14) included 108 RCTs with 23,407 participants. The authors concluded that, based on high certainty evidence, some exercise programmes reduce both rate of falls and the number (risk) of community-dwelling older adults falling (14). These effective exercise programmes typically consist of gait, balance and functional exercises (14, 15). Based on moderate certainty evidence, programmes that incorporate these components plus resistance exercises may also reduce rate and risk of falling; and Tai Chi programmes may also prevent falls (low certainty evidence). The effects of single interventions of resistance exercises, dance or walking only on outcomes of falls rates remains unclear (14).

Despite this evidence, preventing falls remains a public health challenge as the increasing population of older adults' acceptance of and adherence to these interventions remains poor (16, 17). Additionally, there is a lack of quantitative and qualitative evidence as to the long-term effects of falls prevention interventions on health and health behaviours in the older population (18-20). This gap in the evidence needs to be addressed to determine the sustainability and acceptability of these programmes long-term. It is important to consider and understand whether there is any long-

lasting clinical effectiveness and cost-effectiveness of programmes after interventions have come to an end; and to inform how best to promote exercise that can reduce rate and risk of falls, as a life-long intervention.

Therefore, this mixed methods research entitled: Life After Falls prevention Therapy involving ExeRcise (LAFTER), aims to investigate whether a falls prevention exercise intervention had any long-term effects on health-related outcomes in older adults who have participated in a falls prevention clinical trial.

To determine this, an additional wave of questionnaire follow-up of a subset of participants from the Prevention of Fall Injury Trial (PreFIT) was undertaken. In parallel, an interview study with a sample of the same trial participants was carried out to answer the following research questions:

1. Does involvement in a falls prevention exercise programme influence rate and risk of falling, mobility, health-related quality of life (HRQoL), frailty, cognition and general health up to six years later?
2. Do health outcomes differ by adherence to a prescribed exercise programme?
3. What are the experiences of older people participating in a falls prevention clinical trial involving exercise?

This research was generated by the need to understand the long-term effects of falls prevention exercises and was independent of the results of the PreFIT study. Funding for the LAFTER study was obtained during the original trial follow-up period, before statistical analysis of the main trial was completed.

The next section of this introductory chapter briefly describes the rationale and aims of the PreFIT study.

The Prevention of Fall Injury Trial (PreFIT)

Rationale for the PreFIT study

At the time of PreFIT development, well-conducted, larger clinical trials of MFFP interventions reported little or no evidence of fall or fracture reduction (21, 22). In 2008, a systematic review investigating multifactorial assessment

and targeted intervention for preventing falls and injuries among older people in community and emergency care settings concluded that MFFP interventions may be substantially less effective than previously thought (23); thus raising significant questions about the overall effectiveness and cost-effectiveness of MFFP interventions.

Additionally, it was suggested that exercise as a single intervention may be as effective as MFFP, since appropriately designed exercise programmes could reduce falls rates by approximately 25% and risk of falling by 15% (24, 25). There was, however, very limited data on the effects of these interventions on fracture outcomes.

Aims and objectives of the PreFIT study

PreFIT was funded by The National Institute for Health Research (NIHR) and is the largest UK trial to date, testing community-based fall prevention interventions. PreFIT was designed and commenced in 2010. The overall aim of this multi-centred, three-arm cluster RCT was to determine the comparative effectiveness and cost-effectiveness of three falls prevention strategies: advice only, advice plus exercise and advice plus MFFP, on outcomes of fractures, falls and quality of life in community-dwelling adults aged 70 years and over (Figure 1). A full description of the procedures and methods used in the PreFIT study is available in the published protocol and Health Technology Assessment final report (in press) (26, 27).

Summary

Making efficient use of clinical trial data, the aim of the LAFTER study was to use a cohort design nested within an existing RCT and a phenomenological interview study to provide much needed evidence about the long-term effects of falls prevention exercises on falls and other health-related outcomes.

The outline of this thesis will be presented in the final section of this chapter.

Population – People aged 70 and over living in the community, identified from general practice registers

Intervention – The active interventions were exercise and an MFFP assessment with onward referral as necessary. Practices randomised to the active interventions screened participants for falls risk using a postal falls risk screener questionnaire. Those identified at higher risk of falling were invited to treatment.

Comparator - All general practices posted a falls prevention advice leaflet to each participant.

Outcome – Primary outcome was fracture rate over 18-months. Secondary outcomes included rate of falls, HRQoL, mortality, frailty and health service resource use over 18-months. All participants were asked to complete postal questionnaires at baseline, 4, 8, 12 and 18-months.

Figure 1. A summary of PreFIT using the PICO model (28)

Outline of thesis

Chapter 2: Literature review

This chapter will place this research within the context of the current evidence base; highlighting the limitations of the existing evidence providing justification for further study. Following an introductory background to the problem of falls and the role of exercise in falls prevention, the chapter is then divided into two main sections. The first section provides an overview and update of my published systematic review of long-term follow-up of falls prevention exercise interventions (29). The second section presents an overview of older adults' experiences of falls and falls prevention services involving exercise and the barriers and facilitators to on-going exercise post-intervention. This will include a summary and update of my published systematic review of qualitative evidence (30).

Chapter 3: Mixed methods research

This chapter describes and discusses the methodology underpinning mixed methods research. I examine the rationale for using mixed methods and why

this research method was chosen for this study. I also describe the methods, focusing particularly on integration of data.

Chapter 4: Quantitative methodology and methods

This chapter provides an overview of the philosophical background, methodology and methods of quantitative research. The central tenets underpinning cohort studies are described, as well as the rationale for my decision to use an observational cohort study nested within an existing RCT and the methods involved.

Chapter 5: Qualitative study design

This chapter focuses on phenomenology, which was identified as the most appropriate methodology for the interview study. The work of Husserl and Heidegger are described with an emphasis on Heideggerian phenomenology as this was the chosen approach. The methods used to undertake this interview study are then described.

Chapter 6: Results and findings

There are three sections to this chapter. Firstly, the quantitative results of the nested cohort study are presented. Secondly, the themes and sub-themes generated from the interview study are presented. Finally, the two datasets are integrated, and these results and interpretations are described.

Chapter 7: Discussion

This chapter is a discussion of the results and findings with reference to previous and current evidence. This includes a description of the LAFTER study's original contribution to knowledge.

Chapter 8: Conclusions and recommendations

The final chapter draws together overall conclusions and recommendations for research and clinical practice.

Chapter 2: Literature Review

Introduction

The previous chapter introduced how falls are a common and serious health issue affecting one third of community-dwelling people aged 65 years and over and half of adults aged 80 and over, each year (1, 31, 32). Falls are the second leading cause of accidental or unintentional deaths worldwide with 37.3 million falls requiring medical attention each year (2, 3). The physical consequences of a fall in older age range from minor cuts and bruises to lacerations and fractures. This can have additional effects including on-going disability, functional decline, activity restriction, loss of independence, fear of falling, social isolation and depression (4, 5).

For health and social care services, falls are both high volume and costly. Figures from the Public Health Outcomes Framework (PHOF) reported that in 2017 to 2018, across England, there were 220,160 emergency hospital admissions due to falls in people aged 65 and over; 67% of whom were aged 80 years and older (31, 33). The cost of fragility fractures in the UK has been estimated at £4.4 billion per annum. This includes £1.1 billion for social care and approximately £2 billion for hip fractures (31, 33). These figures are extremely important as projections show that the UK's population is ageing, with estimates that over the next 50 years there are likely to be an additional 8.6 million people aged 65 years and over in the UK (34). Therefore, it is imperative to prevent falls in order to limit the related burden to older people and healthcare demand in ageing societies (35).

Risk factors for falling

There are many risk factors for falling in older people. They are often categorised as intrinsic risks, meaning they are related to the individual person and include, but are not limited to age, lower limb weakness, balance disorders, functional or cognitive impairment or visual defects. Extrinsic risks include polypharmacy and environmental factors (36, 37).

In a recent narrative review of the aetiology and risk factors for falls in older adults, Ambrose *et al* (36) found that different studies report various assorted

risk factors for falling. For example, Inouye *et al.* (38) identified older age, previous falls history, functional and cognitive impairment, reduced mobility or physical activity, balance problems and use of a walking aid as the main causes for falls in older adults. In comparison, Rubenstein (39) identified the major causes of falls in older people as being accidental or related to the environment, gait or balance disorders, confusion, dizziness and drop attacks, postural hypotension, visual disorders and syncope. Ganz and colleagues (40) and Tinetti *et al.* (41) also found abnormal gait or strength and balance disorders as the most consistent predictors and strongest risk factors for falls; therefore, these issues will be discussed in more detail in the next section.

Gait, balance and strength disorders

Rubenstein identified 'accidental' or environmental risk factors as the most frequently cited factors in his summary of 12 studies evaluating causes of falls in older people. He also highlighted that many accidental falls are actually attributable to the interaction between environmental hazards and individual susceptibility to these hazards, due to the effects of age and disease (39).

Normal ageing is associated with declines in musculoskeletal, cardiovascular, cognitive, visual, vestibular and proprioceptive systems, with associated slowing of coordination and postural responses (36). Therefore, older people can have altered gait patterns with reduced postural control, body-orienting or balance reflexes, muscle strength and tone and step length and height. Any of these can impair the ability to avoid a fall which commonly occur whilst walking, after an unexpected trip or slip, in stationary standing or bending forwards or laterally (36, 39, 42)

To avoid falling, a series of three movement strategies can be used to return the body to equilibrium in a stance position: two strategies to keep the feet in place and one to change the base of support involving stepping or reaching (39, 43). The first is the ankle strategy, whereby the body moves at the ankle to maintain balance during small amounts of sway when standing on a solid surface (43). Secondly, the hip strategy, which involves rotation at the hips to quickly move the body's centre of mass, occurs when standing on a narrow

base or uneven surface (43). The third strategy is taking a step or reaching to recover balance, especially whilst walking (43). An older person at risk of falling tends to use the stepping/reaching and hip strategies more commonly than an individual at low risk of falling. However, all of these strategies can be affected by ageing and, therefore, results in the loss of ability to correct balance in time to prevent a fall (39, 43).

The ageing process is also associated with reduced isometric, concentric and eccentric muscle strength, with lower body muscle strength declining at a faster rate than upper body muscle strength (44-46). An isometric or static muscle contraction occurs when the muscle fibres fire or are activated but are held at a constant length and there is no movement at the related joint (47). A concentric muscle contraction is a shortening of the muscle fibres which occurs when the muscle is activated as tension is produced i.e. to lift a load, and results in muscle strengthening (47, 48). An eccentric muscle contraction is the phase of activity where the external force acting on the muscle is greater than the force it produces and the muscle lengthens to return to the original starting point (47, 49). Generating adequate muscle power, force and speed is of key importance for normal movement, control of movement and maintenance of balance (50).

In their systematic review and meta-analysis of muscle weakness and falls in older adults (44), Moreland and colleagues found that along with chair stand tests, measuring quadriceps (knee extension) and ankle dorsiflexion strength were the most common methods used to assess lower limb strength. Weakness in these particular muscles has been found to be a significant risk factor for falls (44, 51).

Problems with gait, balance and lower limb strength are considered modifiable risk factors for falling. Therefore, exercises that address these impairments are likely to reduce rate and risk of falling and various exercise modalities have been tested to examine their effectiveness on these outcomes. Exercise as an intervention for gait, balance and strength problems will be discussed in the next section.

Exercise for gait, balance and strength disorders

Exercise involves movements that are planned, structured and repetitive and are undertaken in order to improve or maintain physical fitness. Physical activity refers to any body movement that occurs as the result of a contraction of skeletal muscles that increases energy expenditure (46).

Consistent with the American College of Sports Medicine (ACSM) Position Stand on exercise and physical activity for older adults (46), in 2011, the UK Chief Medical Officers (CMO) produced physical activity guidelines for older adults aged 65 years and older (52). These guidelines recommended that:

- Older adults should aim to be active daily; with activity totalling at least 150 minutes (2.5 hours) of moderate aerobic activity or 75 minutes (1.25 hours) of vigorous aerobic activity, per week.
- Older adults should undertake strength (resistance) exercises on two or more days per week
- Older adults at risk of falls should undertake physical activity or exercise to improve balance and co-ordination on at least two days per week
- Older adults should minimise the amount of time being sedentary for extended periods

These guidelines were very recently updated (September 2019) (53).

Although they have not changed significantly, the guidelines give greater prominence to strength, balance and flexibility exercises (not just in relation to falls prevention) and focus more on the importance of light intensity activity and breaking up patterns of sedentary behaviour. The updated guidelines recommend that:

- Older adults participate in daily physical activity. Since some physical activity is better than none, breaking up patterns of being sedentary with even light activity or standing brings some health benefits. More daily physical activity provides greater health and social benefits.
- Older adults should undertake activities aimed at improving or maintaining muscle strength, balance and flexibility on at least two days per week.

- Older adults should aim to accumulate at least 150 minutes of moderate intensity aerobic activity per week. For those who are already regularly active, 75 minutes of vigorous intensity activity, or a combination of moderate and vigorous activity is necessary to achieve greater benefits.
- To maintain bone health, undertake weight-bearing activities which create an impact through the body.

There is consistently strong evidence that appropriately designed exercise interventions targeting the risk factors of gait, balance and strength problems can reduce rate and risk of falling in community-dwelling older people (15, 54, 55). Stand-alone exercise interventions (interventions only comprising exercise) have been shown to have a similar effect to multi-component falls prevention interventions and it has been suggested that implementing exercise as an individual intervention might be the most effective and cost-effective approach to prevent falls at a population level (24, 54, 56).

Due to the complexity of falls prevention interventions, in collaboration with the Prevention of Falls Network Europe (ProFaNE), Lamb *et al* (57) developed a taxonomy to classify and describe falls prevention interventions. The aim of the taxonomy was to improve the design, reporting and synthesis of evidence from clinical trials of falls prevention (57). Based on this taxonomy, exercise interventions to prevent falls are generally classified as one or a mixture of the following seven categories (57):

- Gait, balance and functional training (including dynamic and static balance exercises, and walking exercises including turning and backward walking)
- Strength/resistance (including weight training with free weights or fixed resistance equipment)
- Flexibility (including Pilates and yoga)
- 3D (including Tai Chi, Qi Gong and dance)
- General physical activity (including walking, swimming and cycling)
- Endurance (including treadmill walking and use of rowing machines)
- Other

Evidence for exercise

Numerous clinical trials have been undertaken to evaluate the effectiveness of a variety of falls prevention exercise interventions on a range of falls outcomes. This is apparent in the most recent 2019 Cochrane review of exercise for preventing falls in older people living in the community (14) which included 108 RCTs. Sherrington and colleagues concluded that, based on high certainty evidence, when compared with a control intervention, exercise (all types) reduces rate of falls by 23% (rate ratio (RaR) 0.77, 95% confidence interval (CI) 0.71 to 0.83) and risk of falling by 15% (risk ratio (RR) 0.85, 95% CI 0.81 to 0.89) (14).

Specific categories of exercise have different effects on falls; but the most effective exercise programmes to reduce rate and risk of falling typically consist of gait, balance and functional exercises. Again, based on high certainty evidence, these types of exercise programmes were found to reduce rate and risk of falling by 24% (RaR 0.76, 95% CI 0.70 to 0.81) and 13% (RR 0.87, 95% CI 0.82 to 0.91), respectively (14). The addition of resistance exercises to such a programme may also prevent falls; based on moderate certainty evidence, a programme of this type will probably reduce rate of falls by 34% (RaR 0.66, 95% CI 0.50 to 0.88) and risk of falling by 22% (RR 0.78, 95% CI 0.64 to 0.96). Programmes of Tai Chi may also reduce rate of falls by 19% (RaR 0.81, 95% CI 0.67 to 0.99, low certainty evidence) and are likely to reduce risk of falling by 20% (RR 0.80, 95% CI 0.70 to 0.91, high certainty evidence). The authors concluded that there is insufficient evidence to determine whether resistance exercises, dancing or walking as a single intervention reduces rate or risk of falling (14).

Duration of exercise programmes in the UK setting

Evidence based recommendations for falls prevention exercise interventions (15, 55) indicate that the exercise must be of the correct:

- Type (high challenge balance exercises plus strength training);
- Frequency (at least three times per week);
- Intensity (sufficiently challenging to the individual and should be progressive);

- Duration (a minimum dose of 50 hours is recommended, which for weekly exercise groups, equates to approximately six-months, although on-going participation is needed to maintain accrued benefits).

A 2006 national survey of UK NHS services for the prevention and management of falls (12) found that 228/231 (99%) of services undertook multifactorial assessments; and 91% included assessment of gait and balance. Exercise, most commonly gait, balance and strength training, was used as a fall prevention intervention in 81% of UK clinics. Those responding to the survey reported that the mean duration of their exercise programmes was eight weeks (standard deviation (SD) 2.96; range 2-24), and the mean number of exercise sessions delivered was one per week (SD 0.04) (12). Therefore, at the time, the authors concluded that in comparison to interventions of known effectiveness, the frequency and duration of some of these programmes were sub-optimal (12).

A separate 2012 UK survey of staff and older people delivering and participating in NHS exercise programmes to reduce falls (58) also found that the majority of services were providing short duration exercise programmes (less than 12 weeks) and there was a lack of long-term follow-up and community-based exercise groups or classes aimed at reducing falls.

Clinical trials and follow-up of exercise interventions

The results of these studies in UK NHS settings highlight the variation in falls prevention service provision. These variations are also reflected in research into falls prevention exercise interventions in terms of duration and follow-up. Randomised controlled trials of falls prevention interventions involving exercise or physical activity need to follow-up participants for at least 12-months as it can take this long to accrue benefits of the exercise interventions (6). The majority of trials generally do not exceed 12-months follow-up (59, 60) but there is variation in length of follow-up. This is illustrated in the systematic review by Sherrington *et al* (14) where 50/108 (46%) of the included trials followed-up participants for less than 12-months (range 1-11 months). A further 37/108 (34%) of the included trials followed-

up participants for 12-months and the remaining 21/108 (19%) trials beyond 12-months.

The evidence-based recommendations highlight the importance of on-going participation in falls prevention exercise programmes. Despite this and the major long-term consequences of falls and fall-related injuries, there is a shortage of quantitative, qualitative or mixed methods evidence relating to the long-term sustainability of exercise programmes (19, 61). There is also a lack of evidence as to the possible long-lasting effects of exercise, including the maintenance of accrued benefits, or changes in physical activity, health behaviours and health status beyond the end of the exercise interventions or clinical trials (18, 59, 62-64). This will be discussed further in the next section.

Long-term follow-up of falls prevention exercise interventions

In their 2008 survey, Lamb *et al* (12) found that although half of falls prevention services undertook post-exercise programme follow-up, duration varied from two to 52 weeks (mean 21 weeks, SD 16.9). Again, using the Sherrington review (14) as an example, they analysed studies with follow-up at more than 18-months after randomisation as a 'longer-term' outcome. There were 15/108 (14%) trials longer than 18-months in duration; of which, 10/108 (9%) followed-up participants either at or beyond 24-months. They pooled data from two studies of gait, balance and functional exercise reporting the rate of falls at more than 18-months after randomisation (65, 66) and concluded that these exercises *may* reduce the rate of falls in the long-term (RaR 0.82, 95% CI 0.66 to 1.01; 858 participants; $I^2 = 41\%$; low certainty evidence). They also pooled data from two studies of gait, balance and functional exercise reporting number of fallers (66, 67) and similarly concluded that these types of exercise intervention *may* reduce risk of falling long-term (RR 0.86, 95% CI 0.78 to 0.94; 1325 participants; $I^2 = 0\%$; low-certainty evidence) (14).

Definition of long-term follow-up

The definition of 'long-term follow-up' in relation to health research is, however, somewhat unclear and there does not appear to be a standard definition of what constitutes long-term follow-up. With regards to falls

prevention interventions involving exercise, Freiburger *et al* (68) defines short-term follow-up as 12-months and long-term follow-up as 24-months in their RCT of the long-term effects of three multicomponent exercise interventions on physical performance and fall-related psychological outcomes in community-dwelling older adults. Similarly, Hauer *et al* (62) define long-term follow up as two years in their prospective long-term follow-up of a training intervention in geriatric patients with a history of severe falls. In comparison, Huang *et al* (69) and Bird *et al* (70) followed-up participants 12-months after a five-month intervention and a 16-week intervention, respectively, and both defined this as long-term. Sousa and colleagues conducted an RCT (71) comparing the long-term effects of two different community-based exercise programmes on falls risk factors and they followed-up participants at 32 weeks.

This illustrates the clinical heterogeneity of exercise interventions and variation in follow-up. In addition to duration, the methodology of these long-term follow-up studies also varies; some repeat objective tests and/or use self-report tools or falls diaries; some collect data on rate of falls as the primary outcome, whilst others examine a range of different outcomes, including the number of people who fall (risk), time to first fall or injurious falls related to certain health conditions. However, a commonly reported feature and limitation of these studies is small sample sizes, ranging between 50 and 200 participants (72-77).

Long-term follow-up of exercise interventions aimed at preventing falls in older people living in the community: a systematic review and meta-analysis

The first phase of this research was to undertake a systematic review to investigate long-term follow-up of exercise interventions aimed at preventing falls in older people living in the community (29) (Appendix 1). For the purposes of this review, long-term follow-up was defined as beyond 12-months. This work was published in *Physiotherapy* in 2019. An overview of this systematic review will be presented here.

Aim

To determine whether there was any evidence for the long-term effects of falls prevention exercise programmes on rate and risk of falling for community-dwelling older people aged 65 years and over.

Methods

Selection criteria

Eligible studies included RCTs, follow-up studies or secondary analyses of RCTs examining the long-term effectiveness of exercise designed to reduce falls in older people. Studies were only included where data was reported on rate of falls and/or risk of falling and follow-up was conducted beyond 12-months from recruitment or randomisation (29).

Participants

Studies were eligible for inclusion if they targeted adults aged 65 years and over, who were living in their own homes. Studies testing falls prevention exercise interventions in hospitals or long-term care facilities, or aimed at people with specific medical conditions such as stroke or Parkinson's were excluded (29).

Interventions

Trials of single or multiple component falls prevention exercise interventions were included. Eligible control groups consisted of 'usual care', placebo interventions or other types of intervention not involving exercise. Multi-arm trials were also included where at least one treatment arm was exercise alone and data were reported separately compared to a control (29)

Outcomes

Outcomes of interest were rate and risk of falling; studies reporting on one or both of these outcomes were eligible for inclusion. Studies using both prospective and retrospective data collection methods to capture these outcomes i.e. monthly calendars or diaries as well as self-report were included (29).

Search strategy

Searches were undertaken on MEDLINE, EMBASE, AMED, CINAHL, psyclINFO, the Physiotherapy Evidence Database (PEDro) and The

Cochrane Library from inception to April 2017. The detailed search strategy is presented in Appendix 1a. Reference lists from the included studies and other relevant texts were also manually searched (29).

Data collection

Titles and abstracts of identified studies were screened with subsequent assessment of full texts based on the selection criteria. Independent data extraction was carried out by pairs of reviewers to include: study design and duration, participant characteristics, description of interventions (classified using the ProFaNE taxonomy) (57), outcome measures and reported data. Any discrepancies were resolved via discussion (29).

Assessment of risk of bias

Using the Cochrane Collaboration's tool for assessing risk of bias in randomised trials (78), two reviewers assessed risk of bias based on the following domains:

- random sequence generation (selection bias)
- allocation concealment (selection bias)
- blinding of participants and personnel (performance bias)
- blinding of outcome assessors (detection bias)
- incomplete outcome data (attrition bias)
- selective reporting (reporting bias)
- other bias

Measures of treatment effect

Falls outcome data were categorised as either occurring between 12-24 months or beyond 24-months post randomisation. Rate ratios (RaR) were used to compare the rate of falls between treatment arms of each included study and were reported with 95% confidence intervals. For studies that did not report RaR, where possible, this was calculated by dividing the total number of falls by the length of time falls were monitored, assuming that unless stated otherwise, all participants were followed-up for the maximum period. Standard error (SE) of the RaR was calculated using the formula in the Cochrane handbook for Systematic Reviews of Interventions (29, 78).

Risk of falling was analysed as a risk ratio (RR); comparing the number of people who fell at least once. Relative risk and 95% confidence intervals were either extracted or calculated if data were reported (29).

Data synthesis

The primary analysis in this review was an overall synthesis of the effect of exercise interventions compared with control interventions on rate and/or risk of falls occurring beyond 12-months after randomisation (29). Subgroup analyses of exercise modality, duration of exercise and duration of follow-up were planned and pre-specified in the review protocol which was registered on PROSPERO on 11/04/2017:

https://www.crd.york.ac.uk/PROSPERO/display_record.asp?ID=CRD42017062461

Forest plots were compiled using the generic inverse variance method in Review Manager (RevMan 5.1). It was anticipated that there would be clinical and statistical heterogeneity between the interventions, therefore, a random effects model was used; with the I^2 statistic used to measure heterogeneity (29, 78).

Results

Study selection and characteristics

Twenty-four studies from 13 different countries were included in the review; 16 RCTs (66-68, 77, 79-90) and eight follow-up or secondary analyses of RCTs (59, 60, 63, 72, 76, 91-93). The median sample size for these studies was 231 participants (range 52 to 1235). Eleven trials (46%) included women only and overall, 79% of the participants in the 24 studies were female (29).

Fifteen studies (63%) tested exercise interventions with multiple components and nine (38%) tested a single component exercise intervention. Twenty studies included gait, balance and functional training exercises. Four trials compared two exercise interventions with one control group, therefore, the control group was apportioned appropriately to avoid double counting (29, 78). A total of 28 comparisons were undertaken. The duration of exercise interventions ranged from 12-weeks to 24-months and the duration of follow-up ranged from 15-months to 10 years (29).

Risk of bias

Overall, 13/24 (54%) studies were rated low risk of bias with three or more items judged at low risk (78). Twelve (50%) of the studies were at risk of selection bias; 23/24 (96%) were judged at high risk of performance bias, as it was not possible to blind participants and personnel taking part in and delivering an exercise intervention; 4/24 (17%) studies were at either high or unclear risk of detection bias and 11/24 (46%) had high or unclear risk of attrition bias because of losses over time (29).

Effects of exercise on rate and risk of falling

Pooling data from 23/24 studies with follow-up beyond 12-months, showed that participants in the exercise interventions had a 21% lower rate of falls (RaR 0.79, 95% CI 0.71 to 0.88) beyond one year compared to participants receiving a control intervention. We also pooled data from 18 studies to estimate the effect of exercise on risk of falling and found that those randomised to exercise interventions had a 17% lower risk (RR 0.83, 95% CI 0.76 to 0.92) of sustaining at least one fall beyond one year. There was however, moderate to substantial statistical heterogeneity in these estimates of effect (29). Similarly, pooling the results of studies following participants for up to 24-months, produced similar findings; 21% reduction in rate of falls (RaR 0.79, 95% CI 0.70 to 0.88; 20 studies) and 17% reduction in risk of falling (RR 0.83, 95% CI 0.75 to 0.93; 16 studies) despite differences in duration of intervention and time to follow-up data collection (29).

At the time of this review, only three studies had followed-up participants beyond 24-months (n=507) (59, 60, 93). Pereira *et al* conducted 10-year follow-up of post-menopausal women who participated in a RCT of a walking intervention on bone health. At 10 years, although not statistically significant, the proportion of women falling during the previous 12-months was 27% (26/96) in the intervention arm and 33% (33/100) in the control arm, while 23% (22/96) and 30% (30/100) of women reported falling more than once in the previous 12-months in the intervention and control arms, respectively (59).

Kim and colleagues did not find any long-term effect of their exercise and nutrition programme on rate of falls in their study investigating the long-term

effects of exercise and amino acid supplementation on muscle mass, physical function and falls in community-dwelling elderly Japanese sarcopenic women (93). Four-year follow-up data were available for 259/304 (85%) women; 83% (124/149) of excluded participants who were considered as non-participants, but were included in the analysis, and 87% (135/155) of participants in the intervention group. Despite the lack of long-term effect, the authors suggested that their exercise intervention had some protective effects; as at four years, participants falls rates only increased by 5% ($\chi^2 = 2.12$, $p = 0.145$) compared with 11% among non-participants ($\chi^2 = 15.41$, $p < 0.001$) (93).

The results of these two studies were combined with a third study with follow-up beyond 24-months (60) in a meta-analysis. When pooled, these three exercise interventions had no effect on rate (RaR 0.80, 95% CI 0.60 to 1.06; $n=507$) or risk of falling (RR 0.79, 95% CI 0.61 to 1.03; $n=248$) long-term (29). Individually, however, the third study by Hars *et al* (60) found that compared with a control group, participants in a long-term (four year) intervention group of music based multi-task exercise experienced fewer falls over the previous year. Additionally, the proportion of participants with ≥ 1 fall was also statistically different between groups (22% vs. 48% in long-term intervention and control groups, respectively).

The studies by Pereira and colleagues and Kim and colleagues were investigating the long-term effect of exercise programmes that had ended, whereas, Hars *et al* followed-up participants still undertaking their exercise programme and, therefore, were able to conclude that on-going maintenance of a music-based multitask exercise program was a promising strategy to prevent falls long-term. In line with the recommendations for duration of falls prevention interventions, they also recommended that community-dwelling older people should be informed of the benefits of sustained long-term participation in exercise for falls prevention (29, 60).

As well as duration of follow-up, the effect of duration of exercise intervention and exercise modality on long-term rate and risk of falling were also analysed (29) (Table 1).

Pooling the results of studies testing exercise interventions of less than six months resulted in a 21% reduction in rate of falls beyond 12-months but had no effect on risk of falling. Exercise interventions between six and 12-months in duration reduced rate of falls by 33% and risk of falling by 36% beyond 12-months. Interventions longer than 12-months in duration also reduced rate and risk of falling beyond 12-months, by 12% and 9% respectively (Table 1) (29).

Pooled data from studies comparing multicomponent exercise interventions and single-component exercise interventions with a control intervention reduced rate of falls by 18% and 35% respectively. Risk of falling reduced by 9% and 26%, respectively (Table 1) (29).

Table 1. Effects of duration of exercise intervention and exercise modality on rate and risk of falling

	No. of studies	No. of participants	Rate ratios		Risk ratios	
			RaR (95% CI)	I ²	RR (95% CI)	I ²
Duration of exercise programme						
<6 months	6 5	1002 694	0.79 (0.72, 0.87)	60%	0.89 (0.77, 1.03)	49%
6-12 months	9 8	1518 1366	0.67 (0.56, 0.80)	57%	0.64 (0.49, 0.83)	58%
>12 months	8 5	3002 1700	0.88 (0.82, 0.94)	51%	0.91 (0.85, 0.98)	0%
Exercise modality						
Multicomponent exercise interventions	15 8	3932 1586	0.82 (0.74, 0.91)	56%	0.91 (0.85, 0.96)	0%
Single-component exercise interventions	10 11	1590 1638	0.65 (0.48, 0.87)	67%	0.74 (0.60, 0.90)	64%

Summary

There were limitations of the systematic review: moderate to substantial statistical and clinical heterogeneity of the included studies; methodological

weaknesses in nearly half of the included studies; variability in the methods used to collect outcome data to capture falls; the majority of the included participants were female; and the very small number of studies with follow-up beyond 24-months. Therefore, the results and generalisability of results should be interpreted with caution; but in summary, this systematic review of falls prevention exercise interventions with long-term follow-up found evidence that certain types of falls prevention exercise programmes can have long-term effects on falling and these effects may be sustained for up to two years. The impact of exercise interventions on falls appears to decline after two years, although very few studies have undertaken follow-up beyond this time point. Of 23 studies, only three followed-up participants beyond two years (29).

Updated review of the literature

I have updated this systematic review using the same criteria and repeating the methods described above, to determine if any new or updated evidence investigating the long-term effectiveness of exercise designed to reduce falls in older people has been produced. The same search strategy (Appendix 1a) was applied to the same databases, but publication year was limited from January 2017 to end of August 2019.

Results

Study selection

This updated electronic search generated 215 studies. After removal of duplicates and ineligible studies based on title and abstract (Figure 2), 14 studies were retrieved for full review but 11 were excluded because they did not follow-up participants beyond 12-months (n=5), did not report on rate or risk of falling (n=5) and one study was not an RCT. Three studies (75, 94, 95) were considered eligible to be added to the existing systematic review.

Study characteristics

Characteristics of these three new trials are summarised in Table 2. Two trials were carried out in the USA (75, 94) and one in Finland (95). In total, the three studies included 305 participants (sample size ranged from 40 to 160 participants); mean age was 73 or 75 years; and 66% of the participants were women.

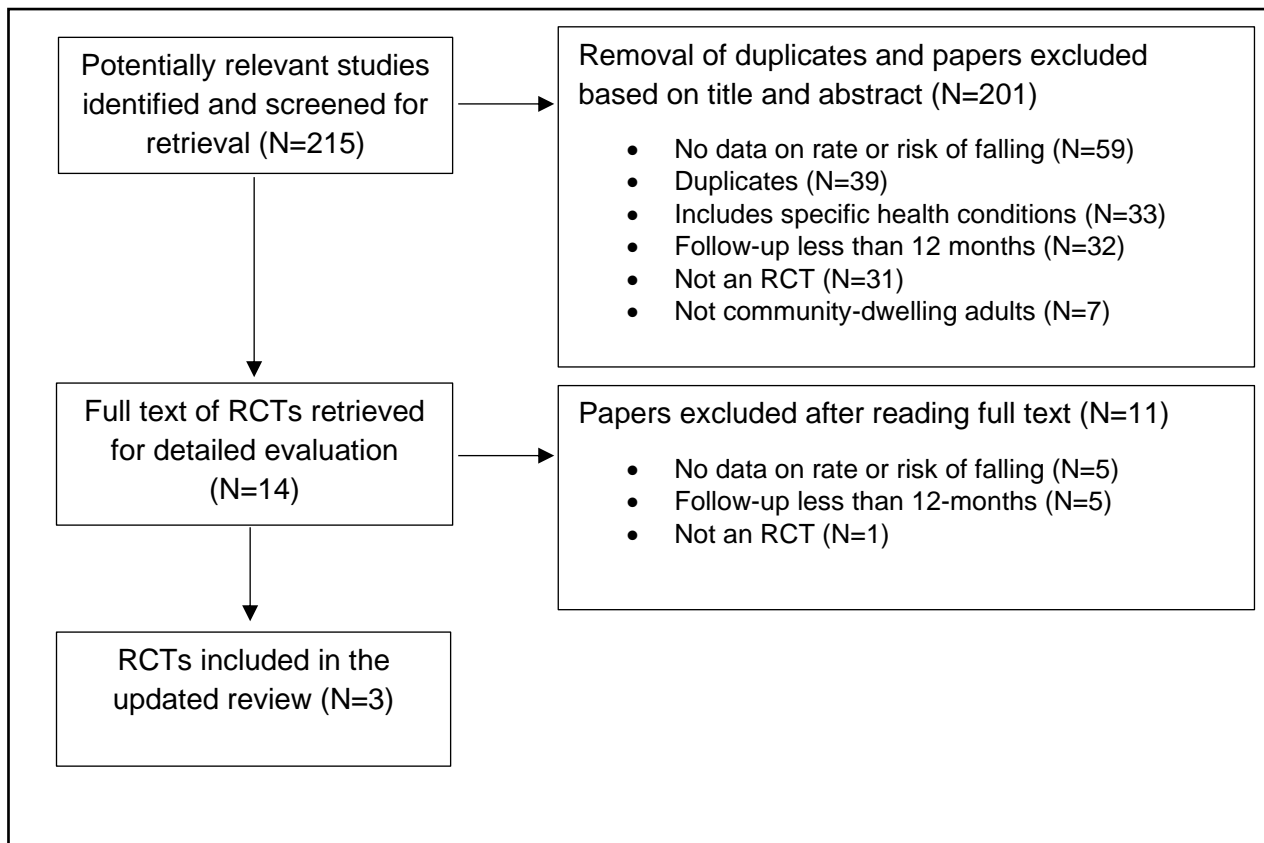


Figure 2. Flow diagram of search and selection process for updated quantitative systematic review

Interventions

Two studies used gait, balance and functional exercises combined with strength/resistance exercises in their intervention, but these were of different durations; one delivered over 15 weeks (75) and one, 30-months (95). The third study compared six-month interventions of endurance training only, strength training only and a combination of endurance and strength training with a control group. However, the authors made an a priori decision to report their falls outcomes by combining the results of the three interventions to form a single exercise group and compared this to the control group (94).

Duration of follow-up and outcomes

Duration of follow-up ranged from 16-months to 30-months. All three studies clearly reported data on rate of falls but only Buchner *et al* (94) also reported data on risk of falling.

Table 2. Characteristics of additional quantitative studies

Study & design	Sample size	Inclusion criteria	Mean age, years (SD)	Type of exercise intervention	Duration of intervention	Duration of follow-up (months)	Control	Falls outcome
Ballard 2004 (75) (USA) RCT	40	Community-dwelling women aged ≥ 65 years; mobile; fall in previous year or fear of future fall; able to undertake moderate exercise	73 (SD 6)	Gait, balance and functional training; strength/resistance	15 weeks	16	Gait, balance and functional training; strength/resistance for 2 weeks	1. Rate of falls
Buchner 1997 (94) (USA) RCT	105	Men and women aged 68-85; unable to do 8-step tandem gait test; <50th percentile in knee extensor strength for height and weight	75	1. Endurance only 2. Strength/resistance only 3. Endurance plus strength/resistance*	24 weeks	25	Usual activity	1. Rate of falls 2. Risk of falling
Korpelainen 2006 (95) (Finland) RCT	160	Women with radius and hip BMD values of >2 SD below the reference value	73 (SD 1.2)	Gait, balance and functional training;	30 months	30	Twice-yearly seminars on nutrition, health, medical treatment and fall prevention	1. Rate of falls 2. Number of people with one or more fall-related fractures

*Authors made an a priori decision to report fall outcomes for "any" exercise, therefore, data from all three exercise groups were combined and compared with control group

Risk of bias

A summary of risk of bias for the three additional studies is shown in Figure 3. Based on the overall key risk of bias items, only the study by Korpelainen *et al* (95) was rated low risk of bias (three or more items judged at low risk) (78). All three studies were assessed at high risk of performance bias because it is not possible to blind participants and personnel involved in an exercise intervention.

	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of participants and personnel (performance bias)	Blinding of outcome assessment (detection bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Other bias
Ballard 2004	?	?	-	-	+	-	+
Buchner 1997	+	?	-	?	?	?	+
Korpelainen 2006	+	+	-	+	+	-	+

Figure 3. Risk of bias summary graph for three new studies

Two of these studies were not identified in the original literature search for the systematic review possibly due to the search terms that were used, and the titles and details included in the abstracts of these papers. The third study was identified but excluded because the authors only reported on two of the interventions delivered and then combined the data of all of the exercise groups. This study was, however, included in the latest Cochrane review of exercise interventions for falls prevention, therefore, we have now included it in this updated analysis.

Effect of exercise on rate and risk of falling

Data from the three additional studies were incorporated and synthesised using the same methods as the original systematic review (29). The effect of including the additional studies have been compared with the original results and are presented in Table 3.

The overall pooled estimate of the RaR and RR for the effect of exercise on fall rates and risk of falling beyond 12-months did not alter with the addition of three new studies. However, the addition of the study by Korpelainen and colleagues (95) did alter the effect of gait, balance and functional training with endurance exercise on rate of falls (Table 3).

Adding two extra studies to the analysis of duration of follow-up changed the effect on rate of falls. Where previously there was no effect (RaR 0.80 95% CI 0.60, 1.06, 3 studies, $I^2 = 0\%$) (29), with the addition of the studies by Korpelainen (95) and Buchner (94), studies following-up participants beyond 24-months showed a reduction in rate of falls by 25% (RaR 0.75 95% CI 0.63, 0.91, 5 studies, $I^2 = 0\%$) despite the differences in intervention duration (Figure 4).

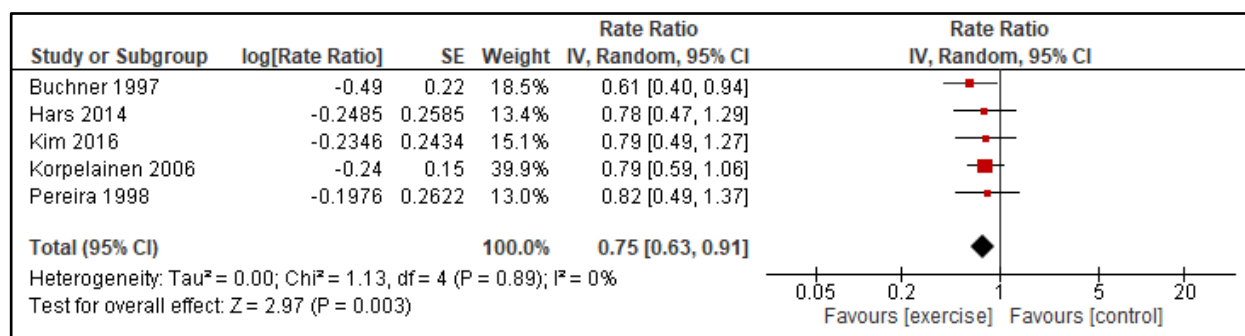


Figure 4. New forest plot: exercise versus control on rate of falls beyond 24-months follow-up (5 studies; 772 participants)

Table 3. A comparison of the effects of exercise on rate and risk of falling with additional three studies

	Original systematic review published in Physiotherapy 2019 (n=24 studies)				Updated review (n=27 studies)			
Characteristic	No. of studies/ participants	Rate ratios (95% CI) I ²	No. of studies/ participants	Risk ratios (95% CI) I ²	No. of studies/ participants	Rate ratios (95% CI) I ²	No. of studies/ participants	Risk ratios (95% CI) I ²
Effect of exercise on:								
Rate of falling beyond 12-months	23/6037	0.79 (0.71, 0.88) I ² = 60%			26/6342	0.78 (0.71, 0.86) I ² = 58%		
Risk of falling beyond 12-months			18/3760	0.83 (0.76, 0.92) I ² = 55%			19/3865	0.85 (0.78, 0.92) I ² = 59%
Type of exercise:								
Multiple component exercise	14/3932	0.82 (0.74, 0.91) I ² = 56%	8/1586	0.91 (0.85, 0.96) I ² = 0%	17/4237	0.81 (0.73, 0.89) I ² = 53%	9/1691	0.92 (0.87, 0.97) I ² = 7%
Gait/balance/functional training and strength/resistance exercises	4/769	0.99 (0.83, 1.17) I ² = 0%			5/929	0.93 (0.81, 1.08) I ² = 0%		
Gait/balance/functional training and endurance exercises	1/48	0.68 (0.40, 1.16) N/A			2/88	0.61 (0.38, 0.99) I ² = 0%		

Endurance and strength exercises						1/105	0.61 (0.40, 0.94) N/A	1/105	0.94 (0.87, 1.02) N/A
Duration of exercise intervention:									
<6-months	6/1002	0.79 (0.72, 0.87) I ² = 60%				7/1042	0.79 (0.71, 0.87) I ² = 58%		
6 to 12-months	9/1518	0.67 (0.56, 0.80) I ² = 57%	8/1366	0.64 (0.49, 0.83) I ² = 58%		10/1623	0.66 (0.56, 0.76) I ² = 54%	9/1471	0.64 (0.46, 0.89) I ² = 87%
>12-months	8/3002	0.88 (0.82, 0.94) I ² = 51%				9/3162	0.87 (0.82, 0.94) I ² = 46%		
Duration of follow-up:									
12 to 24-months	20/5015	0.79 (0.70, 0.88) I ² = 64%				21/5055	0.78 (0.70, 0.88) I ² = 64%		
>24-months	3/507	0.80 (0.60, 1.06) I ² = 0%	2/248	0.79 (0.61, 1.03) I ² = 0%		5/772	0.75 (0.63, 0.91) I ² = 0%	3/353	0.86 (0.65, 1.14) I ² = 69%

Summary

This updated review of the literature reinforces previous work which has shown that certain types of falls prevention exercise programmes, typically those incorporating gait, balance and functional training exercises +/- resistance exercises, have positive (14, 15) effects on rate and risk of falling and these effects may be sustained for up to two years. With the addition of three extra RCTs to this systematic review, the evidence for long-term effects of falls prevention exercises beyond 24-months has changed; effects may continue beyond two years, but this may be influenced by the duration of exercise intervention and modality of exercise being tested and delivered, which, despite the evidence-based recommendations remains variable.

The findings of this update to this systematic review are limited, as there are still a very small number of studies following-up participants who have been through falls prevention exercise interventions long-term. The definition of long-term follow-up is variable and needs standardisation. Therefore, as with the original review, these new results should be interpreted with caution due to the clinical heterogeneity and methodological weaknesses of the included studies.

Older adults' experiences of falls prevention exercise

During the search for this systematic review no mixed methods studies were identified and none of the studies included a qualitative component. It has been reported that there is a shortage of studies examining falls and falls prevention interventions from the older person's perspective (96-98) even though qualitative studies can be crucial to try to understand the 'how and 'why' behind the possible effectiveness of interventions (99). Therefore, the next section of this literature review will focus on qualitative literature in relation to the long-term effects of falls prevention exercise interventions.

Understanding and interpreting older people's experiences of falls and falls prevention services, specifically exercise interventions, and how and why they do or do not continue with their exercises when interventions come to an end is crucial to inform health care providers as to how acceptable and sustainable these interventions might be.

Uptake and adherence to falls prevention exercise programmes

Uptake and adherence to physical activity interventions and falls prevention exercise interventions, by older adults, is poor. This is usually due to a complex mix of physical and psychosocial factors including, but not limited to, health status and physical ability, socioeconomic status, previous experience, perceived need, self-efficacy and mode of delivery and location of exercise programme (98, 100-103).

Additionally, the definition of adherence to exercise programmes is somewhat variable. In a methodological review of the approaches to measure adherence in exercise classes for older people, Hawley-Hague and colleagues (104) concluded that there is very little consensus on the definition and it is described and measured in a variety of ways. In the absence of a consensus, they recommended that adherence needs to reflect the outcomes being measured and might include completion or retention, attendance, duration and intensity.

As described previously, to attain physiological benefits it is recommended that exercise for falls prevention be completed at least three times per week, incorporating approximately 50 hours of exercise over a six month period, with on-going participation to maintain accrued benefits (15, 55). Yet, adherence, in relation to how a person's behaviour corresponds with agreed recommendations from a healthcare provider (105), to both group and home exercise programmes for falls prevention tends to wane over the period of the intervention (16, 106). Therefore, qualitative studies of older people's experiences of exercise programmes for falls prevention tend to focus on the intervention itself. These studies examine factors influencing uptake, engagement and adherence to exercise during the intervention period since understanding and addressing these issues is important for treatment success (107, 108).

On-going participation in falls prevention exercises

There are, however, numerous older adults who do complete their falls prevention exercise programmes, but less is known about the challenges of adherence to continued exercise beyond the intervention period (18-20, 109)

i.e. what motivates or enables these older people to continue exercising, long-term, once their supervised intervention has come to an end.

Qualitative data was collected in a 2012 report of older people's experiences of therapeutic exercise as part of a falls prevention service. Respondents reported on-going participation in exercise, but their narratives suggested they were undertaking other types of exercise rather than evidence-based falls prevention exercises (58).

In another 2012 study, lack of on-going regular contact with a therapist to supervise or oversee an exercise programme was described as a barrier to long-term adherence to falls prevention exercises. This was, however, suggested by physical therapists in a phenomenological study of their clinical decision making processes rather than the older people participating in the programme (110).

What enables older people to continue with their falls prevention exercises? A qualitative systematic review

To promote lifelong behaviour change and long-term commitment to exercise among older people, it is important to understand the barriers and facilitators to adherence, not only during delivery of structured exercise interventions, but, also, once the intervention has ended. Therefore, as part of this research a second systematic review was undertaken: what enables older people to continue with their falls prevention exercises? A qualitative systematic review (30) (Appendix 2). The aim of this review was to explore the barriers and facilitators to continued participation in falls prevention exercise once structured programmes come to an end. The review protocol was registered on PROSPERO on 30/11/2017:

https://www.crd.york.ac.uk/prospero/display_record.php?ID=CRD420170826

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As with the previous systematic review, an overview of this published review of qualitative studies will be described below, followed by the results of an update of this review.

Methods

The synthesis of qualitative studies is important in understanding the broad range and complexity of experiences and perspectives of participants across different health care contexts. This allows for the development of new theoretical or conceptual paradigms, whilst identifying gaps in research evidence and providing new evidence for advancement of health interventions (111). This is achieved by systematically searching for primary qualitative studies incorporating data that can be integrated using methods including thematic synthesis (112).

Search strategy and selection criteria

For this systematic review (30), MEDLINE, PSYCHinfo, AMED, ASSIA, CINAHL and EMBASE were systematically searched from inception until November 2017. The detailed search strategy is presented in Appendix 2a. Additionally, a manual search of relevant reference lists was undertaken to identify additional papers.

Qualitative studies and mixed methods studies (clearly reporting separate qualitative findings) were included if participants were 65 years or older and living in the community; had participated in a falls prevention exercise programme (either home-based or group-based); and one of the aims of the study was to explore the participants experiences of on-going exercise after the completion of their structured exercise programme. This was defined as: (1) continuation of exercise in a new exercise group or setting; (2) continuation of prescribed exercises at home; or (3) undertaking different or new types of exercise to replace falls prevention exercises. Studies were excluded if participants lived in residential or nursing care; qualitative methods were not used for data collection i.e. interviews or focus groups; or findings were not related to on-going participation in falls prevention exercise (30).

Quality appraisal

A qualitative checklist from the Critical Appraisal Skills Program (CASP) (113) was used to assess the validity, transparency and relevance of the included studies. The checklist includes 10 questions about: study aim; appropriateness of qualitative research methods, recruitment strategy and

data collection; relationship between researcher and participant; ethical issues; rigorous data analysis and clear statement of findings. No studies were excluded as a result of CASP assessments, but the results were discussed. To ensure that this review represented the area of interest, the GRADE-Confidence in the Evidence from Reviews of Qualitative Research (CERQual) framework for assessing individual review findings was also applied to studies (114, 115). Pairs of reviewers assessed each study independently; any disagreements were resolved via discussion (30).

Data extraction

Key characteristics including country of origin; study aim; participant attributes; underpinning qualitative methodology and analytical approach; and data collection methods were extracted and independently checked by two reviewers. Additionally, pertinent text and accompanying participant quotations were extracted and organised in NVIVO V.11. Any differences were resolved through discussion (30).

Data synthesis and analysis

Thematic synthesis was used to integrate the data from the included studies (112). This involved line by line coding of the included studies by one reviewer, with a second reviewer (KS) double coding 20% of studies; recording and interpreting the older adult's experiences of participation in on-going exercise from one study into another; whilst continually re-reading the studies, comparing the codes and organising and integrating them into descriptive themes. An analytical theme was also constructed using mind mapping which allowed for expansion of the descriptive themes by identifying conceptual links across the primary studies (30, 112).

Findings

Literature search results

Of the 804 potentially relevant studies, 69 articles were retrieved for detailed evaluation and 14 (involving 425 participants, aged 65 years and older; range 65-94 years) were included in the final review. The 14 studies were based in the UK (n=7) (107, 116-121), Australia (n=3) (122-124), New Zealand (n=1) (125), Norway (n=1) (97), Denmark (n=1) (126) and Hong Kong (n=1) (127). The 425 participants had all taken part in group-based

falls prevention exercise programmes, delivered as either stand-alone interventions or as part of an MFFP programme. One study restricted participant inclusion to men only (124).

Quality of reporting

All studies clearly sought ethical approval, described the overall study aim, used qualitative research appropriately and gave a clear statement of their findings. However, only 2/14 (14%) studies adequately described or considered the relationship between the researcher and the participants, therefore, potentially introducing researcher bias (30, 113). Based on the GRADE-CERQual framework, we determined that two themes (identity and motivators/deterrents) were a reasonable representation of the phenomenon of interest (moderate confidence) and the nature of the intervention theme was highly likely to represent the phenomenon of interest (high confidence) (30, 115).

Synthesis

Synthesising the findings from the 14 primary studies resulted in one overarching analytical theme, incorporating three descriptive themes with sub-themes (Figure 5). These were presented with narrative exemplars (30).

Analytical theme

The descriptive themes were encapsulated by an overarching analytic theme of agency (30) (Figure 5). Agency is defined as the free will attributed to an individual to act autonomously, making their own choices and decisions based on their own belief structure. This belief structure comes about as a result of the individuals' experiences and objectives, as well as societal views and perceptions, and the context and structure of the surrounding environment (128-130). Therefore, in this instance, the older adults in these studies used their individual agency to decide whether to continue to exercise after the end of their intervention; and they based their decisions on their own perceptions of identity, their own personal motivators and deterrents and the nature of the exercise intervention (30).

Descriptive themes

Three descriptive themes were identified: 1) Identity; 2) Motivators/deterrents; and 3) Nature of the intervention (30). A brief overview of each theme will be presented here.

1) Identity

Identity was used to encompass sub-themes of “fallers”, “I’m not old” and exercisers/non-exercisers. These titles captured how the participants perceived or identified themselves in relation to falls and falls prevention exercise and how those perceptions affected their on-going participation in exercise programmes (30).

- “Fallers” – despite having fallen and their participation in exercise programmes aimed at preventing falls, often these older adults did not identify with the term ‘faller’ and preventing falls was infrequently mentioned as a reason for continued exercise. Instead, the focus and reasons for continued exercising were to maintain or improve strength and balance, confidence and functional abilities in order to remain independent and maintain quality of life (30):
 - “The results showed that motivating factors to adhere to recommended exercise were perceived prospects of staying independent, maintaining current health status, and improving physical balance and the ability to walk” (97)
- “I’m not old” – it was acknowledged by participants that older age is a risk factor for falling but many did not identify themselves as old; and even if age were an issue, it was not considered a barrier to on-going exercise (30):
 - “...they did not readily identify with the population that they perceived to be the target of the intervention, that is, ‘people who fall’ or ‘old people’” (126)
- Exerciser/non-exerciser – the participants expressed a variety of attitudes and perceptions towards exercise. Some identified themselves as exercisers and continued to exercise post-intervention due to the perceived benefits including increased confidence; improvements in general health and function and maintaining

independence. Whilst those who identified themselves as non-exercisers were able to provide clear and definite reasons for no longer participating in exercise and often labelled themselves in their justification (30):

- “Intrinsic motivators predominantly revolved around the notion held by participants that exercise in general was good for them. They anticipated that the exercise would be beneficial to them for ‘keeping fit’, and ‘keeping young’”(118)
- “However, others gave a variety of reasons why they had found it difficult to maintain an exercise regime, including ‘being the sort of person who hates exercise’, ill health, lack of interest, being too busy and laziness” (126)

2) *Motivators/deterrents*

The theme motivators/deterrents described some of the reasons that participants gave for continuing to exercise after the end of their exercise programmes and in contrast, the deterrents which caused some to stop exercising. These included health; social interaction; time; family support; and “I’m already doing enough” (30):

- Health – compared to preventing falls, which was seldom mentioned as a reason to continue exercising, maintaining, improving and preventing deterioration of health were all described. However, in contrast, health issues were also talked about as a barrier to on-going participation (30):
 - “When patients who became active were asked about their motivation to change their behaviour, the leading response was their own belief that exercise was important to their health” (119)
 - “One barrier to on-going participation was that of illness” (121)
- Social interaction – the social elements of participating in group exercise were frequently described as a facilitator to continued participation. These included: being in the company of and supported by others; encouragement from an instructor; and the pleasure of being with other people. However, transition to new groups could

prove challenging and participants who continued to exercise independently, without the company of others, reported missing the social interaction (30):

- “From community Otago to long-term maintenance in an Active Always class, it was...often a lot of the same group members which made participants feel more reassured and comfortable”(107)
- “Continuing to do exercises at home independently was often discussed as being less enjoyable”(118)
- Time was a recurrent factor affecting on-going participation in exercise. Those who discontinued exercise described lack of time or being too busy as a barrier whilst some of those who did continue described how they integrated their exercises into their daily routines (30):
 - “Perhaps a more surprising reason for not attending an intervention was that older people, although retired, often had other commitments, so found it difficult to attend regular interventions. Time pressures, due to caring responsibilities were another constraint” (116)
 - “...changes in their everyday schedule to accommodate the new and more active lifestyle” (124)
- Family support in the form of encouragement and assistance were described as facilitators to on-going exercise. However, on occasion, the responsibility placed on family members to support and help these older adults to continue to exercise was too great and the extra burden became a barrier to on-going exercise; whilst for others, relatives had concerns over safety and restricted some participants activity (30):
 - “For the participants who had finished the course... one person repeated some of the exercises with another friend from the group. Another person... had a carer who helped her do the exercises at home...” (125)

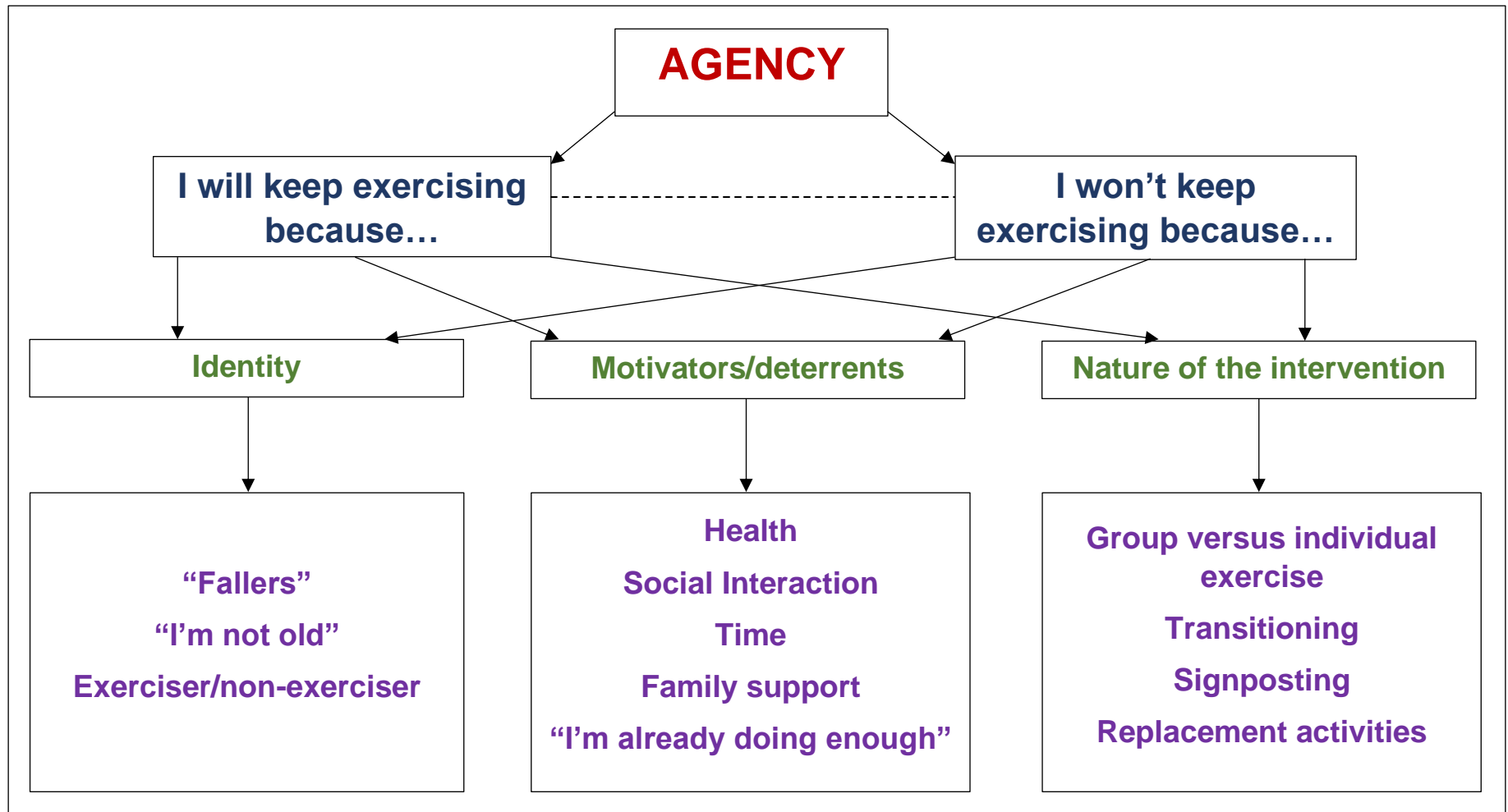


Figure 5. A diagram of the analytic and descriptive themes and sub-themes (30)

- “Several relatives described trying to prompt patients to exercise, but without success. Indeed, the need to remind patients, or monitor their exercise engagement, could constitute an unwelcome obligation” (122)
- “I’m already doing enough” – participants were willing to continue with their exercises, but for some, once they had achieved their desired goals, their participation waned (30):
 - “Previously practiced exercises were recognised to have been beneficial, but were discontinued once the need had passed, or only practised occasionally, as the habit had ‘just drifted off somewhere’ or exercise sheets were ‘filed away’. Participants reported that they were currently ‘doing enough’ exercise through ‘normal activity’...”(122)

3) *Nature of the intervention*

The third theme: nature of the intervention, illustrated the real-world experiences of older people participating in falls prevention exercise programmes and was categorised using the following sub-themes: group-based programmes versus individual exercise; transitioning; sign-posting and replacement activities (30):

- Group-based programmes versus individual exercise – linked with the social interaction sub-theme, for some, having exercised in a group was a facilitator to continue to exercise. Whereas, for some, the group exercise environment made them feel uncomfortable and uneasy and, therefore, was a barrier to on-going participation (30):
 - “...exercising together with others gave them pleasure and had motivated them to continue exercising in the municipality” (127)
 - “Despite such observations, however, the older people indicated that they preferred to exercise at home” (123)
- Transitioning - despite their wish to continue to exercise, once their intervention had ended, some participants described the difficulty transitioning from their group or class to another exercise format. This included moving from an existing group to a new exercise group or

independent exercise. For those wishing to continue to participate in a group format, the main barriers included obtaining information about and identification of an appropriate local group and potential financial implications (30):

- “Difficulties were also caused when a fixed programme of exercise came to an end... participants found them to be beneficial and would have liked the classes to have continued... often there were no suitable classes to which people could progress...” (116)
- Signposting – guidance from the exercise instructor or health care professional (HCP) as the intervention comes to an end was highlighted as an important factor in continued participation in exercise. Participants considered the provision of appropriate, up-to-date, and relevant information about other groups or new exercise opportunities as a facilitator (30):
 - “The provision of informational support in the form of ‘exit routes’ to other exercise opportunities facilitated them to continue exercise. They praised the exercise class leaders’ support during the transitional phase, and the available information about exercise choices in their local community” (124)
- Replacement activities – due to difficulties in finding appropriate long-term falls prevention activities, some participants took it upon themselves or worked with their instructors to find other ways to continue exercising. Thus, for some older people, these replacement activities were not specific falls prevention exercise interventions (30):
 - “Participants seemed more likely to walk as a regular form of on-going exercise than performing exercises specific to falls prevention. This was perhaps because walking was seen as functional and necessary (for example, to get to/from the shops)” (118)

Summary

There is a lack of evidence about the barriers and facilitators that older people face when contemplating on-going exercise once their falls prevention exercise interventions come to an end. This dearth of evidence is illustrated in this review as even in the 14 included studies, on-going participation in exercise was not the sole focus of any of the primary research. It is important to understand what these factors are, in order to promote behaviour change and life-long exercise (30).

Older people have a clear sense of their own identity and if health care interventions threaten that identity or self-sufficiency, then the potential risks associated with falling may be considered the lesser threat (100, 131).

Therefore, often using maintenance of independence rather than preventing falls as the reason, older adults use their own agency to decide whether exercise is an appropriate and relevant long-term activity (30, 132-134).

Choosing to continue with exercises after their intervention ends appears to be an active process where older people construct their own story as to why it is important for them to continue (30, 117, 120, 123). Conversely, discontinuing exercise seems to be a more passive process; where participants still create their own story and do not necessarily perceive themselves as passive, but acknowledge that exercise is just not a priority for them (30, 122, 123).

Similar to the barriers and facilitators to uptake and adherence to exercise (135), this review identified factors such as identity, health, social interaction and support and exercise delivery as reasons to continue or stop exercising, long-term. These findings give meaning to the participants' agency, encapsulating both the barriers and facilitators to on-going exercise.

Updated review of the literature

In the same way that I updated the quantitative systematic review, for this current literature review I have also updated the published qualitative systematic review, repeating the methods described above to determine whether there is any new information about the barriers and facilitators to on-going falls prevention exercises post-intervention. The same search strategy (Appendix 2a) was applied to the same databases, but publication year was

limited from January 2017 to end of August 2019. Additional studies were evaluated to determine whether their findings linked with the themes already derived from the original review or whether any new concepts or themes came to light.

Results

Literature search results

An update of the original search generated 58 studies which were potentially relevant. Following removal of duplicates and ineligible studies based on title and abstract (Figure 6), six studies were retrieved for full review. Three of these studies were excluded as they were not related to on-going exercise.

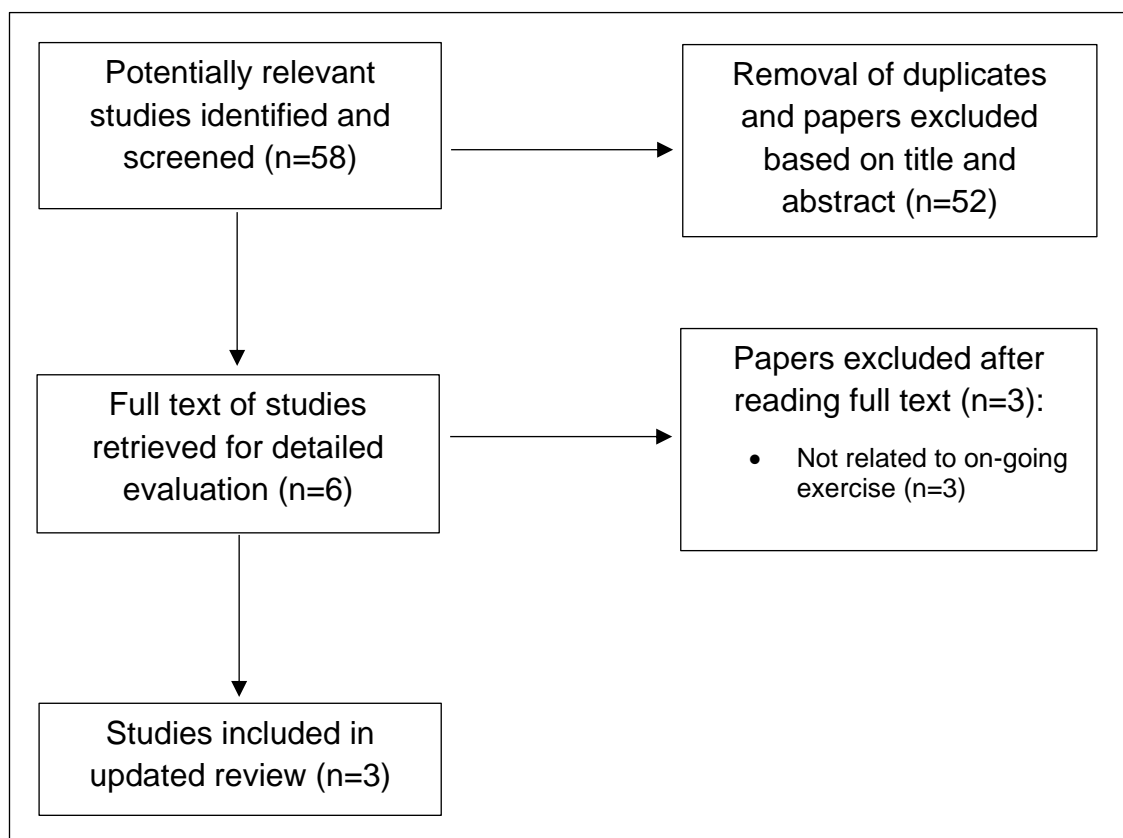


Figure 6. Flow diagram of search and selection process for updated qualitative systematic review

Study characteristics of the three additional studies (one conference abstract) are described in Table 4. Two were undertaken in the UK (136, 137) and one in Australia (138). The primary aim of the research was to explore either housebound patients' experiences of a falls-prevention service (137), a community-delivered post-hospital programme (138), or an

instructor-led postural stability class (136). Therefore, none focused exclusively on the barriers and facilitators to on-going falls prevention exercises post-intervention but did discuss the participants' ideas and suggestions for on-going participation.

Quality of reporting

The CASP checklist was used to assess the validity of these additional studies (Table 5). All three studies chose and clearly described qualitative research or mixed methods research appropriately for the aim of the study. Myrsep and Thomson (137) were reflexive about their relationship with their participants but this was not considered in the other two studies. The study by Wright and Shannon (136) was a conference abstract, and lacked detail about their ethical procedures, data analysis methods and in-depth findings.

Synthesis of findings

Descriptive themes

The relevant findings from these three additional studies linked well with the analytic and descriptive themes and sub-themes identified in the original systematic review.

Linked to the health and social interaction sub-themes of the motivators/deterrents theme (30), Myrsep and Thomson's (137) study explored 'exercise' and 'motivation to exercise'. Their participants were asked if they were still performing their exercises post-intervention and four reported to exercising regularly, whilst three said they did their exercises every day. The reasons these participants gave for continued exercise related to health and social interaction:

- "All the participants described their motivation for exercise was to be able to go out and to have social contacts in the future" (137)

Similarly, Wright and Shannon identified 'socialisation and being part of a group' as a key theme. Based on the experiences of their participants, they went on to recommend:

- "Provisions following the completion of the falls class would be best practice to enable the group members to continue socialising with one another if desired" (136)

Table 4. Characteristics of additional qualitative/mixed methods studies

Author/year	Country	Aim	Participants	Data collection	Underpinning methodology	Analysis
Myrsep and Thomson 2018 (137)	UK	To explore the experiences of a falls service in housebound, older patients who have fallen	Six housebound men and women; mean age 85.7 years (range 74 to 90 years)	Interviews	None described	Thematic analysis following a model described in detail by Braun and Clarke (2006).
Renehan <i>et al</i> 2019 (138)	Australia	A mixed methods study to determine feasibility and acceptability of a community-delivered post hospital multifactorial program	Thirteen men and women; mean age 82.2 years (SD 9.7) being discharged home after hospitalisation following a fall	Semi-structured interviews	None described	Descriptive topic coding followed by open coding and grouping of codes according to key variances and similarities and contextualised with emerging phenomena
Wright and Shannon 2019 (136)	UK	To explore the experiences, feelings and perceptions of participants who attended a fall-prevention exercise group	Nine white British women with a mean age of 77 years recruited from a single falls exercise class held in the London Borough of Haringey	Semi-structured interviews	Grounded theory	Inductive thematic analysis

This recommendation by Wright and Shannon also links to the nature of the intervention theme, in particular the importance of transitioning and signposting and providing appropriate and up to date information about on-going exercise opportunities to meet the individual's needs (111). The requirement for on-going supervised exercise is also highlighted in the mixed methods study by Renehan *et al* (138). They categorised their qualitative findings into three domains, one of which was 'feedback on intervention'. Within this, 'benefits of the intervention' and 'suggestions for improvement' emerged as sub-themes:

- "Most participants felt the exercise intervention had been helpful and increased their concentration, range of motion and/or confidence levels, despite this not being supported by the quantitative fear of falling data. Some participants expressed a desire for the exercise support to continue, as they felt they were not as confident in falls prevention as they could be" (138)
- "...potential improvements for future programmes included suggestions for more frequent exercise physiology visits to assist exercise adherence" (138)

Summary

The additional three qualitative studies exploring older adults' experiences of falls prevention programmes and on-going exercise beyond the intervention link well with the analytic theme of agency and descriptive themes of motivators/deterrents and nature of the intervention.

These studies provide more evidence for the importance of social interaction and perceived health benefits of exercise, not necessarily preventing falls. Only one of these studies focussed on the experiences of older people partaking in individual home-based exercise and revealed that even for those exercising alone, their long-term goal was ultimately linked to socialising i.e. to improve their health to enable them to socialise with friends and family. However, it also seems crucial that for some older adults, a key facilitator or enabler to on-going participation in their exercise programme, is on-going support or supervision from an instructor or HCP; a finding which is extremely important for those providing falls prevention services.

Table 5. CASP results for additional three studies identified in update of qualitative systematic review

Study	Clear aim	Appropriate for qualitative research	Appropriate design	Appropriate recruitment strategy	Data collection	Relationship between researcher and participant	Ethical issues considered	Rigorous data analysis	Clear statement of findings
Myrsep and Thomson 2018 (137)	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Renehan <i>et al</i> 2019 (138)	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes
Wright and Shannon* 2019 (136)	Yes	Yes	Yes	Yes	Yes	No	Can't tell	No	No
% of yes'	100	100	100	100	100	33	67	67	67

*Conference abstract

Conclusion

There is consistently strong evidence that appropriately designed exercise programmes aimed at the modifiable risk factors of abnormal gait or strength and balance disorders can reduce rate and risk of falling in community-dwelling older people. Understanding the long-term effects of these exercise programmes is important in terms of effectiveness, as well as acceptability and sustainability.

To put this research into the context of the current evidence base, I undertook two systematic reviews, with subsequent updates, to explore long-term follow-up of exercise interventions aimed at preventing falls in older people living in the community, and what enables (barriers and facilitators) older people to continue with their falls prevention exercises.

Quantitatively, this literature review found evidence that certain types of falls prevention exercise interventions can have sustained effects for up to two years. The number of studies following-up participants beyond two years is small, but in the updated review there was also an effect. This result must be interpreted with caution, however, due to limitations including statistical and clinical heterogeneity and methodological weaknesses.

Qualitatively, from the limited available evidence, older people use their own agency to choose whether or not to continue with exercise. Factors including personal identity, health, social interaction/support, and exercise delivery are important to older people when making this decision. Additionally, their decision is often linked to maintaining independence rather than preventing falls.

Overall, this literature review highlighted that there is a lack of quantitative, qualitative and mixed methods studies investigating and exploring the long-term effects of falls prevention exercises on health-related outcomes of older people. Therefore, there is a need for this research to determine what the effects are, as well as what this means to participants who have been through a falls prevention exercise programme.

Chapter 3: Mixed methods research

Introduction

In governing the choice of research methodology, researchers should take into consideration the nature of the knowledge required to answer the research question, have an understanding of the philosophical assumptions and appropriateness underpinning the methodology and also the epistemological lens through which they view the world (139, 140). The researcher's chosen methodology shapes the methods used; and in truly understanding the methodology, interpretation and analysis of the data is more robust (141, 142).

This research is a mixed methods study using quantitative data from a cohort study nested within the PreFIT study and qualitative data from interviews with a sample of the PreFIT participants. This design has been selected to investigate whether a falls prevention exercise intervention has any long-term effects on health outcomes in older adults participating in a falls prevention clinical trial. The study explores the experience of being involved in the trial, including the barriers and facilitators to continuing or maintaining exercise following an individual, home based, falls prevention exercise programme.

The aim of this chapter is to present and discuss the methodology underpinning mixed methods research, the rationale for using mixed methods in this study and the methods that were undertaken.

Methodology

Mixed methods research has been described as the third major research approach or paradigm used in health and social sciences, alongside quantitative and qualitative research (143, 144). In 2007, Johnson *et al* sought consensus on a definition of mixed methods research by combining different classifications used by a number of highly published mixed methods researchers (143, 145). Based on these results, they offered this definition:

“Mixed methods research is the type of research in which a researcher or team of researchers combines elements of qualitative and quantitative research approaches (e.g. use of qualitative and quantitative viewpoints, data collection, analysis, inference

techniques) for the purposes of breadth and depth of understanding and corroboration” (143) (p.123).

The definitions that Johnson and colleagues reviewed highlight that mixed methods research is both a mixing of methods and methodologies i.e. it includes what is being mixed, at what point in the research process, the scope of the mixing and the rationale for mixing (143, 145). But fundamental to all definitions is the integration of at least two datasets and subsequent interpretations based on the combined data (145).

A post-positivism paradigm?

Positivism is the most dominant paradigm in the field of scientific enquiry and is the belief that a single reality exists and can be observed, measured and verified objectively (146-148). Positivism has been criticised for excluding certain sources of understanding including human experiences, reasoning or interpretation; ignoring context and denying the role of reflexivity among researchers (149, 150). As a result of these criticisms, late nineteenth century and 20th century philosophers such as Max Weber (1864-1920) and Thomas Kuhn (1922-1996) moved beyond positivism to a post-positivist perspective (149). This philosophical view theorises that no human knowledge can be proven with absolute certainty although people can accept many scientific conclusions as though they are a universal truth (151). Like positivism, post-positivism encourages the use of ordered scientific methods of observation and experimentation to discover new information but differs from positivism in that it assumes that the scientific method will always be affected by some type of human shortcoming or error.

It has been suggested that using multiple research methods sits within a post-positivist paradigm. Post-positivist researchers believe that knowledge exists in the social world and, therefore, also believe in multiple perspectives from participants rather than a single entity (positivism) (152). This knowledge, may, therefore, be best understood using both quantitative and qualitative methods and analysis (148, 150, 151).

Development of mixed methods as a research method

Historically, mixed methods research was first seen in the work of cultural anthropologists and sociologists such as Hollingshead (1949), Lynd (1929) and Gans (1963) (143). Campbell and Fiske (153) formalised the practice of using multiple research methods for social science research in 1959, introducing the idea of 'multiple operationalism', which Webb (154) later called triangulation.

This sociological research method was further developed by Denzin (155) who first outlined four methods of triangulation: i) data triangulation (using a variety of data sources in a study), ii) investigator triangulation (incorporating several different researchers), iii) theory triangulation (using multiple viewpoints and theories in interpreting results), and iv) methodological triangulation (using multiple methods to answer a research question).

Subsequently, to meet the research needs of contemporary health care, in the late 20th century, mixed methods research spread from sociological research into health research, health policy and health evaluation (143, 156). In the context of health, several authors have outlined various rationales for using mixed methods (157-159), which, in 1989, after examination of published research, Greene *et al* (160) identified as:

1. Triangulation – using data obtained by both methods to corroborate findings;
2. Complementarity – using data obtained by one method to elaborate, illustrate or clarify the results obtained using the other method;
3. Development – using results from one method to develop or inform the use of the second method;
4. Initiation – using the results from both methods to specifically identify paradoxes or contradictions in order to generate new insights;
5. Expansion – using different methods in order to expand the breadth and range of inquiry.

Tariq and Woodman (161) have also suggested that researchers use mixed methods to employ the strengths of quantitative research in producing generalizable results whilst concomitantly representing the voices of their participants with qualitative research. All of these rationales rely on the underlying assumption that mixed methods research draws on the strengths and counterbalances the weaknesses of both quantitative and qualitative methods to address a research question more comprehensively than by using either method individually (145, 157, 162, 163).

There are some who do not advocate the mixing of quantitative and qualitative methods (164, 165) but it is argued that the choice of research methodology and methods should be dependent upon the research question (145, 156). Research questions that are best answered using a mixed method design tend to be broad and complex, exploring diverse perspectives and uncovering relationships that exist in research questions with multiple components (161, 162).

Therefore, using the rationales of triangulation, complementarity and initiation, mixed methods was identified as an appropriate approach for this study to answer the broad research question about the long-term effects of falls prevention exercises on health outcomes in older adults.

In the next sections of this chapter I will describe the different study designs for mixed methods research and the methods adopted specifically for this research. As part of the overall methods, I will also describe how public and patient involvement (PPI) contributed to the study.

Methods

Study design

There are various ways of mixing methods e.g. during data collection, data analysis or interpretation. Creswell (145) describes three basic mixed methods designs:

- An explanatory sequential design – a design which uses quantitative methods followed by qualitative methods to explain the quantitative results in more depth with integration occurring during the interpretation phase;

- An exploratory sequential design – using qualitative methods initially to understand the problem under investigation and to inform the quantitative phase which then follows, with integration of data occurring during the interpretation phase;
- A convergent (or concurrent) design – a design whereby both quantitative and qualitative data are collected and analysed separately but in parallel, then the results are merged during the analysis or interpretation phase with the purpose of comparing or validating one set of results with the other.

Additional features or frameworks can be added to these basic designs.

These include: an intervention, where qualitative data is collected to support the development and design of an intervention; a case study, where very detailed qualitative and quantitative data are collected to build a comprehensive understanding of a single case; a multistage evaluation which combines exploratory sequential, explanatory sequential and convergent approaches; or a participatory research framework approach where the focus is on involving participants from a target population to inform the research (166, 167).

For this study, a basic convergent design was used. The quantitative phase of the study was a prospective cohort study nested within an RCT (described in Chapter 4) and the qualitative phase was an interview study (described in Chapter 5). The two parts of the study ran in parallel. The results from the two datasets were analysed separately then integrated during the interpretation phase of the project to fully answer the research questions in one coherent account. Further information about how the data were integrated is presented in the next section.

Integration of data

Integrating quantitative and qualitative data is a key part of the process of mixed methods research to maximise the data and generate a comprehensive set of results to answer the research question.

Creswell and colleagues describe four approaches for integrating data through ‘linking’ at the basic method level (145, 166). This linkage can occur

in several ways: (1) connecting, which happens when one database links with the other through sampling; (2) building, when the results of one method of data collection informs the data collection approach of the other; (3) merging, when the two databases are brought together for analysis and comparison; and (4) embedding, when data collection and analysis are linked at multiple time points (166).

A basic convergent design typically involves merging of data as a means of integration and occurs at the interpretation stage (168, 169). This involves analysing the quantitative and qualitative data separately, then bringing the results together to compare findings and draw meta-inferences i.e. how the qualitative data aids our interpretation of the quantitative data and vice-versa.

Integration at the interpretation stage occurs through: (1) narrative integration, whereby researchers describe the quantitative and qualitative findings in a single or series of reports or discussions, using a weaving, contiguous or staged approach; (2) data transformation which happens in two stages where one type of data is converted into the other and then integrated with data that has not been transformed; or (3) joint displays where researchers bring data together simultaneously, visually organising the information in a figure, table, matrix or graph (166, 167).

O’Cathain and colleagues (2010) illustrate the points of application for integrating data in mixed methods research in Figure 7 (169). This model reiterates that integration can occur at different points of a project i.e. during data analysis or interpretation of the results (168-170). Similar to the methods outlined above, O’Cathain *et al* (2010) describe methods including triangulation (using different methods to answer a question or understand a problem), following a thread (selecting one theme from one source – the thread - and following it across all the other data) and mixed methods matrices (studying single cases who have provided both quantitative and qualitative data) (169).

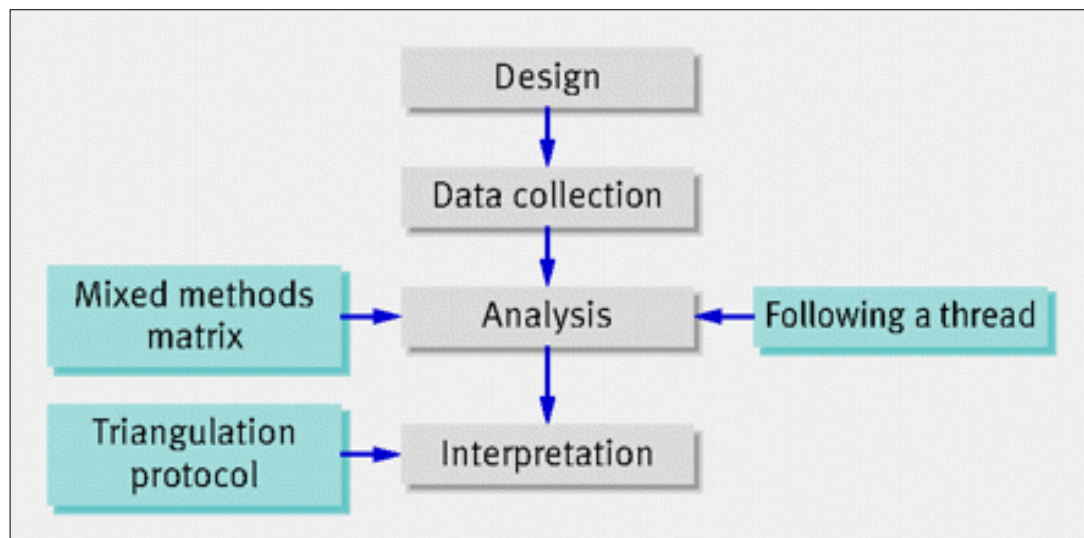


Figure 7. Point of application for three techniques for integrating data in mixed methods research (from O’Cathain *et al* (2010), reproduced with permission from the BMJ)

To achieve integration at the interpretation stage, the data in this study were merged using a joint display and the triangulation protocol highlighted in Figure 7 (169).

Joint displays

Guetterman and colleagues (2015) recommend using visual joint displays to facilitate integration (167). This brings the data together visually to draw out new insights beyond the information gained from the separate quantitative and qualitative results, whilst providing structure to discuss the integrated analysis (167). Therefore, using these types of display helps readers to understand how the qualitative and quantitative results interface and complement and/or contradict one another (168).

Statistics-by-themes or side-by-side comparison displays are appropriate for convergent design mixed method studies (167, 168). For this thesis, a side-by-side comparison was used, whereby the joint display table displays key quantitative results and qualitative findings side by side.

When using a procedure such as a joint display, the ‘fit’ or coherence of the quantitative and qualitative findings may be called into question. According to Fetters and colleagues (166), assessment of this coherence leads to three possible outcomes: (1) confirmation, which is when the results or findings

from the two datasets concur, confirming the results of the other and, therefore, having greater credibility; (2) expansion, which occurs as a divergence of the quantitative and qualitative data and gives rise to a broader understanding of the area of interest by exploring different aspects of the same phenomena and (3) discordance, whereby the data from the two sources are inconsistent, contradictory, oppose or disagree with one another.

These approaches to assessing coherence are similar to that outlined in Farmer *et al's* (2006) triangulation protocol, which is described in the next section and was used as the basis for comparing and verifying the two datasets for convergence, complementarity, and dissonance (171).

Triangulation protocol

The term triangulation can be used to describe the processes involved in answering a research question using multiple methods (169). Like joint displays, triangulation of findings from different methods takes place at the interpretation stage of a study after both datasets have been analysed separately. The primary purpose of triangulation is to explore convergence (agreement of results), complementarity (results that complement one another) and dissonance or discrepancy (contradictions in results) between two or more datasets. This adds depth and credibility to the findings and understanding of often complex health issues (163, 169, 171).

In practical terms, this requires the researcher to list the findings from each component of the study together and consider where the results converge, complement one another or are contradictory (169). Farmer *et al* (171) provide a detailed description of how to undertake triangulation using a triangulation protocol, which, although designed originally for integrating data from multiple qualitative studies, is also relevant for mixed methods (169). This method was used as a template for assessing coherence and integration of the data in this study.

Sorting

Step one of the triangulation protocol involves sorting the data. In this study, this was based on inductive and deductive approaches to the indicative interview schedule and reading the interview transcripts, as well as analysis

of responses to questions included in the extended follow-up questionnaire. The health outcomes under investigation i.e. falls, mobility, HRQoL, frailty, cognition and general health were used as a means of sorting the data from the two datasets. These outcomes formed the rows of a side-by-side joint display and a convergence coding matrix was used to summarise similarities and differences between the two data sets (171).

Convergence coding

The two datasets were compared with respect to the data on health outcomes as well as meaning, interpretation and importance of themes regarding these health outcomes. Specific examples are provided to support or explain particular findings. A convergence coding scheme was applied to the data to determine convergence between the two sets of results on the meaning, prominence and coverage of the findings (171). The degree and type of convergence was characterised using the descriptions in Table 6 (171).

Feedback

The final step of the triangulation protocol is feedback. The quantitative results and qualitative findings, both separately and integrated, were discussed with my supervisors for review and comment, not just as a final step but throughout this process.

Summary

It was deemed appropriate to use a mixed methods research design to answer my research question which is broad and has multiple components. My rationale for doing so was based on the principles of triangulation, complementarity and initiation outlined by Greene *et al* (160).

I undertook a prospective cohort study nested within an RCT and phenomenological interview study. The two ran in parallel and the results were analysed separately before being integrated during the interpretation phase of the project.

Table 6. Example of a convergence coding scheme (adapted from Farmer et al, 2006)

Convergence coding scheme	
Agreement	There is full agreement between the sets of results on both elements of comparison e.g. meaning and prominence are the same, coverage of findings are the same and specific examples provided are the same.
Partial agreement	There is agreement on one but not both components e.g. the meaning or prominence of themes is the same, or coverage of findings are the same.
Silence	One set of results covers the results or theme, whereas the other set of results is silent on the results or theme.
Dissonance	There is a disagreement between the sets of results on both elements of comparison e.g. meaning and prominence are different; and coverage of findings and specific examples provided are different.

Patient and public involvement in the LAFTER study

I have actively involved patients, carers, and individuals with an interest in falls and falls prevention to ensure that my research is relevant to the public, particularly community-dwelling older people.

I formed a lay advisory group consisting of seven older adults with an interest in or experience of falls. They were recruited via local NHS Falls Services, AGE UK groups across Coventry and Warwickshire or from People in Research via the NIHR INVOLVE scheme. I also accessed the User Teaching and Research Action Partnership (UNTRAP) which is a partnership between users of health and social care services, carers, and academic staff at the University of Warwick.

Using the model of Patient and Public Involvement in the research cycle (172), the lay advisory group assisted at the design and development stages.

We met as a group prior to the commencement of this work to discuss the proposed study and to get their input into the overall research aim and research questions. The group reviewed and commented on a summary of the project and looked at and evaluated examples of potential questions and outcome measures for inclusion in the questionnaire. They also discussed specific questions and reasons for including them.

The group have had continued involvement throughout the study in a monitoring and evaluation capacity. They assisted in the development of patient information sheets (PIS), consent forms and the interview schedule, as well as advising on physical activity outcome measures. I aim to involve the group in the future during dissemination of the results of this research so that we can produce information relevant for a lay audience. I aim to use their links to relevant groups/organisations to jointly promote and present the research findings.

In the next two chapters, I will describe the methodology and methods for the cohort study and interview study that make up this mixed methods research.

Chapter 4: Quantitative methodology and methods

Introduction

The overall aim of quantitative research is to answer specific research questions through the systematic measurement and analysis of variables in quantifiable terms (173). Researchers use quantitative research to establish and explain relationships between variables. This focus on describing and explaining results means that quantitative research operates under well established and widely agreed-on procedures that guide the research process (174).

In the first section of this chapter I will give an overview of the philosophical background and methodology behind different types of quantitative research. A prospective nested cohort study has been selected for this mixed methods research. Therefore, this section will also focus specifically on cohort studies and the central tenets underpinning this method, as well as the rationale for using a cohort study design.

Methodology

The positivist paradigm

Although this research does not sit in a positivist paradigm because it is incorporating mixed methods, the philosophical framework for quantitative research does align with a positivist model, based on empiricist traditions established by philosophers and sociologists including Auguste Comte (1798-1857) and Emile Durkheim (1858-1917) (144, 145, 147, 175).

Positivism is an objectivist epistemology which suggests that a single reality exists and can be observed objectively and measured statistically or in a quantifiable method to determine one definitive answer (146-148).

Therefore, a positivist approach requires quantitative researchers to be independent from the study (176). They should be impartial, objective observers; obtaining results in an unbiased manner; and making estimations based on scientific and statistical methods (177). However, contradictory to this, many of the ideas in statistical analysis have been developed to take into account the importance of the role of chance, and therefore,

probabilities, as a measure of chance, are not 'one definitive answer' but are a prediction of how likely it is that a specific event will occur (178, 179).

Types of quantitative research

Quantitative approaches are commonly described as deductive as they set out to test an a priori hypothesis to produce potentially generalisable results (144, 146). There are a variety of quantitative research methods. They can be broadly categorised as experimental methods, such as RCTs, whereby the researcher designs different treatments or conditions to test and subsequently studies the effects on participants. Non-experimental methods are a group of techniques where there is no manipulation of variables and includes observational research such as cohort studies (174, 180).

To illustrate the robustness of each method in underpinning evidence-based practice (EBP) in healthcare, a hierarchy of research designs or evidence was developed based on the rigour of research methods i.e. internal validity or risk of bias (181, 182). Figure 8 is an adapted representation of the hierarchy of quantitative evidence for questions of effectiveness provided by the National Health and Medical Research Council (183).

Although disputed by some researchers (184), the hierarchy of evidence ranks well-conducted systematic reviews as the most rigorous research method to answer questions of effectiveness due to their methodology and minimisation of risk of bias (185). Systematic reviews usually combine results from experimental RCTs which are next down in the hierarchy and are considered the 'gold standard' of evidence for questions of clinical effectiveness (181). Well conducted RCTs are deemed extremely reliable as they incorporate three major characteristics of an experiment i.e. randomisation, a control group and manipulation of the independent variable, as well as controlling for systematic error (bias), which also allows for replication and generalisability of results (186).

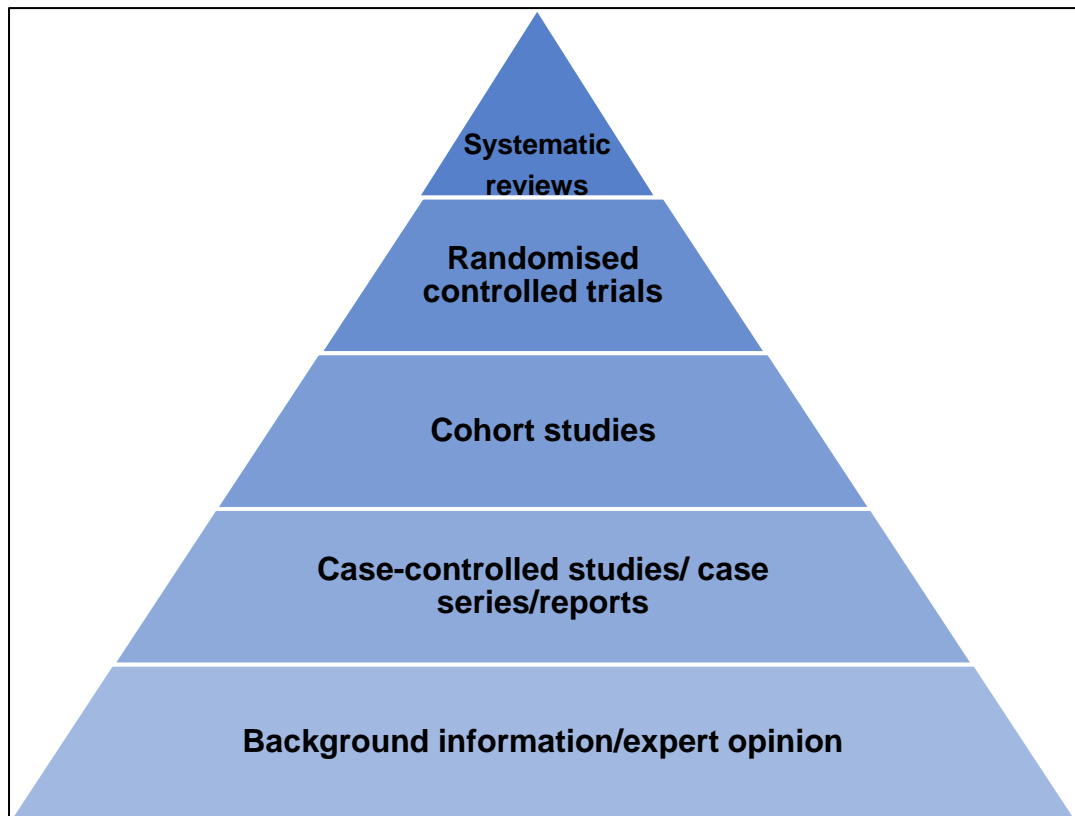


Figure 8. The hierarchy of quantitative evidence for questions of effectiveness (adapted from the National Health and Medical Research Council, 2009)

Observational studies such as cohort studies and case-controlled studies are at greater risk of bias than RCTs because of the inability to control for selection and other biases (184, 187). However, the best research design for a primary study is dependent on the research question. In some situations, observational studies can complement the results of RCTs or are most appropriate to answer questions relating to aetiology of diseases, examining interventions designed to prevent rare events and evaluating prognosis or long-term outcomes (187, 188).

Cohort studies

The epidemiologist, W.H. Frost (1880-1938) was the first to use the word 'cohort' in his 1935 publication assessing age-specific mortality rates and tuberculosis (189). Cohort studies are epidemiological studies concerned with observing events over time. They involve identifying a group of patients or participants who share a common characteristic or experience which defines the sampling, and following them over time, focusing on their longer-

term well-being (179). The temporal aspect of a cohort study can be either retrospective (carried out at the present time but looking to the past to investigate risk factors and/or outcomes) or prospective (carried out from the present time into the future to identify risk factors and/or outcomes) (190).

Cohort studies are commonly used in health services research to investigate issues such as:

- whether patients need long-term follow-up;
- any long-term adverse effects of medical interventions;
- continued health care use;
- patient well-being in the longer-term;
- clarification of the natural history of a disease (179).

The key tenets of cohort studies

There are certain key principles and theories underpinning all types of quantitative research methods. Some of the key tenets of cohort studies and their relation to the LAFTER study are described here.

Sampling

As with all quantitative research, the type of participants to be sampled and studied in a cohort study are determined by the research question. It is important that the source(s) for participant selection for a cohort study are sufficient to recruit an adequate number of participants. These participants must have a certain condition, risk factor or have received a particular treatment. They are followed over time and compared with another group who are not affected by the condition or treatment under investigation (179).

Given the size of the original PreFIT study, the sample of older people available to invite to participate in the LAFTER cohort was ample. Although participants from all three arms of the trial were included in the extra wave of data collection, the focus of the research question for the LAFTER study was about the long-term effects of an exercise intervention. Therefore, participants from the advice plus exercise arm of PreFIT were followed-up for up to six years post randomisation and compared with participants from the advice only arm. Those in the advice arm acted as a comparator group as none had received the PreFIT exercise intervention as part of the main trial.

Measurement

Measurement is a crucial principle of all quantitative research, stemming from its positivist roots (147). In experimental research it involves the accurate measurement and analysis of independent variables (the variable that is changed or manipulated in an experiment) and dependent variables (the variables being tested and measured and presumed to be influenced by the independent variable) (144, 191). These measurements should be as objective, valid and reliable as possible in order for the results to be generalisable to the whole target population and limit confounding. Confounding is the influence of uncontrolled extraneous variables which can affect results (144, 146, 147).

In the main PreFIT study, the independent variables were the interventions of advice only, advice plus exercise and advice plus MFFP. The dependent variables included falling, mobility, HRQoL, frailty, cognition and general health. Therefore, for the LAFTER study, I chose to use the same objective measurements for comparison over time.

To capture this information, as is common in observational research (144), a postal questionnaire, was sent to all LAFTER participants up to six-years post-randomisation. Duration of follow-up is another important consideration during the design of a cohort study (179). In this instance, duration of follow-up was variable because like recruitment and randomisation in the main trial, follow-up data collection in the LAFTER study was staggered and took place over a six-month period.

Postal questionnaires are particularly advantageous as large numbers of individuals can be contacted in a short period for a comparatively small cost (174). However, this type of method is very susceptible to non-response. And, since non-responders are likely to be different to responders, like all quantitative methods, cohort studies are prone to systematic errors or biases such as threats to reliability and validity of the results (144, 146). Selection bias and loss to follow-up (179) are particularly pertinent to my study and thus will be described in more detail in the following sections.

Selection bias

In epidemiological studies, including cohort studies, selection bias occurs when there is a systematic difference between the characteristics of those selected for the study and those who are not selected (192). The sampling method for a cohort study does not allow for randomisation and, therefore, the sample obtained may not be representative of the population as a whole i.e. the participants taking part in the follow-up study differ from those who did not take part. This selection effect can be sufficiently strong to distort the results (179).

Selection bias may be a result of:

- volunteering;
- systematically excluding or over-representing certain groups (sampling bias);
- systematic differences in the way participants are recruited into different study groups (allocation bias);
- missed or non-responders (responder bias) (178).

Loss to follow-up

If the participants who drop out of a cohort study differ from those who continue, this type of selection bias or responder bias is a threat to the internal validity of results. The bias that is introduced by loss to follow-up can act in either direction (179, 193). If loss to follow-up occurs in one group more than the other and the reasons are associated with the outcome of interest e.g. symptomatic individuals opposed to asymptomatic individuals, then the comparison between the two groups ceases to be unbiased (192).

Confounding

Another potential problem with quantitative research, including cohort studies, is confounding. It occurs when the association between two variables might be explained because both are related to a third variable that can influence the risk factor or outcome being investigated in a cohort study. This can seemingly create effects where actually there are none or can obscure relationships (178, 179).

Systematic errors, biases and confounding cannot be eliminated completely. However, because the LAFTER cohort study was nested within the existing PreFIT study, the risk of these errors is reduced because the sample stemmed from an RCT; randomisation reduces the risk of confounding, sampling and allocation bias (179).

Implications for selection of research design

Cohort studies can be used for evaluating long-term outcomes and, therefore, it is appropriate to use this method to answer my research question about the long-term effects of falls prevention exercises on health outcomes in older adults.

The quantitative research approach in this mixed methods study is a prospective cohort study nested within an RCT. This study is described as a nested cohort because the sample have been selected from a pre-determined population whose characteristics are already known as they are the subjects of an on-going RCT (26).

The next section of this chapter will describe the methods used to undertake the prospective nested cohort study.

Methods

Prospective cohort study nested in a randomised controlled trial

Introduction

To evaluate the long-term effects of falls prevention exercises on outcomes of falls, mobility, HRQoL, frailty, cognition and general health, extended follow-up postal questionnaires were sent to a cohort of the PreFIT participants between three and six years after randomisation. The nested component of the cohort study is the subset of participants allocated to two of three interventions: advice only and advice plus exercise. The results of these extended follow-up questionnaires were compared over time, from baseline to 18-months to final (extended) follow-up.

The methods used in PreFIT are described elsewhere (26, 27, 194, 195) but I will give a very brief overview of those methods in the following section then a detailed description of the methods used for the LAFTER cohort study.

PreFIT study methods

PreFIT is a three-arm, pragmatic, cluster RCT, with economic analysis, conducted within primary care in England, UK. There were 9803 participants aged 70 and over who were recruited from 63 general practices across England and randomly allocated to receive one of three interventions: (1) advice only; (2) advice plus exercise; or (3) advice plus MFFP (26).

All participants were sent the Age UK 'Staying Steady' advice booklet. Those randomised to exercise or MFFP were screened and offered treatment if they were at higher risk of falling i.e. reported balance problems; had a single fall in the previous year; had a single fall plus balance problems; or had sustained multiple falls in the previous year (26, 27).

The PreFIT exercise intervention was an individually prescribed, progressive, six-month exercise programme based on the Otago Exercise Programme (OEP), which targets lower limb strength, balance retraining and walking (26, 65, 195). The PreFIT MFFP intervention was a one-hour falls risk assessment of seven risk factors with onward referral for treatment as necessary (26, 194).

The primary outcome was fracture rate over 18-months with secondary outcomes including falls, HRQoL, frailty, mortality and health service resource use at 18-months. Trial data were obtained from self-report questionnaires and routine healthcare activity data (26, 27).

LAFTER cohort study methods

Selection criteria

Participants were selected for the nested cohort study from two intervention arms of the PreFIT study: advice only (n=3223) and advice plus exercise (n=3279). Participants from the MFFP arm (n=3301) were also surveyed in the extra wave of data collection, but these data are not used here.

Eligibility

Participants were eligible if they provided signed consent for the extra wave of data collection for this thesis. Prior to extended follow-up questionnaire mail out, vital status (alive or deceased) was requested from NHS Digital and supplemented with up to date checks of GP data. The aim of this check was

to prevent causing distress to relatives in writing to participants who had died by the time the study was done.

Data collection

Each eligible participant was sent an extended follow-up study pack (Appendix 3) between June and December 2017. This pack contained the following:

- Invitation letter: this letter thanked participants for completing questionnaires to date and explained the purpose of the additional extended follow-up study.
- Participant Information Sheet: included a reminder for participants about the aims of the original trial, explained the aims of this extra wave of data collection and described what this entailed.
- Consent form: all willing participants were asked to provide informed signed consent. They consented to complete a further questionnaire and to allow access to their medical records. Patients could decline to participate.
- Extended follow-up questionnaire: the postal questionnaire consisted of components used in earlier approved PreFIT questionnaires. It included questions on falls; balance; mobility; health-related quality of life; frailty; cognition and general health. This version also included additional questions about exercise and physical activity.

Response rates to surveys decline with increasing age (196). Therefore, the following evidence-based strategies were used to encourage response rates and reduce attrition: personalised cover letters; questionnaires printed in a large font; pre-paid envelopes for return of questionnaires; and providing non-respondents with reminder letters and/or telephone calls two weeks after the initial mail out. This process worked successfully in the PreFIT study, where 12-month and 18-month follow up rates were 83% and 76%, respectively (27).

Outcome measures

To capture the long-term effect of falls prevention exercises on health outcomes, measures used to collect data on falls, mobility, health-related

quality of life, frailty, cognition and general health in the main trial were also collected at the extended follow-up time point for comparison.

Primary outcome

Falls (measured at baseline, 18-months (main trial) and extended follow-up (LAFTER study))

A fall was defined using the ProFaNE consensus definition: “an unexpected event in which the participant comes to rest on the ground, floor or other lower level” (6) (p.1619).

At baseline and extended follow-up, participants were asked “Have you had a fall in the past 12 months? And if yes, how many times?” This question has high specificity and acceptable sensitivity for detecting falls in the previous 12-months (197). At 18-months, participants were asked “Have you had a fall in the past 4 months? And if yes, how many times?” The proportion of participants who sustained one or more falls at each time point were analysed.

Reporting and recall bias

There remains a risk of reporting and recall bias in this method of retrospective data collection, particularly with an older population. Therefore, to acquire accurate prospective falls data, using monthly falls diaries or calendars is recommended (6). In this project, willing participants were invited to complete a falls diary to capture falls events over a one-month period (Appendix 4).

Secondary outcomes

Mobility (measured at baseline, 18-months and extended follow-up)

A range of questions about mobility, adapted from population surveys of older adults (198, 199) captured ability to balance on a level surface; ability to walk outside; and average time spent walking per day (hours).

Health-Related Quality of Life (measured at baseline, 18-months and extended follow-up)

The Euroqol-5-Dimensions or EQ-5D™ is a standardised instrument for use as a measure of health outcome and health-related quality of life (200). The EQ-5D-3L was used and comprises the following five dimensions: mobility,

self-care, usual activities, pain/discomfort and anxiety/depression. Each dimension has three levels: no problems, some problems, extreme problems. Participants indicated their health state by ticking the box next to the most appropriate statement in each of the five dimensions. Answers given are used to calculate a 1-digit number representing the level selected for that dimension (200). The numbers for the five dimensions can be combined into a single summary or index score that describes the participant's health. This score is calculated by applying a formula which attaches values (weights) to each level in each dimension. The index score is determined by deducting the appropriate values from one, the value for full health i.e. 11111 (200).

Frailty (measured at baseline, 18-months and extended follow-up)

Frailty is a physical and/or psychological clinical condition in which an individual has an increased vulnerability for developing adverse health outcomes and/or dying when exposed to a stressor (201, 202). Frailty was measured using the Strawbridge 16-item questionnaire (203) which assesses frailty using the following four domains of functioning:

- physical - sudden loss of balance; weakness in arms; weakness in legs; and getting dizzy or fainting when standing up quickly;
- nutritive – loss of appetite; and unexplained weight loss;
- cognitive – difficulty paying attention; trouble finding the right word; difficulty remembering things; and forgetting where you have put something;
- sensory – difficulty reading a newspaper; difficulty recognising a friend across the street; difficulty reading signs at night; difficulty hearing over the phone; difficulty hearing a normal conversation; and difficulty hearing a conversation in a noisy room (203).

Each item in the first three domains is scored using a 4-point ordinal scale (1 = rarely or never, 2 = sometimes, 3 = often and 4 = very often). The items in the sensory domain were scored as follows: 1 = have no difficulty, 2 = have a little difficulty, 3 = have some difficulty and 4 = have a great deal of difficulty. Participants scoring three or more on at least one item in any domain were considered to have difficulty with that particular domain.

Participants were classified as frail if they reported difficulties in two or more domains (203).

Cognition (measured at baseline and extended follow-up)

Although it was originally used to assess visuo-constructive abilities, it is recognised that abnormal clock drawing occurs in other cognitive impairments (204). Therefore, the Clock Drawing Test is used in screening for cognitive impairment and dementia and as a measure of spatial dysfunction and neglect (204). This test is scored using a simple 6-point scale scoring system according to visuo-spatial aspects and the correct denotation of time: normal cognition (score 6); minor visuospatial errors (score 5); mild (score 4), moderate (score 3) or severe (score 2) visuospatial disorganisation of time, or no reasonable representation of a clock (score 1) (205).

Measured at baseline in the main trial, this test was repeated as a long-term measure to analyse any cognitive changes in this cohort. Participants with cognitive impairment from PreFIT were also eligible for invitation to the follow-up study.

General health (measured at baseline, 18-months and extended follow-up)

All participants were asked to describe their general health using the following options: excellent, very good, good, fair or poor across all time-points in the main trial. At 18-months, participants were also asked to rate how their general health now compared to four-months ago with options of much better now, somewhat better now, about the same, somewhat worse now or much worse now. This question was repeated at extended follow-up with participants being asked to rate their general health compared to 12-months ago.

Exercise/Physical Activity (measured at extended follow-up only)

Following a review of the literature to short list appropriate exercise/physical activity measures for inclusion, the Physical Activity Scale for the Elderly (PASE) (198) and Community Health Activities Model Program for Seniors (CHAMPS) (206) were presented to my lay advisory group for their opinion

as to which measure to use. They described both measures as being too long and burdensome. Therefore, after further consultation with my supervisors and other experts, and using the then current physical activity guidelines for older adults (52), four multiple choice questions were designed to capture data on strength and balance exercises as well as other exercise and physical activity e.g. Q. Over the past week, how often did you do any exercises for muscle strength? A. Never; 1-2 days; 3 or more days.

This measure was not used at baseline or 18-months but was added for long-term follow-up. It was considered important as the amount of exercise/physical activity currently being undertaken is important to answer the research question about the long-term effect of exercise.

Data Management

As per the original trial, the extended follow-up questionnaires were scanned using FORMIC FUSION™ software, which includes internal validation checks, onto a bespoke database designed for the PreFIT study. Consistent with the PreFIT study, all extended follow-up questionnaires were manually checked by a member of the PreFIT study team and all data were validated using date discrepancies, missing data, range checks and outliers. All discrepancies were checked and rectified against returned questionnaires (27).

Data Analyses

Recruitment and participant flow through the original PreFIT study and LAFTER follow-up study are reported using a Consolidated Standards of Reporting Clinical Trials (CONSORT) flow diagram in the results chapter (Figure 11).

Participant data from baseline to extended follow-up were analysed by intervention arm and by adherence to exercise for those in the exercise arm. As the extra extended follow-up data was compared with PreFIT baseline and 18-month follow up data, only those participants who completed questionnaires at all three time points (baseline, 18-months and extended follow-up) were eligible for the analysis.

Sociodemographic variables were summarised by treatment arm with mean and standard deviation (SD), median (range) and missingness reported for continuous variables and number (%) for categorical variables. Unadjusted and adjusted estimates were obtained for all statistical regression models. Adjustment was made for the corresponding baseline variables: participant falls risk, age, sex, and GP deprivation score.

Falls analyses

Falls data were summarised and analysed as proportion (number) of people reporting a fall or more than one fall in the previous time period (either four or 12 months). Univariate and multivariate logistic regression analyses were conducted to identify potential risk factors for falling (yes/no) in the previous 12-months at extended follow-up. Logistic regression is appropriate for binary outcome variables and is especially useful when it is necessary to adjust odds ratios and other statistics for possible confounding factors (207). Given that these risk factors may change in the presence of others, a stepwise modelling approach was implemented, using all of the variables of interest i.e. those with p value ≤ 0.2 in the univariate analysis. The multivariate model accounted for baseline risk of falling, sex, age and GP deprivation score using the same statistical analysis plan as the PreFIT trial. Rate of falls was also calculated at two different time intervals; between baseline and 18-months; and from baseline to extended follow-up. Falls rate was expressed as falls per person 1000 months. This approach to analysing events-per-person-years is estimated by dividing the total number of events across all participants by total duration of participant follow-up. This method, however, has been found to substantially underestimate variation in the data, therefore, using the same statistical analysis plan as the main PreFIT study, a negative binomial model was used to accommodate the expected variation in the rate between different participants and excess of zeros in the data (208, 209). Unadjusted and adjusted falls rate ratios (RaR; 95% CI) were calculated using all data collected between baseline and 18-months and baseline and extended follow-up. The adjusted model accounted for baseline risk of falls, sex, age and GP deprivation score.

Secondary outcomes

Secondary outcomes (mobility, HRQoL, frailty, cognition and general health) were summarised by treatment arm and adherence to exercise. Continuous data were summarised using mean, standard deviation (SD), median (range) and missingness. Analysis of variance (ANOVA) with repeated measures was used to compare treatment group means over time. Categorical data were summarised as frequencies and proportions (%) and missingness. These data were analysed for association using a chi-square Test of Independence or Fisher's Exact Test to determine whether variables were independent or related. Univariate and multivariate logistic regression analyses were conducted to identify potential risk factors for frailty at extended follow-up. These analyses were all carried out using SPSS version 25.

Monitoring and approval

The extended follow-up study amendment, as part of the LAFTER study, was approved by the National Research Ethics Service (REC reference 10/H0401/36) with approval granted by the Derbyshire Research Ethics Committee on 01/03/2017 (Appendix 5).

Summary

In summary, the quantitative element of this mixed methods study is a prospective cohort study nested within an existing RCT. Health outcomes including falls, mobility, HRQoL, frailty, cognition and general health were measured at baseline and 18-months in the main PreFIT RCT and these measures were repeated in a postal questionnaire sent to participants up to six years post randomisation. These questionnaires were sent to a selected cohort of participants from two intervention arms from PreFIT: advice only and advice plus exercise. This longitudinal follow-up allows for assessment of the effects of the exercise intervention long-term.

To complement this quantitative work, a phenomenological interview study was also undertaken and the methodology and methods for this part of the study are described in the next chapter.

Chapter 5: Qualitative methodology and methods

Introduction

An inductive, naturalistic methodology was chosen for this qualitative interview section of the study. Naturalistic inquiry seeks to explore individuals' experiences within a natural, social context whilst they are engaging in life experiences and is characterised by the central tenets that human existence consists of multiple realities and is socially constructed (210, 211).

The naturalistic paradigm has evolved into subsidiary philosophies from which a number of 'qualitative' or 'naturalistic' research approaches such as grounded theory, discourse analysis and phenomenology have evolved. Although these approaches are the products of different intellectual traditions, their co-development means that they share some similarities as well as differences (212, 213).

Residing within the naturalistic paradigm, phenomenology was identified as the most appropriate methodology for this research as it closely examines individuals lived experiences, studying the way in which things present themselves in order to gain a deeper understanding of everyday experiences (212, 214).

Methodology

Phenomenology

Phenomenology is the study of lived experience from the viewpoint of the individual experiencing the phenomenon (139, 215, 216). However, phenomenology does not seek to only describe things which are already self-evident. It also illuminates that which is hidden or concealed and typically taken for granted or not ordinarily questioned (217, 218).

Although frequently described and used as a qualitative research method, phenomenology is actually rooted in philosophy (140, 215). None of the philosophers developed research methods but their work is often used as a framework to augment and underpin contemporary qualitative research (139, 219).

Phenomenology emerged in early 18th century philosophy but is considered as being founded by the German philosopher and mathematician Edmund Husserl (1859-1939) before World War 1 (215, 220). His one-time student, Martin Heidegger (interpretivist) and other philosophers including Maurice Merleau-Ponty (post-positivist), Hans-Georg Gadamer (constructivist) and more recently, Max van Manen, subsequently expounded Husserl's phenomenology (215, 220).

Husserl developed the philosophical tradition of phenomenology as an alternative to the empirically based positivist paradigm when he became disillusioned with the objectivity of the natural sciences as a means of understanding human experience (139, 220). The principles of positivism postulate that researchers can study reality; a reality that is ordered, rational, logical, and therefore objectively measurable (221). In contrast, the naturalistic paradigm, where phenomenology sits, presumes that reality is not so rigid but is based on individual and subjective realities which are not reduced to numbers (148, 221).

Husserlian Phenomenology

Husserl defined phenomenology as the science of consciousness and its structures or essences (139, 220). He sought to describe the manner in which the world is constituted and experienced through conscious awareness or the internal experience of being conscious of a phenomenon and, therefore, his philosophy is often described as epistemological or transcendental (139, 220, 222, 223).

The key concepts of his transcendental phenomenology include intentionality; life-world; essences; and phenomenological or eidetic reduction. These ideas will be discussed as many of the later philosophers drew their ideas from Husserl.

Intentionality

Husserl espoused Brentano's (1838-1917) account of intentionality as the essential element of understanding and organising conscious acts and, thus, understanding of human experience (215, 220). The term intentionality refers to the process by which humans direct their mind towards objects, being

aware of objects, allowing them to reason about and give meaning to objects in the world (139, 224). Objects has been defined as a generic term and can refer to anything i.e. things in the external world, facts, data, concepts, pains, or dreams (225).

Life-world

Husserl's *lebenswelt* (life-world) (224) is the world approached in a pre-reflective way or 'as-lived' without resorting to analysis or interpretation (139, 215).

Phenomenological (eidetic) reduction

Husserl's phenomenology was aimed at the rigorous study of the essence of things as they appear in the life-world, to facilitate the understanding of human consciousness and experience (214, 215). Thus, to truly allow the essence of the phenomena to emerge and be described without prejudice, he proposed phenomenological reduction or *epoché* as a means of bracketing or putting aside natural attitudes, preconceptions and preconceived ideas towards objects or phenomenon (139, 215).

The Greek word *Epoché* means to refrain from judgement or stay away from the conventional way of comprehending things (215). This is key to Husserl's phenomenology where his focus is on the description of the phenomenon, that which is immediate to human consciousness before interpretation or explanation (215, 226).

Implications for research

Husserlian phenomenology has several implications for research. Husserl aimed to describe the internal experience of being conscious of a phenomena (intentionality) (223) and, therefore, puts the person and their experiences at the centre of all inquiry (220). Since the individual and the experience are inextricably linked in the life-world, the phenomenon of interest must be accessed via the participants' life-world (227) and, therefore, data collection is typically by interview rather than observation or measurement (228).

Husserl developed phenomenological reduction or bracketing to suspend beliefs or natural attitudes and facilitate the essence of the phenomena to

emerge (215, 222). Bracketing is subject to much debate in the health research community, as to truly undertake Husserlian research, the researcher must consider their biases and preconceptions and then suspend them, setting them aside in order to clearly understand the participant's experiences (215, 220, 228). But is this even possible? Paley suggests not; as to do so would involve the researcher removing themselves from the social world and consequently the life-world would then become inaccessible to them (225). Instead it has been suggested that what actually happens is rather than bracketing the natural attitude, researchers typically bracket *in* the natural attitude, thereby, remaining true to the participant's experiences but not to the phenomenon itself (229, 230).

Primarily due to the issues around bracketing, I do not feel that Husserlian phenomenology is appropriate for this research. Although a Husserlian approach would put the participants and their experiences at the centre of the study, as a physiotherapist and researcher interested in the care of older people and falls prevention, I feel it would be impossible to truly suspend my natural attitude and preconceptions associated with an older person's experience of participating in a falls prevention clinical trial involving exercise. Therefore, a Heideggerian approach will now be considered.

Heideggerian Phenomenology

Heidegger (1889-1976) shared Husserl's view that phenomenology is concerned with human experience as it is lived (215). Regardless of the approach taken, the common element of phenomenology is "to the thing themselves" whereby the 'thing' is the lived experience; allowing the things to speak for themselves whilst simultaneously contextualising them provides greater meaning of the phenomenon under review (139, 231). However, in contrast to Husserl's descriptive perspective, and in his 1927 publication, *Being and Time*, Heidegger expounded the importance of ontology (the nature of Being) (217); existentialism (a philosophical theory which emphasises the existence of the individual person who determines their own development and gives meaning to life through acts of free will) (232); and the interpretation of lived experience (a representation and understanding of human experiences and choices and the knowledge gained from these

experiences and choices) (173). In this way, Heidegger thereby advocated the use of hermeneutics (140, 142, 215).

Originally, hermeneutics was a means of studying theological scripture, but Heidegger redefined it as a method to study lived experience (139, 233). The basis of hermeneutics is interpretation, allowing the text to speak for itself in order to analyse, explain and describe lived experiences (139, 214, 233).

This is not merely relating to factual or descriptive characteristics of an entity, but rather with an ontological understanding i.e. taking into consideration the nature of being (234). More broadly, ontology is the study of the characteristics or concepts that directly relate to being, such as becoming, existence and reality. As a branch of metaphysics, ontology examines what entities exist, the very nature and structure of reality and of entities i.e. their being, cause or identity and how such entities may be categorised (235).

From his ontological standpoint, Heidegger's primary focus was that phenomenology should uncover the meaning of Being (218, 236).

Interpretation discloses what is 'already there' and a phenomenon is revealed when entities in the world have been understood and are given meaning via interpretation to understand the totality of a lived experience (140, 237). Some of the key concepts of Heidegger's hermeneutic phenomenology include Being-in-the-world, fore-structures, useful things (equipment), the care structure and time and temporality. These will be discussed in the following sections.

Being-in-the-world

Heidegger's concept of Being-in-the-world maintains that a person and the world are inseparable and the two are co-constructed (222, 238, 239). The concept of Being-in-the-world is an a priori state (218). This suggests that this state existed before we came to think about it, but we are always already there (142, 240). Heidegger considered the world to be a totality of entities and, therefore, Being-in-the-world describes the co-constitution between humans and these entities that they encounter (218, 222). This suggests that individuals have a practical engagement and involvement with their surrounding world (223, 241). Thus, humans are shaped by the world they

inhabit and simultaneously construct their world and existence from their own experiences and background (222).

Heidegger termed this ontological focus on the nature of human existence and capability to inquire into one's own Being as 'Dasein' (140, 234, 239). The term is often left untranslated but literally means 'being-there' from *da* (there) and *sein* (being) (142) and refers to the human qualities or entities that allow us, as Dasein, to wonder about and question our own existence (139, 214, 218). Stumpf (242) describes Dasein as an inherent thing i.e. a person is always within their world. McConnell-Henry et al (139) give an example of Dasein as a nurse leaving a hospital; regardless of the fact that they are no longer in the hospital, they will still be within the world of nursing and able to understand, or give meaning to Being-in-the-world of nursing.

Heidegger's phenomenology starts with Dasein's understanding of Being. His goal for phenomenology was to discover what is fundamental to the understanding of Being by focusing on Dasein's encounters with entities i.e. making explicit the structure of understanding involved in those encounters. Because Dasein's understanding of Being is so pervasive, each and every encounter with an entity is potentially illuminating. Thus, Heidegger's phenomenology is an exploration of everydayness (234, 239). He believed that the meanings of these interactions with entities are interpreted in relation to the practical engagement that individuals have with their surrounding world (218). It points to Dasein being permanently immersed in the world, not in the physical sense but in a metaphysical way, meaning we are inseparable from the connections between ourselves and the world around us and this is the pre-condition for moving towards our possible modes of Being in our every day (142, 243).

Heidegger also wanted to reveal the 'who' of Being-in-the-world i.e. Dasein's encounters with 'others' (other Dasein) (239). Within its everydayness Dasein's existence is not one of "Being alone" but of "with world," or "Being with" others (218) (p.155). This existence is, however, influenced by 'the they' (das Man) (218). He depicts 'the they' as an impersonal or anonymous normative entity reflecting what Dasein views as its social reality, including encounters with equipment and other Dasein (234, 239, 244). By others,

Heidegger does not mean every other human but those with similar characteristics and beliefs. In being with these others, Dasein assumes an *'inauthentic'* existence whereby it is conformist or passive, defining oneself and one's possibilities as everyone else might and unquestioningly accepting the shared norms and value of 'the they' (239, 241, 244). This is opposed to an *'authentic'* existence in which Dasein chooses to live life with explicit awareness, allowing Dasein to be aware of its own Being and take hold of its own possibilities (218, 239, 241).

'Being-with' is a critical structure of Dasein's Being-in-the-world and is what Heidegger refers to as solicitude (245). He describes different modes of solicitude which fall into two categories: the 'indifferent' i.e. passing one another by or not mattering to one another and the 'positive' i.e. leaping in or leaping ahead (218). Heidegger suggests that for the most part, we are in the indifferent mode towards others as we go about the business of our daily lives. However, positive solicitude (although not better than indifferent solicitude as the name might suggest) denotes ways Dasein actively behaves toward other Dasein (245).

When Dasein 'leaps-in' for another, Dasein "takes over for the Other that which with (the other) is to concern himself" (218) (p.158). It is a manner of Being-with, whereby, one Dasein might dominate the other and can lead to the latter's dependency on the former (245). In 'leaping-ahead', however, one Dasein's solicitude does not take away the 'care' or existence of another Dasein but gives it back to him or her authentically "and helps the other become transparent to himself in his care and become free for it" (218) (p.158-159). Heidegger concludes that 'Being-with-one-another' in everydayness involves a mixture of the two extremes of positive solicitude – that which leaps in and dominates and that which leaps ahead and liberates (218).

Using Heideggerian phenomenology in research involves working to uncover what Being-in-the-world means by interpreting entities and events involving everyday experiences (142, 217). Both the researcher's and the research participant's Being-in-the-world are equally relevant in this situation and need to be taken into consideration since the participant's experience of Being-in-

the-world can only be interpreted by another Being-in-the-world (139, 246). Therefore, Heideggerian phenomenology is significantly different to that of Husserl, as Heidegger dismissed intentionality for Dasein and strongly disagreed with the notion of phenomenological reduction as he advocated that interpretation and understanding are never without presuppositions and preconceptions or fore-structures (139, 142, 220, 233).

Fore-structures

Heidegger rejected Husserl's notion of phenomenological reduction or bracketing because he postulated that since we are all human and perceive things in our context of Being-in-the-world, any interpretations of lived experience must be reliant on previous knowledge and understanding (140, 241). These prior understandings, based on the social, cultural and historical contexts of a person's Being-in-the-world, are what he called fore-structures and are always present or known in advance of interpretation (140, 220, 233, 241).

Since human beings always approach a situation with their own preunderstandings, Heidegger argued that to conduct research based on hermeneutic phenomenology, the researcher must use these fore-structures to ensure that questions posed to participants be pertinent (139, 222). Additionally, in order to interpret text about the phenomenon of interest these fore-structures have to be openly acknowledged. An attempt at bracketing these prior understandings would mean the researcher would be ignoring their own Being-in-the-world and understanding of human existence (241). For these reasons, as the basis for a research project, Heideggerian phenomenology has been called into question as it has been suggested that the researcher's own Being-in-the-world and fore-structures can affect the findings. Therefore, it is crucial that researchers using this method be open and candid about their philosophical standpoint and pre-understandings before and during the process (139, 222)

Heidegger's concept of the hermeneutic circle which allows for reciprocal activity between pre-understanding and understanding is a means of addressing these issues (215, 222). In the hermeneutic circle, the researcher looks to understand the participant's lived experience by first examining their

own fore structures of the phenomenon of interest (220). Subsequently, as Inwood (217) explains, they move reciprocally between the whole and the parts in this circular relationship which allows for greater understanding of parts of the text which consequently provides a fuller understanding of the whole of it. This deeper understanding of the whole text, in return allows for a focused understanding of its parts. The participant offers their story and rather than simply reconstructing the text, the researcher must interpret the meaning behind the words by utilising the hermeneutic circle to illuminate a new horizon of understanding and uncover the ontological essence about the experience and phenomenon of interest (139, 142, 222).

Useful things (equipment)

The way that Dasein understands things and *how* they are understood are influenced by the way that Dasein's own Being is an issue for it (234). In its everyday activities Dasein is always 'taking a stand' on the type of Being it is, not by actively declaring itself to be one thing or another but through engagement in specific activities, tasks or roles (234). Therefore, how things manifest themselves to Dasein will be determined by Dasein's opinions and ideas about its own existence and will show themselves in ways that are relevant and appropriate to those activities, tasks and goals (234).

The entities that manifest in our everyday activities are what Heidegger called *zeug* (useful things) (218) or equipment (247). These useful things are considered to be 'ready-to-hand' and characteristically manifest themselves as having a role in a particular task e.g. a hammer is for hammering. When used skilfully, familiar useful things almost withdraw from the activity as it runs smoothly i.e. a person who is engaged in a task does not actively think about the things they are using or even what they are doing, and the piece of equipment might be considered as an extension of the body and, therefore, remains unnoticed (234, 241, 248).

This concept of readiness-to-hand was used by Heidegger to distinguish entities from 'mere things' (239). He did acknowledge that entities can manifest themselves objectively or as material things (present-at-hand) and can be described in terms of their objective properties i.e. a table is wooden,

brown, and heavy, but this detached way of understanding an entity does not capture what entities really are (234, 241, 248).

Instead, he argued that useful things must be understood in terms of the activities they are involved in i.e. a hammer is only a hammer in so far as it belongs to a totality that includes nails and wood and other tools, 'in-order-to' build or repair something (247). Furthermore, this 'in-order-to' highlights the relational way of Being of useful things (234). A useful thing is only that because of its relations to other useful things, the activities they are involved in and the self-understanding of Dasein in engaging in those activities. Heidegger defines this as 'referential totality' e.g. "a hammer is something *with-which* to hammer in nails *in-order-to* hold pieces of wood together *towards* the building of something *for-the-sake-of* Dasein's self-understanding as a carpenter" (234) (page 40).

This referential totality is what Heidegger means by 'world' and highlights the co-constitution of Dasein with it (234). Belonging to a world is fundamentally a matter of what Heidegger called 'familiarity' (218) or a sense of feeling at home in our everyday lives. Similar to the withdrawal of useful things which are ready-to-hand, our familiarity with our world can be taken for granted or scarcely noticed (234). However, there are occasions when disruptions or breakdowns in the referential totality means that the world does announce itself. These breakdowns result in the withdrawal of useful things or activities being reversed i.e. equipment goes missing, is broken or becomes an obstacle and that useful thing then becomes conspicuous or unready-to-hand (234, 247, 249).

Although Heidegger rarely mentions the human body in Being and Time (250), Benner has gone on to extrapolate Heidegger's notion of readiness-to-hand to also include the body. Therefore, like any other useful thing, when the body is working efficiently, it performs whilst going unnoticed and is, therefore, taken for granted. It is only during times of breakdown i.e. illness or injury that the body becomes conspicuous or unready-to-hand and its functionality is no longer taken for granted (248).

Heidegger later gave an account of bodily being in his lectures, *Zollikoner Seminare*, which were a series of philosophical lectures (1959 – 1969) on his ontology and phenomenology in relation to medicine, psychology, psychiatry and psychotherapy (251, 252). He claimed that the human body or bodily being co-determines Dasein's existence as Being-in-the-world and that bodily nature is necessary to be able to apprehend that which is encountered (251). Askay has tried to illuminate this idea with the following example: in reading this text you must have a body to be able to read and distinguish between the front, back, top and bottom of the page etc. However, your body does not entirely encompass your Being-in-the-world as you read, as it is done against an assortment of backgrounds including your familiarity with Heidegger's work, how much it interests you, and how things are generally going in your life etc. Therefore, reading this text is not reducible to just the body (252). Heidegger went on to suggest that the human body may be a worthwhile focus of investigation; but he did not wish to focus on just one aspect of Being as this would reduce his work to philosophical anthropology which is the opposite of what he wished to achieve (252).

The care structure

Heidegger described the fundamental structure of Being-in-the-world as 'care' (239) and he offers this formulation to define the care structure; an umbrella term for the structural whole of Dasein's existence:

“The being of Dasein means being ahead-of-oneself-already-in (the world) as being-together-with (inner worldly beings encountered)”
(218) (p.236)

This definition purports that Dasein's Being is an *issue* for it; it is a being for whom things *matter*, that the everyday tasks it undertakes and others it engages with are marked by various modes of *concern* and *solicitude* (234, 244). Simply, the care structure exposes what matters most to us or what we care about as human beings (239) and as things matter to us they can have meaning and, therefore, be intelligible (244).

The formulation of the care structure is divisible into three constitutive aspects: ahead-of-itself, being-already-in and being-alongside or together-with. Each of these will be discussed in turn.

Ahead-of-itself (understanding)

Since Heidegger purports that Dasein is a Being whose Being is an issue for it, its way of Being is always an on-going concern i.e. ahead-of-itself, and is something that it is constantly taking a stand on and deciding (234, 244).

Therefore, Heidegger claims that Dasein should be understood in terms of *possibility*. However, this possibility does not refer to some future event or actuality but rather that Dasein *is* its possibilities and engages in its current activities 'for-the-sake-of' one or several on-going ways to be (234).

Heidegger also called this being-ahead-of-itself, *understanding*, which in turn he explains in terms of *projection* (253). Dasein is always projecting itself into possibilities, again, demonstrating that Dasein's on-going activity has a future dimension that cannot be ignored. The 'for-the-sake-of' always points beyond what is currently actual, and considered in reference to the possibilities Dasein is projecting (234).

Being-already-in

This second section of the formula, 'being-already-in', suggests that Dasein is already situated in some type of on-going activity and projecting on the basis of some already-given orientation. Heidegger calls this way of Dasein's Being, '*Befindlichkeit*', (139) which although not readily translatable, has been dubbed as 'attunement', 'state of mind', 'predisposedness' or 'situatedness', of which, none is considered ideal (234). However, the term '*finding*' has been considered more useful and suggests that Dasein finds itself in a world that it did not choose for itself.

Similarly, Heidegger relates *Befindlichkeit* to mood. Dasein finds itself in moods which are not something it necessarily chooses but ultimately can affect how things show up, how activities are undertaken and what that activity might actually be i.e. how an experience is lived (139, 234). These ideas reveal what Heidegger calls "*thrownness*", that is the ways in which Dasein finds itself already engaged in an existence it was born into, with

already existing norms and values, over which it had no say (239). However, what Dasein chooses to make of or do with this existence in the future will always be determined by this thrownness (139, 234). Cerbone (234) summarises these first two aspects of the care structure as “Dasein is ‘thrown possibility’” (p.61).

Being-together-with

Heidegger refers to being-together-with (already Being-in-the-world and being with other Dasein) as falling (239). Falling represents the current involvement Dasein has with the world and Heidegger emphasises that falling is connected to Dasein’s inauthenticity i.e. Dasein’s failing to be anything other than ‘das man’ or ‘the they’ (234, 239).

Falling means closing off or covering up a real understanding of the world and manifests instead in *idle talk* (conversing in a non-committal, irrelevant, critically unexamined way about facts and information), *curiosity* (a disengaged search for novelty in the world rather than with any contemplative thought), and *ambiguity* (a lack of distinction between true understanding and superficial chatter) (218, 253, 254).

Heidegger’s care structure demonstrates factual existence, meaning that Dasein understands and interprets its encounters with entities with concern and solicitude and, therefore, with purpose, ultimately revealing the human being’s purpose, that is “for the sake of which” and “in order to” with regard to their future possibility (239).

Time and temporality

Heidegger’s philosophy dictates that understanding through interpretation is only possible if that interpretation is considered in relation to time (140). This reliance on temporal notions is illustrated in the concept of everydayness which already suggests that understanding Dasein occurs in relation to its time (234).

Heidegger considered time to be “the horizon for all understanding of Being and for any way of interpreting it” (218) (p.39). Therefore, Dasein must be temporally situated in-the-world, with temporality referring to the awareness of time and our own existence through the experience of being in time (218).

It is clear that the three parts of Heidegger's care structure (ahead-of-itself, being-already-in and being-together-with) invoke temporal notions i.e. understanding relates to the future, thrownness to the past and falling to the present, but all three are always active in Dasein's everyday existence (140, 234, 239, 244). Heidegger believed temporality to include the horizon of all possibilities of Being or existence, so that experiencing past, present and future together allows for present experiences to be consistent with past expectations and what is expected to be experienced in the future (140, 220, 241).

This philosophical conceptualisation of time as temporal must be reflected during the process of interpretive phenomenological research (140). The researcher must situate themselves, the participants and their experiences in time and, thus, in-the-world. To be situated like this is to recognise the significance of their involvement in-the-world and reveal their experience of time, in the search for ontological understanding (218).

Implications for research

Heideggerian research aims to understand the meaning of Being through interpretation. To investigate the experiences of older people who have participated in a fall prevention clinical trial involving exercise, using a Heideggerian approach is appropriate as it will provide an in-depth understanding of this phenomenon as experienced by the participants themselves.

This methodology allows for exploration of the individual nature of Being-in-the-world and how the participants construct their world and existence from their own experiences, entities (useful things) and background (222). Additionally, in contrast to Husserl's phenomenological reduction or bracketing, Heidegger advocated the inclusion of prior understandings or fore-structures in his phenomenology (241). Thus, I will openly acknowledge my fore-structures (Chapter 6, section 2 and Appendix 8) in the co-construction of understanding and interpretation of the phenomenon of interest, to provide a rich and authentic account of the experiences of the older people involved in this study.

There is one further issue that needs to be addressed in my decision to use Heideggerian phenomenology to underpin the qualitative part of this study; that is the question of his association with Nazism. In 1933, a few months after it had come to power in Germany, Heidegger joined the Nazi party giving his support as Rector of Freiburg University. The extent of his involvement is contentious but for many, the main controversy is his lack of acknowledgment or apology after the war (255, 256). Therefore, the critique appears to lie with his behaviour and not with any fascist qualities in his writing (256-258). I am, therefore, extremely mindful of this, but as a researcher and a physiotherapist seeking to reveal the lived experiences of the older people in my study, what I have read and understand of Heideggerian philosophy provides me with the appropriate methodological underpinning to do this and I am open to reading and re-reading Heidegger's texts.

The next section of this chapter describes the methods employed in the interview study and explores how Heideggerian phenomenology might be reconciled as a research method.

Methods

Phenomenological Interview Study

Introduction

Phenomenological philosophies are commonly used to underpin contemporary qualitative research, although none of the phenomenological philosophers set out to develop research methods (215).

Van Manen (214) proposes that phenomenology aims to discourage predetermined or fixed procedures and techniques to undertake a research project whilst also suggesting that phenomenology has a certain 'way'; one that reflects Heidegger's description of phenomenological investigation as following a path, albeit without any fixed signposts, towards a clearing where something might be revealed or clarified in its essential nature (218).

In the pragmatic world of research, providing a clear description of and rationale for methods used is a necessary, but often challenging part of the research process (211). This is particularly true of phenomenological

research due to the lack of clear guidelines and literature on how to address the practical aspects of conducting such a study (259, 260). Walters (261) suggests that research based on Heideggerian traditions seeks to uncover what it means to be a person in the world, which involves the researcher as an active participant in the interpretive process. This 'co-constitution of data' is what Koch (262) described as a combination of information provided by the participant and the researcher's own experiences all placed in context.

In the next section of this chapter I will describe the methods used in this research project, beginning with an overview of the critique of Heideggerian phenomenology as a health research method.

Heideggerian phenomenology as a research method?

The critique and debate regarding phenomenology as a research method is often directed at nursing research where it is commonly used. Michael Crotty, controversially, first criticised nurse researchers for misinterpreting and misusing phenomenology in his 1996 book, *Phenomenology and Nursing Research* (263). He especially criticised North American nurses, suggesting that, without knowing the difference, they were undertaking what he called a 'new' phenomenology and it was not based on 'pure' European phenomenological philosophies. Instead he asserted that it consisted of little more than symbolic interactionism and humanistic psychology incorporating a third-person subjective description of a phenomenon rather than a critical examination of the phenomenon itself (264).

John Paley (265) also criticised nurse researchers for misinterpreting Heidegger's phenomenology to create a type of 'lived experience research' (LER); the concern of which is to examine individuals subjective accounts of their experiences or interpretations of the circumstances in which they find themselves. He believes that nurses undertaking LER are right in thinking that Heidegger's position is incompatible with positivism, but wrong in assuming that positivism and science are the same thing. In doing so, they fail to appreciate that Heidegger's work infers scientific realism – a very different concept to positivism in an approach to social enquiry (265).

Therefore, this LER method is not derived from Heidegger's *Being and Time* but in actual fact is a Cartesian approach entrenched in the subject-object

dualism that Heidegger's philosophy is attempting to undo and therefore, not true to Heideggerian ontology (265-267).

Furthermore, Paley goes on to criticise nurse researchers' acceptance of participants' stories in this lived experience research under the principle of incorrigibility, which Heidegger rejected and again reintroduces Cartesianism by splitting reality from experience (265). This principle assumes that each participant's experience cannot be disputed, is invariably true and, therefore, is exempt from criticism (265). He claims that 'lived experience' interviews should be avoided by Heideggerian researchers so as to remove this subjectivity. Instead he promotes methods such as observation, naturalistic experiments or discourse analysis which allow for objectivity (266). Similarly, Crotty also argued that an uncritical acceptance of participants experiences would not enlighten the phenomenon of interest but actually undermine the research (263).

The responses to Crotty's critique are divided (264). Benner, who introduced phenomenology into nursing research with her work on expertise in nursing (223), described Crotty's book as 'uncritical and unobjective' as he uses a disparaging tone to describe phenomenological nursing research only in terms of what it is not, not what it is (268). Darbyshire et al (269) used direct quotations from *Being and Time* to illustrate their point that Crotty takes a "narrow, existentialist view of Heidegger's work" (p.17), offering little or no textual evidence for the basis of his arguments. Conversely, Barkway (264), although in agreement with some of the criticisms of his book, concluded that Crotty's opinions were a well-argued critique of nursing phenomenological research that should not be ignored, calling for engagement with the on-going debate.

Crotty and Paley's critiques of nursing research demand improved rigour in the interpretation of the methodology and selection of research methods (260). This is appropriate for any discipline carrying out phenomenological research, not just nursing. However, it is also noted that there is a lack of guidance or description of the methods involved in phenomenological research. Researchers regularly undertaking Heideggerian research report a gap between how their methods are reported in a few paragraphs in a

research paper and the experience of actually undertaking the research (260, 270).

Therefore, to describe the methods used in this part of the research study, I have continually referred back to Heidegger's philosophy to ensure accurate interpretation; I have read numerous Heideggerian hermeneutical research papers looking for guidance as to methods used, taking into consideration Crotty and Paley's criticisms; and I have reflected upon and considered my own presuppositions and fore-structures before returning to the research question: "What are the experiences of older people participating in a fall prevention clinical trial involving exercise?" to guide the methods that I have used to answer this question.

Participants

Sampling

The aim of this phenomenological study was to understand the experiences of older people participating in a falls prevention clinical trial involving exercise, both during and after the intervention period. This would generate in-depth, patient centred narratives or stories of what it means to participate in such a trial, recognising the individual nature of Being-in-the-world and the inseparability of the participants' experiences of falls and falls prevention interventions from the context within which their experiences occur.

Participants were asked to indicate their interest in taking part in the qualitative study at the end of their extended follow-up questionnaire. It was made clear that only a small sample would be needed for this part of the study, thus, not everyone who expressed an interest would be contacted.

Returned questionnaires were used to identify a purposive sample of participants from the exercise arm only. The aim was to recruit up to 30 participants. For phenomenological studies, Creswell (271) recommends a sample size of 5-25. Thirty participants were considered adequate to incorporate a diverse sample from the large number of available participants and, thus, achieve maximum variation to maximise the range of different perspectives. A balanced representation of men and women; young-old (up to 75 years), old (76 – 84 years) and old-old (85 years and over); participants

at low and higher risk of falling; and participants who declined to attend for exercise, withdrew from the exercise programme prior to six-months or completed the six-month intervention, were included.

Eligibility

To participate in the interview study, participants had to meet the following inclusion criteria:

- have provided written consent to participate in the LAFTER cohort study
- randomised to the PreFIT exercise intervention
- completed baseline, 18-month follow-up and extended follow-up PreFIT questionnaires

Participants with severe cognitive impairment were excluded as, due to the time lapse, they may have had difficulty remembering their participation in the study and I did not wish to cause them or their carers any undue distress. Level of cognitive impairment was based on the results of the clock drawing test which they completed in the extended follow-up questionnaire (score 5-6 = no impairment, score 1-4 = mild impairment and score 0 = severe impairment) (205). Therefore, only participants scoring 5-6 were invited to participate in the interview study.

Consent

Upon receipt of the questionnaire, a separate interview study pack containing an invitation letter, participant information sheet and consent form (Appendix 6) was sent to those participants interested in taking part in the interview study. Participants were encouraged to discuss the study with friends or relatives and were free to ask the researcher any questions about the study.

Upon receipt of a signed consent form, I contacted the participant to arrange a mutually agreeable date, time and location for the interview, at which point I went through the consent process again to ensure that the participant was still willing and able to take part.

Data Collection

Phenomenological interviews

Despite Paley's critique (266), interviews are often considered the most appropriate method of data collection in phenomenological research (241, 246) since it is through language that Being-in-the-world is both manifested and understood whilst preserving the historical context of the phenomenon of interest (241, 243, 272).

The characteristics of an interview should be shaped by the methodology underpinning the study (246). Acknowledging the relationship between the philosophy and method distinguishes a phenomenological interview from other forms (273). Phenomenological interviews should align with Heideggerian philosophy whilst aiming to co-construct shared meanings. This is achieved by obtaining a vivid, detailed picture of the lived experience and context that shapes the experience from the participant (274). And, since the participant's Being-in-the-world can only be interpreted by another Being-in-the-world i.e. the researcher, their fore-structures (prior understandings based on social, cultural and historical contexts) must be acknowledged and are imperative in the research process to co-construct the shared meanings of the phenomena of interest (246).

During this dialogue, the researcher interprets the participants' original narrative and effectively assists in the re-telling or co-construction of their story (275). Therefore, participants may recount their experiences to convey a specific perspective with particular meanings and not necessarily a singular truth. This reiterates the aim of a phenomenological interview, that is, to gain insight into the participant's individual experience and not an objective decontextualized truth (276). Thus, phenomenological research uncovers the meanings that people attribute to their experiences of the world, which in the context of healthcare, are vital for the understanding of and provision of care/services.

In a Heideggerian phenomenological interview, the researcher shapes the discussion but is also shaped by the process, acknowledging their own Being-in-the-world (273). Thus, phenomenological interviews are not 'conducted' but rather they are 'participated in' by both parties and are

commonly referred to as 'conversations' rather than interviews (223, 270, 274). Although, Kvigne and colleagues (277) suggest that any qualitative research interview does not allow for the mutual openness of a normal conversation and this difference between an interview and a conversation is characterised by a disparity in power i.e. the researcher has greater power as they decide on the setting and has more control over the situation.

Structure of phenomenological interviews

The careful framing of an opening question for a phenomenological interview is essential for generating data to answer a specific research question (274). Annells (278) proposes that to conform with Heideggerian philosophy, only one question is necessary – 'what is your lived experience of...' based on the premise that the process will generate sufficiently rich data without further direction from the researcher. Sorrell and Redmond (274) suggest that once the researcher has established rapport with the participant, they should be encouraged to describe their unique perspective of an experience, often in the form of a narrative e.g. 'Tell me about a time when...'. However, although philosophically robust, unstructured interviews like this are very difficult to carry out due to issues such as sustaining the interview i.e. participants may only respond for a limited time and without guidance may become concerned about the relevance of their narrative, thus requiring the researcher to intervene anyway (279). This common starting point is also one of Crotty's criticisms. He suggested that it does not fit with traditional phenomenological approaches as the researcher's question leads onto the exploration of the participant's subjective interpretation of the phenomenon rather than a manifestation of the experience (263, 273).

Semi-structured interviews incorporating open questions and probes offer more assurance that the generated data is relevant to the research question (214) whilst providing the participants with some direction, although wording should not be too standardised as the researcher should try to use the participant's own vocabulary (280). It is recommended that questions beginning 'Why?' are less useful than those beginning 'Tell me more about...' or 'What was that like?' since 'why' questions take participants out of their descriptions of their current experiences or feelings and channel

them either into an intellectual or defensive response (281). Additionally, interruptions or comments from the researcher such as 'I totally understand' may constrain the participants' response as it suggests to them that the researcher has heard enough about a certain topic even though they have more to say (281). Instead, probes such as the 'uh-huh' probe (positive encouragement), 'echo probe' (repeating the last point), the 'tell me more probe' and 'silent probe' (282) can enhance a phenomenological interview; augmenting the participant's description of the lived experience and maximising the co-construction of meaning (246).

Due to the size of the original PreFIT study, randomisation occurred at staggered time points (26). Therefore, for those who were willing and eligible, interviews took place between 3-6 years after randomisation. The interviews were semi-structured, using open questions, prompts and probes. This gave the participants the opportunity to talk freely about their experiences of falls, falls prevention interventions, exercise, physical activity, their general health and taking part in the PreFIT study. To minimise some of the potential power difference that Kvigne et al (277) described, participants were offered a choice about how the interview would be conducted i.e. face to face (in their own home or a venue of their choosing) or via telephone and were advised that the interview would last approximately 60 minutes.

With the participants' consent, interviews were audio digitally recorded on an encrypted recorder. This data was transferred to a password protected secure database at Warwick Clinical Trials Unit in line with Good Clinical Practice (GCP) and Data Protection Act (DPA) (1998) legislation. Interviews were anonymised and transcribed verbatim by an appropriately trained transcriber.

Interview schedule

Although phenomenological interviews should not require an interview schedule, to meet the requirements of the ethics committee, an indicative interview schedule was produced enabling the committee to review the types of question that could potentially be asked of the participants and this was used as a prompt as necessary during the interviews, particularly the early ones (Appendix 6).

Additional techniques

Active listening is a key element of the researcher's role in a phenomenological interview. The researcher needs to communicate to the participant that they are involved in the conversation and are giving them their undivided attention, which although challenging and requiring concentration, shapes the researchers interpretation of what is happening during the interview (274, 283).

Use of body language and non-verbal cues (body position, eye contact etc.) are an accepted demonstrable way of letting the participant know that you, as a researcher, are listening and also assist in maintaining the participant's conversational flow (274). Van Manen also advocates the use of silence or simply remaining patient as another means of encouraging the participant to recollect their experiences, giving them time to contemplate what they want to say and proceed with their story (214).

As well as actively listening, during the interview, the researcher must also reflect and interpret the participant's narrative in terms of their own forestructures. This requires a high degree of concentration and, therefore, has implications for the number and duration of interviews. Given this and the potential frailty of some of the older people taking part in this study, the interviews were planned to last approximately 60 minutes and a maximum of two interviews were conducted in one day. Immediately following the interview, so as not to forget, I also wrote field notes and reflections in a diary to capture any important ideas, details or considerations.

Number of interviews

Interpretive phenomenology usually involves repeated observations or interviews (249) in order to build the necessary rapport for the co-construction of more authentic shared meanings (246, 273). It has been suggested that multiple interviews with the same participant allows the researcher to continually elaborate on the participant's life history; expand on or refine specific issues and events that appear important during previous interviews; provide new lines of enquiry for all participants; and obtain the participants thoughts on the researchers interpretations of previous interviews (273, 284).

However, with multiple interviews and even in carrying out successive interviews, there is a risk that the preceding interview will influence the next. Therefore, the process may be directed by emerging theory and is perhaps reflective of a grounded theory approach rather than phenomenology (273). However, as the researcher and their forestructures are an essential part of a phenomenological interview it may be considered of no consequence if those forestructures include what has occurred in previous interviews.

In my reading of Heideggerian based research, many reported studies describe a single interview with participants. Pragmatically, one interview is more realistic for researchers with limited time and resources and ethically, making repeated demands on the time of participants may be questionable. Taking all of this into consideration, plus the geographical distribution of the participants in this study, I undertook one interview with each participant.

Pilot Interviews

Britten (280) recommends that novice researchers use pilot studies to identify how directive they are being, whether they are asking leading questions, whether cues are recognised or missed, and if participants are given sufficient time to answer. This evaluation of the researcher's techniques can be assessed from the initial transcripts and used to guide subsequent interviews (284). Pilot interviews offer the researcher the opportunity to try out a variety of openings and probes before undertaking actual interviews and help avoid situations where participants respond with long silences, confusion or irrelevant chatter (274).

Therefore, as a novice at interviewing participants, I undertook three pilot interviews. The results of which were reflected upon and discussed with my supervisors. My interview technique was refined, focussing particularly on the opening question, the use of silence and my timing. These interviews were included in the main analysis as changes made were minimal.

Data Analysis

The process of conducting interpretive phenomenology, including analysis and interpretation of the participants narratives, is not linear (284); nor is it easy to find guidance on how to carry out such a study (285). However, Max

van Manen has produced a tried and tested iterative and inductive hermeneutic-phenomenological method for data analysis which has been described as solid and rigorous (243, 286). I have used this framework in the analysis of my participant stories.

Van Manen's framework (214) involves several steps:

- Reading and re-reading the interview transcripts;
- Adding preliminary comments including summaries, associations or interpretations to the transcripts;
- Highlighting noteworthy comments or phrases that are particularly relevant to the participants' experiences;
- Identifying important themes and reports both common and divergent to all the participant's interview transcripts;
- Organising the themes across the narratives for patterns and relationships;
- Exemplifying the themes using participant quotations.

These steps overlapped and were non-linear. As narratives were being examined and interpreted, I was continuing to interview participants, identifying new themes and returning to all the narratives to look for patterns and differences, thus complementing the 'uncovering' that Heideggerian phenomenology aims to demonstrate.

Thematic analysis, like that described in van Manen's framework, is often considered to be a perfunctory application of some frequency count or coding of selected terms in transcripts or texts (214). However, in terms of phenomenological research, creating a thematic understanding of a text is not a rule-bound process but an uninhibited act of "seeing" meaning (214) (p.79). Therefore, phenomenological themes can be thought of as the structures of the experience (214), but whilst ensuring the analysis moves beyond description, interpretation should not move beyond the data or out of the hermeneutic circle (287).

The themes emerging from the text may be interpreted differently by each reader but, critically, although readers may not completely agree with the researcher's interpretation, they should be able to understand the process

that led to the interpretation given (249). Therefore, as described previously, Heideggerian phenomenology recognises the possible influence of researcher's forestructures on data analysis, and these forestructures must be disclosed or revealed (287). However, there is some debate and lack of guidance as to when to reveal and how explicit the researcher has to be in this revealing i.e. is it enough to disclose that they have recognised that their presuppositions have influenced their interpretation without knowing what those forestructures actually are?

I will describe my forestructures and how they may have influenced the interpretation of my findings in the next chapter.

Monitoring and approval

Ethical approval for this qualitative work was sought as a substantial amendment to the original PreFIT study (REC reference: 10/H0401/36) and approved by Derby Research Ethics Committee in August 2017 (Appendix 7)

Potential risk to the participants was considered to be small. There is no evidence to suggest that any of the methods used are harmful. Although it was not planned to ask any sensitive questions, conducting interviews can sometimes result in people recounting experiences that may be distressing. In this instance, participants were given the option to stop the interview if necessary. The interview schedule was devised with guidance from experienced qualitative researchers and input from my lay advisory group, ensuring the indicative questions were appropriate and acceptable to older people. I also referred to the Code of Safety within the Code of Practice for Social Researchers (288) which includes topics such as risk assessment, interview precautions, conduct of interviews, safety of respondents and safety control measures.

Rigour

Criteria or standards of rigour are necessary to guarantee systematic, accountable and high-quality research (289). There has been much debate about quality in qualitative research and researchers face difficulties ensuring that standards are addressed in respect of methodological rigour (273, 289).

What is rigour in qualitative research?

Davies and Dodd (213) suggest that traditionally, rigour refers to a systematic, ordered and visible approach to research methods, encompassing features such as objectivity, replication, reliability, validity and standardisation. However, they also conclude that these features are inherently quantitatively biased. Instead, they propose that any criteria for evaluating rigour should be appropriate to the research and methods used e.g. qualitative research needs to be reliable, but this does not mean it should be replicable over time and across contexts, rather reliability relates to consistency and carefulness in the application of research practices. Similarly, Koch (262) describes establishing trustworthiness in qualitative data by incorporating criteria of credibility, transferability and dependability. de Witt and Ploeg (2006) proposed a framework of 'expressions' of rigour, rather than criteria of rigour (289). These expressions are balanced integration, openness, concreteness, resonance and actualisation (289). I believe these expressions of rigour are amenable to the chosen research approach and will be discussed here.

Balanced Integration

Defined by three definitive characteristics, balanced integration is the:

1. Explanation of the philosophical approach and its appropriateness for the research and the researcher
2. Connection between the philosophical approach and research methods and findings
3. Balance between the voice of study participants and the philosophical explanations

I have aimed to make explicit what Heideggerian phenomenology incorporates and how it fits with me as a researcher and my research topic in this and the previous chapter.

Openness

An interpretive phenomenological researcher must stay oriented and attuned to the phenomenon of inquiry throughout the process and in doing so, must

be explicit in accounting for all decisions made in relation to the research, thus allowing the study to be opened up to scrutiny (287, 289).

The researcher's self-awareness or reflexivity is an essential part of the decision making involved in the research process and must be detailed to achieve this openness (246, 290). Very much in keeping with Heideggerian philosophy, the researcher's openness about their own Being-in-the-world and forestructures needs careful reflection and consideration. This can be achieved by keeping a journal (290) which is used to describe and interpret experiences, decisions made and interactions and relationships with participants.

Some authors suggest that the construction of an audit trail may enhance rigour i.e. the extent to which the researcher makes actions clear to the reader (222, 291, 292). Although this does not necessarily fit with a Heideggerian approach, a reflexive diary acts as a means of auditability and therefore, I kept a diary, using it to reflect on my own experiences, on my interviews and on the research process as a whole. I considered my own experiences as a physiotherapist and a researcher working with older people and the role of exercise within those contexts and in my own personal life. I used my diary to prepare for my interviews, examining my preconceptions about how I anticipated the interview might proceed and what I expected to hear from the participants and then immediately after the interview I made notes of my impressions of how the interview went i.e. practical or technical considerations and interpretations of my preconceptions and what was actually said. I used my diary to reflect on the interview transcripts and it helped me clearly focus on the important things that were being revealed to me, and therefore, the subsequent development of themes. An extract from my reflexive diary illustrating some of these reflections is presented in Appendix 8.

As I have alluded to, the development of themes is another aspect of the research process that requires openness. It has been suggested that as a means of improving credibility, identified themes can and should be validated by another person (284, 293). However, this poses a problem for

Heideggerian research which is based on the co-construction of shared meanings between the researcher and participant only.

In practical terms, independent validation gives the researcher the opportunity to explain their decision-making process to others (openness) and may add to their reflexivity. Therefore, I did discuss my interpretations with my supervisors, which gave me the chance to reflect further on my decisions and openly acknowledge my forestructures of understanding.

Concreteness

Similar to van Manen's 'lived throughness' (294), de Witt and Ploeg's concreteness means that the phenomenon of interest is placed concretely in the lifeworld or in context, so that the reader may experientially recognise it (289). By giving specific examples of the experience of the phenomenon from the texts it places the reader in the middle of lived reality (294)

Therefore, the research study aimed to orientate towards older adults' experiences of exercise for falls prevention. However, exercise was not described as a single entity but rather within the context of a falls prevention clinical trial.

Resonance and actualisation

The fourth proposed expression of rigour is resonance. That is the observed or felt effect that reading the findings has upon the reader (289, 294). Van Manen describes this 'epiphany' as a "sudden or intuitive grasp of the life meaning of something" (p.364) and in turn this understanding can lead to self-understanding. This subsequently leads to the fifth expression of rigour, actualisation, which suggests that phenomenological interpretation does not end when the study does but addresses an on-going potentiality of the findings (289, 291).

These final expressions are difficult to monitor or record and, therefore, are somewhat subjective examples of rigour. De Witt and Ploeg (289) also point out some other limitations of their framework including the broadness of their terminology i.e. openness. However, they conclude that their framework, although possibly generic, is generic for interpretive phenomenology rather than qualitative research as whole.

Summary

Despite the lack of predetermined or fixed procedures for carrying out phenomenological research, I have used guidance from van Manen and other qualitative researchers to produce a rigorous method for undertaking my interview study. It is my aim that these methods reflect Heidegger's description of phenomenological investigation as I have followed a path towards a clearing where participants have revealed their stories and experiences to me.

Using the underpinning methodologies and methods outlined in this and the previous chapters, the quantitative and qualitative data will be analysed and presented separately and then integrated and discussed in the following results/findings and discussion chapters.

Chapter 6: Results and Findings

Introduction

This chapter presents the results of the LAFTER prospective cohort study in the first section; followed by the findings from the interview study in section two; and the integrated results/findings in the third section.

Section 1: Prospective nested cohort study

Introduction

The sample of participants in the LAFTER cohort study was drawn from two of three intervention arms of the PreFIT RCT. Therefore, to put the LAFTER study into context, this introduction will briefly describe the setting and timeline of the PreFIT study. Further detail on the trial design is available in the published protocol (26) and Health Technology Assessment final report (in press) (27).

Sixty-three general practices took part in the trial from six areas across England: Birmingham and Black Country (n=2/63), Cambridgeshire (n=6/63), Devon (n=18/63), Warwickshire/Herefordshire (n=12/63), Newcastle (n=11/63) and Worcestershire (n=14/63). These practices were randomised to deliver only one of three PreFIT interventions (advice only, advice plus exercise or advice plus MFFP). Recruitment for PreFIT commenced in September 2010 and the final practices were randomised in June 2014; 18-month follow-up of participants completed in January 2016.

Approvals for the LAFTER study were granted in March and August 2017 (Appendices 4 and 7). Final (extended follow-up) questionnaires for LAFTER were posted to participants between June 2017 and December 2017. Follow-up data collection was staggered similar to recruitment, randomisation and data collection processes in the main trial. Participant interviews took place between December 2017 and June 2018.

No general practices withdrew from PreFIT, but one practice randomised to exercise closed after recruitment and intervention delivery were complete. These PreFIT participants were registered with new practices. This did not affect main trial follow-up at 18-months, but we were unable to obtain up to date details regarding change of address and vital status for these

participants, so this practice (n=133 participants) was excluded from the LAFTER study. Thus, 41/63 practices were included in the LAFTER study.

Participants

An overview of participant flow from recruitment (PreFIT) to final LAFTER follow-up is presented in the CONSORT diagram (Figure 9).

Eligible for LAFTER cohort study

Based on 18-month PreFIT trial data, 2777/3223 participants (86%) in the advice arm and 2766/3279 (84%) participants in the exercise arm were eligible to participate in the LAFTER study. Only those who had died or specifically withdrawn by 18-months were not invited to participate in LAFTER. Prior to mail out, vital status (alive or deceased) was checked. Following this check, a further 202/2777 (7%) participants from the advice arm were excluded. In the exercise arm, including the 133 participants from the general practice that closed, 317/2766 (11%) participants were excluded following this check. Therefore, 4891 participants were eligible to be posted an invitation to take part in the cohort study; 2575/2777 (93%) and 2316/2766 (84%) from the advice and exercise arms respectively (Figure 9).

Response rate at extended follow-up

Overall response rate to the LAFTER study was 2980/4891 (61%). Of the 1572 participants responding to the extended follow-up questionnaire in the advice arm, 65 (4%) participants had not completed questionnaires across all three time points (baseline, 18-months and extended follow-up) and were, therefore, excluded. Similarly, of the 1538 participants responding to the questionnaire in the exercise arm, 65 (4%) participants had not completed questionnaires at all three time points and were also excluded.

The total number of participants included in the final LAFTER analyses were 1507 and 1473 from the advice and exercise arms, respectively, accounting for 30% of the recruited PreFIT trial cohort (2980/9803).

Participants in the exercise arm of PreFIT were invited to the exercise intervention based on the results of a postal falls risk screener. Of the 3279 participants randomised to exercise, 1079 (33%) were at higher risk of falling

and were eligible for exercise (27). Four hundred and eighteen of these 1079 (39%) participants returned extended follow-up questionnaire data.

Of the 418 participants, 299 (72%) completed some or all of the six-month exercise intervention (these participants will now be referred to as exercise completers) and 119/418 (28%) declined to participate in the exercise programme (these participants will now be referred to as exercise non-completers). Of the completers, 238/299 (80%) finished the exercise programme and final assessments (median number of sessions attended was seven (range 4-8). The remaining 61/299 (20%) participants partially completed the programme (median number of sessions attended was four (range 1-7)).

Time to extended follow-up

Median time between randomisation and return of the extended follow-up questionnaire was four years (IQR 3-4), this ranged from three to six years (Table 7). Using this median, from now on, the extended follow-up time point will be described throughout as four-year follow-up.

Table 7. Time from randomisation to return of extended follow-up questionnaire (years)

	Responders to LAFTER (n=2980)		
Years	Advice (n=1507)	Exercise (n=1473)	Total (n=2980)
Mean (SD)	3.74 (0.75)	3.55 (0.67)	3.64 (0.72)
Median (IQR)	4 (3-4)	3 (3-4)	4 (3-4)
Range	3-6	3-5	3-6

Missingness

Missingness (no response) is presented as proportion of missing data across treatment arms and by adherence to exercise. The amount of missing data was minimal for most variables and patterns of missingness were similar between groups. Missingness of falls, mobility, general health and exercise outcome data was <1% at four-year follow-up for participants responding from both the advice and exercise arms. Missingness across all domains of the health-related quality of life measure at four-year follow-up was 5% and

3% in the advice and exercise arms, respectively. Whilst, missingness across all domains of the Strawbridge frailty questionnaire was 3% in both groups. Missingness of cognitive outcome data was 1% in the advice arm and 2% in the exercise arm at four-years.

Non-responders

Of the 4891 participants invited to take part in the LAFTER study, 1911 (39%) either responded to decline or did not return a questionnaire.

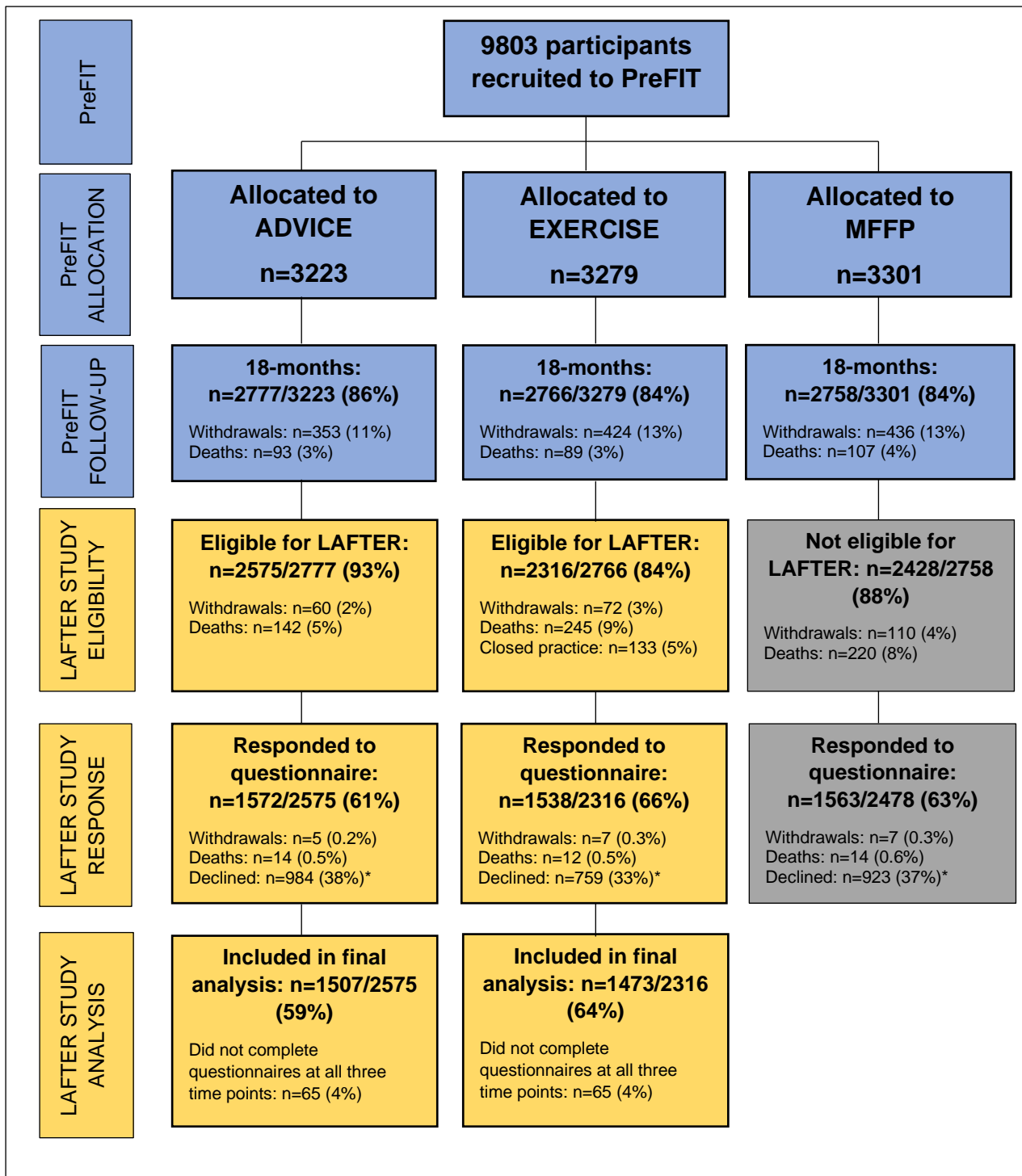
The baseline characteristics of LAFTER cohort responders and non-responders are compared in Table 8. Non-responders at four years were more likely to be older when recruited to the trial and they had more problems with mobility and cognition at baseline. They also reported poorer health-related quality of life and a higher proportion of non-responders were frailer when recruited to the trial compared to those who responded.

Baseline characteristics of LAFTER cohort participants

The baseline characteristics of the participants from the advice and exercise arms of the PreFIT study and those responding to the LAFTER cohort were compared (Table 9). Mean baseline age of the participants remaining in the cohort was 76.2 years (SD 4.97; range 70-100), thus was younger than the mean age of the main trial cohort. The majority of participants were white, either married or cohabiting, and a third lived alone.

At baseline, almost one third of those responding to the LAFTER study had fallen in the previous year. Overall, the LAFTER cohort were moderately active, and results indicated good levels of physical and mental health-related quality of life. The prevalence of frailty in the LAFTER subset was 14% compared to 20% in PreFIT and the majority of participants (94%) had no cognitive impairment when they were recruited to the trial.

In summary, those participants in the LAFTER study were, on average, slightly younger, and had fewer problems with health, mobility and cognition than the main PreFIT trial cohort.



*Includes participants who responded to decline and non-responders

Figure 9. Consort Diagram

Table 8. Baseline characteristics of responders and non-responders to LAFTER cohort study (n=4891)

	Eligible for four-year follow-up (n=4891)		P value
	Responders (n=2980)	Non-responders (n=1911)	
Mean age (SD) on recruitment, years	76.2 (5.0)	78.8 (6.0)	<0.001
Range	70-100	70-101	
Female, n (%)	1514 (50.8)	990 (51.8)	0.50
Ethnicity, n (%)			0.90
White	2935 (98.5)	1876 (98.2)	
Other	24 (0.8)	16 (0.8)	
Missing	21 (0.7)	19 (1.0)	
Marital status, n (%)			<0.001
Married/Cohabiting	1995 (66.9)	1168 (61.1)	
Widowed	694 (23.3)	551 (28.8)	
Divorced/Separated	177 (5.9)	113 (5.9)	
Single	106 (3.6)	69 (3.6)	
Missing	8 (0.3)	10 (0.5)	
Living arrangements, n (%)			<0.001
Lives alone	879 (29.5)	661 (34.6)	
Lives with others	2086 (70.0)	1237 (64.7)	
Missing	15 (0.5)	13 (0.7)	
Fallen in previous year, n (%)			<0.001
Yes	829 (27.8)	637 (33.3)	
No	2136 (71.7)	1253 (65.6)	
Missing	15 (0.5)	21 (1.1)	
n (%) at higher risk of falling, baseline questionnaire	1090 (36.6)	977 (51.1)	<0.001
On average, hours/day walking, n (%)			<0.001
None or < 1 hour	615 (20.6)	517 (27.1)	

More than 1 but less than 2 hours	1152 (38.7)	720 (37.7)	
2-4 hours	828 (27.8)	471 (24.6)	
>4 hours	371 (12.4)	193 (10.1)	
Missing	14 (0.5)	10 (0.5)	
Balance difficulties walking, n (%)			
Never	2036 (68.3)	1036 (54.2)	<0.001
Sometimes/often	885 (29.7)	764 (40.0)	
Very often/always	49 (1.6)	98 (5.1)	
Missing	10 (0.3)	13 (0.7)	
Able to get outside, n (%)			
Unaided	2644 (88.7)	1438 (75.2)	<0.001
With stick/support or help only	319 (10.7)	456 (23.9)	
I can't get outside at all	3 (0.1)	10 (0.5)	
Missing	14 (0.5)	7 (0.4)	
HRQoL, EQ-5D-3L ¹			
Mean (SD)	0.82 (0.19)	0.76 (0.23)	<0.001
Frailty, n (%)			
Frail	425 (14.3)	392 (20.5)	<0.001
Non-frail	2525 (84.7)	1502 (78.6)	
Missing	30 (1.0)	17 (0.9)	
Clock drawing test score ² , n (%)			
0-4	142 (4.8)	176 (9.2)	<0.001
5-6	2811 (94.3)	1702 (89.1)	
Missing	27 (0.9)	33 (1.7)	
General health, n (%)			
Excellent	340 (11.4)	155 (8.1)	<0.001
Very good/good	2274 (76.3)	1328 (69.5)	
Fair/poor	342 (11.5)	412 (21.6)	
Missing	24 (0.8)	16 (0.8)	

¹ EQ-5D-3L scale range 0-1, where higher score indicates better HRQoL; ² Clock drawing test scale range 0- 6, where higher score indicates better cognitive function

Table 9. Baseline characteristics of advice and exercise participants from the PreFIT and LAFTER studies

	PreFIT Study (All participants randomised from advice and exercise arms, n=6502)			Responded to LAFTER Study (Four-year follow-up only, n=2980)		
	Advice (n=3223)	Exercise (n=3279)	Total (n=6502)	Advice (n=1507)	Exercise (n=1473)	Total (n=2980)
Mean age (SD) on recruitment, years	77.9 (5.7)	78.1 (5.7)	78.1 (5.7)	76.2 (4.9)	76.3 (5.0)	76.2 (5.0)
Range	70-101	70-100	70-101	70-95	70-100	70-100
Female, n (%)	1666 (51.7)	1724 (52.6)	3390 (52.1)	775 (51.4)	739 (50.2)	1514 (50.8)
Ethnicity, n (%)						
White	3166 (98.2)	3225 (98.3)	6391 (98.2)	1487 (98.7)	1448 (98.3)	2935 (98.5)
Other	30 (1.0)	25 (0.8)	55 (0.8)	12 (0.8)	12 (0.8)	24 (0.8)
Missing	27 (0.8)	29 (0.9)	56 (0.9)	8 (0.5)	13 (0.9)	21 (0.7)
Marital status, n (%)						
Married/Cohabiting	2050 (63.6)	2035 (62.1)	4085 (62.8)	1010 (67.0)	985 (66.9)	1995 (66.9)
Widowed	857 (26.6)	887 (27.0)	1744 (26.8)	368 (24.4)	326 (22.1)	694 (23.3)
Divorced/Separated	175 (5.4)	236 (7.2)	411 (6.3)	71 (4.7)	106 (7.2)	177 (5.9)
Single	130 (4.0)	108 (3.3)	238 (3.7)	55 (3.6)	51 (3.5)	106 (3.6)
Missing	11 (0.4)	13 (0.4)	24 (0.4)	3 (0.2)	5 (0.3)	8 (0.3)
Living arrangements, n (%):						
Lives alone	1048 (32.5)	1104 (33.7)	2152 (33.1)	453 (30.1)	426 (28.9)	879 (29.5)
Lives with others	2155 (66.9)	2154 (65.7)	4309 (66.2)	1047 (69.5)	1039 (70.5)	2086 (70.0)
Missing	20 (0.6)	21 (0.6)	41 (0.6)	7 (0.3)	8 (0.5)	15 (0.5)
Fallen in previous year, n (%)						
Yes	1019 (31.6)	1033 (31.5)	2052 (31.5)	425 (28.2)	404 (27.4)	829 (27.8)
No	2179 (67.6)	2225 (67.9)	4404 (67.7)	1075 (71.3)	1061 (72.0)	2136 (71.7)
Missing	25 (0.8)	21 (0.6)	46 (0.7)	7 (0.5)	8 (0.5)	15 (0.5)

n (%) higher risk of falling, baseline questionnaire	1382 (42.9)	1422 (43.4)	2804 (43.1)	553 (36.7)	537 (36.5)	1090 (36.6)
n (%) higher risk of falling, GP falls risk screener	N/A	1079 (32.9)	1079 (16.6)	N/A	418 (28.4)	418 (14.0)
On average, hours/day walking, n (%)						
None or <1 hour	822 (25.5)	847 (25.8)	1669 (25.7)	312 (20.7)	303 (20.6)	615 (20.6)
More than 1 but less than 2 hours	1213 (37.7)	1271 (38.8)	2484 (38.2)	569 (37.8)	583 (39.6)	1152 (38.7)
2-4 hours	810 (25.1)	816 (24.9)	1626 (25.0)	425 (28.2)	403 (27.4)	828 (27.8)
>4 hours	357 (11.1)	329 (10.0)	686 (10.6)	194 (12.9)	177 (12.0)	371 (12.4)
Missing	21 (0.6)	16 (0.5)	37 (0.6)	7 (0.5)	7 (0.5)	14 (0.5)
Balance difficulties walking, n (%)						
Never	1876 (58.2)	1921 (58.6)	3797 (58.4)	1000 (66.4)	1036 (70.3)	2036 (68.3)
Sometimes/often	1176 (36.5)	1200 (36.6)	2376 (36.5)	473 (31.4)	412 (28.0)	885 (29.7)
Very often/always	151 (4.7)	141 (4.3)	292 (4.5)	29 (1.9)	20 (1.4)	49 (1.6)
Missing	20 (0.6)	17 (0.5)	37 (0.6)	5 (0.3)	5 (0.3)	10 (0.3)
Able to get outside, n (%)						
Unaided	2580 (80.0)	2599 (79.3)	5179 (79.6)	1336 (88.7)	1308 (88.8)	2644 (88.7)
Stick/support/help only	611 (19.0)	656 (20.0)	1267 (19.5)	162 (10.7)	157 (10.7)	319 (10.7)
I can't get outside	16 (0.5)	11 (0.3)	27 (0.4)	3 (0.2)	0	3 (0.1)
Missing	16 (0.5)	13 (0.4)	29 (0.4)	6 (0.4)	8 (0.5)	14 (0.5)
HRQoL, EQ-5D-3L ¹						
Mean (SD)	0.76 (0.23)	0.78 (0.23)	0.78 (0.23)	0.82 (0.19)	0.82 (0.19)	0.82 (0.19)
Frailty, n (%)						
Frail	647 (20.1)	625 (19.1)	1272 (19.5)	234 (15.5)	191 (13.0)	425 (14.3)
Non-frail	2535 (78.6)	2603 (79.4)	5138 (78.9)	1263 (83.8)	1262 (85.7)	2525 (84.7)
Missing	41 (1.3)	51 (1.5)	92 (1.4)	10 (0.7)	20 (1.4)	30 (1.0)

Clock drawing test score ² , n (%)	0-4	294 (9.1)	271 (8.3)	565 (8.7)	80 (5.3)	62 (4.2)	142 (4.8)
	5-6	2882 (89.4)	2952 (90.0)	5834 (89.6)	1413 (93.8)	1398 (94.9)	2811 (94.3)
	Missing	47 (1.5)	56 (1.7)	103 (1.6)	14 (0.9)	13 (0.9)	27 (0.9)
General health, n (%)	Excellent	278 (8.6)	298 (9.1)	576 (8.9)	169 (11.2)	171 (11.6)	340 (11.4)
	Very good/good	2304 (71.5)	2327 (71.0)	4631 (71.2)	1147 (76.1)	1127 (76.5)	2274 (76.3)
	Fair/poor	625 (19.4)	622 (19.0)	1247 (19.2)	184 (12.2)	158 (10.7)	342 (11.5)
	Missing	16 (0.5)	32 (1.0)	48 (0.7)	7 (0.5)	17 (1.2)	24 (0.8)

¹ EQ-5D-3L scale range 0-1, where higher score indicates better HRQoL

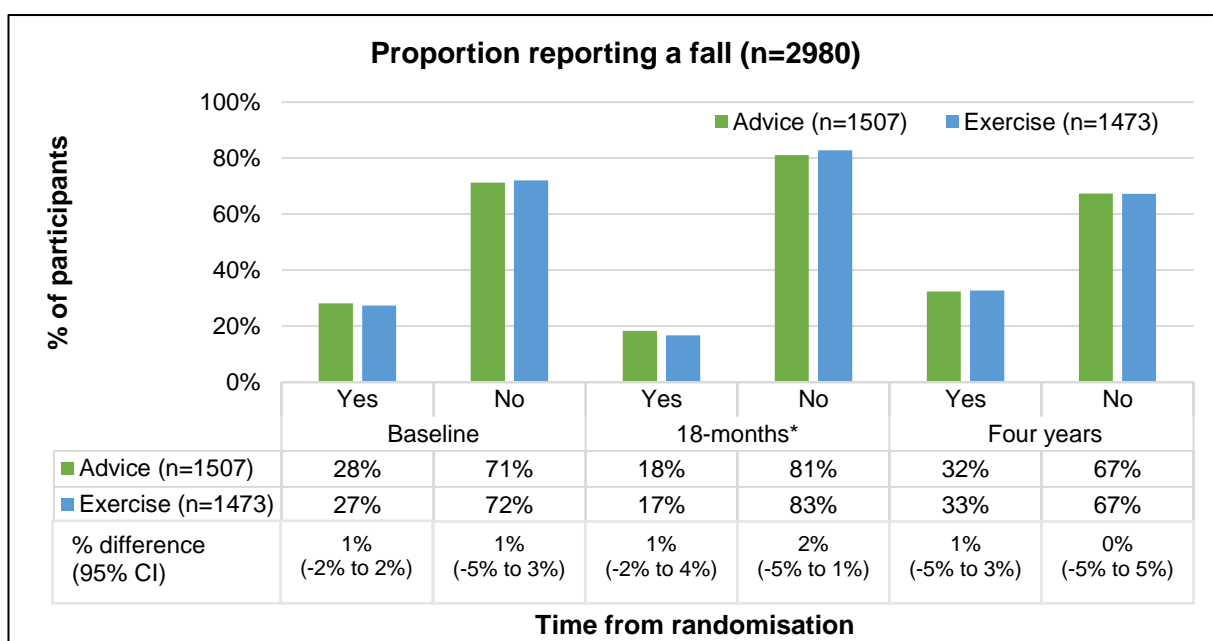
² Clock drawing test scale range 0- 6, where higher score indicates better cognitive function

Health outcomes over four years by treatment arm

Falls

There was no difference in the proportion of participants reporting a fall by treatment arm at all three time points (Figure 10).

The proportion of participants in the LAFTER sample reporting a fall increased over time. Between baseline and four-year follow-up, the number reporting a fall in the previous year increased by 4% (95% CI 0% to 8%) in the advice arm; and 6% (95% CI 2% to 10%) in the exercise arm (Figure 10).



*Proportion reporting a fall over previous four-months

Figure 10. Proportion of participants reporting a fall over time (n=2980)

Rate of falls

There was a higher rate of falls over 18-months in those responding to the LAFTER study in the advice arm compared with the exercise arm; RaR 1.13 (95% CI 1.02 to 1.24; $p = 0.02$) (Tables 10 and 11). Similarly, there was also an increased rate of falls over 18-months in the advice arm when adjusted for age, sex and GP deprivation score; RaR 1.11 (95% CI 1.01 to 1.23; $p = 0.04$) (Table 11).

Although there was a higher rate of falls in the advice arm between baseline and four years compared to exercise, the unadjusted rate ratio (RaR 1.08, 95% CI 0.99 to 1.18; $p = 0.08$) and adjusted rate ratio (RaR 1.07, 95%CI 0.98 to 1.17; $p = 0.16$) were not statistically significant (Table 11).

Table 10. Rate of falls by treatment arm by time period

	Advice (n=1507)	Exercise (n=1473)	Total (n=2980)
n. (%) of reported falls over 18-months	2018 (54.5)	1685 (45.5)	3703
n. (%) of reported falls over four years	3232 (53.5)	2809 (46.5)	6041
Crude falls rate per 1000 person months over 18-months	73.9	63.2	68.6
Crude falls rate per 1000 person months between baseline and four-year follow-up	42.1	39.0	40.6

Table 11. Unadjusted and adjusted rate ratios (RaR) of falls over time

	LAFTER cohort Advice vs Exercise RaR (95% CI)	P value
Falls over 18-months		
Unadjusted RaR	1.13 (1.02 to 1.24)	0.02
Adjusted RaR ¹	1.11 (1.01 to 1.23)	0.04
Falls over four years		
Unadjusted RaR	1.08 (0.99 to 1.18)	0.08
Adjusted RaR ¹	1.07 (0.98 to 1.17)	0.16

¹ adjusted for baseline risk of falling, age, sex and GP deprivation score

Risk factors for falling

Univariate logistic regression analyses were conducted to identify risk factors associated with falling (yes/no) in the previous year at four-year follow-up (Table 12). Being at higher risk of falling at baseline was strongly associated with falling at four-year follow-up (OR 2.27, 95% CI 1.93 to 2.68; $p = <0.001$). Older age was also associated with falling (OR 1.03, 95% CI 1.02 to 1.07; $p = <0.001$).

Table 12. Odds ratio of falling at four-year follow-up*

	Falls (yes/no) at four years	
Risk factor	OR (95% CI)	p-value
Higher risk of falling	2.27 (1.93 to 2.68)	<0.001
Age ¹	1.03 (1.02 to 1.07)	<0.001
GP deprivation score ²	1.01 (0.98 to 1.04)	0.43
Exercise treatment arm	1.00 (0.86 to 1.17)	0.97
Female sex	0.98 (0.84 to 1.15)	0.78

*Univariate logistic regression analysis

1 & 2 Continuous variables

The univariate factors of risk of falling and age were included in the stepwise regression model using a backward stepwise technique (Table 13). Higher risk of falling at baseline was strongly associated with falling at four years (OR 2.27, 95% CI 1.93 to 2.68; $p = <0.001$) followed by increased age (OR 1.04, 95% CI 1.03 to 1.06; $p = <0.001$).

Table 13. Odds ratio of falling at four-year follow-up*

	Falls at four years	
Predictor	OR (95% CI)	p-value
Higher risk of falling	2.27 (1.93 to 2.68)	<0.001
Age ¹	1.04 (1.03 to 1.06)	<0.001

*Multivariate stepwise logistic regression analysis

1 Continuous variable

Falls diaries

Of the 2980 responding participants in the LAFTER cohort study, 1136 (38%) agreed to complete a prospective falls diary for one month. The characteristics of these participants and the results from their falls diaries are presented in Table 14.

The majority of responding participants (87%) did not experience any falls during their month of data collection. There was very little difference in the proportion of participants reporting a fall in the advice arm compared to those in the exercise arm.

Table 14. Characteristics of participants returning a falls diary (n=1136)

	Advice (n=560)	Exercise (n=576)	Total (n=1136)
Female, n (%)	266 (47.5)	283 (49.1)	549 (48.3)
Age, mean (SD)			
Baseline	76.4 (4.9)	76.5 (4.7)	76.5 (4.8)
Four-year follow-up	80.8 (4.9)	80.9 (4.8)	80.8 (4.8)
Risk of falling at baseline, n (%)			
Low	378 (67.5)	402 (69.8)	780 (68.7)
Higher	182 (32.5)	174 (30.2)	356 (31.3)
Number of participants reporting a fall in the past month, n (%)	78 (13.9)	72 (12.5)	150 (13.2)
Number of falls reported in the past month on falls diary, n (%)			
0	482 (86.1)	504 (87.5)	986 (86.8)
1	49 (8.8)	43 (7.5)	92 (8.1)
2	18 (3.2)	14 (2.4)	32 (2.8)
>3	11 (2.0)	15 (2.6)	26 (2.3)

Mobility

Average hours spent walking per day was compared across time points (Table 15). Patterns of mobility are presented in Figure 11. In both treatment arms, the proportion of participants doing very little (either none or less than an hour of walking per day) decreased between baseline and 18-months; advice = 3% (95% CI 1% to 5%); exercise = 4% (95% CI = 2% to 6%) but then increased between 18-months and four-year follow-up; advice = 7% (95% CI 4% to 10%); exercise = 7% (95% CI 5% to 9%) (Table 15 and Figure 11).

Although data on participants' difficulties balancing on a level surface was not collected at 18-months, by four years, the proportion of participants reporting balance problems increased by 17% (95% CI 13% to 22%) in both treatment arms from baseline (Table 15). This coincided with an increase in the proportion of people needing a stick or assistance to go outdoors (Table 15).

Table 15. Mobility outcomes over time by treatment arm (n=2980)

	Advice (n=1507)			Exercise (n=1473)			Total (n=2980)		
	Baseline	18-months	Four years	Baseline	18-months	Four years	Baseline	18-months	Four years
Hours/day walking, n (%)									
None or <1 hour	312 (20.7)	268 (17.8)	378 (25.1)	303 (20.6)	257 (17.4)	347 (25.6)	615 (20.6)	525 (17.6)	725 (24.3)
More than 1 but less than 2 hours	569 (37.8)	567 (37.6)	548 (36.4)	583 (39.6)	564 (38.3)	591 (40.1)	1152 (38.7)	1131 (38.0)	1139 (38.2)
2-4 hours	425 (28.2)	463 (30.7)	431 (28.6)	403 (27.4)	430 (29.2)	360 (24.4)	828 (27.8)	893 (30.0)	791 (26.5)
>4 hours	194 (12.9)	205 (13.6)	137 (9.1)	177 (12.0)	218 (14.8)	168 (11.4)	371 (12.4)	423 (14.2)	305 (10.2)
Missing	7 (0.5)	4 (0.3)	13 (0.9)	7 (0.5)	4 (0.3)	7 (0.5)	14 (0.5)	8 (0.3)	20 (0.7)
Balance difficulties walking on level, n (%)									
Never	1000 (66.4)		747 (49.6)	1036 (70.3)		784 (53.2)	2036 (68.3)		1531 (51.4)
Sometimes/often	473 (31.4)		683 (45.3)	412 (28.0)		631 (42.8)	885 (29.7)		1314 (44.1)
Very often/always	29 (1.9)		72 (4.8)	20 (1.4)		57 (3.9)	49 (1.6)		129 (4.3)
Missing	5 (0.3)		5 (0.3)	5 (0.3)		1 (0.1)	10 (0.3)		6 (0.2)
Going outdoors, n (%)									
Unaided	1336 (88.7)		1136 (75.4)	1308 (88.8)		1151 (78.1)	2644 (88.7)		2287 (76.7)
Stick/support/help	162 (10.7)		357 (23.7)	157 (10.7)		312 (21.2)	319 (10.7)		669 (22.4)
I can't get outside	3 (0.2)		10 (0.7)	0		10 (0.7)	3 (0.1)		20 (0.7)
Missing	6 (0.4)		4 (0.3)	8 (0.5)		0	14 (0.5)		4 (0.1)

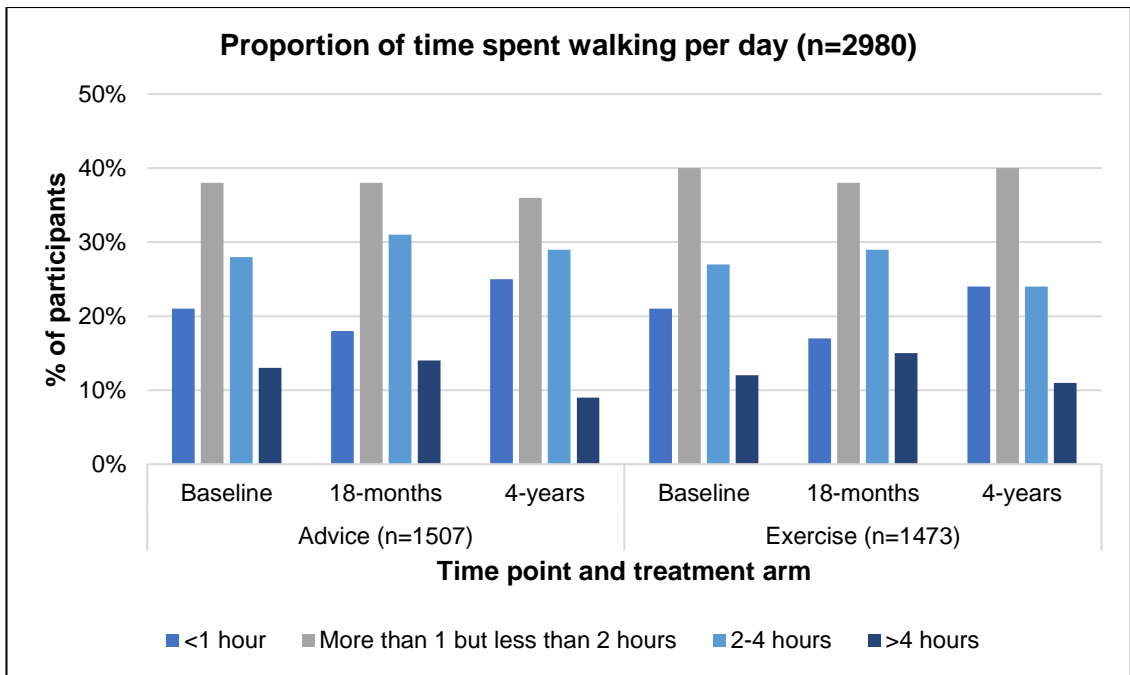


Figure 11. Time spent walking (hours per day) over time by treatment arm (n=2980)

HRQoL

Health-related quality of life was reported as a mean EQ-5D-3L index score (Table 16). An ANOVA with repeated measures was used to compare the treatment group mean quality of life scores over time. Mean EQ-5D-3L index scores decreased in both treatment arms over the three time points (Table 16 and Figure 12), indicating declining quality of life over time. This change over time was statistically significant ($p = 0.001$).

Table 16. Health outcomes (HRQoL, frailty, cognition and general health) over time by treatment arm (n=2980)

	Advice (n=1507)			Exercise (n=1473)			Total (n=2980)		
	Baseline	18-months	Four years	Baseline	18-months	Four years	Baseline	18-months	Four years
HRQoL, EQ-5D-3L ¹ Mean, (SD)	0.82 (0.19)	0.80 (0.20)	0.78 (0.20)	0.82 (0.19)	0.81 (0.20)	0.78 (0.22)	0.82 (0.19)	0.80 (0.20)	0.78 (0.21)
Frailty, n (%)									
Frail	234 (15.5)	300 (19.9)	302 (20.0)	191 (13.0)	273 (18.5)	259 (17.6)	425 (14.3)	573 (19.2)	561 (18.8)
Non-frail	1263 (83.8)	1181 (78.4)	1181 (78.4)	1262 (85.7)	1197 (81.3)	1197 (81.3)	2525 (84.7)	2393 (80.3)	2378 (79.8)
Missing	10 (0.7)	24 (1.6)	24 (1.6)	20 (1.4)	17 (1.2)	17 (1.2)	30 (1.0)	14 (0.5)	41 (1.4)
Clock drawing test ² , n (%)									
0-4	80 (5.3)		167 (11.1)	62 (4.2)		149 (10.1)	142 (4.8)		316 (10.6)
5-6	1413 (93.8)		1325 (87.9)	1398 (94.9)		1302 (88.4)	2811 (94.3)		2627 (88.2)
Missing	14 (0.9)		15 (1.0)	13 (0.9)		22 (1.5)	27 (0.9)		37 (1.2)
General health compared to 12 months ago, n (%)									
Better	169 (11.2)	171 (11.3)	143 (9.5)	171 (11.6)	182 (12.4)	156 (10.6)	340 (11.4)	353 (11.8)	299 (10.0)
About the same	1147 (76.1)	1106 (73.4)	1024 (67.9)	1127 (76.5)	1081 (73.4)	988 (67.1)	2274 (76.3)	2187 (73.4)	2012 (67.5)
Worse	184 (12.2)	158 (10.5)	331 (22.0)	158 (10.7)	130 (8.8)	317 (21.5)	342 (11.5)	288 (9.7)	648 (21.7)
Missing	7 (0.5)	72 (4.8)	9 (0.6)	17 (1.2)	80 (5.4)	12 (0.8)	24 (0.8)	152 (5.1)	21 (0.7)

¹ EQ-5D-3L scale range 0-1, where higher score indicates better HRQoL

² Clock drawing test scale range 0- 6, where higher score indicates better cognitive function

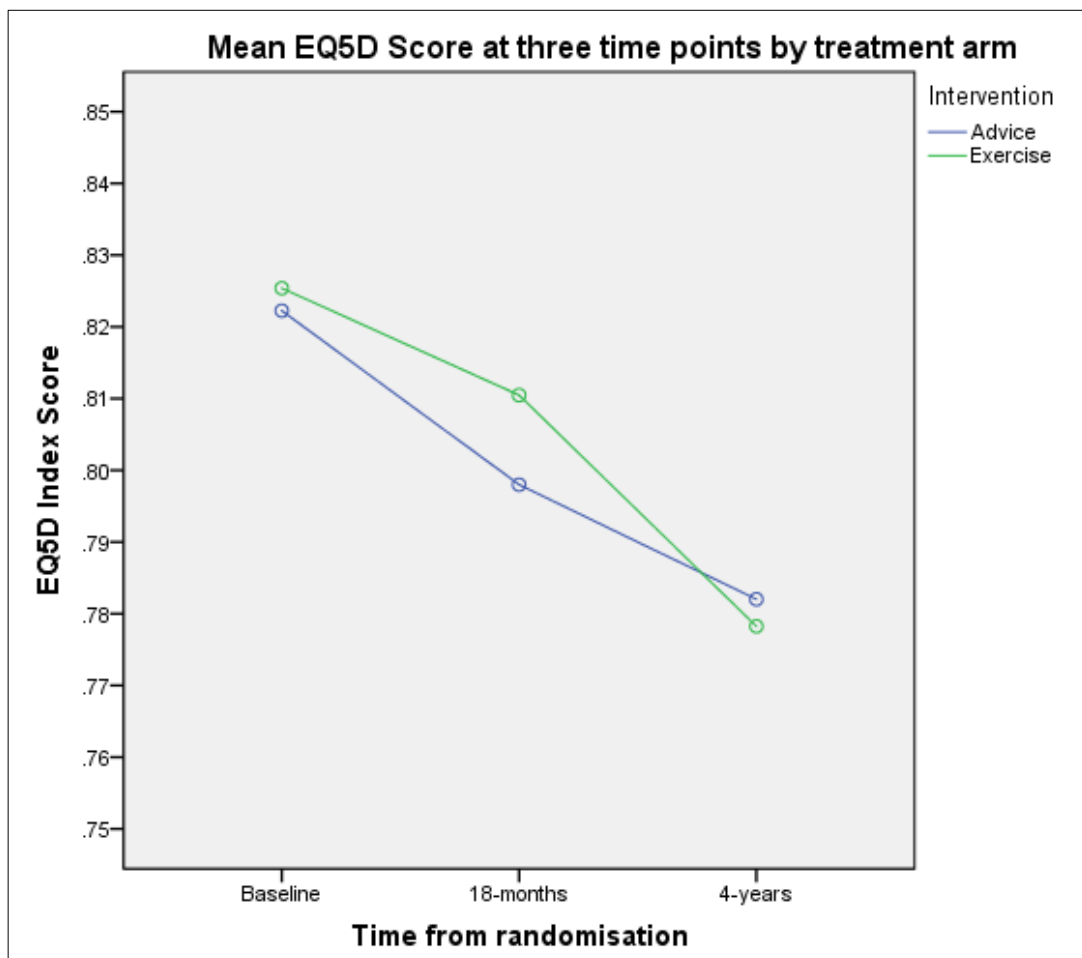


Figure 12. ANOVA with repeated measures to compare mean EQ-5D-3L Index Score over time by treatment arm (n=2980)

Frailty

There was little difference in the prevalence of frailty between the two treatment arms (Table 16). Figure 13 presents the pattern of frailty over time. Overall, the proportion of participants taking part in the LAFTER study who reported frailty increased by 5% (95% CI 3% to 7%) in both treatment arms over time (from 14% to 19%).

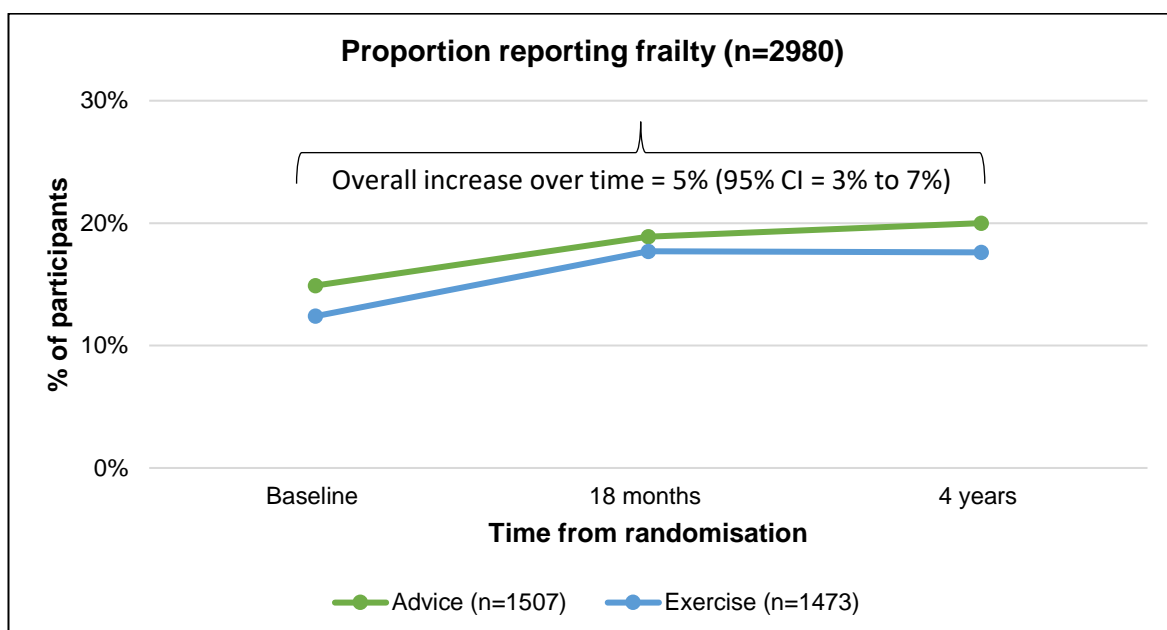


Figure 13. Proportion of participants reporting frailty over time by treatment arm (n=2980)

Risk factors for frailty

Univariate logistic regression analyses were conducted to identify risk factors associated with frailty at four years (Table 17). Baseline frailty was most strongly associated with frailty at four years (OR 13.1; 95% CI 10.4 to 16.5; $p = <0.001$). Three other factors were associated with frailty at four-year follow-up: higher risk of falling at baseline, being female and older age on recruitment to the trial.

Table 17. Odds ratio of being frail at four-year follow-up*

Risk factor	Frailty at four years	
	OR (95% CI)	p-value
Baseline frailty	13.1 (10.4 to 16.5)	<0.001
Higher risk of falling	2.44 (2.02 to 2.94)	<0.001
Female sex	1.24 (1.03 to 1.49)	0.02
Age ¹	1.09 (1.07 to 1.10)	<0.001
GP deprivation score ²	0.99 (0.96 to 1.02)	0.43
Exercise treatment arm	0.85 (0.70 to 1.02)	0.08

*Univariate logistic regression analysis

1 & 2 Continuous variables

Four univariate variables were eligible for inclusion in the frailty stepwise regression model (Table 18). Adjusted risk factors were similar to the univariate analysis; baseline frailty was strongly associated with frailty at four years (OR 11.06; 95% CI 8.69 to 14.10; $p = <0.001$) as was being at higher risk of falling, female sex and older age.

Table 18. Odds ratio of being frail at four-year follow-up*

Risk factor	Frailty at four years	
	OR (95% CI)	p-value
Baseline frailty	11.06 (8.69 to 14.10)	<0.001
Higher risk of falling	1.62 (1.30 to 2.02)	<0.001
Female sex	1.35 (1.09 to 1.67)	<0.001
Age ¹	1.06 (1.04 to 1.08)	<0.001

*Multivariate stepwise logistic regression analysis

¹ Continuous variable

Cognition

Based on the clock drawing test scores of those who responded to the LAFTER study, the number of participants with cognitive impairment increased from baseline to four years in both treatment arms. However, the majority of participants (88%), showed no sign of cognitive impairment at four years (Table 16).

General Health

Overall, the majority of participants in both treatment arms reported their general health to be about the same as a year ago at both 18-months and at four years. However, there was an increase in the proportion of participants reporting somewhat worse or much worse health over time (Table 16).

Exercise

Focusing on strength, balance and general exercise, at four years the participants were asked how often they had undertaken such activities over the past week (Table 19). There was very little difference between treatment arms with regards to how much exercise the participants were, reportedly, doing at time of follow-up. A slightly higher proportion of people in the exercise arm reported doing balance exercises compared to those in the advice group (Table 19).

Overall, 45% of those who responded to the LAFTER study reported never doing any specific muscle strengthening exercises; 71% reported never doing any exercises to improve balance; and approximately half (46%) reported never doing any other form of exercise or recreational activity (e.g. brisk walking, dancing, swimming, tennis, bowls).

Table 19. Exercise being undertaken by treatment arm at four-year follow-up (n=2980)

	Advice (n=1507)	Exercise (n=1473)	Total (n=2980)
Exercises for muscle strength in the past week, n (%)			
Never	668 (44.3)	657 (44.6)	1325 (44.5)
1-2 days	378 (25.1)	368 (25.0)	746 (25.0)
3 or more days	453 (30.1)	445 (30.2)	898 (30.1)
Missing	8 (0.5)	3 (0.2)	11 (0.4)
Exercises for balance in the past week, n (%)			
Never	1097 (72.8)	1025 (69.6)	2122 (71.2)
1-2 days	231 (15.3)	254 (17.2)	485 (16.3)
3 or more days	172 (11.4)	191 (13.0)	363 (12.2)
Missing	7 (0.5)	3 (0.2)	10 (0.3)
Other exercise or recreational activity in the past week, n (%)			
Never	697 (46.3)	667 (45.3)	1364 (45.8)
1-2 days	431 (28.6)	430 (29.2)	861 (28.9)
3 or more days	371 (24.6)	372 (25.3)	743 (24.9)
Missing	8 (0.5)	4 (0.3)	12 (0.4)
If yes, hours spent exercising in the past week, n (%)			
Less than 1 hour	114 (7.6)	126 (8.6)	240 (8.1)
More than 1 but less than 2 hours	336 (22.3)	297 (20.2)	633 (21.2)
2-4 hours	251 (16.7)	279 (18.9)	530 (17.8)
More than 4 hours	101 (6.7)	99 (6.7)	200 (6.7)
N/A	705 (46.8)	672 (45.6)	1377 (46.2)

Association between treatment arm and health outcomes

Chi-square tests were used to determine if there was any association between treatment arm and health outcomes at 18-months and four years in the participants responding to all questionnaires.

18-month follow-up

At 18-months, there was no evidence of an association between treatment arm and any of the health outcomes of interest.

Four-year follow-up

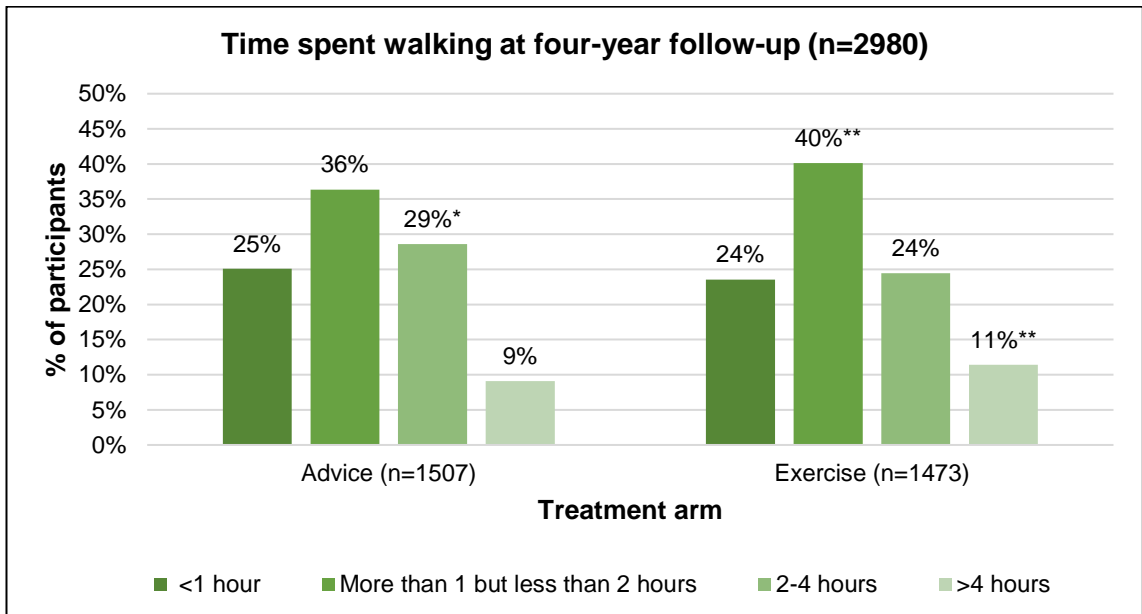
At four years, there was some evidence of an association between treatment arm and time spent walking and the physical functioning domain of the Strawbridge frailty questionnaire (Table 20). To determine the direction of association, binary chi square tests were carried out.

Table 20. Chi square test of association between health-related outcomes and treatment arm at four-year follow-up (n=2980)

Outcome	Advice (n=1507)	Exercise (n=1473)	p-value
Mobility questions, n (%) <i>Hours a day spent walking:</i>			
None or <1 hour	378 (25.1)	347 (23.6)	<0.01
More than 1 but less than 2 hours	548 (36.4)	591 (40.1)	
2-4 hours	431 (28.6)	360 (24.4)	
>4 hours	137 (9.1)	168 (11.4)	
Missing	13 (0.9)	7 (0.5)	
Frailty, n (%) <i>Strawbridge Questionnaire</i> Physical functioning			
Problem	283 (18.8)	232 (15.8)	0.03
No problem	1213 (80.5)	1236 (83.9)	
Missing	11 (0.7)	5 (0.3)	

Hours spent walking

A higher proportion of participants in the exercise arm walked between one to two hours per day and more than four hours per day compared to those in the advice arm at four years. (Figure 14). However, a higher proportion of participants in the advice arm walked 2-4 hours per day at four-year follow-up (Figure 14).

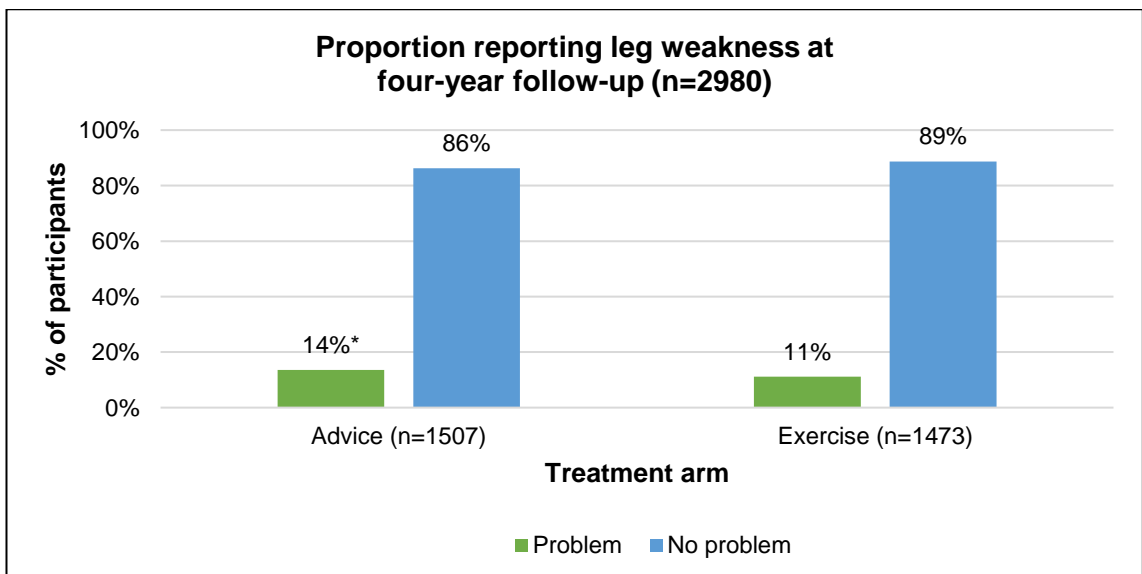


*p = <0.01; **p = 0.04;

Figure 14. Time spent walking (hours per day) at four-year follow-up (n=2980)

Physical functioning (Strawbridge questionnaire)

At four years, a slightly higher proportion of participants in the advice arm reported a problem with leg weakness (203) compared to those in the exercise arm (Figure 15).



*p=0.05

Figure 15. Proportion of participants reporting leg weakness at four-year follow-up (n=2980)

Summary

There were no differences by treatment arm in the proportion of participants reporting a fall over the longer-term. Between baseline and four-year follow-up, the proportion of participants reporting a fall increased in both arms (statistically significant in the exercise arm). Rate of falls was higher in the advice arm over the extended follow-up period, but this was not statistically significant. Two risk factors were significantly associated with falling in the previous year at four-year follow-up: being at higher risk of falling at baseline and older age.

Nearly three quarters of those who responded to the LAFTER questionnaire were not undertaking any exercise to improve their balance. Nearly half of the sample reported that they were not doing any exercises to improve strength, nor were they undertaking any other form of exercise or recreational activity.

There were also no differences by treatment arm on other secondary outcomes. Overall, across the cohort of participants responding to the LAFTER study, there was a decline in health outcomes including balance and mobility, HRQoL, frailty, cognition and general health over the four-year follow-up period.

Exercise intervention

This section of the quantitative results chapter will focus on the sub-group of participants who responded to the LAFTER study and had also been invited to take part in the exercise intervention.

Baseline characteristics of participants eligible for the PreFIT exercise intervention

Based on the results of their falls risk screener, 1079/3279 (33%) PreFIT participants were eligible for and invited to the exercise intervention. Of those who responded to the LAFTER study, 418 participants had been offered the exercise intervention. This equates to 13% of those allocated to exercise in PreFIT, thus is a small subset of the recruited sample.

As described previously, of the 418 participants, 299 (72%) were categorised as completers (completed some or all of the six-month exercise intervention) and 119/418 (28%) declined to participate in the exercise programme (non-completers). Of the completers, 238/299 (80%) finished the six-month exercise programme and final assessments (median number of sessions attended was seven (range 4-8)). The remaining 61/299 (20%) participants partially completed the programme (median number of sessions attended was four (range 1-7)).

The baseline characteristics of these participants are presented in Table 21. The non-completers reported fewer mobility problems, were more active, less frail and had better overall general health despite a slightly higher proportion reporting more falls than those who participated in the intervention.

Table 21. Baseline characteristics of responders to LAFTER study who were offered exercise (n=418)

	Participants eligible for exercise followed-up at four years		
	Exercise completers (n=299)	Exercise non-completers (n=119)	Total (n=418)
Mean age in years (SD) on recruitment	77.1 (5.3)	77.0 (5.2)	77.0 (5.3)
Range	70-92	70-95	70-95
Female, n (%)	169 (56.5)	67 (56.3)	236 (56.5)
Fallen in previous year, n (%)			
Yes	188 (62.9)	78 (65.5)	266 (63.6)
No	110 (36.8)	40 (33.6)	150 (35.9)
Missing	1 (0.3)	1 (0.8)	2 (0.5)
On average, hours/day walking, n (%)			
None or < 1 hours	80 (26.8)	26 (21.8)	106 (25.4)
1-2 hours	121 (40.5)	47 (39.5)	168 (40.2)
2-4 hours	68 (22.7)	31 (26.1)	99 (23.7)
>4 hours	29 (9.7)	15 (12.6)	44 (10.5)
Missing	1 (0.3)	0	1 (0.2)
Balance difficulties walking on level, n (%)			
Never	142 (47.5)	62 (52.1)	204 (48.8)
Sometimes/often	146 (48.8)	50 (42.0)	196 (46.9)
Very often/always	10 (3.3)	6 (5.0)	16 (3.8)
Missing	1 (0.3)	1 (0.8)	2 (0.5)
Able to get outside, n (%)			
Unaided	233 (77.9)	96 (80.7)	329 (78.7)
With stick/support or help only	64 (21.4)	21 (17.6)	85 (20.3)
I can't get outside at all	0	0	0
Missing	2 (0.7)	2 (1.7)	4 (1.0)
HRQoL, EQ-5D, mean (SD)	0.74 (0.23)	0.74 (0.24)	0.74 (0.23)
Frailty, n (%)			
Frail	73 (24.4)	22 (18.5)	95 (22.7)
Non-frail	214 (71.6)	93 (78.2)	307 (73.4)
Missing	12 (4.0)	4 (3.4)	16 (3.8)
Clock drawing test, n (%)			
0-4	8 (2.7)	6 (5.0)	14 (3.3)
5-6	288 (96.3)	112 (94.1)	400 (95.7)
Missing	3 (1.0)	1 (0.8)	4 (1.0)
General health, n (%)			
Excellent	18 (6.0)	9 (7.6)	27 (6.5)
Very good/good	217 (72.6)	91 (76.5)	308 (73.7)
Fair/poor	57 (19.1)	18 (15.1)	75 (17.9)
Missing	7 (2.3)	1 (0.8)	8 (1.9)

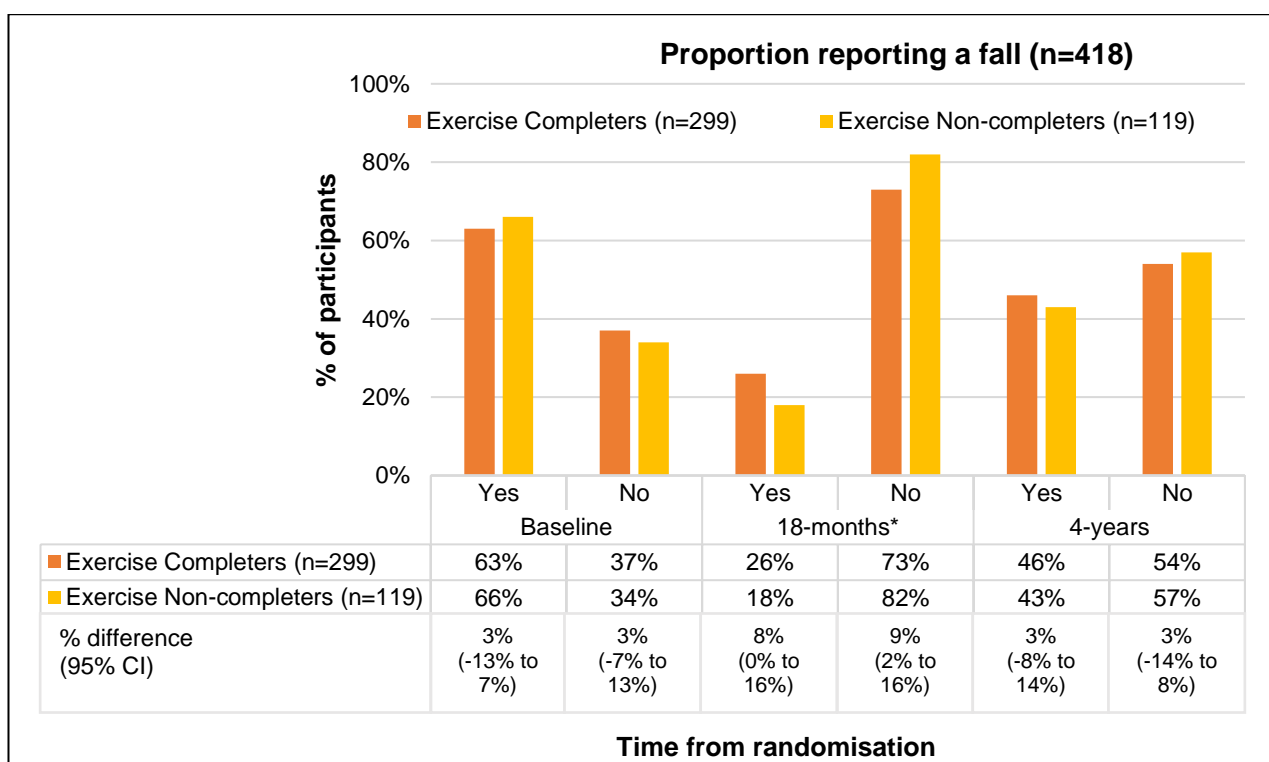
Health outcomes over four years for those offered exercise

By 18-months, all participants had completed their exercise intervention.

Falls

There were no significant differences between the responders and non-responders in the proportion of participants reporting a fall in the previous year at baseline and four years (Figure 16).

Overall, the proportion of participants who had been offered the exercise intervention reporting a fall, decreased over time, in both groups. Between baseline and four-year follow-up, the number reporting a fall in the previous year decreased by 17% (95% CI 9% to 25%) in those who completed the exercise intervention and 23% (95% CI 15% to 31%) in those who declined the exercise intervention (Figure 16).



*Proportion reporting a fall over previous four months

Figure 16. Proportion of participants offered the exercise intervention reporting a fall over time (n=418)

Mobility

Patterns of mobility are presented in Figure 17. The proportion of completers doing very little walking (either none or less than an hour of walking per day) initially decreased by 4% (95% CI -4% to 12%) between baseline and 18-

months, but then increased by 3% (95% CI -5% to 11%) between 18-months and four years. Whereas, the proportion of non-completers doing very little walking increased over time; by 3% between baseline and 18-months (95% CI -7% to 13%) and by 10% between 18-months and four-years (95% CI 0% to 20%) (Figure 17 and Table 22).

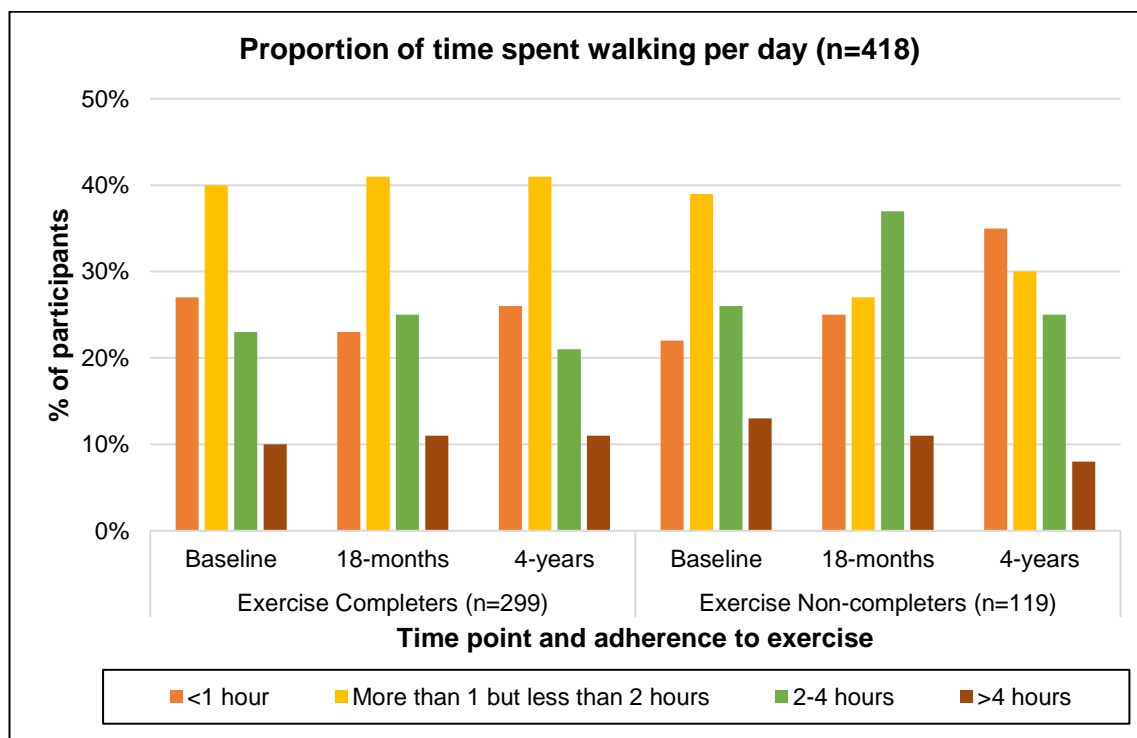


Figure 17. Time spent walking (hours per day) over time by adherence to exercise (n=418)

By four years the proportion of completers and non-completers reporting a problem with balance whilst walking had increased by 14% (95% CI 7% to 23%) and 13% (95% CI 1% to 25%), respectively. This coincided with a 12% (95% CI 5% to 21%) and 18% (95% CI 8% to 32%) increase in the proportion of completers and non-completers needing a stick or assistance to go outdoors (Table 22).

Table 22. Mobility outcomes over time by adherence to exercise (n=418)

	Exercise completers (n=299)			Exercise non-completers (n=119)			Total (n=418)		
	Baseline	18- months	Four years	Baseline	18- months	Four years	Baseline	18- months	Four years
Hours/day walking, n (%)									
None or < 1 hour	80 (26.8)	69 (23.1)	79 (26.4)	26 (21.8)	30 (25.2)	42 (35.3)	106 (25.4)	99 (23.7)	121 (28.9)
More than 1 but less than 2 hours	121 (40.5)	122 (40.8)	124 (41.5)	47 (39.5)	32 (26.9)	36 (30.3)	168 (40.2)	154 (36.8)	160 (38.3)
2-4 hours	68 (22.7)	74 (24.7)	64 (21.4)	31 (26.1)	44 (37.0)	30 (25.2)	99 (23.7)	118 (28.2)	94 (22.5)
>4 hours	29 (9.7)	34 (11.4)	32 (10.7)	15 (12.6)	13 (10.9)	10 (8.4)	44 (10.5)	47 (11.2)	42 (10.0)
Missing	1 (0.3)	0	0	0	0	1 (0.8)	1 (0.2)	0	1 (0.2)
Balance difficulties walking, n (%)									
Never	142 (47.5)		100 (33.4)	62 (52.1)		47 (39.5)	204 (48.8)		147 (35.2)
Sometimes/often	146 (48.8)		174 (58.2)	50 (42.0)		61 (51.3)	196 (46.9)		235 (56.2)
Very often/always	10 (3.3)		25 (8.4)	6 (5.0)		10 (8.4)	16 (3.8)		35 (8.4)
Missing	1 (0.3)		0	1 (0.8)		1 (0.8)	2 (0.5)		1 (0.2)
Able to get outside, n (%)									
Unaided	233 (77.9)		196 (65.6)	96 (80.7)		73 (61.3)	329 (78.7)		269 (64.4)
Stick/support/help	64 (21.4)		100 (33.4)	21 (17.6)		42 (35.3)	85 (20.3)		142 (34.0)
I can't get outside	0		3 (1.0)	0		3 (2.5)	0		6 (1.4)
Missing	2 (0.7)		0	2 (1.7)		1 (0.8)	4 (1.0)		1 (0.2)

HRQoL

Mean quality of life scores decreased in both exercise completers and non-completers over the three time points (ANOVA: $p = 0.001$) (Figure 18 and Table 23).

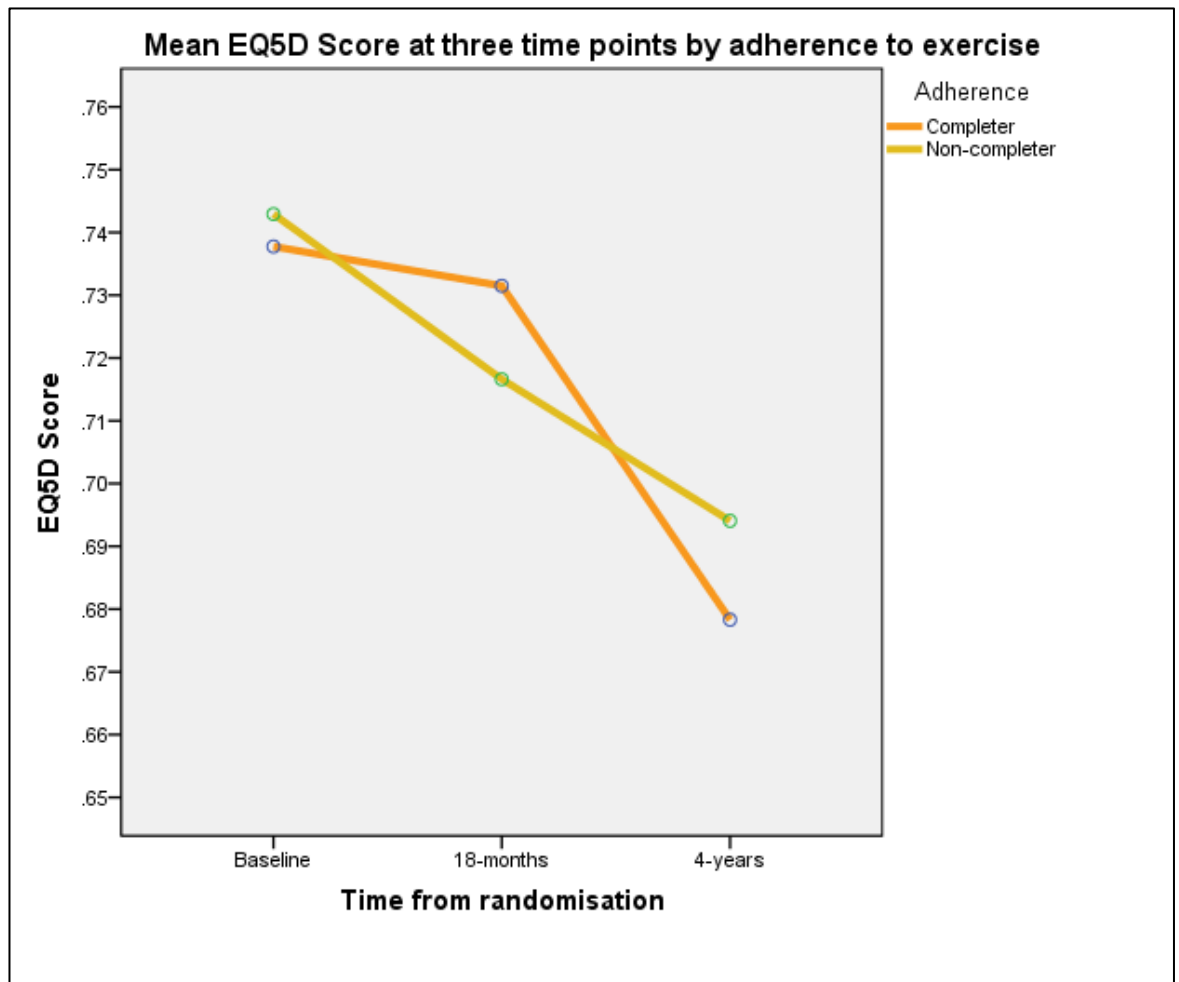


Figure 18. ANOVA with repeated measures to compare mean EQ-5D-3L Index Score over time by adherence to exercise (n=418)

Table 23. Health-related outcomes (HRQoL, frailty, cognition and general health) over time by adherence to exercise (n=418)

	Exercise completers (n=299)			Exercise non-completers (n=119)			Total (n=418)		
	Baseline	18-months	Four years	Baseline	18-months	Four years	Baseline	18-months	Four years
HRQoL, EQ-5D-3L ¹ Mean (SD)	0.74 (0.23)	0.73 (0.23)	0.68 (0.27)	0.74 (0.24)	0.72 (0.25)	0.69 (0.27)	0.74 (0.23)	0.73 (0.23)	0.68 (0.27)
Frailty, n (%)									
Frail	73 (24.4)	97 (32.4)	89 (29.8)	22 (18.5)	27 (22.7)	22 (18.5)	95 (22.7)	124 (29.7)	111 (26.6)
Non-frail	214 (71.6)	193 (64.5)	209 (69.9)	93 (78.2)	84 (70.6)	97 (81.5)	307 (73.4)	277 (66.3)	306 (73.2)
Missing	12 (4.0)	9 (3.0)	1 (0.3)	4 (3.4)	8 (6.7)	0	16 (3.8)	17 (4.1)	1 (0.2)
Clock drawing test ² , n (%)									
0-4	8 (2.7)		26 (8.7)	6 (5.0)		19 (16.0)	14 (3.3)		45 (10.8)
5-6	288 (96.3)		269 (90.0)	112 (94.1)		98 (82.4)	400 (95.7)		367 (87.8)
Missing	3 (1.0)		4 (1.3)	1 (0.8)		2 (1.7)	4 (1.0)		6 (1.4)
General health compared to 12 months ago, n (%)									
Better	18 (6.0)	49 (16.4)	29 (9.7)	9 (7.6)	13 (10.9)	13 (10.9)	27 (6.5)	62 (14.8)	42 (10.0)
About the same	217 (72.6)	194 (64.9)	165 (55.2)	91 (76.5)	83 (69.7)	71 (59.7)	308 (73.7)	277 (66.3)	236 (56.5)
Worse	57 (19.1)	48 (16.0)	101 (33.8)	18 (15.1)	19 (16.0)	33 (27.7)	75 (17.9)	67 (16.0)	134 (32.1)
Missing	7 (2.3)	8 (2.7)	4 (1.3)	1 (0.8)	4 (3.4)	2 (1.7)	8 (1.9)	12 (2.9)	6 (1.4)

¹ EQ-5D-3L scale range 0-1, where higher score indicates better HRQoL

² Clock drawing test scale range 0- 6, where higher score indicates better cognitive function

Frailty

A higher proportion of the completers were frail at baseline compared to non-completers (Table 23). However, over time the proportion of participants reporting difficulties on the Strawbridge questionnaire increased in both groups by 18-months then decreased at four years (Figure 19). Additionally, 34% of those with frailty did not complete the intervention, withdrawing from treatment before completing the programme (mean number of sessions attended = 3).

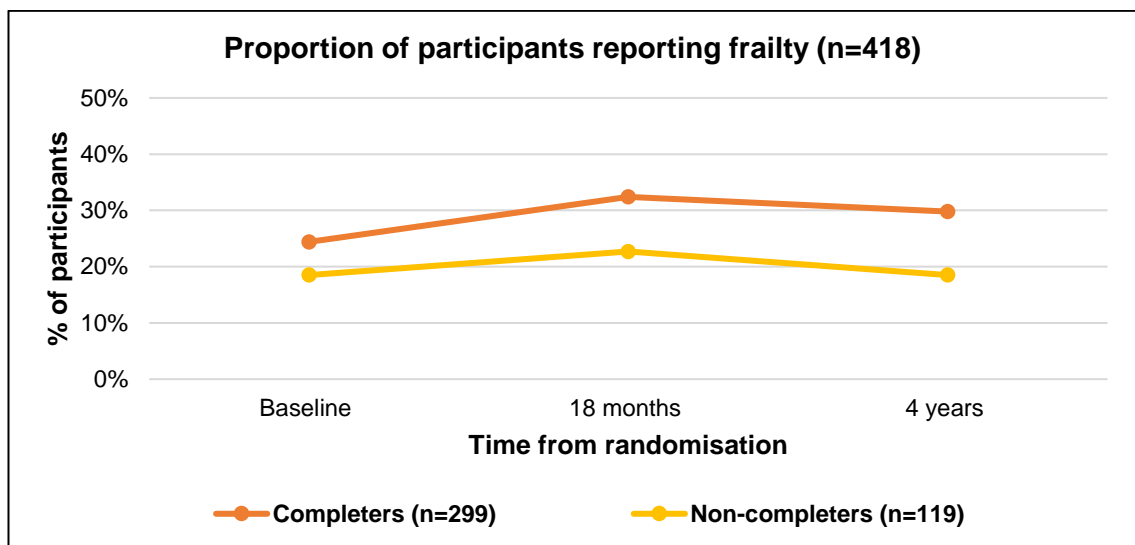


Figure 19. Proportion of participants reporting frailty over time by adherence to exercise (n=418)

Cognition

The majority of exercise completers and non-completers scored high (5 or 6) on the clock drawing test at both time points (Table 23).

General health

The majority of participants reported their general health to be about the same compared to a year ago at both 18-months and four years. However, there was an increase in the proportion reporting worse health in both groups over time (Table 23).

Exercise

The participants who took part in the exercise intervention completed strength and balance exercises and a walking plan as part of the programme. By four years, over half (58%) of the 299 completers were

undertaking strength exercises and 43% were doing exercises for balance (Table 24). A similar proportion of the 119 non-completers were carrying out strength exercises (58%) and one third (32%) reported doing balance exercises (Table 24).

Table 24. Exercise being undertaken at four years by LAFTEP participants offered the exercise intervention (n=418)

	Exercise completers (n=299)	Exercise non-completers (n=119)	Total (n=418)
Exercises for muscle strength in the past week, n (%)			
Never	124 (41.5)	49 (41.2)	173 (41.4)
1-2 days	88 (29.4)	29 (24.4)	117 (28.0)
3 or more days	85 (28.4)	40 (33.6)	125 (29.9)
Missing	2 (0.7)	1 (0.8)	3 (0.7)
Exercises for balance in the past week, n (%)			
Never	171 (57.2)	80 (67.2)	251 (60.0)
1-2 days	76 (25.4)	17 (14.3)	93 (22.2)
3 or more days	51 (17.1)	21 (17.6)	72 (17.2)
Missing	1 (0.3)	1 (0.8)	2 (0.5)
Other exercise in the past week, n (%)			
Never	162 (54.2)	62 (52.1)	224 (53.6)
1-2 days	78 (26.1)	27 (22.7)	105 (25.1)
3 or more days	58 (19.4)	29 (24.4)	87 (20.8)
Missing	1 (0.3)	1 (0.8)	2 (0.5)
Hours spent exercising in the past week, n (%)			
Less than 1 hour	16 (5.4)	7 (5.9)	23 (5.5)
More than 1 but less than 2 hours	62 (20.7)	15 (12.6)	77 (18.4)
2-4 hours	37 (12.4)	30 (25.2)	67 (16.0)
More than 4 hours	21 (7.0)	4 (3.4)	25 (6.0)
N/A	163 (54.5)	63 (52.9)	226 (54.1)

Association between exercise adherence and health-related outcomes

18-month follow-up

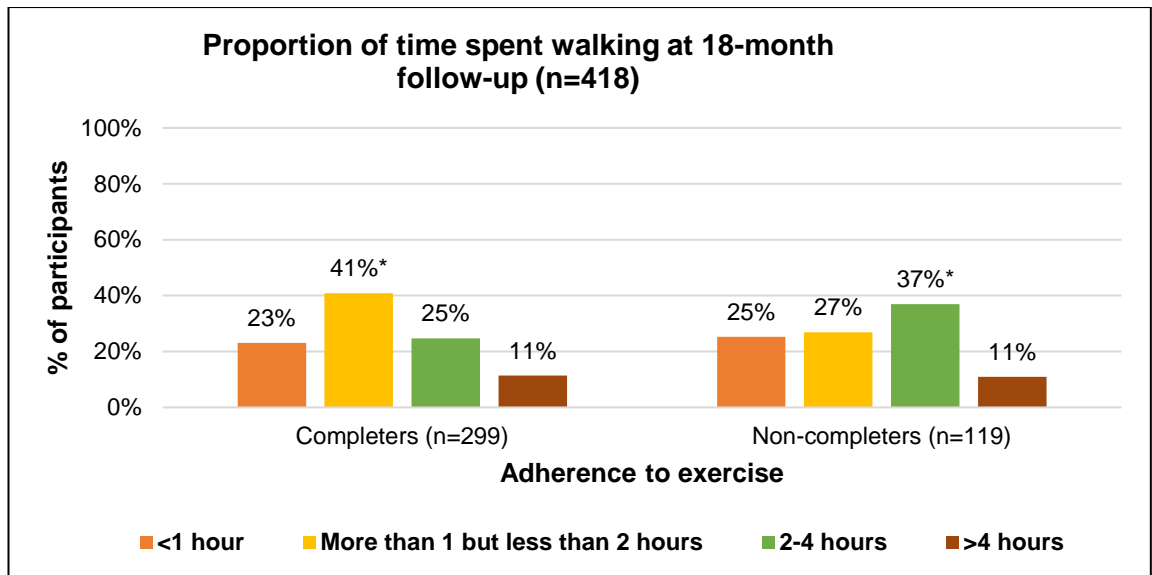
In the sub-sample of 418 participants invited for exercise, at 18-months, there was an association between adherence to exercise and time spent walking per day and also between exercise adherence and the sensory functioning domain of the Strawbridge frailty questionnaire (Table 25).

Table 25. Chi square test of association between health-related outcomes and adherence to exercise at 18-month follow-up (n=418)

Outcome	Exercise completers (n=299)	Exercise non-completers (n=119)	p-value
Mobility questions: <i>Hours a day spent walking:</i>			
None or <1 hour	69 (23.1)	30 (25.2)	0.02
1-2 hours	122 (40.8)	32 (26.9)	
2-4 hours	74 (24.7)	44 (37.0)	
>4 hours	34 (11.4)	13 (10.9)	
Missing	0	0	
Frailty: <i>Strawbridge Questionnaire</i> Sensory functioning			
Problem	141 (47.2)	39 (32.8)	0.01
No problem	151 (50.5)	74 (62.2)	
Missing	7 (2.3)	6 (5.0)	

Hours spent walking

There was evidence of an association with time spent walking where a higher proportion of completers walked one to two hours per day compared to non-completers (41% vs 27%; $p = 0.01$). There was also an association with walking two to four hours per day where a higher proportion of non-completers walked more than completers (37% vs 25%; $p = 0.01$) (Figure 20).

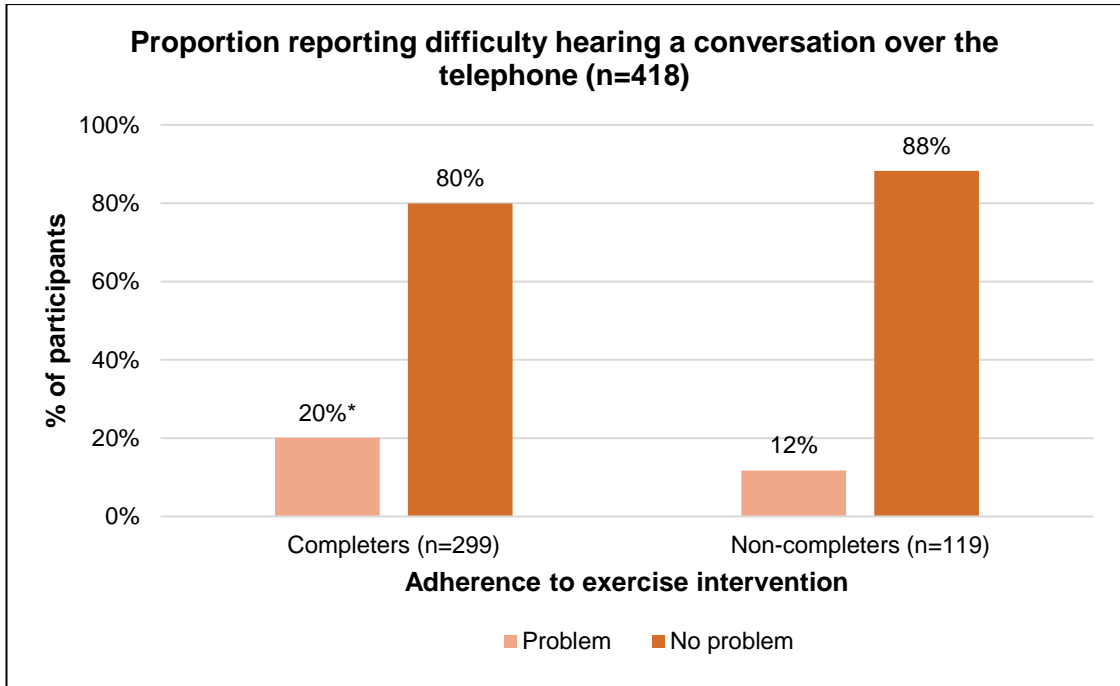


*P=0.01

Figure 20. Time spent walking (hours per day) at 18-month follow-up by adherence to exercise (n=418)

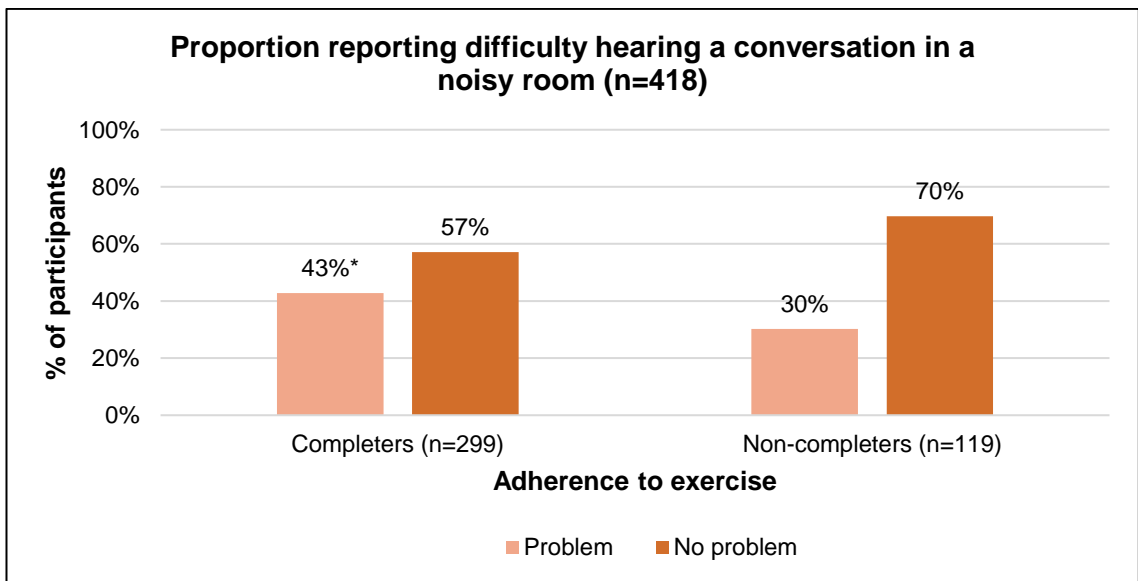
Sensory functioning

There are six items used to assess sensory functioning on the Strawbridge frailty questionnaire relating to vision and hearing (203). Using binary chi square tests, there was evidence of a significant association between adherence to exercise and difficulty hearing a conversation over the telephone ($p = 0.05$) and difficulty hearing a conversation in a noisy room ($p = 0.02$) where a higher proportion of exercise completers had a problem with these tasks compared to non-completers (Figures 21 and 22).



*p=0.05

Figure 21. Difficulty hearing a conversation over the telephone at 18-month follow-up by adherence to exercise (N=418)



*p=0.02

Figure 22. Difficulty hearing a conversation in a noisy room at 18-month follow-up by adherence to exercise (n=418)

Four-year follow-up

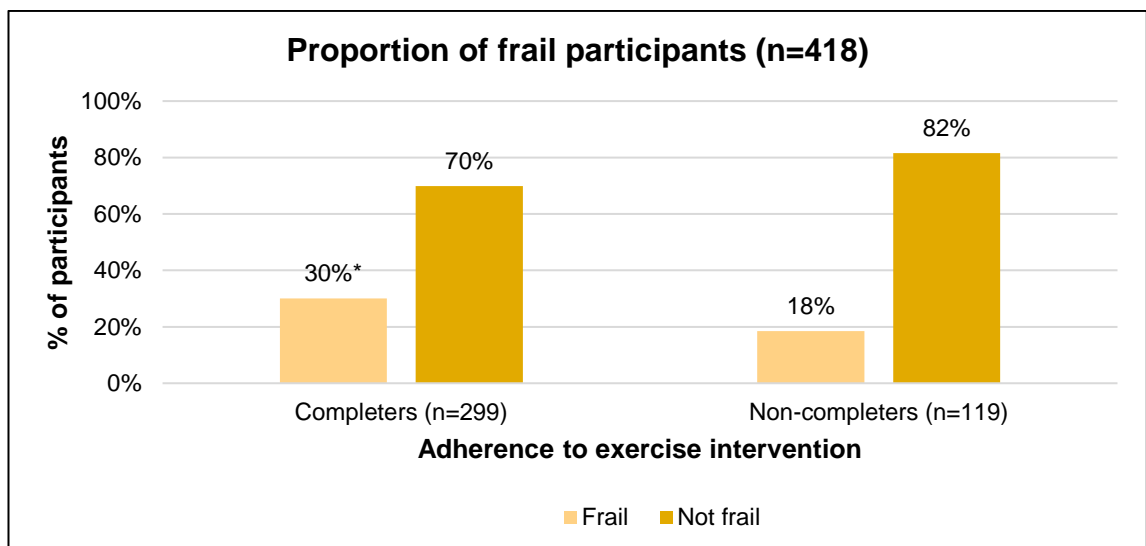
At four years there was evidence of a significant association between exercise adherence and frailty and exercise adherence and cognitive function (Table 26).

Table 26. Chi square test of association between health-related outcomes and adherence to exercise at four-year follow-up (n=418)

Outcome	Exercise completers (n=299)	Exercise non-completers (n=119)	p-value	
Frailty: <i>Strawbridge Questionnaire</i>	Frail	89 (29.8)	22 (18.4)	0.02
	Not frail	209 (69.9)	97 (81.6)	
	Missing	1 (0.3)	0	
Cognition: <i>Clock drawing test</i>	0-4	26 (8.7)	19 (16.0)	0.03
	5-6	269 (90.0)	98 (82.4)	
	Missing	4 (1.3)	2 (1.7)	

Frailty

There was evidence of a significant association between adherence to exercise and frailty at four years, where a higher proportion of the frail participants had participated in the exercise intervention (30% versus 18%; $p = 0.02$) (Table 26 and Figure 23). However, as described previously, over a third of those with frailty withdrew from the intervention before completing it.



* $p=0.02$

Figure 23. Proportion of participants reporting frailty at four-year follow-up by adherence to exercise (n=418)

Cognition

There was evidence of a significant association between adherence to exercise and score on the clock drawing test, where a higher proportion of

non-completers scored four compared to completers (12% vs 4%; $p = <0.01$) (Table 26).

Summary

There were no significant differences by adherence to exercise on proportion of participants reporting a fall in the previous year at baseline and extended follow-up. However, by four-years the proportion reporting a fall in the previous year had significantly reduced in both groups.

Over time, patterns of mobility were slightly different between groups, but these results were not statistically significant. However, a statistically significant increase in problems with balance and walking aid use was noted in both groups.

Perhaps somewhat counterintuitively, a higher proportion of exercise completers were frail at baseline compared to non-completers. However, over one third of those with frailty withdrew from treatment and did not go on to complete the intervention. Additionally, by four-years, nearly half of the exercise completers reported that they were not undertaking any strength exercises, whilst over 50% of the sample were not doing any balance exercises or other forms of exercise or recreational activity.

Similar to the cohort as a whole, in this small subset of the sample, overall, there was a decline in health outcomes over the longer-term.

The next part of this results section will explore the participants' experiences of the exercise intervention, and my interpretations of this data using Heideggerian phenomenology.

Section 2: Phenomenological Interview study

Introduction

This section of the chapter presents the themes and sub-themes drawn from the analysis of the participant interviews. These themes are presented separately, although they do interact. There is no hierarchy amongst the themes as all represent the participants' stories and experiences of participating in a falls prevention clinical trial involving exercise.

In keeping close to the participants' accounts, quotations are used to both illustrate and authenticate the themes, as well as highlight contrasting experiences or divergence within the themes. At times, quotations are lengthy to incorporate contextual information, whilst others have been edited to include only the text relevant to the theme; omitted text is represented by a triple dot ellipsis (...). To ensure participant anonymity, names have been replaced with pseudonyms and any other detail that might compromise participant confidentiality has been replaced with generic descriptors written within square brackets.

My forestructures

In choosing to use Heideggerian philosophy to underpin this research, I have rejected Husserl's notion of bracketing and, therefore, the following interpretations of the data and subsequent themes should be taken into consideration alongside my forestructures of understanding.

My Being-in-the-world includes 20-years' experience as a physiotherapist working either clinically or in a research setting, primarily with older people in both a rehabilitation capacity and in testing exercise-based interventions to treat a variety of health conditions including falls. My research background is very quantitative and although I have read qualitative literature, prior to this study I had never personally undertaken qualitative research.

My primary reason for undertaking this research was based on some anecdotal evidence from participants in the PreFIT study who reported that they would continue to exercise once their intervention ended. This led me to ask myself the question "I wonder if they did and if so, what effect has it had"? This has subsequently led to this point, where I have undertaken a

three-year PhD to answer this question, therefore, although I did not know the answer, I understandably had some preconceived ideas as to what I might find.

To help in answering this question I interviewed older adults who had participated in an exercise intervention that I helped develop and deliver as part of the PreFIT study. Therefore, I also had preconceptions about the exercise programme and kept these and all other presuppositions in mind throughout the interview process and during the interpretation of the generated data.

In this chapter, whilst presenting the rich descriptions of participants' experiences of a falls prevention clinical trial involving exercise, I will offer accompanying commentary explaining my interpretations and where appropriate I have included my preconceptions and notes from my reflexive diary and field notes.

Participant characteristics

The original aim was to recruit up to 30 participants. However, similar to the principle of data saturation (grounded theory terminology) (211), the size of the sample was considered adequate when interpretations were visible and clear and new participants no longer revealed additional information relevant to the topic (211, 249).

In total, 23 participants were interviewed between three and six years after randomisation to the PreFIT study. Participant characteristics (including pseudonyms) are described in Table 27. Twelve participants (52%) were female and mean age at time of interview was 81 years (range 74-93 years).

Three participants (13%) were at low risk of falls at the time of the intervention, therefore, had not been invited to participate in the exercise programme. However, it was considered important to interview some low risk participants, not only to capture their experiences of exercise and physical activity but to determine if their falls risk had changed from low to higher over time; if they had sustained a fall, how they dealt with it; and whether they perceived falls to be a problem in the same way as those who were at higher risk of falling. At the time of their interview all three low risk participants had

fallen at some point, one a long time ago and two, more recently, but not during the PreFIT data collection periods.

All interviews took place face to face (in the participants' homes) at their own request and mean interview duration was 43 minutes (range 17 to 63 minutes).

Introduction to themes

The aim of the interview study was to explore older adults' experiences of participating in a falls prevention clinical trial involving exercise. To uncover their experiences, interviews were used to capture each participant's story about their involvement in the trial, what it meant for them and their related experiences. Their stories often started with a brief overview of their reasons for participating in the trial and what it involved but they also relayed more in-depth experiences of falling, being active, what it is to be an older person and the importance of remaining independent. Figure 24 is an overview of themes and sub-themes.

Happy to help	Exercise behaviours	"It keeps me going"	"It wasn't a real fall"	Loss
Being involved	Benefits	Age is just a number	Playing it down	Narrowing horizons
	Good intentions		Normalising falls	Isolation
	"I don't do those exercises but..."		Emotions	
	Walking			

Figure 24. Schema of themes and sub-themes

Starting at the beginning of their stories, the first theme captures the reasons and motivations these older people had for participating in PreFIT.

Understanding what motivates these participants to take part in a clinical trial may be beneficial in the design, recruitment and retention to future clinical trials involving community-dwelling older people.

Table 27. Interview participant characteristics

Pseudonym	Age	Sex	Risk of falling (baseline)	Outcome of exercise intervention	Time between randomisation and interview	Length of interview (minutes)
Ann	85	Female	Higher	Completed intervention	4 years 8 months 4 days	16:53
Kath	76	Female	Low	Not eligible	5 years 1 month 18 days	29:29
Ted	89	Male	Higher	Completed intervention	4 years 11 months 21 days	24:11
Phyllis	86	Female	Low	Not eligible	5 years 0 months 7 days	25:58
Pat	88	Female	Higher	Completed intervention	4 years 11 months 17 days	30:16
Sylvia	81	Female	Higher	Eligible but declined intervention	4 years 11 months 17 days	31:51
Bob	75	Male	Low	Not eligible	3 years 11 months 356 days	48:32
Frank	88	Male	Higher	Eligible but declined intervention	3 years 7 months 244 days	29:12
Barbara	77	Female	Higher	Eligible but declined intervention	4 years 3 months 114 days	43:27
John	79	Male	Higher	Completed intervention	4 years 11 months 25 days	48:25
Deirdre	77	Female	Higher	Completed intervention	3 years 8 months 270 days	47:03
Tom	88	Male	Higher	Eligible but declined intervention	5 years 4 months 5 days	57:03
Barry	84	Male	Higher	Completed intervention	4 years 10 months 326 days	47:50
Phillip	74	Male	Higher	Completed intervention	3 years 10 months 309 days	52:56

Mary	80	Female	Higher	Completed intervention	6 years 4 months 135 days	51:44
Geoff	88	Male	Higher	Completed intervention	6 years 1 months 54 days	32:14
Donald	81	Male	Higher	Withdrew from intervention before completion	4 years 8 months 258 days	63:15
Alice	77	Female	Higher	Eligible but declined intervention	6 years 7 months 241 days	39:29
Charles	88	Male	Higher	Withdrew from intervention before completion	4 years 10 months 331 days	61:26
Sarah	77	Female	Higher	Completed intervention	4 years 10 months 331 days	44:03
Molly	93	Female	Higher	Completed intervention	4 years 8 months 245 days	59:53
Terry	76	Male	Higher	Completed intervention	4 years 8 months 245 days	38:06
Jane	89	Female	Higher	Completed intervention	5 years 8 months 8 days	53:41

Theme 1: Happy to help

Given the time lapse since their initial participation in the trial, some participants struggled to remember exactly why they had originally agreed to take part, however, they described their willingness to participate. Frequently, they agreed to help with the research either because the request came from their GP and/or they hoped it would be of benefit to others; they were very altruistic in their motivation:

“I was asked to, and I always try to cooperate” (Ann, 85)

“I’ve always gone along with everything that the [GP] surgery says...if they ask me to do something... yes I’ll do it...no other reason other than to say well ok it must be of some value to someone...you know...if it helps somebody” (Bob, 75)

Few participants mentioned falling or poor balance as a reason for taking part in the study but those that did were still altruistic in their motivation but hoped it might also provide some personal benefit:

“I just thought it can help anybody or even me then why not” (Ted, 89)

“I thought well I’m going to help...and that in a sense is gonna help me and I presume help other people as well along the way” (Terry, 76)

“Well... my balance has been getting worse and worse... I’m inclined to sort of fall or nearly fall and... mmm... and then I was just sent this I think... mmm...so I thought that sounds a good thing and I thought it’s nice to have you know to contribute to the whole literature of falls...” (Sylvia, 81)

It was not surprising that the reasons given for participating in the trial were mainly altruistic. Having worked on several clinical trials, I have often heard participants give selfless reasons for being involved, hoping their involvement might be of benefit to them but more often they hope it will be of benefit to others.

This is what Heidegger might describe as an 'authentic' existence; whereby Dasein chooses to live life with explicit awareness, aware of its own Being and taking hold of its own possibilities (218, 239), i.e. participating in the trial for the sake of helping themselves or others. However, the participants also alluded to the importance and influence of the role of health care professionals, in this case their GPs, as a motivator to take part. In exploring Dasein's encounters with 'others', Heidegger claimed that Dasein's existence is one of being 'with world' or 'Being with others'; an existence that is, however, often influenced by 'the they' (das Man) whom Heidegger depicts as an unspecified normative entity reflective of Dasein's social reality (218, 241). Ann and Bob appear to both be influenced by das Man in their reasons for participating in the trial, demonstrating 'inauthenticity' by passively and unquestioningly *"going along with everything the [GP] surgery says"*.

Being involved

The participants' stories progressed from why they got involved to what *being* in the trial involved for them personally. For some, it was just completing questionnaires and falls diaries, which overall, they found to be straightforward and simple. For others there was also the exercise intervention which they either declined to attend or started and then withdrew from or completed. Their recall of what they had to do varied:

"It was just ticking a box... daily" (Alice, 77)

"I think initially it was answering all the questions... the questionnaire and then from that I was asked to participate in... mmm... a course of exercises...and I had to go now and again down to see the nurse down at... mmm... [practice name] and so I completed that and then anything that's come through... any requests... any questionnaires recording how many times you fall in a month... although it looks a lot it doesn't take long to fill it in and they are just straightforward questions, nothing difficult at all, you can just go through it in minutes really" (Deirdre, 77)

“A lady who told me she was an occupational therapist was going to... was going to be my carer or minder if you like to do a series of exercises regularly and gave me a book of exercises... exercises to do at the time...” (Charles, 88)

This first theme sits well with Heidegger’s goal for phenomenology: discovering what is inherent in the understanding of Being by focusing on Dasein’s encounters with entities. In this instance, the entity might be considered to be the trial and/or the participants’ therapists and by enquiring as to why they participated in the trial, these older people understood their existence ‘authentically’ in terms of helping themselves and/or others or ‘inauthentically’ conforming to the influence of ‘das Man’.

Theme 2: Exercise behaviours

This theme covers a broad range of exercise experiences. Often, whilst relaying their experience of taking part in the PreFIT exercise intervention, the participants went on to describe other activities or exercise that they did, the reasons for doing so and what exercise means to them or what it means to be active.

Benefits

Overall, the participants who completed the intervention reported it to be beneficial. Some participants described a general benefit, without any specific detail, but Geoff, Deirdre and Pat were able to describe physical improvements including lower limb strength and balance. Interestingly, none of the participants mentioned falls prevention or reduction in falls because of the exercise programme:

“...I’ve felt the benefit from here on down... from my hips down...more than anything...and yes I enjoyed it at the end of it...I mean my little booklet there was wonderful” (Geoff, 88)

“I couldn’t see at the time exactly what it was going to do for me but now I can see the benefit of it... you know I just thought well I’ll do it... but obviously it has borne fruit...going to this group well one of the

other lady's in the class did comment on my balance being so good...well I said if it is then it's thanks to this course I had to do for Warwick University" (Deirdre, 77)

"I was pretty well balanced to start with but the only thing that... err... that struck me... mmm... there was a sitting down you know... getting up and sitting down so many times... err... at the end she timed me with a stop watch and after year and being a year older I was quicker than I was when I started. There was a change yes, yeah, yeah..." (Pat, 88)

"I think I probably had [improved]... I suppose I found them [exercises] surprisingly difficult...yes, yes, I could see some value in it to be honest... mmm... I would challenge anybody to go through those without a stumble...a bit of a wobble it.... it's really quite difficult...for something that looks incredibly simple. I saw the value of it and... and she [therapist] was excellent that you really felt that you were the only person that she was interested in... mmm... and the fact that I remember her name is... tells you something" (John, 79)

Conversely, some participants reported not feeling any better or any worse; they did not experience a direct benefit of taking part in the programme, but simply did it because they had been asked to:

"...as I remember they were standing on one leg and the other leg and walking tip to toe and then backwards tip to toe...I suppose [the exercises were] a bit boring in the end but I think I remember I was quite conscientious about doing it and I don't think it made me feel any better or any worse I just did it...I can't honestly say that I was any better at the end of that than at the beginning... I just did it" (Ann, 85)

"Yes, it was... it was a chore really... it wasn't a pleasure... it was just something that I've got to get through, and I've got better things to do" (Jane, 89)

For those experiencing benefits, the exercises might be considered as 'useful things'. This reflects how Dasein's understanding of things is influenced by the way that Dasein's own Being is an issue for it i.e. the exercises were deemed beneficial for some participants because they could see tangible improvements or changes in strength and balance.

On the other hand, since Ann and Jane reported no real benefit from the specific exercise programme, how the exercises manifested themselves will have been influenced by this outcome and their experience was that they were only doing them because they were told to (acting inauthentically by going along with 'the they'). Therefore, the exercises were not considered useful because a) they could not see any real benefits in doing them and b) they had no relevance to tasks or goals that were important to them.

Good intentions

In my exploration of the experiences of older people participating in a falls prevention clinical trial involving exercise and the impact of this on long-term health outcomes, I wanted to learn more about, and understand their experiences when the intervention came to an end. On completion of the programme, all the participants were encouraged to continue independently with their exercises. Those participants who enjoyed the intervention and found it beneficial described good intentions towards continuing with their exercise. Several of these participants were undertaking some of their exercises intermittently:

"As and when I feel like I need to do it..." (Phillip, 74)

"Some of them, yeah definitely yeah... and I do the lovely walking one where you do heel to toe forwards and backwards... I done that this morning... and I do all... well getting up out of the chair and these things like that and I stand on my toes every time I boil the kettle and as I am only 5'4" I've got to stand on my toes to reach the cupboards!" (Pat, 88)

“Well sometimes when there is an advert on television... I’ll stand next to the sideboard and I’ll try this business of lifting the leg and seeing how... do you know I can no more do that than fly and keep my balance...” (Molly, 93)

However, although some participants were able to demonstrate or describe some of their exercises, none was continuing with the whole exercise programme as it had been prescribed:

“I did them, but I was only... only doing them because I was expected to do them, but I’ve dropped back in to my old [habits]...” (Molly, 93)

“...I had to do them, and I had to because I’d promised I was going to do them, and I was intending to do that but after that, as I say, it’s just... you don’t make the effort to make the time because there’s other things going on...” (Deirdre, 77)

“...unfortunately, and I intended with all the best of intentions, but I didn’t I’m afraid...to carry on” (Jane, 89)

Some participants who had stopped their exercises reported that they would like to start them again. However, it is unclear whether they were saying this because they felt they should as I was interviewing them or because of a genuine desire to start exercising again. This co-constitution and interpretation of data, as described by Koch (262), is based on a combination of information provided by the participants, the context of the interview and my own Being-in-the-world and forestructures.

“Yeah what I can’t find is the initial book with the diagrams in it... unfortunately I haven’t done anything on it for the last year or two. I’d like to see that exercise book again actually and go through it again. Yeah, I would be interested to see it again” (John, 79)

“...but I’ve been thinking seriously now of getting back on with it again...” (Geoff, 88)

“...they said, ‘you should keep this going all your life really’ is what they said, and I keep meaning to start again but I never get around to doing it...” (Terry, 76)

These responses were not unexpected, as from my own personal experience and previous clinical experience, I know that changing exercise behaviours (in both older and younger patients) is a huge challenge. Molly and Deirdre’s descriptions allude to the importance of having someone supervising or facilitating exercise. They felt they had to do them because they had made a commitment to their therapist and to the trial to do so. Once that connection had come to an end so did their motivation to continue with their prescribed exercises.

Hearing that participants were completing some of the exercises some of the time is also a common occurrence for a physiotherapist. This highlights the misconceptions that people have about dose and intensity of exercise, whether that be due to poor explanation by the therapist or lack of comprehension or memory by the participant. In my experience, often, participants think that doing their exercises every now and then will have the same effect as doing them regularly.

These experiences of good intentions might also be considered in terms of Heidegger’s concept of inauthenticity. Molly and Deirdre both report exercising because they “had to” or were “expected to” and as such, might be considered to be acting under the influence of ‘das Man’; as they were being passive, unquestioningly doing what was asked of them. Yet when they described the experience during the interview they responded authentically, reporting that they had slipped back into old habits or were too busy with other things to continue exercising at the end of the intervention. This also suggests they were being or living authentically with regards to exercise i.e. exercising in their own way, for their own purpose and not to please others.

Some participants detailed the genuine barriers they faced to on-going participation.

“Well can I just say this...? I haven’t been sticking to it... because over the last two years I’ve had terrible kidney stones... and been busy as well... I’ve not felt like it... I was really ill... these stones I’ve never experienced anything like it... It went on for nearly a year... yeah a full year; in hospital three times!” (Geoff, 88)

“Yes, yes she came here one day somebody, and they had me toeing a line you know and... err... all sorts of bits and pieces but most... but a lot of them I just couldn’t do because when it came to balance... or the more you do it she said you know... I thought why don’t they listen to you... I am not going to get better I’m going to get worse you know” (Sarah, 77)

“I stopped doing them because my... my GP we’d been talking about them and he wasn’t at all happy about my doing this strength and balance... and he said, ‘no it’s too much for you...” (Charles, 88)

Sarah and Charles’ experiences are examples of Dasein’s mode of positive solicitude in ‘being-with’ others and in this instance, the mode of leaping in. The HCPs working with these participants both dominated them, taking over, assuming they knew best. For Sarah, this led to frustration, as she felt she was not being listened to and, therefore, was not being allowed to take hold of her own possibilities. Similarly, Charles’ GP, thinking he knew best and without any real discussion as to why or suggesting any alternative options, told him to stop attending an exercise group for strength and balance, which Charles did, and thus closed off his possibilities.

This is another example of potential inauthenticity of both the participants and HCPs. The participants went along with what they were told by ‘the they’, who, they often assume know best and the HCPs, who at times, thinking they know best, just tell patients or participants what to do, without any real explanation as to why. HCPs can leap in and try taking over the participants’ health problem for them, rather than leaping ahead explaining what the treatment options are and why they feel they are the best options, thus,

opening up possibilities which may be more appropriate for the participant's Being-in-the-world.

Leaping in as an HCP resonated with me and made me consider my own clinical practice and wonder what patients or participants really want from HCPs. Do they become dependent, wanting the doctor or nurse or therapist to leap in and take over their care or would they rather be in a leaping ahead situation where the HCP works with them to give the care back to them?

“I don't do those exercises but...”

Apart from health problems and lack of time, another reason for not continuing with their exercises, and common to a lot of the participants, was that they reported being active enough or being involved in different types of exercise or activities. These activities did not always include specific strength or balance exercises and, therefore, may not be what HCPs would consider appropriate for preventing falls. This theme highlights that older adults are active in many ways, choosing to exercise or be active in ways which are important, meaningful and enjoyable to them:

“I don't do those exercises, but I do... do exercises for... mmm... my knees but all in Pilates or Yoga...” (Kath, 76)

“I'm in a Thai Chi class at the beginning of this academic year which was run by the organisation called the... mmm... U3A...I've been going at least 3 times a week” (Charles, 88)

“...they have a gymnasium class in the morning and in the afternoon and if we stay in there's golf on the carpet...and play bowls” (Tom, 88)

“I do me own exercises! Well I just lay in the bed in the morning before I get out of bed I do me back exercises and me knees up to me chin and all sorts of manoeuvres but that's on the bed in the morning before I get up.” (Ted, 89)

Participants were aware that being inactive is not good for you, but again, highlighting personal choice, some described satisfaction in being sedentary:

“...well they always tell us the doctors and everybody that the worst thing you can do is just to sit in a chair and quite honestly I can't think of anything nicer than just sitting in a chair...reading a book or looking at the paper or something but... so one needs to make a bit of an effort not to just slump into that...” (Sylvia, 81)

“I'm a person who quite enjoys sitting down (laughs)...what I don't want to join in I don't, you know. If you enjoy... if you can do it... do it that's... that's what I say. My little friend downstairs is 90 and she loves walking and I mean if it's a dull day she's like a tiger in a cage she's need to get out and it really worries her... whereas I sit here and I think 'oh good it's raining out there' I'm quite happy (laughs)...Happy to stay in...” (Phyllis, 86)

Here, the participants describe what matters to them and what they enjoy, whilst also realising that their care structure may not always align with what is expected of them by 'the they'. These experiences exemplify how Dasein's *mood* and *thrownness* or past experiences can affect its possibilities and, therefore, how activities are undertaken and the importance that this part of the care structure can have on uptake and adherence to exercise.

Walking

Most commonly, the alternative activity was walking, whether specifically for exercise or for a purpose.

“I do try to walk a lot and in fact you...I have a pedometer...and this acts as a great goad really...if I do 1.5 kilometres, I'm happy...mmm... if like yesterday I didn't go out at all and it was 0.6 and I was very unhappy...” (Jane, 89)

“It's mainly walking for me I don't go and do... I don't go to the gym or anything (laughs)” (Kath, 76)

“...I do try to walk everyday but I can assure you it's not every day, but I try and make sure I go four or five times a week, but I only do about two or three miles I don't do masses” (Mary, 80)

“I think most elderly people can’t do anything but walk really” (Jane, 89)

For some participants, the meaning of exercise or physical activity and walking appeared to be inextricably linked.

“...well anytime you walk that’s physical activity isn’t it...” (Jane, 89)

“How do you mean physical activity... day to day living? Yeah, I don’t know I suppose I don’t think about it I just do it. Yeah just get on and do things. We always walk...” (Barbara, 77)

Jane comments that *“most elderly people can’t do anything but walk really”*. Walking appears to be the most accessible and manageable type of exercise for these older people because it is functional and can be incorporated into daily life. Therefore, exercise that is ready-to-hand i.e. something that can be used skilfully whilst forming part of their routine or they don’t have to think about, such as walking, becomes inconspicuous as an exercise. The emphasis these older adults place on walking highlights its importance, less as a means of exercise but perhaps more importantly for their referential totality (the relationship between Dasein, useful things and the activities it is involved in) of functional independence and quality of life. Similar to Heidegger’s analogy of the hammer (234) (page 40), these older people think of walking as something *‘with-which’* I am enabled to move around *‘in order to’* look after myself, get out and about and do the necessary tasks that I have to *‘for the sake of’* remaining an independent older adult and not being a burden to anyone else.

What is not clear from these discussions is whether the participants think that walking is an appropriate exercise for preventing falls. However, from my experience as a clinician and researcher, and from undertaking these interviews, I would interpret this emphasis on walking as an exercise to mean that older people think it is important for all types of health problems including falls prevention. Again, this highlights a potential lack of knowledge or understanding as to the long-term benefits of the specific exercises

prescribed in the PreFIT programme which is illustrated in the following quotes:

“I suppose I thought there was no need [to continue exercising] then I fell over!” (John, 79)

“I couldn’t do that now I’m certain I couldn’t do that now...now whether I would’ve still been able to manage it if I’d continued, I don’t know...” (Jane, 89)

This theme and sub-themes illustrate that older people have their own approaches to exercise and reasons to exercise or remain active. Their choice to exercise is determined by the stand they (as Dasein) take on their own existence; they base their choices on their mood, their possibilities, their thrownness and on what matters most to them (their care structure) and this appears to be maintaining mobility, independence and quality of life.

Theme 3: “It keeps me going”

This theme encapsulates the participants’ experiences of activity and why they felt it is important to be active, even if they weren’t undertaking specific exercises themselves. They also described barriers and motivators they perceive or believe others perceive to exercise and physical activity in general.

The most common motivator to exercise or be physically active was to “keep going”. This encompassed several things including remaining independent and capable of managing everyday life without help from others, maintaining physical and/or mental health and wellbeing and doing the things they want to do and/or enjoy for as long as possible:

“Well it keeps me going doesn’t it... again if you are sitting in the chair you start thinking that wart on your finger’s cancer... mmm...you know it’s... you’ve gotta have interests...” (Alice, 77)

“I don’t get other people to do it [gardening and jobs around the house] ... I want to do it because it keeps me going... I won’t... I won’t give...I

won't give in no... I couldn't imagine us just sitting I just couldn't... I don't want to...just don't want to" (Geoff, 88)

"...my idea of exercise is just continuing for as long as I can and that probably is my biggest fear that eventually I won't be able to continue... it is a quality of life... the quality of life that you've had... been used to... achieved... kept... in other words for 75 years why... why let it go in the last 10 or 20" (Bob, 75)

"I want to stay able to look after myself basically... to keep fit and to be able to manage things on my own...and to be proud of it" (Mary, 80)

"I want to keep as active as I can for as long as I can. Just keeping myself going and active and it keeps me free of pains and aches... (Barry, 84)

These exemplars illustrate what exercise and physical activity mean to these older people in terms of their referential totality. They appreciate the need to exercise *in order to* maintain physical and mental health *for the sake of* 'keeping going' and remaining independent. Thus, although Heidegger did not refer to the human body as a 'useful thing' or equipment, Benner's extrapolation to include the body as ready-to hand is a relevant concept in this referential totality and will be discussed further in relation to theme four.

Age is just a number

Many of the participants did not perceive their age as an obstacle to being active or "keeping going" and reported not feeling their age:

"I know it sounds ridiculous... I don't feel the age I am...I don't feel the age I am. I feel sorry for people I see who are the same age as me who are creeping about like geriatrics" (Kath, 76)

"When it started in October '13, I thought I don't fall over... mmm... I'm not old (laughs) why is... who is going to be interested in me...it's hard to believe I'm 79 and I look at people and think 'he's an oldie' and then you think well hang on a minute (laughs)... mmm... yeah you don't look at yourself in the mirror in that way you just... yeah it's

difficult to believe you are 79 whatever that means I don't know" (John, 79)

"...thinking you are old... you are old! I don't feel... I don't feel my age...and... err... hope I never will I am just grateful for what I've got. Cause I am active... yeah... yeah... and I'm lucky I suppose physically I haven't got that many aches and pains... mmm... just the odd one... if you make... if you dwell on them you can make yourself old you know" (Barbara, 77)

Instead, a lot of participants compared themselves to others, either wanting to be like other older people, using them as role models or conversely, not wanting to be like them:

"Well they won't exercise or don't want to exercise you know and they don't move around enough...I don't want it to be like that..." (Barry, 84)

"...my mother who was truly independent and I think if we could bring her back and ask her those self-same questions you are asking me I think her answer would be...she would not let this happen... she would not go into a home... she would not go into hospital... which you know was a motivation... it was a motivation not to fall apart... she achieved that objective and that's what I hope I will be able to achieve that you know how ever long we have if you can keep going right to the very end..." (Bob, 75)

"we've got some very good friends; he was 90 at the beginning of March and she's nearly 90... incredible... they are our role models... mmm... they are going to Mexico this year and they have a caravan... they go every year, every summer they go to France...tow the caravan for two months... it's good to have role models I think... they are incredible. They always look ahead...Yeah and that's as I say we all look at them as our role models. Yeah, they are they are really inspirational..." (Barbara, 77)

These experiences described by Barry, Bob and Barbara align with the 'ahead-of-itself' part of Heidegger's care structure. For these participants, their Being is an issue and on-going concern for them. In taking a stand on their Being, they compare themselves to others as a way of *projecting* themselves into possibilities i.e. they do or do not want to be like others they know. Therefore, they engage in their current activities for the sake of their possibilities, demonstrating that Dasein's on-going activity has a future dimension that cannot be ignored (234).

The participants also shared their experiences of other people's perceptions of them and their age. As the oldest participant that I interviewed, Molly talked a lot about her age but particularly about other people's perception of her age, how they treat her once they knew how old she is and how this makes her feel:

"I am just that little bit too old for joining in with the people who go to the local exercise groups and that... I feel that age does bother me... I think that people... err... I think that once people know your age as I said before that they tend to want to do things for you and they tend to say, 'oh she's 93 you know' and I think to myself well am I supposed to have two heads! Yeah and if they leave the age alone and... and let you get on with things but 'no, no you sit down are you sure you are alright there, are you sitting comfortably... you are not in a draught are you... no you should have a chair here' and you think 'don't do that... don't do it' It makes me feel cross sometimes ... I don't like it..."

(Molly, 93)

Similarly, Phyllis admits that a wheeled frame may be of significant benefit to her mobility, but she also admits that her pride and perception of what it means to be old are putting her off using one. This is a common occurrence that I encountered as a clinician; older people's reluctance to use walking aids as they don't want people to think that they are old, even if the walking aid might improve their quality of life.

“My son was trying to say to me to get one of these pushers you know... I dunno what they call them... it’s like a... [frame] on wheels yeah and... mmm... I’m too proud to do that I don’t want to do that. Well he think’s if I can push a supermarket trolley round a supermarket, I could do that and not get breathless which is probably right, but I don’t want to do that...that’s old ladies and I don’t want to be an old lady!” (Phyllis, 86)

Likewise, because of their age, Bob and Barbara have encountered other people’s preconceptions and expectations about older people and what they should look like.

“...in theory I should be coming up the street with a stick you know” (Bob, 75)

“...limited a bit perhaps. Mmm... slowed down... stopped doing things... mmm... acting old I suppose...stooped...” (Barbara, 77)

Dasein’s world, like useful things which are often taken for granted or scarcely noticed, becomes more conspicuous via what Heidegger called signs. Signs associated with ageing e.g. physical appearance, walking aids etc. can be interpreted in a variety of ways, but make the participants’ worlds more explicit to themselves and to others. This conspicuousness may manifest in the way they view their existence i.e. wanting to be like others or the opposite of others, but it can also conflict with their referential totality of wishing to remain independent, as once people know their age or even just assume their age based on the signs, they are often treated differently.

Theme 4: “It wasn’t a *real* fall”

Although not everyone mentioned falling as a motivator for participation in the trial or as a motivator to exercise, in exploring their experiences of taking part in the trial, participant stories often included the topics of falls. This theme describes the participants experiences of falling, what falling means to them and how they deal with it.

Although only one participant reported that they had never fallen: “No (falls) so far...no I’m careful where I put my feet” (Alice, 77), several participants described or intimated that their falls were not ‘real’, i.e. they could describe what they considered to be a legitimate reason for their falls, or their falls were their own fault and could have happened to anyone:

“I’ve had no falls; I remember one day I didn’t class as a fall... there was this step and a shiny carpet and... I went down from one step onto the other and I went down... but I don’t think it was a fall as probably you would think”. (Terry, 76)

As Terry alludes to, it is possible that older people have their own preconceptions or forestructures as to what constitutes a fall and there may be some mismatch between this definition and that used by researchers and HCPs. Another example of this occurred in Ann’s interview, when asked if she had ever fallen, she answered “no” and later in the interview went on to explain “I’ve never had a bad fall in my life” (Ann, 85). She does not consider any falls that she may have had as ‘real’ or worth mentioning because she would not describe them as a “bad fall”. Therefore, her interpretation of a fall is potentially very different to that of the standard definition and she does not consider herself to have fallen at all.

Similarly, if the participants could assign a reason for their fall, usually by describing it as a trip or slip or an accident as the result of some external influence, then it was not considered to be a ‘real’ fall:

“I have to be perfectly honest twice since I said I’d see you I’ve fallen over but not because I’ve fallen because I’ve slipped” (Kath, 76)

“...went around the table in the kitchen tripped over my own feet ‘cause I was probably leading with the wrong leg as I went round or something...” (Donald, 81)

“... I’m agile and I’m not dodderly so it’s a case of sheer accident or something; that’s not me being you know aged and old and no good... they’ve got just small paving’s and I stood on one and it tilted up and I

fell flat on me face and there was... eyes... (laughs)... yeah but that was just...pure accident” (Geoff, 88)

“I was hurrying one day to the lift and I... I fell and of course it bumped my nose and I finished up on the carpet... I realised that I was rushing forward, but it was really the soles on my shoes that had... err... just didn’t slide on the carpet so I think footwear and what you are wearing that’s an important thing” (Molly, 93).

“It’s usually my own stupid fault ‘cause I walk backwards, and I lose my balance and I fell over.” (Tom, 88)

Tom’s experience is slightly different; he implies that his falls are not ‘real’ because they are his own fault but at the same time, he does acknowledge losing balance as a problem. However, he does not appear to attach much importance to this problem or consider that there are reasons for poor balance which might be addressed.

This might be where Benner’s extrapolation to include the body as ‘ready-to-hand’ is useful. The participants consider their strength, balance and walking as being ready-to-hand i.e. something that is used with such familiarity it almost withdraws from the activities they are undertaking. That is until a breakdown (a disruption of the referential totality which results in the withdrawal of useful things or activities being reversed) occurs, and they come to undertake a task or activity and cannot do it because of a lack of strength or balance or because of the effects of a fall. However, rather than acknowledge a potential problem with strength or balance, the participants blame external things, which, normally ready-to-hand, become unready-to-hand instead i.e. the kitchen table or the paving slab. Molly’s example of her shoes is very pertinent as Cerbone gives the example: “most of us most of the time scarcely notice or feel our shoes as we walk” (234) (p.38), but for Molly, her shoes have become conspicuous to her. She does not consider the problem to be a lack of lower limb strength or decreased range of movement in her ankle causing her to have difficulties clearing the floor with

her foot, because these are not relevant to her as they would be to me as a physiotherapist; she considers the problem to be only her shoes.

I originally interpreted these participants' experiences as inauthentic, but with further consideration and reflection, I have realised that my forestructures were influencing this interpretation. These participants were being authentic in describing their experiences of falling; they are aware of and open about their falls and are explicit about what they believe to be the causes of their falls; choosing to act accordingly to take hold of their own possibilities. Their rationales for falling may, however, conflict with how HCPs would interpret the situation i.e. focusing on the underlying issues with strength and balance and decreased range of joint motion that meant that Molly could not clear the floor with her foot. As I did, HCPs might consider the participants to be inauthentic, denying their falls are real, so as not to be perceived or "labelled" as fallers because of the potential implications this can have; they wish to appear to 'das Man' as capable and self-reliant.

In contrast, for those experiencing a 'real' fall, or what was often described as a "bad fall", it usually involved a fall that happened for no reason, difficulties or inability to get up from the fall independently or a fall resulting in a serious injury:

"I assume a fall is if you just fall over for no reason..." (Terry, 76)

"I don't know what happened I just found myself on the ground... and I broke my arm very badly and was... I had to be in hospital and had an operation and got a great big thing along there with studs in... so... mmm... that was a bad fall" (Phyllis, 86)

"I was walking along... and then I was on the floor the next minute and my falls do seem to be rather like that... I don't really know why but I'm just sort of on the ground" (Sylvia, 81)

"I misjudged where the bridge was, and I went past it... fell over the little kerb that was there and fell into... down upside down...and it was half past ten so I couldn't call anybody... I didn't like to shout because

people were in bed and I... so I just pulled myself to be steady and just wait for my heart to settle down and how was I going to get myself back... I thought well I'm gonna find a way to do it so in the end I had to get up on my hands and knees... and because there are stinging nettles there, so I've had lots of stings and I crawled out... now that is the worst fall I've had" (Mary, 80)

These accounts from Phyllis, Sylvia and Mary offer more insight into what actually happened or happens when they fall and the significance and meaning this has for them. Experiences like these disrupt the participants' referential totality. Their familiarity with the world, which, similar to useful things can be taken for granted or scarcely noticed, suddenly becomes very apparent and the world announces itself. This kind of breakdown in the referential totality can lead to reversal of activity and will be explored in more detail in Theme 5: loss.

Playing it down

Even when participants described 'real' falls, some often went on to try to justify or explain why they think they fell. There were some contradictions in the way participants described falls and the importance they placed on these events. Although Mary described her latest fall as "the worst fall I've had" suggestive of it being a 'real' fall, she then went on to give a reason for the fall: "...definitely in the dark I wouldn't have done it otherwise I mean gosh no I am not that stupid!" It seems that even if the fall was very 'real' some participants want to attribute a reason to it and assume 'it could have happened to anyone'.

Similarly, Pat, 88, described one of her falls as what might be described as a 'real' fall, but she quickly changes the description of her experience from a fall to a trip which was not the result of any balance problems, and even though it resulted in a fractured hip, she still did not seem to attach much importance to it:

“Actually... mmm... I did... mmm... well I... I broke my hip about five or six years ago... I fell over in the garden gardening. Trip a trip. I didn't over balance or anything no... I tripped over just in the front here... I was in the hospital nine days I think... err... eleven days...”
(Pat, 88).

Pat's experience and Ann's description of never having had a *bad* fall suggests that some falls are not of significance or bad enough to be considered important to certain individuals; Pat even describes herself as *“not a falling down person”* despite experiencing recurrent, injurious falls. Linked closely with falls not being 'real', their importance is played down and the word 'nothing' was used in several instances to describe the fall; suggesting a lack of significance:

“... oh, I did fall again... usually I trip over something... but nothing... nothing terrible” (Barbara, 77)

“I've had one since; some of the steps down there... one day... one's shorter than the rest and of course your heel went, and I just sit down... again nothing... nothing...” (Geoff, 88)

There are, however, some contrasts to these experiences. For those who felt that falling was a 'real' phenomenon, the whole experience was more significant, and those participants described lasting consequences:

“Well I've got two broken wrists...” (Mary, 80)

“...from previous falls I've broken both my wrists...” (Molly, 93)

“It just sort of got worse and I kept falling you see and... mmm... and luckily I didn't do myself any harm apart from that one ...when... err... I did that [points to arm] ended up in [city] for a week having a skin graft” (Sarah, 77)

“... just slows me down terribly... around the house I mean because I suppose I feel so safe and there's always something to clutch onto... you know one doesn't feel so... mmm... constrained... but I just can't

do things... I am aware that I am liable to fall and so there are things that I can't do anymore (Sylvia, 81)

The significance of these 'real' falls and the subsequent consequences have situated the participants' in-the-world by disrupting the referential totality, making the events or experiences stand out; experiences that were potentially the time when things changed and became something different. Linked with Heidegger's temporality, the falls, although not an illness as Mackey describes (140), have disrupted the flow of time, slowing it down or interrupting the previous taken for granted way of being.

Normalising falls

Similarly, in normalising falls, some participants' experiences were that nothing could be done about their health conditions that they believe cause them to fall:

"So... mmm... of course you know there's nothing they can give me, and it will just get worse... I am not going to get better" (Sarah, 77)

"... but I can't get any better that's the trouble..." (Donald, 81)

As part of their experience of falling, and linked closely with the playing it down theme, some participants described the frequency with which they fall or the number of falls they have had. This highlighted the idea that falling is a normal part of their Being-in-the-world and almost acceptable or inevitable:

"They don't talk about it... some joke... 'Oh I went [fell] again you know'... 'What does the doctor say'... 'oh I haven't been yet, what can they do'..." (Alice, 77)

"... well you know I did have quite a lot of... well not a lot of falls but you know I noticed I was falling, and I was known for it... well very often I'm in... I think it was in last November I filled in a.... and I had several falls in that month..." (Sylvia, 81)

"... about three times a week" (Tom, 88)

Emotions

As well as physical consequences, participants also described how the experience of falling, whether 'real' or not, made them feel. Most described negative emotions, except for Geoff, 88, who told me *"it doesn't bother me, you know, I don't even think about it..."* More commonly participants felt unnerved, foolish or angry, which is somewhat contradictory to the laissez-faire attitude that some exhibited when 'playing it down' or 'normalising' their falls:

"Well it gives you a bit of a shake-up you know" (Molly, 93)

"...you know it was more the foolishness of falling rather than the actual fall... only that the foolishness of... of thinking well if I'd just been a little bit more careful" (Bob, 75)

"Err... cross! (Laughs) I think how stupid can you get (laughs)... No only to my pride" (Pat, 88)

"It shook me up a lot more than I thought it would to be honest... it disturbed me that it had happened... let's put it that way... I suppose it has shown me that the older you get the more vulnerable you are" (John, 79)

The vulnerability that John describes is also apparent in another emotion that is commonly experienced; fear of falling. Several participants described wariness of falling, being cautious and subsequent lack of confidence following a fall:

"It's not that I'm frightened... I'm very wary about falling... mmm..." (Donald, 81)

"It knocked your confidence to a degree; well to a big degree to be honest. I am much more conscious of walking now than I have ever been..." (John, 79)

"... I mean after those last two I have been petrified of going down again... Oh it has stopped everything at the moment yeah" (Sarah, 77)

Disruptions to the body as a useful thing as a result of falling can affect an older person both physically (fractures, bruises, lacerations) and/or psychologically (fear of falling). Consequently, whereas it was something they never considered before, the useful thing i.e. the body, becomes more conspicuous and people start to worry about falling, how vulnerable it can make them feel and, therefore, some older people become conscious of walking and how they are moving. This in turn can lead to reduced mobility, reduction in activity and social isolation.

Theme 5: Loss

Whilst discussing exercise and being active, some participants went on to describe different types of physical loss and limitations. These losses, or breakdowns in the referential totality, due to reduced mobility, ill health and falling, have ultimately resulted in activities being reversed; affecting levels of exercise, pursuits and participation and the consequences associated with this were also described.

Narrowing horizons

Sylvia describes a consequence of her physical limitations and falls as: *“horizons are forever shrinking”*, whilst Sarah’s fear of falling meant she has *“stopped everything at the moment, yeah”*. Due to limited mobility, fear of falling or poor health, participants shared their experience of activity restriction, either imposed by others or self-imposed.

Restrictions in mobility, activities of daily living (ADLs), hobbies and socialising were conveyed by the participants with a sense of loss or ‘giving up’ of things they used to do, places they used to go and people they used to see. This resulted in spending more time at home since the planning or organisation needed to get to places was more challenging than in previous times. Thus, a reduction in activity and getting out and about led to a narrowing of their horizons and might be considered as a restriction in the projection of Dasein’s possibilities.

“Well going... going places like I thought of going to [town name] is quite daunting and I couldn’t do it on my own... now it’s things like that you know... one’s horizons are forever shrinking... it has restricted me from doing things... on my quality of life yes because it has restricted me from doing things... horizons just closing down... you know somebody says shall we do this, that or the other... I have to think quite hard before I can say ‘yes’, or you know I have to be sure I should get a lift... I rely on other people...” (Sylvia, 81)

“... towards the end of last year... up ‘til then I would go down to my clubs and everything... you know but I don’t I don’t go to anything now... We’d go out for... on trips and things I should’ve gone last Friday to see... mmm... [artist name] at the [theatre name] in [town]... mmm... but I had to cancel that because I couldn’t... there was nobody that was going to wheel me were they so that was the end of that...” (Sarah, 77)

“...we’ve had to cancel a couple of holidays... which is a pity... we’ve still got one booked, but we’ll probably have to cancel it you know I can’t see me manoeuvring myself around much so... I don’t move much I’d realised yesterday lunch time I’d been sitting here all morning... mmm... and not moved...” (Donald, 81)

Whereas some participants had become accustomed to or accepted these breakdowns leading to a reduction in activity, others described their experience of not giving in to limitations and how they would feel if they were unable to project themselves into possibility i.e. were unable to get out and about:

“I would... I should deteriorate fast... I would if I couldn’t get out... I’ve gotta get out off around the town” (Ted, 89)

“Completely shattered... I should be... I should be desperately unhappy... err... yeah... mmm... if I couldn’t get out” (Pat, 88)

“... mind you if I couldn’t get around so well I had to stay in the flat the of whole time I wouldn’t want to be around at all... that’s how I feel about it...’cause it’s mixing with people that’s really my life really” (Molly, 93)

Jane was also able to share a recent experience of visiting somewhere she hadn’t been in a long time and the extremely positive effect this had:

“... I mean when I went the other day to [town] I felt a new women really because I felt I was in the world... in a different world not just [town] coffee shops... mmm... and I felt you know you feel normal again and like everybody else and I know you’ve got the rollator and what not... that 40 miles or whatever it was... is the furthest I’ve been this year...” (Jane, 89)

These contrasting experiences and especially Jane’s description of “being in a different world” show how Dasein is shaped by the world it inhabits and how at the same time, it constructs its world from its own experience and background.

Isolation

Loss was also experienced in terms of bereavement. Heidegger described Dasein’s existence as not one of “Being alone” but of “with world” and therefore, other people constitute part of human existence. Therefore, in some instances, loss of a spouse or friend led to significant changes to the referential totality including reduced activity and subsequently an increased risk of isolation, loneliness and potentially depression. Some participants were able to find ways to overcome this whereas others struggled:

“... the biggest blow to me was in October when a friend of mine who lived on the ground floor and we went out to lunch every week... she was a lovely person and then she was killed... it was it was awful... awful I couldn’t believe... my life has changed completely” (Jane, 89)

“I must admit there are some... there are times when I think oh God, I wish I was somewhere where I’ve got company you know...” (Sarah, 77)

“I don’t like being in the house on me own too long... I don’t like being in here on me own now... you don’t see many people you know now do ya.” (Ted, 89)

As Ted highlights, risk of isolation is a consequence of bereavement but for him and some of the other participants this was also a motivator to remain active:

“When you are on your own you do get lonely at times... mmm... and you have to do something... you know I make myself get out and do something if I’m feeling like that...” (Mary, 80).

“...my husband died 14 years ago and first of all I did everything myself I did the probate... I did everything and that was ok... that kept me busy and then I thought what am I going to do now... I will go to the library and I happened to notice that the library was putting courses on for the computer so I thought I will join this, so I joined” (Jane, 89)

“I go out... I go out somewhere pretty much... well I do go out every day because I make a point of it because I live alone yeah...” (Pat, 88)

Summary

The findings from this interview study highlight experiences that matter and are important to people as they age. Even though these older people were interviewed within the context of a falls prevention clinical trial involving exercise, and most had fallen at some point, the experience of falling fluctuates between an inconvenience which participants described as of no real importance or consequence, to a life changing event. However, as highlighted within the ‘it wasn’t a real fall’ theme, the playing down or normalising of falls was common. Given the emotions that were reported to

be caused by a fall, this may suggest an element of denial as a way of coping with the impact that falls can and do have for older people.

Participants acknowledged exercise and physical activity as being important and it was undertaken in a variety of ways for a range of personal reasons. As such, older adults exhibit individual agency or control; choosing what exercise or activities they feel are most appropriate for them, whether this concurs with health professional's advice or not. This is apparent in the "I don't do those exercises but..." theme which highlights that for some, despite having completed strength and balance exercises which they found to be beneficial, they choose to undertake exercise or activities that they prefer and perceive to have more personal relevance.

Heidegger purports that in its everyday activity, Dasein is always taking a stand on the kind of thing it is Being, not necessarily by declaring itself to be one thing rather than another, but in engaging in some activities or tasks rather than others (233). In this sense, these older people are taking a stand on the kind of thing they are being by choosing to participate in the activities and tasks that they enjoy and/or feel will be beneficial to their own personal goals which usually includes remaining independent, but interestingly was not preventing or reducing falls.

Section 3: Integration of results/findings

Introduction

The aim of this research was to use a mixed method design to answer the question: does a falls prevention exercise intervention have any long-term effects on health-related outcomes in older adults participating in a falls prevention clinical trial. To achieve this, results from a cohort study nested within the original PreFIT study have been integrated with findings from interviews with a sample of the cohort who were randomised to the exercise arm of the trial.

The questionnaire data were analysed quantitatively, using appropriate statistical techniques (and were presented in Chapter 6, section 1). The interviews were undertaken and analysed phenomenologically to identify themes and sub-themes (and were presented in Chapter 6, section 2). Results and findings were integrated based on the rationales of triangulation, complementarity and initiation (160).

A side-by-side joint display table (167) was produced (Table 28) to illustrate convergence (agreement of results), complementarity (results that complement one another), dissonance (contradictions in results) and silence (where one dataset produces some results or findings, and other dataset is silent on the same results or theme) (163, 169, 171) between the results of the questionnaires and findings from the interviews, in relation to the health outcomes of interest.

Falls

Although some of the interviewed participants reported recent falls i.e. since their participation in the trial, they were not asked directly if they had noticed an increase in their falls. Therefore, these qualitative findings cannot be used to support the quantitative results which show an increase in the proportion of people falling over time.

There is also only partial agreement between the two datasets as to the meaning or definition of a fall. The qualitative findings suggest that some

participants' explanation or perception of what a fall is, may be different to the definition used to collect the quantitative data. This may impact on how patients and participants report or record their falls and may be a reason for underreporting of falls. This has implications for the methods used to collect falls data in both research and clinical practice and will be discussed further in Chapter 7.

Mobility

The participant stories complement the quantitative results about mobility and time spent walking. However, there was only partial agreement, verging towards silence between the datasets about balance problems and falls. Although the quantitative results showed an increase in balance problems over time, on the whole, the participants rarely mentioned problems with balance during walking or poor balance as a cause of their falls.

HRQoL

Over time, the mean EQ-5D-3L index scores decreased in both treatment arms, indicating poorer HRQoL across the cohort. Although only a few of the participants directly mentioned quality of life during their interviews, several described events reflective of the decline in HRQoL scores. This partial agreement was particularly connected to the mobility and usual activities domains of the EQ-5D-3L.

Frailty

The prevalence of frailty in the LAFTER cohort increased slightly, over time. However, the term or concept of frailty was not used by any of the interviewees, and for the most part, there was silence between the two datasets on this particular topic. Without directly mentioning frailty, there were some instances where the participants described experiences that could be linked to the domains of the Strawbridge questionnaire i.e. cognition and John touched on frailty when he talked about vulnerability, but as a concept, frailty was not discussed. The quantitative frailty results might also be explained further by the qualitative results linked to the cognition and general health questions, described in the next sections.

Table 28. Integrated findings from LAFTER cohort and interview studies

	Quantitative results	Qualitative findings
Falls	<p>The proportion of participants responding to questionnaires at all three time points, reporting a fall, increased over time in both treatment arms</p> <p>There was no difference in the proportion of participants reporting a fall by treatment arm at all three time points</p>	<p>“...don’t think there were any occasions actually when I fell down while I was filling in the form... I’ve fallen down since!” (Frank, 88, balance problems only, declined exercise intervention)</p> <p>“The first one? In the garden on the slope my foot gave way and I went for about 10 or 20 yards on my backside... I’ve had one since...” (Geoff, 88 fallen once, completed exercise intervention)</p> <p>“When it [PreFIT] started I thought I don’t fall over... mmm... I’m not old (laughs) who is going to be interested in me...” (John, 79, fallen once, completed exercise intervention)</p> <p>“No not any down on the ground falls... did have a tumble out of bed... but that’s different from falling down” (Charles, 88, fallen once, withdrew from exercise intervention)</p> <p>“I had one fall and it’s the only fall that I can remember having... I keep saying whatever exercises I do I can’t see that I would’ve stopped falling because it was one of these falls you were up standing then you were on the floor...within a second” (Deirdre, 77, fallen once, completed exercise intervention)</p> <p>“No, never fallen...I have never had a bad fall in my life” (Ann, 85, fallen more than once, completed exercise intervention)</p>
Mobility Hours spent per day walking	Overall, the proportion of participants doing little or no walking increased over time; those undertaking	

<p>Difficulty balancing whilst walking</p> <p>Able to get outside</p>	<p>moderate levels of walking remained fairly stable and the proportion of very active participants decreased over time</p> <p>By four years, the proportion of participants reporting balance problems increased in both treatment arms</p> <p>Over time the proportion of people needing a stick or assistance to go outdoors increased in both treatment arms</p>	<p>“We try to go out most days and have at least an hour walk...yes, it’s the main activity...” (Terry, 76, fallen once, completed exercise intervention)</p> <p>“...it’s quarter of an hour from the car park to walk into the town so I have about an hour and a half walking around, that’s pretty well most days yeah...” (Pat, 88, fallen more than once, completed exercise intervention)</p> <p>“It’s usually my own stupid fault ‘cause I walk backwards, and I lose my balance and I fell over.” (Tom, 88)</p> <p>“I find if I walk, I get very breathless...and... mmm... and that puts me off walking quite frankly...my son was trying to say to me to get one of these pushers...I’m too proud to do that I don’t want to do that...that’s old ladies and I don’t want to be an old lady!” (Phyllis, 86, low risk, no exercise intervention)</p> <p>“Mainly walking...no I always walk with a stick I have done...for years and years you know it’s... err... more a prop...it’s something to hang onto” (Alice, 77, balance problems only, declined exercise intervention)</p> <p>“I don’t feel confident without the stick now. I think I gonna fall because if I haven’t got the stick!” (Ted, 89, fallen once, completed exercise intervention)</p>
<p>HRQoL: Mobility Self-care</p>	<p>Mean EQ-5D health-related quality of life index scores decreased over time in both treatment arms</p>	<p>“...on my quality of life...it has restricted me from doing things...well going... going places is quite daunting and I couldn’t</p>

<p>Usual activities Pain/discomfort Anxiety/depression</p>		<p>do it on my own...you know one's horizons are forever shrinking..." (Sylvia, 81, fallen once, declined exercise intervention)</p> <p>"At the moment I'm having to try and do it [cleaning] myself. It's awful...I don't actually like people in my...you know coming and doing I don't like it, but needs must you know" (Jane, 89, fallen more than once, completed exercise intervention)</p> <p>"if we start to lose it a bit through inactivity then how do you deal with that do you get a mass of cleaners in...do you get a carer in and I'm not one for that I... I don't want anybody what can I say... messing around with me..." (Bob, 75, low risk, no exercise intervention)</p>
<p>Frailty</p>	<p>Over time, the prevalence of frailty increased slightly in both treatment arms</p>	<p>"I suppose it has shown me that the older you get the more vulnerable you are!" (John, 79, fallen once, completed exercise intervention)</p> <p>"I can't always get the words I want out..." (Mary, 80, fallen once, completed exercise intervention)</p> <p>"I can walk from one room to another now and I've forgot what I've gone for you know and go back and think about it for a while and go back again..." (Frank, 88, balance problems only, declined exercise intervention)</p> <p>"... because of my deafness I like to get the phone a portable phone and... because I can put it on loudspeaker" (Jane, 89, fallen more than once, completed exercise intervention)</p>

<p>Cognition</p>	<p>Very few participants had cognitive impairment on recruitment, but the proportion with cognitive problems increased over time</p>	<p>“I get time muddled... my memory is not as good as it could be...I think it’s got worse” (Mary, 80, fallen once, completed exercise intervention)</p> <p>“...that’s the trouble when you get to my age you see...I can’t remember!” (Ted, 89, fallen once, completed exercise intervention)</p> <p>“I have... senior moments... my memory” (Ann, 85, fallen more than once, completed exercise intervention)</p>
<p>General health Compared to 12-months ago</p>	<p>At four years, the majority of participants in both arms reported their general health to be about the same. But there was an increase in the proportion of participants reporting worse general health compared to 12-months ago</p>	<p>“Yes, I’ve got COPD. No, no it doesn’t stop me!” (Alice, 77, balance problems only, declined exercise intervention).</p> <p>“...it progressed into discitis...which affected all my mobility and ended up... having an operation to clean the abscess off my spine” (Donald, 81, fallen once single faller with balance problems, withdrew from exercise intervention)</p> <p>“I’ve got osteoarthritis in the neck...and it’s... mmm... it’s affecting the blood supply to the cerebellum...So... mmm... of course you know there’s nothing they can give me, and it will just get worse!” (Sarah, 77, fallen once with balance problems, completed exercise intervention)</p> <p>“Unfortunately, about 18-months ago I had this silent heart attack... which I was completely unaware of... and the top man came along and said... ‘you will have to have a triple by-pass’” (Terry, 75, fallen once, completed exercise intervention)</p>

<p>Exercise</p>	<p>The proportions of participants completing strength, balance and other exercises at four years were very similar across both treatment arms</p> <p>The proportion of exercise completers and non-completers undertaking strength exercises and other exercises was very similar at four years</p> <p>The proportion of completers undertaking balance exercises at four years was higher than non-completers</p>	<p>“Yes, I’m actually doing them [exercises]...that’s the group I go to this afternoon and I think they’ve been really beneficial” (Deirdre, 77, fallen once, completed exercise intervention)</p> <p>“I’ve been going to strength and balance exercises at a weekly class...” (Charles, 88, fallen once, withdrew from exercise intervention)</p> <p>“I had to do some exercises... walking and standing on one leg and all that sort of thing yeah. Yeah, I did do them for a bit, but I am fairly active, and I do aqua aerobics and... mmm... I think I’m pretty active for my age!” (Barbara, 77, fallen once, withdrew from exercise intervention)</p> <p>“I try to walk rather than use the car... I do Scottish dancing once a week...I love it... I love it...I want to keep going as long as I can” (Ann, 85, fallen more than once, completed exercise intervention)</p> <p>“... she gave things to do at home which involved... err... standing in the corner with one foot in front of the other...mmm... that was for a minute ... no I stopped doing it... I couldn’t do it...” (Frank, 88, balance problems only, declined exercise intervention)</p> <p>“...standing on one leg and holding on the table and they say, ‘if you keep going, you’ll be able to stand without’ I said, ‘I won’t...it don’t make a bit of difference!’” (Ted, 89, fallen once, completed exercise intervention)</p>
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Cognition

Based on the clock drawing test, there was an increase in cognitive impairment in responding participants in both treatment arms over time. However, 88% of participants showed no sign of cognitive impairment at four years. By only interviewing participants who scored five or six on the cognitive screening test, I excluded people with moderate or significant cognitive impairment. Nevertheless, and potentially highlighting a discrepancy between the results, problems with memory was raised as an issue by six of the 23 interviewed participants. Their experiences and the way they described their problems did suggest that they were not particularly worried about these lapses in memory or were not deemed serious enough for them to do anything except find their own ways of coping as the need arose.

General health

The majority of participants recorded that their general health was 'about the same' as the previous year at both follow-up time points. However, by four years, the proportion of participants reporting worse general health than a year ago had increased.

At interview, participants discussed their experiences of general health with regards to long-term conditions that they were living with i.e. Chronic Obstructive Pulmonary Disease (COPD), osteoarthritis (OA), Parkinson's or acute medical events that had occurred unexpectedly i.e. discitis, cardiac problems, and kidney stones. Some of these conditions had resolved whilst others resulted in on-going problems.

Several participants were living well with their conditions and, therefore, converging with the quantitative results, considered their general health to be 'about the same'. However, others living with long-term conditions felt the opposite; their general health was deteriorating because of their condition and the subsequent effects it had, such as pain, reduced mobility and falls.

Exercise/Physical Activity

Of the 418 responding participants who had been invited to the exercise intervention, nearly 60% of completers and non-completers reported that they

were undertaking exercises for muscle strength at least once per week. Approximately half of completers and non-completers were involved in some 'other' type of exercise or activity and one third of non-completers were doing balance exercises, compared to 43% of completers.

The results about 'other' types of exercises are complemented by the experiences described in the "I don't do those exercises but..." theme from the interview study. Some participants were, completing their 'own' individual programmes at home, including exercises prescribed for other health conditions i.e. following cardiac surgery and OA. Additionally, other types of exercise were being undertaken including Scottish country dancing, aqua aerobics, and Pilates and the reasons given for participating in these activities were enjoyment, socialising and keeping fit to be able to continue to live independently. Falls prevention was never mentioned as a reason for exercising.

There was also some agreement between results, with regards to balance exercises. The results of the questionnaire show that balance exercises were least likely to be undertaken. This is reiterated by participants' experiences; some did not believe they had any issues with their balance whilst others described the balance exercises as the most challenging. They discontinued with these exercises because they did not see a need for undertaking them, they struggled to complete them or did not perceive any improvement or change in their balance over time.

Convergence coding

In addition to the joint display table, a convergence coding matrix (171) was used as a basis for exploring convergence and dissonance between the questionnaire results and interview findings with regards to the meaning and prominence of the results/findings and examples of themes (Table 29).

This table highlights that there was agreement between the two data sets in relation to the mobility and general health outcomes. There was partial agreement between the two datasets on all other outcomes except frailty, where there was silence.

Table 29. Convergence coding matrix to summarise similarities and differences between quantitative and qualitative datasets

	Convergence Code							
	Meaning and prominence of results and findings				Examples of themes			
Theme	AG	PA	S	DA	AG	PA	S	DA
Falls		•				•		
Mobility <i>Balance</i>	•	•			•	•		
HRQoL		•				•		
Frailty			•				•	
Cognition		•				•		
General health	•				•			
Exercise		•				•		

AG = agreement; PA = partial agreement; S = silence; DA = dissonance

Summary

Integrating the quantitative and qualitative data from this study has highlighted mainly convergence (either full or partial agreement of results) and complementarity of results about the health-related outcomes of interest. There were some instances of disagreement but not complete dissonance on both the meaning and prominence of results and coverage of findings; and there was silence from the interviews on the medical concept of frailty.

Chapter 7: Discussion

Introduction

There is high quality, consistent evidence for the clinical and cost-effectiveness of certain types of exercise programmes in reducing rate and risk of falls (14). There is, however, a shortage of quantitative and qualitative evidence for the long-term effects of such exercise programmes on health and health behaviours in the older population (18-20, 109). Although there have been some long-term follow-up studies of RCTs of falls prevention exercise programmes, these vary in methodology and duration of follow-up (29). Some studies have partially explored older adults' experiences, perceptions and ideas about on-going participation in falls prevention exercise post-intervention in studies examining the experiences of falls prevention services as a whole; but no qualitative studies have specifically explored on-going participation as a stand-alone issue (30).

The LAFTER study is the first mixed methods study to collect and integrate cohort study data and phenomenological interview study data to investigate the long-term effects of a falls prevention exercise programme on rate and risk of falls and other health-related outcomes.

A large cohort of participants from the advice only and advice plus exercise arms of a clinical trial were invited to complete a questionnaire up to six years post-randomisation. In parallel, a phenomenological interview study involving 23 participants from the exercise arm explored their experiences related to taking part in the exercise intervention within a clinical trial. The quantitative and qualitative data were analysed separately before being integrated.

The aim of this mixed methods study was to understand the long-term effects of falls prevention exercises by answering the following research questions:

1. Does involvement in a falls prevention exercise programme influence rate and risk of falling, mobility, and health-related quality of life, frailty, cognition and general health up to six years later?
2. Do health outcomes differ by adherence to prescribed exercise programmes?

3. What are the experiences of older people participating in a falls prevention clinical trial involving exercise?

Participant characteristics

Older adults, particularly the oldest old (over 80 years), are often underrepresented in health research despite their growing population (295). A quarter of the LAFTER cohort were over 80 years old (n=746). However, and perhaps unsurprisingly, the majority of those who returned a completed extended follow-up questionnaire were more likely to be younger when they were recruited to the trial.

An equal proportion of men and women responded to the LAFTER extended follow-up questionnaire; and those who responded had better mobility, cognition, health-related quality of life and were less likely to be frail on recruitment to the original trial than those who did not respond. Therefore, it is acknowledged that there is evidence of healthy respondent bias amongst the cohort who were followed up longer term.

Long-term effect of exercise on health outcomes

There were no long-term effects of exercise on falls or other health outcomes. There were no differences by treatment arm or by adherence to exercise over time. The overall health of this cohort of 2980 older adults declined in multiple domains.

Falls and the effects of exercise

There was no difference by treatment arm on the proportion of participants reporting a fall over time. Overall, across the whole cohort of 2980 participants, the proportion of people falling increased in both treatment arms over four years (Figure 10).

There was a difference in rate of falls over 18-months (significant) and over four years (non-significant) (Table 11). Rate of falls was lower in those participants responding to LAFTER from the exercise arm compared to the advice arm. This was potentially as a result of the exercise intervention, but these results are not consistent with the findings of the main PreFIT trial. Although PreFIT found there was an interim effect of exercise on rate of falls at eight-months, this was not sustained over 18-months follow-up (27). The

findings of LAFTER suggesting a difference in fall rates between the exercise and advice arms at 18-months and four years, is therefore, more likely explained by participant characteristics of the LAFTER cohort rather than long-term effects of the exercise programme. The responding participants were, on average, slightly younger and had fewer health problems compared to both those in the original study sample and compared to the non-responders to the extended follow-up questionnaire.

Adherence to exercise

In the sub-group analysis comparing exercise completers (those participants who had completed some or all of the exercise intervention) and non-completers (those who although invited, declined to participate in the exercise programme), there was no difference in the proportion of participants reporting a fall over the longer term (Figure 16). This might also be explained by the differences in participants characteristics, where the non-completers were more active, had fewer mobility problems, were less frail and had better general health compared to the exercise completers.

The number of exercise completers and non-completers reporting a fall in the previous year at four-year follow-up decreased compared to baseline, in both groups. A possible explanation for this is in the quantitative results which show that nearly 60% of both exercise completers and non-completers reported that they were regularly undertaking strength exercises; and between 30-40% were doing regular balance exercises at four years. These results are similar to the studies by Korpelainen et al (95) and Hars et al (60) who followed-up older adults who were still participating in their exercise intervention at 30-months and four years, respectively, and found positive long-term effects on rate of falling.

Quantitative results versus qualitative findings

There is, however, some dissonance between these quantitative results and data from the LAFTER interview study which indicates that those who participated in the exercise intervention stopped their specific falls prevention exercises once the supervised programme ended and, therefore, were not undertaking strength and balance exercises, long-term.

Although generalisability of qualitative research findings has been described as a conceptual transferability of the themes or ideas generated (211), it is acknowledged that the extent to which the findings from qualitative research are applicable to a wider population can be an issue (211). This is particularly pertinent to phenomenology which is the study of lived experience from the perspective of the individual experiencing the phenomenon (139, 215, 216). Therefore, the interview data from the sample of 23 participants who participated in the exercise arm of the trial may not be representative of or be generalisable to the larger cohort population of 2980, as a whole.

Alternatively, the difference between the quantitative results and qualitative findings may be due to over-reporting and social desirability. In an attempt to project a more favourable image of themselves to others, some participants may have answered the quantitative questions on exercise in a way they believed to be more socially desirable or acceptable, rather than giving the actual answer (296, 297). This social desirability links with Heidegger's concepts of 'the they' (the influence of an anonymous normative entity reflecting Dasein's social reality) and 'inauthenticity' (a conformist or passive existence) (218, 234, 239). In this situation, Dasein (the participants) define themselves and how much exercise they are doing based on what they believe 'the they' expect. This social desirability or inauthentic existence may have been more difficult to achieve or maintain during the face-to-face interviews.

Instead, and despite their good intentions, evidence of objective improvements in strength and balance, encouragement from therapists and perceived beneficial effects of the programme, the interviewed participants did not continue with their prescribed exercises after the supported intervention ended. However, they were happy to discuss their exercise behaviours and described the other activities they were undertaking i.e. "I don't do those exercises but..."

Reasons for discontinuing exercise

The reasons the LAFTER interviewees gave for discontinuing their home-based falls prevention exercises are supported by the findings from qualitative research exploring uptake and adherence to group-based falls

prevention exercise programmes (97, 116, 117, 123, 125). These included: health issues; lack of time; lack of on-going supervision; no longer perceiving a need; no perceived benefit; and preference for other types of exercise or activity. These results support those identified in the motivators/deterrents theme in my qualitative systematic review exploring the barriers and facilitators to continued participation in falls prevention exercises, where all of the evidence was from group-based exercise programmes (30).

This discontinuation of exercise is consistent with work by Rejeski and Mihalko (298) who concluded that older adults participating in supervised physical activity programmes do successfully increase their physical activity over the duration of the intervention, but maintenance of exercise behaviours is poor, once the supervised intervention ends. Similarly, in their systematic review of the long-term effectiveness of interventions promoting physical activity, Muller-Riemenschneider *et al* (299) found that without maintenance strategies in place, improvements in physical activity declines. Although these studies were reviews of physical activity rather than falls prevention exercises, the results may be transferable to exercises specifically for falls prevention in older adults.

It has been suggested that there may be some disparity between the strategies that older people are willing to accept for preventing falls and those that are evidence-based and most effective i.e. older people are not motivated to undertake regular strength and balance exercises or physical activity solely to help prevent falls (98, 134, 300). This was evident in the LAFTER study interviews, where no-one reported preventing falls as a motivator to exercise. Instead, reasons to exercise included a range of perceived benefits, such as improvements and maintenance of health and mobility linked to independence, enjoyment and socialising. It is, therefore, possible that the interviewed participants discontinued their falls prevention exercises because the very specific falls-related strength and balance exercises, which they were doing on their own, at home, were not considered as relevant to their motivations and needs, or what Heidegger would describe as Dasein's Being-in-the-world.

Agency

Using Heideggerian phenomenology and his concept of Being-in-in-the-world to interpret the data revealed that the participants interviewed for the LAFTER study chose to exercise or be physically active in ways and for reasons that were meaningful to them. Heidegger proposes that how Dasein understands things is influenced by the way that its own Being is an issue for it (234); Dasein is constantly 'taking a stand' on the type of Being it is by engaging in specific activities, tasks or roles (234). Therefore, how exercise or physical activity manifest themselves to these older people is based on their own ideas about their own existence and as such they used their own individual agency to engage in tasks that were beneficial and enjoyable.

Agency is defined as an individual's ability to act independently, making their own choices and decisions in pursuit of goals or values that they regard as important (128, 129). Another element of agency is an individual's choice and ability to bring about change in themselves (301). This element of change was also apparent in the LAFTER study, where participants used their agency to choose whether to continue with their strength and balance exercises and, therefore, change their exercise behaviours long-term or "*drop back into old habits*" (Molly, 93).

The participants articulated their agency in describing and explaining their own personal reasons for continuing or discontinuing with their exercises. These reasons were based on their own forestructures of understanding including their previous experiences and beliefs as well as those of society and their environment (129). These interpretations support the idea of agency that was highlighted as the analytical theme in my systematic review of qualitative literature exploring the barriers and facilitators to on-going falls prevention exercise (30).

It is important then that HCPs understand older peoples' individual rationales for exercising (30). An understanding of agency would allow HCPs the opportunity to work with individuals, using behaviour change strategies such as shaping knowledge, goal setting, setting graded tasks, self-monitoring of behaviour and habit formation (302). This would then give older people more skills and knowledge and, therefore, agency over their abilities and

capabilities to continue to exercise. Formal motivational-volitional behaviour change strategies, as highlighted in my systematic review of barriers and facilitators to on-going exercise, are, therefore, an extremely important element of falls prevention exercise programmes, which currently, are lacking (30, 303-305).

Exercise opportunities

As well as the ability and capability to continue with exercise, a further consideration with regard to participants' agency, is the opportunity to exercise. In the interview study, participants reported that on-going supervision or support from a professional is an important factor and potential facilitator to continued participation. Yet the provision of community-based falls prevention or strength and balance exercise programmes is extremely variable (117, 118, 306). Therefore, for participants who are willing to continue, but need on-going support, they may wish to join an appropriate group-based intervention, but a lack of service provision may curtail their opportunities.

These issues are highlighted and addressed in a recent (2019) report by the Centre for Ageing Better (306). The authors of 'Raising the bar on strength and balance: The importance of community-based provision' conclude that multiple stakeholders (commissioners; healthcare and allied healthcare professionals; exercise providers and instructors; and the voluntary and public and private sectors) should take responsibility for increasing older peoples' uptake of strength and balance activities.

Some key actions recommended in the report include the development of clear and robust referral pathways into exercise programmes and the vital role that HCPs have in supporting older adults in continued participation in exercise to maintain any improvements in strength and balance made during therapy (306).

Mobility

Most commonly, and consistent with previous research (58, 118, 122, 123, 307) the LAFTER interview participants described a preference for walking as their alternative activity to doing strength and balance exercises. This was

because walking was perceived as 'ready to hand' (234, 248) i.e. an accessible, enjoyable, sociable, convenient and necessary, functional part of daily life. This preference for walking was complemented by the quantitative results which showed that although the numbers of participants in both treatment arms doing little or no walking increased over time and the proportion of very active participants decreased over time; those undertaking moderate levels of walking remained comparatively stable over four years (Figures 11 and 17).

This is also supported by Haas et al (123) who reported that participants followed up for twelve-months after a 15-week falls prevention programme were more likely to walk as a regular form of on-going exercise than do specific exercises for falls prevention. However, although there is evidence that walking has health benefits including, but not limited to, improved cardiovascular and pulmonary fitness (308), there is no evidence that walking, as a single intervention, is effective at reducing rate or risk of falls and it has been associated with an increased risk of falls (14, 15, 80, 309).

Balance

High challenge balance exercises should be the main component of any falls prevention exercise programme (15, 79). The recently updated UK Chief Medical Officers' physical activity guidelines recommend that older adults "should maintain or improve their physical function by undertaking activities aimed at improving or maintaining muscle strength, *balance* and flexibility on at least two days a week" (53), (p.40). However, none of the interviewed participants in the LAFTER study were still performing all of the balance exercises they had been prescribed as part of the original trial.

Compared to strength exercises and other types of exercise, balance exercises were the least likely to be undertaken over the longer-term by study participants. Less than one third of those responding to the four-year questionnaire reported that they did balance exercises at least once per week in comparison to half doing exercise for muscle strength and/or undertaking other types of exercise (Table 19). These lower levels of regular on-going participation in balance exercises may account for the high proportion of participants experiencing problems with their balance over time.

The exercise completers were more likely than non-completers to be doing balance exercises at four-year follow-up (Table 24). This higher proportion may be due to exposure to balance exercises as part of the intervention and may be a contributory factor in the lower proportion of falls at four years compared to baseline. However, it is not clear whether participants still partaking in balance exercises (or any other type of exercise) were achieving an adequate dose of exercise i.e. high challenge, progressive, balance exercises at least three times per week (15).

Overall, participants appeared to lack knowledge and understanding as to what constitutes good balance, the effect of ageing on balance, what exercises should be undertaken to improve balance and the benefits and importance of such exercises. Interview study participants either did not perceive they had any issues with their balance or those who had tried balance exercises often found them too difficult. A qualitative study by Yardley and colleagues (100) explored older people's views of advice for falls prevention, and only one participant, from their sample of 66 older people, knew that balance could be improved and that risk of falling could be reduced by appropriate forms of exercise. Therefore, from a public health perspective, it may be appropriate to not only publicise the Chief Medical Officers' physical activity guidelines, but accompany the recommendations with links, informatics or signposts to detailed examples of the types of exercise that need to be undertaken and how to integrate them into daily routines.

Other health outcomes

There were either no or clinically unimportant differences in the other health outcomes by treatment arm or by adherence to exercise; thus, for outcomes of HRQoL, frailty, cognition and general health at 18-month and four-year follow-up.

Perceptions about falls and risk of falling

Regression analysis identified two risk factors associated with falling in the LAFTER cohort at four-year follow-up: increased age and being at higher risk of falling at baseline (Tables 12 and 13). These results are consistent with evidence suggesting that the chances of falling increase with age due to both

physiologic and pathologic changes and if older people have a prior history of falls (36, 38).

The majority of participants interviewed for the LAFTER study had experienced a fall, either during or since their involvement in the PreFIT study. Despite these previous falls, and the presence of other risk factors for falls, some participants did not consider themselves to be at risk e.g. *“I’m not a falling down person” (Pat, 88)*. In line with previous research, and Heidegger’s concept of Being-in-the-world, the LAFTER study found that some older adults do not consider falls prevention a priority and even those who have fallen and/or are participating in falls prevention interventions do not deem themselves to be at risk of falling (96, 97, 107, 122, 310, 311). Instead, the participants or Dasein understand and interpret falls based on their own Being-in-the-world and the way their own Being is an issue for it. Therefore, falls, which were often described as ‘not real’, just a ‘trip’, ‘sheer accident’, or ‘it could have happened to anyone’ were attributed to an immediate and definable cause such as illness; temporary inattention; a simple trip; or a totally unavoidable event, rather than a specific risk or vulnerability (100).

As well as discrepancies in their perception of risk of falling, the participants definition of what constitutes a ‘real’ fall may not match what HCPs or researchers would define as a fall i.e. “an unexpected event in which the participants come to rest on the ground, floor, or lower level” (6) (p.1619). This mismatch has potential implications for how older people may record or report falls.

Commonly, and as was the case in the PreFIT and LAFTER studies, epidemiological studies and clinical trials often capture falls data by asking participants to recall how many falls they have had during a specific time period (312). It has been suggested that this type of self-report measure can be inaccurate and subject to recall bias. Underreporting or overestimation of falls can occur as a result of general forgetfulness, denial, cognitive impairment and/or pride (197, 313-315).

To minimise the risk of recall bias, prospective falls data collection methods i.e. monthly calendars or diaries, are considered the gold standard, as they allow participants to record events in real time (6). However, follow-up telephone calls or face to face interviews may be necessary to collect more information about recorded falls or to capture missing data, thus introducing a retrospective element to this method.

The LAFTER participants' experiences, as described in the "It wasn't a *real* fall" theme suggest another potential reason for underreporting falls. If participants do not believe their fall was 'real', either because their interpretation of the incident i.e. their Being-in-the-world does not fit with the standard definition that researchers or HCPs provide, or because they have their own preconceptions of what constitutes a fall, they are, potentially, less likely to recall it retrospectively or record it on a prospective falls diary.

Although the ProFaNE definition of a fall came from a consensus conference involving user groups (6), data from the LAFTER interviews suggests that the definition may not fit with older people's Being-in-the-world, as it is perhaps clinically driven rather than evolving from patient perceptions and ideas. This, therefore, has implications for collecting information about falls. Careful and specific questioning may be required when determining falls history and this should be taken into consideration in the wording used when HCPs and researchers actually ask older people about falling over.

These interpretations of risk of falling and what defines a fall may also have an effect on uptake, adherence and maintenance of exercises specifically for preventing falls and may explain why strength and balance exercises were not perceived as necessary over the longer-term. Instead, as previously discussed, being able to walk; care for themselves and others; participate in activities that they enjoy; and manage their lives independently were much more important goals and reasons to exercise. Based on the experiences of the LAFTER interviewees, falls prevention became more of a priority once a fall interfered with everyday life or caused significant injury; only then did it become a 'real' fall.

Original contribution to knowledge

There is a dearth of studies following-up participants beyond two years after recruitment or randomisation to clinical trials of falls prevention programmes. Additionally, none of the long-term follow-up studies that have followed-up participants beyond two years include a qualitative element or mixed methods approach to better understand the meaning of the results.

To place this study in the current research evidence, I have completed and published two peer reviewed systematic reviews exploring the quantitative literature on the long-term effect of exercise interventions for preventing falls in community-dwelling older adults (29) and the qualitative literature on the barriers and facilitators to continued participation in falls prevention exercise after completion of a structured exercise programme (30).

The unique mixed methods design of the LAFTER study is the first research to make efficient use of clinical trial data to integrate a large cohort study and phenomenological interview study to produce evidence as to the long-term effects of falls prevention exercises on falls and other health-related outcomes. The study provides quantitative and qualitative evidence about the long-term effects (median of four years) of a well-established, evidence-based, falls prevention exercise programme incorporating strength and balance exercises on these outcomes after the supervised intervention comes to an end. This is also the first study to explore the long-term effect of a home-based, rather than group-based, falls prevention exercise programme. Integrating data in this way has produced results and findings that give a broader and deeper understanding, not only of what the long-term effects of exercise are but also why these observations arise.

Strengths and limitations of the study

Mixed methods

Despite the potential issues of bias within the cohort study and generalisability of qualitative findings, using a mixed methods approach has employed the strengths of quantitative research whilst concurrently representing the voices of the same participants with qualitative research (161). Using a mixed methods approach has provided the flexibility and depth

to answer the research questions more comprehensively than by using individual quantitative and qualitative methods alone.

There is some debate as to whether phenomenology which resides in a naturalistic paradigm can or should be used in post-positivist or pragmatic research which includes mixed methods research (165, 316). However, Mayoh and Onwuegbuzie (317) suggest that mixing phenomenology with other research methods is justified for the purposes of triangulation and complementarity. These rationales were identified in my decision to choose a mixed methods approach involving phenomenology.

In choosing a basic convergent design, I followed recommended techniques for integration which involved merging the data at the interpretation stage, discussing the results and how they compare as well as presenting them in a joint display table (166-168). I also chose to use Farmer *et al's* triangulation protocol (171) to compare the data about the health outcomes of interest, following their convergence coding scheme to determine the degree of agreement between datasets.

Prospective cohort study

The design and methods used in the cohort study were based on the key tenets of observational quantitative research. To answer the research question, valid quantitative measures were collected from an appropriate sample of participants and analysed using comparison groups.

The large sample for the nested cohort study were recruited from a robust, rigorous, falls prevention clinical trial; the largest undertaken in the UK to date.

The number of participants responding to the invitation to take part in the LAFTER cohort study (2980/4891; 61%) was good given the age of the population. Other studies following-up participants of falls prevention exercise interventions beyond two years report variable response rates to long-term follow-up. For example, of their sample of 134 older people, Hars et al (60) enrolled 52 (39%) participants into their four-year follow-up study. Whereas, Kim et al (93) achieved 85% (259/304) uptake to four-year follow-up and Pereira and colleagues (59) achieved 86% (196/229) response rate at 10-

years. The samples in these studies are considerably smaller than the LAFTER study.

However, as with all cohort studies, the results from the LAFTER study may be limited by a number of biases. There is a risk of selection bias or healthy responder bias in the cohort as those who did not participate had different characteristics compared to those who did participate (192). Additionally, those who either responded to decline or did not return a questionnaire were classified as non-responders. It is acknowledged that this data could have been presented separately as it is likely that there are also characteristic differences between those who replied to decline and those who did not make any contact.

Although using a self-report measure has allowed for data collection from a large sample of participants, response bias is widely accepted and acknowledged as a problem with these types of questionnaire. Fixed choice questions may have been misunderstood and they can lack flexibility, forcing participants to provide an answer that may not be quite accurate; or answer yes more than no (acquiescence bias) (297). As discussed earlier, respondents may answer in a way that they deem to be socially acceptable, especially on questions that they perceive as sensitive or that might result in them being judged negatively. Instead they may answer in a socially acceptable way to project a more favourable image (social desirability bias) (296, 297).

In using a nested design to compare outcomes between the two arms of the cohort over time, a further limitation of the design of the study was the restriction in available outcome measures and what could be followed-up. In repeating the measures used in the main PreFIT trial, only data on the same outcomes was collected and, therefore, may have resulted in a missed opportunity to collect other important outcomes from the LAFTER cohort.

Phenomenological Interview Study

The interview study was undertaken based on the philosophy of Martin Heidegger and thus I have aimed to understand the meaning of Being for the older adults participating in the study through interpretation, whilst

acknowledging my own fore-structures and preunderstandings (Chapter 6, section 2 and Appendix 8).

I have followed de Witt and Ploeg's (289) expression of rigour to achieve balanced integration, openness, concreteness and resonance and actualisation. The challenges associated with understanding and interpreting the older peoples' experiences is characteristic of Heidegger's concept of Being-in-the-world. However, given the lack of previous qualitative research into older adults' experiences of life after a falls prevention exercise programme, a Heideggerian approach has allowed for a meaningful exploration of the phenomenon; providing a broad and rich understanding of participants' experiences of what happens when a falls prevention exercise intervention comes to an end and how this effects health outcomes.

In interviewing a sample of participants randomised to exercise, I may have missed the opportunity to interpret experiences about broader participation in the trial or falls prevention interventions and exercise in the advice arm. Nevertheless, by interviewing a diverse range of exercise participants including those who were low risk or declined to attend for exercise, I do have a spread of experiences.

To meet the requirements of the ethics committee, an indicative interview schedule was produced and used. Such a guide is not deemed necessary when using a phenomenological approach and, therefore, may have undermined the very methods that I was using, particularly in early interviews when I was quite reliant on the schedule. It has been suggested that I could have made this point to the ethics committee but as an early career researcher, I did not feel confident to do so, but may think differently in future projects involving phenomenology.

It is possible that others may generate different interpretations and themes from the interview data, but I have been rigorous and explicit in the processes and methods that I have undertaken that have led me to my interpretations.

I have been reflexive throughout the process; placed the phenomenon of interest into context and as such, the participants' accounts of participating in

the exercise intervention of the trial were a synthesis of their overall experiences of being an older person; experiencing a fall and what that means; and their agency in decisions regarding exercise.

Reflections

The opportunity to conduct a mixed methods study, whilst totally new for me, and despite its challenges, is one that I have thoroughly enjoyed and hope to repeat in the future.

Having previously worked on quantitative clinical trials, I felt reasonably comfortable with the methods and processes of quantitative data collection and analysis. However, before I started this PhD, I do not think that I have ever really thought about my epistemology, nor do I think that I have ever regarded myself as a positivist, as I have always appreciated the importance of patient or participant experience in both my clinical and research work.

Choosing phenomenology as the philosophy behind the qualitative part of the study seemed quite straight forward as I knew the participants' individual experiences were going to be important to answer my research question. However, the intricacies of what phenomenology actually is and the different approaches to it were a steep learning curve. Fortunately, I was able to attend a Hermeneutic Phenomenology Institute Conference in Denver, Colorado to learn more about the philosophical underpinnings of phenomenology and Heideggerian concepts in particular. I supplemented this by attending a Hermeneutic Phenomenology Course at Robert Gordon University in Aberdeen. This reinforced the Heideggerian concepts that I had learnt about in the U.S., but also gave me some practical skills on how to conduct a Heideggerian phenomenological study, including interview techniques. As well as knowledge, these courses gave me the opportunity to meet and network with like-minded people, immersing ourselves in Heidegger; an experience which I look back on fondly as it affected me as both a researcher and more personally, as it has made me think about my own Being-in-the-world in a very different way.

When I reflect on my interviews with the participants, I know that some could have gone better, but with time, my techniques and abilities improved greatly.

I found my reflexive diary a great help to capture my thoughts and reflect on how the interviews went and I used this to help improve over time. For future work, I know that I need to do my best to leave my physiotherapist hat at the door when I go into an interview situation; but I have acknowledged how my forestructures, including my experiences as a physiotherapist and a researcher working with older people, may have affected the interviews and my interpretation of the data. And I believe that I have been rigorous in my methods, following a path towards a clearing where participants have revealed their experiences to me.

The key aspect of a mixed methods study, integration, was another aspect that proved challenging and I am grateful for the guidance that my supervisors gave to me to achieve this. I was also fortunate to be surrounded by an expert team who were more than willing to help me with any queries that I had, and I am truly grateful for their support. This is definitely an area that I would like to develop in as I feel that mixed methods research is crucial to answer important health research questions that I have for the future.

Summary

There were no long-term effects of exercise on falls or other health outcomes. There were no differences by treatment arm or by adherence to exercise over time.

The small differences in rate of falls by treatment arm and reduction in proportion of exerciser completers and non-completers reporting a fall at four years compared to baseline are most likely explained by participant characteristics of the LAFTER cohort rather than long-term effects of the exercise programme.

This is supported by the findings from the interview study which indicated that the older adults who had participated in the intervention were no longer undertaking their falls prevention exercises, long-term. These older people preferred walking and considered this as exercise as this was meaningful to them and their Being-in-the-world. Falls and exercising to prevent falls was not a priority for them until they experienced what they perceived to be a 'real' fall.

Chapter 8: Conclusion and Recommendations

The LAFTER study was undertaken to address the gap in the evidence regarding the long-term effects of falls prevention exercises. Existing evidence is limited, and findings are inconsistent, because of differences in type and duration of exercise intervention as well as length of follow-up post-intervention. There is also a dearth of qualitative and mixed methods research focusing specifically on the barriers and facilitators to on-going participation in falls prevention exercise after the end of a supervised intervention.

An individual, home-based, strength, balance and walking exercise programme of six-month duration delivered within the PreFIT trial did not have any long-term effects on falls or other health outcomes. There were no differences in health-related outcomes by treatment arm or by adherence to exercise over time. The observed differences in falls outcomes were small and likely explained by the characteristics of the responding cohort who were younger and fitter than non-responders.

A possible explanation for the lack of any long-term effects is that the participants stopped their strength and balance training once their supervised intervention came to an end. The reasons often given by older people for discontinuation of exercise are multiple. These include health problems; lack of time; lack of perceived benefit or effect; lack of perceived need or relevance; lack of on-going support from a therapist or HCP; and being active enough or already involved in different types of exercise or activities.

Therefore, continuation of falls prevention exercises post-intervention is as challenging as uptake to and adherence during exercise programmes.

Using a Heideggerian approach to underpin the qualitative section of this study has provided insight into older people's experiences of a specific health system. Concepts such as Being-in-the-world, forestructures, useful things, the care structure and time and temporality have been valuable to better understand that older people's participation in falls prevention exercise programmes is not necessarily based on a desire to improve balance or prevent falls, but rather to maintain independence. Additionally, older adult's perceptions of what constitutes a 'real' fall varies and differs from the

professional definition and interpretation of health care professionals. Thus, for some older people, participation in falls prevention exercise programmes may only be relevant when they experience what they perceive to be a real fall i.e. an event which may have an impact on their independence. This in turn may impact on uptake, adherence and on-going participation in preventative programmes aimed at reducing rate and risk of falls.

Clinical implications

Based on the results of this study the following recommendations are made for clinical practice:

1. Increase awareness about the importance of strength and balance exercises for older people, through public health campaigns, education and training. Promote and enable access to resources about what strength and balance are (including specific examples of exercises) and what they can do to improve or maintain it.
2. HCPs working with older people should explore both falls and the idea of “it wasn’t a real fall” to ensure they take an accurate falls history.
3. HCPs working with older adults should be able to explain the health benefits of walking; but explain that, for falls prevention, walking alone is not an evidence-based intervention.
4. HCPs delivering strength and balance exercise programmes, whether individually (home-based) or group-based, should consider including behaviour change techniques and take into account older people’s agency. They should use this knowledge and shared decision making to enable older people to make informed decisions about continuing with their exercises during and post-intervention.
5. Ensure there are clear and easy referral pathways from healthcare-based strength and balance interventions to community-led interventions and vice versa to support on-going maintenance of exercises.

Research implications

The areas arising from this study that have implications for research are:

1. A review of the definition and agreement over 'long-term follow-up' in falls prevention and other health interventions is needed to ensure standardisation and thereby improve the design, reporting and synthesis of research evidence.
2. Using mixed methods to integrate quantitative research methods with qualitative methods is possible, improves understanding and can be used to answer future health research questions.
3. More research into what HCPs can do or add to their exercise interventions to ensure that older people continue with strength and balance exercises post-intervention.
4. Ensure patients and the public are involved effectively to help shape the future of this field of research in a meaningful way.

Final reflections

Participation in life-long exercise is important to maintain accrued benefits from exercise interventions. It is important that all the relevant stakeholders understand the importance of an individual older person's agency and work with them to understand their needs and wants. For falls prevention this means finding ways to combine evidence-based strength and balance exercises with activities that are meaningful to older adults' Being-in-the-world; otherwise, the problem of falls will continue:

"I suppose I thought there was no need [to continue exercising] then I fell over!" (John, 79)

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Appendices

Appendix 1 - Long-term follow-up of exercise interventions aimed at preventing falls in older people living in the community: a systematic review and meta-analysis



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Systematic review

Long-term follow-up of exercise interventions aimed at preventing falls in older people living in the community: a systematic review and meta-analysis



Susanne Finnegan^{a,*}, Kate Seers^b, Julie Bruce^a

^a Division of Clinical Trials, University of Warwick, Coventry, CV4 7AL, UK
^b Division of Health Sciences, University of Warwick, Coventry, CV4 7AL, UK

Abstract

Background Fall-related injuries are the leading cause of accident-related mortality for older adults, with 30% of those aged 65 years and over falling annually. Exercise is effective in reducing rate and risk of falls in community-dwelling adults; however, there is lack of evidence for the long-term effects of exercise.

Objectives To assess the long-term effect of exercise interventions on preventing falls in community-dwelling older adults.

Data Sources Searches were undertaken on MEDLINE, EMBASE, AMED, CINAHL, psycINFO, the Physiotherapy Evidence Database (PEDro) and The Cochrane Library from inception to April 2017.

Study selection Randomised controlled trials (RCTs), cohort studies or secondary analyses of RCTs with long-term follow-up (>12 months) of exercise interventions involving community-dwelling older adults (65 and over) compared to a control group.

Data extraction/ Data synthesis Pairs of review authors independently extracted data. Review Manager (RevMan 5.1) was used for meta-analysis and data were extracted using rate ratio (RaR) and risk ratio (RR).

Results Twenty-four studies (7818 participants) were included. The overall pooled estimate of the effect of exercise on rate of falling beyond 12-month follow-up was rate ratio (RaR) 0.79 (95% confidence interval (CI) 0.71 to 0.88) and risk of falling was risk ratio (RR) 0.83 (95% CI 0.76 to 0.92) Subgroup analyses revealed that there was no sustained effect on rate or risk of falling beyond two years post intervention.

Conclusions Falls prevention exercise programmes have sustained long-term effects on the number of people falling and the number of falls for up to two years after an exercise intervention.

Systematic review registration number CRD42017062461.

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Keywords: Falls prevention; Exercise; Older adults; Long-term effects

Introduction

As the proportion of older people continues to increase, managing long-term health conditions, including the prevention of falls, remains a global public health challenge.

Fall-related injuries are the leading cause of accident-related mortality and disability for older adults [1], with 30% of those aged 65 years and over falling at least once per year, and risk of falling increasing with age [2].

Falls have a multifactorial aetiology, associated with identifiable and some modifiable risk factors, including lack of physical activity, and commonly, disturbances of gait and balance and loss of lower limb strength [3]. Appropriately designed exercise programmes have been established as an effective stand-alone intervention for reducing risk and rate of falls in community-dwelling older people [4].

* Corresponding author at: Warwick Clinical Trials Unit, Warwick Medical School, The University of Warwick, Gibbet Hill Road, Coventry, CV4 7AL, UK.

E-mail address: Susanne.finnegan@warwick.ac.uk (S. Finnegan).

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The UK physical activity guidelines are due to be reviewed and updated in 2018, but current guidelines recommend that adults aged 65 and over should be undertaking at least 150 minutes of moderate intensity activity per week. This includes muscle strengthening on at least two days and for those at risk of falls, incorporating exercises for balance and coordination on at least two days each week [5]. Best practice recommendations suggest that falls prevention exercise programmes should include moderate to high challenge balance exercises; must be of sufficient dose (2-hours per week for at least 6-months) and that ongoing exercise is essential [6].

As fall prevention interventions can take time to for benefits to accrue, the recommended follow-up period for fall prevention clinical trials is 12 months [7]. Few community-based randomised controlled trials (RCTs) of exercise to prevent falls extend data collection beyond this time point [8,9]. This is highlighted in a recent systematic review of exercise to prevent falls in older adults, where the mean (SD) duration of follow-up was 51 [27] weeks [6]. There is a shortage of follow-up data relating to the possible long-lasting effects of exercise in older adults, and uncertainty whether there is ongoing maintenance of any accrued benefit from exercise and changes to health behaviours beyond the end of a trial intervention [8,10]. It is an important public health question to determine whether prevention interventions are effective and potentially cost-effective in the long-term.

Therefore, the aim of this systematic review and meta-analysis was to determine whether there was any evidence for the long-term effects of falls prevention exercise programmes on rate and risk of falling for community dwelling older people aged 65 years and over.

Methods

This systematic review was conducted in accordance with the PRISMA guidelines [11]. The review protocol was prospectively registered on 11/04/2017: (CRD42017062461; https://www.crd.york.ac.uk/PROSPERO/display_record.asp?ID=CRD42017062461)

Selection criteria

This review included any study examining the long-term effectiveness of exercise designed to reduce falls in older people. Eligible studies included RCTs, follow-up studies or secondary analyses of RCTs where follow-up was conducted 12-months or more from the date of participant recruitment or randomisation.

Participants

Any study targeting community-dwelling (living in their own home, excluding long-term care) adults aged 65 years and over. Trials testing interventions designed to prevent

falls in hospital, or targeted at people with specific medical conditions such as stroke, Parkinson's disease and multiple sclerosis were excluded.

Interventions

Studies were eligible if the exercise intervention was designed to prevent falls. Eligible comparisons included 'usual care', a 'placebo' control intervention or another falls prevention intervention not involving exercise e.g. vitamin D supplementation, environmental modifications. Studies testing single component exercise interventions i.e. walking, or interventions with multiple exercise components i.e. a combination of two or more categories of exercise such as Tai Chi and walking were included. Multi-arm trials were included, but only those where one of the treatment arms was exercise alone (as opposed to exercise combined with other interventions such as medication or environmental reviews) with data reported separately compared to control.

Outcomes

The primary outcomes of interest were rate of falls and number of people falling. Studies that reported data on rate (incidence) of falls and/or number of participants sustaining at least one fall were included. Prospective data collection, using monthly calendars, postcards or diaries, is considered the gold standard for collecting data on falls [7,12]. However, RCTs often use postal questionnaires to capture falls data retrospectively by asking participants about previous falls over a specific period. Therefore, as per the Cochrane falls prevention reviews [4], we included both prospective and retrospective data collection methods.

Search strategy

Searches were undertaken on MEDLINE, EMBASE, AMED, CINAHL, psycINFO, the Physiotherapy Evidence Database (PEDro) and The Cochrane Library from the earliest record to April 2017. Studies published in the English language were included. Key search terms included relevant Medical Subject Headings (MeSH) and free text including falls, prevention, and exercise, physical activity, long-term and follow-up with modifications for each database as necessary. The search strategy is available in supplementary material Appendix A. In addition, reference lists of the included studies and other relevant texts were manually searched.

Data collection

Based on the selection criteria, titles and abstracts of identified studies were screened for possible inclusion (SF). Subsequently, full texts were assessed for potential inclusion. Pairs of review authors (SF and JB/KS) independently extracted data including the following study characteristics: study design, duration, and participant information, description of interventions, outcome measures and reported data.

Any discrepancies were resolved via discussion. Each exercise intervention was classified using the Prevention of Falls Network Europe (ProFaNE) taxonomy [13].

Assessment of risk of bias in included studies

The Cochrane Collaboration's tool for assessing risk of bias in randomised trials was used [14]. The following domains for risk of bias were assessed by pairs of review authors (SF/JB and SF/KS): random sequence generation (selection bias); allocation concealment (selection bias); blinding of participants (not possible to blind participants in trials of exercise interventions) and personnel (performance bias); blinding of outcome assessment (detection bias); incomplete outcome data (attrition bias); selective reporting (reporting bias) and any other bias [14]. Differences were resolved by discussion.

Measures of treatment effect

Outcome data were categorised by follow-up time point as either falls occurring between 12 to 24 months or beyond 24 months after recruitment or randomisation.

Rate of falls is the total number of falls per unit of time of falls monitoring e.g. falls per person years [4]. The rate ratio (RaR) compares the rate of falls between the intervention and control group within each study. The treatment effect of exercise on rate of falls is reported as an unadjusted incidence rate ratio (IRR) with 95% confidence interval (CI) if these were reported.

Where the RaR was not reported, this was calculated from the total number of falls divided by the length of time falls were monitored (person years) for participants contributing data. We calculated the standard error of the RaR using the formula given in the Cochrane Handbook for Systematic Reviews of Interventions [14]. The analytical approach assumed that participants were followed-up for the maximum period unless otherwise reported. When calculating the RaR, we used an available case analysis i.e. included data from every participant for whom the outcome was obtained at follow-up out of the denominator randomised [14].

Number of people falling at least once (risk of falling) is a dichotomous outcome and, therefore, was analysed as a risk ratio. The risk ratio compares the number of people who fell once or more. We extracted or calculated relative risk (RR) and 95% CI if reported.

Where trials had multiple exercise intervention arms but one control group, the control group was apportioned appropriately to prevent double counting [14].

Data synthesis

The primary analysis was an overall synthesis of the effect of exercise vs control on falls occurring within both specified time points of interest. Subgroup analyses were planned, as

pre specified in the protocol, to investigate whether exercise modality (single vs multiple exercise component interventions) and duration of exercise interventions and follow-up impacted upon outcomes. Exercise modality was grouped using the ProFaNE categories.

Duration of exercise intervention was categorised as <6 months, 6 to 12 months and >12 months. Each subgroup analysis was considered by length of follow-up i.e. between 12 to 24 months or >24 months from recruitment or randomisation.

All forest plots were compiled using the generic inverse variance method in Review Manager (RevMan 5.1). A random effects model was used due to expected clinical and statistical heterogeneity amongst the interventions. The I^2 statistic was used for measuring heterogeneity. This statistic describes the percentage of variability in effect estimates that is due to heterogeneity rather than chance [14].

Results

Study selection

Electronic searches generated 515 studies. After removal of duplicates and ineligible studies (Fig. 1), 29 studies were potentially eligible for inclusion. Five trials were excluded on full review because they did not follow up participants for longer than 12 months ($n = 1$) or report rate of falls or number of people falling ($n = 4$).

The systematic review includes 24 studies with 7818 participants. Of these, 16 were RCTs and eight were either cohort studies or secondary analyses of RCT data. Sample sizes ranged from 52 [15] to 1235 participants [16] with a median of 231 participants. Overall, 79% of the included participants were women; 11 trials (46%) included females only.

Four trials had two exercise groups for comparison with one control group [16–19]. For these trials, the numbers of participants and falls in the control groups were apportioned appropriately. A total of 28 comparisons were undertaken.

Study characteristics

Characteristics of the trials are summarised in Table 1. One USA trial [8] recruited participants aged 50 to 65 years but long-term follow-up was carried out ten years later, therefore, the mean age of the participants was 70.9 (SD 4.28) and 70.3 (SD 4.03) years in the intervention and control group, respectively. Another trial recruited adults aged 60 and older but mean age was 72 (SD 8.1) years [20]. A sensitivity analysis was undertaken on the primary analysis and exclusion of these studies did not change the direction or magnitude of summary of effect. These two studies were therefore included in the final analyses. Nine studies used retrospective falls data collection methods rather than the gold standard prospective falls diary method [8,9,15,16,21–25]. A post hoc sensitivity analysis was undertaken to explore impact on falls rate;

Table 1
Characteristics of included studies.

Study & design	Sample size	Inclusion criteria	Mean age (SD or range)	Type of exercise intervention ^a	Duration of intervention (weeks)	Duration of follow-up (months)	Control Intervention	Falls outcome measures/collection
Campbell 1999 (New Zealand) [10] Follow-up of RCT	233	Community dwelling women ≥80 years old who could move around their own homes independently and were not receiving physiotherapy.	83.9 (3.0)	Gait, balance and functional training; strength/resistance	52	24	Social visits and telephone calls	Number of falls collected using 12 monthly prospective falls postcards
Dangour 2011 (Chile) [21] Cluster RCT	984	Community dwelling men and women aged 65 to 67.9 years old who could walk unaided, were not seeking advice for weight loss and had an MMSE > 13	66.1 (1.0)	Gait, balance and functional training; strength/resistance; 3D (dance)	2 years	24	No intervention.	Retrospective self-reported incidence of falls and fractures
Day 2002 (Australia) [26] RCT	272	Community dwelling men and women aged ≥70 years; living in their own home; could walk 10 to 20 m.	76.1 (5.0)	Gait, balance and functional training; strength/resistance; flexibility	15	18	No intervention	Number of falls collected using monthly prospective falls postcards. Number of fallers
Ebrahim 1997 (UK) [22] RCT	165	Postmenopausal women who had sustained an upper arm fracture in the past two years.	66.4 (7.8) to 70.5 (11.0)	General physical activity	2 years	24	Placebo group – general advice and simple upper limb exercises	Retrospective self-reported number of falls.
El-Khoury 2015 (France) [27] RCT	706	Community dwelling women aged 75 to 85; with diminished balance or gait (taking ≥ 7 seconds to walk 6 m or unable to do four consecutive tandem steps)	79.8 (2.8)	Gait, balance and functional training; strength/resistance; flexibility	2 years	24	Information brochure	Number of falls and injurious falls collected using prospective monthly calendar postcards. Number of fallers. Fear of falling
Fitzharris 2010 (Australia) [28] Secondary analysis of RCT	272	Community dwelling men and women aged ≥70 years; living in their own home; could walk 10 to 20 m.	76.1 (5.0)	Gait, balance and functional training; strength/resistance; flexibility	15	18	No intervention	Number of falls collected using monthly prospective falls postcards. Number of fallers.
Freiberger 2012 (Germany) [19] RCT	216	Community dwelling men and women aged ≥70 years having fallen in the past 6 months or fear of falling.	76.1 (4.1)	(2 exercise interventions – strength and balance group and fitness group). Gait, balance and functional training; strength/resistance; endurance training	16	24	No intervention	Number of falls and injurious falls collected using monthly fall calendars.
Gawler 2016 (UK) [16] Secondary analysis of RCT	1235	Community dwelling men and women aged ≥65 years and physically able to attend group exercise.	72.4 (5.8)	(2 exercise interventions – FaME and OEP). Gait, balance and functional training; strength/resistance; flexibility; 3D (Tai Chi); general physical activity	24	24	Usual care	Retrospective self-reported number of falls and injurious falls during long-term follow-up period. Number of fallers.

Halvarsson 2012 (Sweden) [23] Follow-up of RCT	59	Community dwelling healthy men and women aged ≥ 65 years; fear of falling and/or at least one fall in previous 12 months	77 (67 to 93)	Gait, balance and functional training	12	15	No intervention	Retrospective self-reported number of falls. Number of fallers. Fear of falling.
Hars 2014 (Switzerland) [9] Follow-up of RCT	134	Community dwelling men and women aged ≥ 65 years; increased risk of falling based on self-report falls after the age of 65; balance assessment and frailty phenotype.	76 (6.6)	Gait, balance and functional training	45	48	Delayed intervention	Retrospective self-reported number of falls. Number of fallers.
Hwang 2016 (Taiwan) [20] RCT	456	Community dwelling men and women aged ≥ 60 years; received fall-related medical attention between Jan 2011 and Dec 2012; independently mobile.	72 (8.1)	3D (Tai Chi)	24	18	Lower extremity training	Number of falls collected using monthly prospective falls diaries. Number of fallers. Time to first fall
Kemmler 2010 (Germany) [29] RCT	246	Women: ≥ 65 years old.	68.9 (3.9)	Gait, balance and functional training; strength/resistance; flexibility; 3D (dance)	18 months	18	Wellness programme	Number of falls collected using monthly prospective falls calendars. Number of fallers and fallers with injuries.
Kim 2016 (Japan) [24] Follow-up of RCT	78	Community dwelling women aged over 75; diagnosed with sarcopenia.	79.2 (2.8)	Gait, balance and functional training; strength/resistance	12	48	Health Education	Retrospective self-reported number of falls. Fractures.
Liu-Ambrose 2005 (Canada) [17] Follow-up of RCT	98	Women aged 75 to 85 with a diagnosis of osteoporosis or osteopenia	79.0 (3.0)	(2 exercise interventions – Resistance Training Group and Agility Training Group) Gait, balance and functional training; strength/resistance	25	18	Stretching (sham exercise)	Number of falls collected using monthly prospective falls calendars. Falls risk.
Laukainen 2007 (Finland) [25] RCT	486	Adults aged 85 years and over with ≥ 1 risk factor for falling or ≥ 2 falls in past year	88.0 (3.0)	Gait, balance and functional training; general physical activity	16 months	16	Visit their physician without an intervention	Retrospective self-reported number of falls. Number of fallers.
McMurdo 1997 (UK) [32] RCT	118	Community dwelling postmenopausal women	64.5 (range 60 to 73)	Gait, balance and functional training	30	24	Calcium supplementation	Rate of falls (data collection method not reported). Number of fallers.
Patiil 2015 (Finland) [30] Secondary analysis of RCT	409	Women aged 70 to 80; living at home independently; fallen at least once in previous 12 months	74.4 (2.9)	Gait, balance and functional training; strength/resistance	24 months	24	No exercise	Number of falls collected using monthly prospective falls diaries. Number of fallers. Fall related injuries.
Pereira 1998 (USA) [8] Follow-up of RCT	229	Postmenopausal women not taking HRT	70.9 (4.28)	General physical activity	2 years	10 years	No intervention	Retrospective self-reported number of falls.

Table 1 (Continued)

Study & design	Sample size	Inclusion criteria	Mean age (SD or range)	Type of exercise intervention ^a	Duration of intervention (weeks)	Duration of follow-up (months)	Control Intervention	Falls outcome measures/collection of falls. Number of fallers.
Suzuki 2004 (Japan) [15] RCT	52	Community-dwelling women aged 75 to 90 years living in Koganei City and able to attend a Comprehensive Geriatric Assessment	77.68 (3.41)	Gait, balance and functional training; strength/resistance; flexibility; 3D (Tai Chi)	24	20	Advice pamphlet	Retrospective self-reported number of falls. Number of fallers.
Taylor 2012 (New Zealand) [18] RCT	684	Aged 65+ (55 years if Maori or Pacific Islanders to account for ethnic disparities in health); at least one fall in the previous 12 months or considered to be at risk of falling (FRAT).	74.5 (6.5)	(2 exercise interventions both Tai Chi but of different frequency i.e. once/week or twice/week) 3D (Tai Chi)	20	17	Low-level exercise	Number of falls collected using monthly prospective falls calendars. Number of fallers.
Uusi-Rasi 2015 (Finland) [31] RCT	205	Women aged 70 to 80 years; living at home independently; had fallen at least once in the previous year; no use of vitamin D and no contraindication to exercise.	74.4 (2.9)	Gait, balance and functional training; strength/resistance	24 months	24	Placebo without exercise	Number of falls collected using monthly prospective falls diaries. Number of fallers and injured fallers.
Yamada 2010 (Japan) [33] Pilot RCT	60	Community dwelling adults ≥65 years old; MMSE of 24 or greater; able to walk independently (or with a stick); excluding those with other comorbidities such as PD or stroke	79.5 (6.2)	Gait, balance and functional training	16	16	Walking exercise	Number of falls collected using monthly prospective falls diaries. Number of fallers.
Yamada 2012 (Japan) [34] RCT	157	Community dwelling adults ≥75 years old MMSE of 24 or greater; able to walk independently (or with a stick); excluding those with other comorbidities such as PD or stroke	85.8 (5.9)	Gait, balance and functional training	24	18	Simple course with obstacle negotiation	Number of falls collected using monthly prospective falls diaries. Number of fallers.
Yamada 2013 (Japan) [35] RCT	264	Community dwelling adults ≥65 years old MMSE of 24 or greater; able to walk independently (or with a stick); excluding those with other comorbidities such as PD or stroke	76.2 (8.5)	Gait, balance and functional training	24	18	Indoor walking programme	Number of falls collected using monthly prospective falls diaries. Number of fallers.

^a ProFANE classification of exercise.

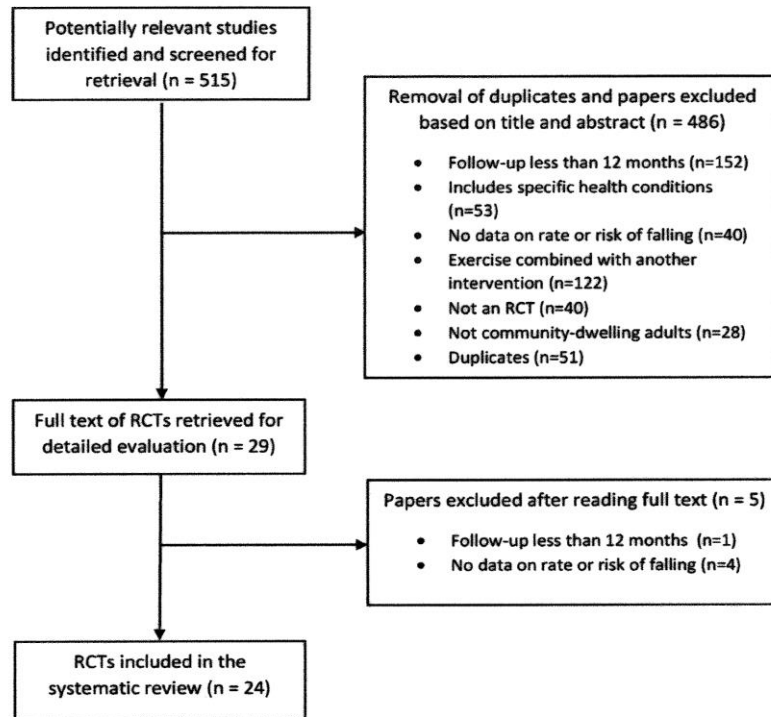


Fig. 1. Flow diagram of search and study selection process.

exclusion of these nine studies did not change the magnitude of the effect estimate, therefore, all studies were included in the meta-analysis.

Interventions

Of the 24 included studies, 15 (63%) tested multiple exercise component interventions [10,15,21,24–31] and nine (38%) tested a single exercise intervention [8,9,20,22,23,32–35]. Four of the studies compared two exercise interventions: two compared multiple exercise component interventions [16,19], one compared a single component intervention and a multiple exercise component intervention [17] and finally, one tested a single intervention of different frequencies of Tai Chi (3D) [18].

All but four trials [8,18,20,22] included gait, balance and functional training within the exercise intervention. These four studies investigated either single 3D interventions of Tai Chi or general physical activity i.e. walking.

The duration of exercise intervention varied from relatively short-term interventions of less than 6-months duration (range 12 to 20 weeks; $n = 7$ studies) [18,19,23,24,26,28,33], those lasting between 6 and 12 months ($n = 9$ studies) [9,10,15–17,20,32,34,35] and those testing exercise inter-

ventions of longer than 12-months duration (range 12 to 24 months; $n = 8$ studies) [8,21,22,25,27,29–31].

Duration of follow-up

The range of follow-up time points from recruitment or randomisation varied across the studies from 16-months to 10 years. Twenty-one (88%) studies followed participants up for between 12 to 24 months. Of these, seven trials [21,22,25,27,29–31] collected outcome data from participants immediately at the end of the exercise intervention at either 16, 18, or 24 months. Eight trials collected follow-up data 12-months after the intervention ended [10,17,18,20,23,33–35]. The remaining nine studies collected outcome data at 14 months [15,26,28], 16 months [32], 20 months [19], 37 months [9], 45 months [24] and 10 years [8] after delivery of the exercise intervention.

Outcomes

Rate of falls were clearly reported in 11 studies and was calculated using reported data for 12 studies. The remaining study did not include sufficient data to calculate falls rate but

did report results on risk of falling. Data on risk of falling (number of people falling) were available for 18 studies.

Risk of bias within studies

Risk of bias for each study is shown in Fig. 2. Based on the overall key risk of bias items, 13/24 (54%) studies were rated low risk of bias (three or more items judged at low risk). For individual risk of bias items, half (12/24) failed to adequately describe either sequence generation or allocation concealment. Almost all studies (23/24; 96%) were judged at high risk of performance bias, as it was not possible to blind participants and personnel delivering an exercise intervention. Four studies (17%) were at either high or unclear risk of detection bias and 11 studies (46%) had high or unclear risk of attrition bias because of losses over time.

Effects of exercise on rate and risk of falling

The overall pooled estimate of the RaR for the effect of exercise on fall rates beyond 12-month follow-up was 0.79 (95% CI 0.71 to 0.88; 6250 participants, 23 studies, Fig. 3a). A RaR value of 0.79 indicates that participants in the exercise interventions had a 21% lower rate of falls after one year compared to those receiving a control intervention. Based on the 95% CI, the range for this estimate was from 12% to 29%. (The 95% CI is the interval of values in which the true rate ratio is likely to lie with a probability of 95%). However, there was moderate to substantial statistical heterogeneity in the estimate of the effect of exercise ($I^2 = 60\%$).

The overall pooled estimate of the effect of exercise on risk of falling (RR) was 0.83 (95% CI 0.76 to 0.92; 4690 participants, 18 studies, 21 interventions, Fig. 3b) with evidence of moderate statistical heterogeneity ($I^2 = 55\%$). A value of 0.83 indicates that participants in the exercise interventions had a lower risk of sustaining at least one fall after one year compared to those participants receiving the control interventions. Those receiving exercise had a 17% lower risk of sustaining at least one fall after one year (relative risk reduction).

Exercise type: multiple component exercise interventions vs control

Overall, in studies testing multiple exercise component interventions i.e. a combination of two or more categories of exercise, there was a 18% reduction in rate of falls beyond 12 months when compared to control interventions (RaR 0.82; 95% CI 0.74 to 0.91; 4323 participants, 14 studies, 15 interventions, $I^2 = 55\%$, Table 2). There was also a reduction in the risk of falling (9%) beyond 12 months (RR 0.91, 95% CI 0.85 to 0.96; 2710 participants, 8 studies, 9 interventions; $I^2 = 0\%$, Table 2).

Single component exercise interventions vs control

Similarly, single component exercise interventions reduced rate of falls (RaR 0.65, 95% CI 0.48 to 0.87; 1932 participants, 10 studies, 11 interventions, $I^2 = 67\%$, Table 2)

and risk of falling in the longer-term (RR 0.74, 95% CI 0.60 to 0.90; 1980 participants, 11 studies, 12 interventions, $I^2 = 64\%$, Table 2).

Duration of exercise interventions

Studies testing exercise interventions of less than six months in duration suggested a 21% reduction on rate of falls beyond 12 months (RaR 0.79, 95% CI 0.72 to 0.87, 1575 participants, 6 studies, 8 interventions, $I^2 = 60\%$, Table 2). There was no difference in the risk of falling between intervention and control (RR 0.89, 95% CI 0.77 to 1.03, 1334 participants, 5 studies, 6 interventions, $I^2 = 49\%$, Table 2).

The studies testing exercise interventions of 6 to 12 months duration reduced rate of falls by 33% (RaR 0.67, 95% CI 0.56 to 0.80, 1732 participants, 9 studies, 11 interventions, $I^2 = 57\%$, Table 2) and risk of falling by 36% beyond 12 months (RR 0.64, 95% CI 0.48 to 0.85, 1540 participants, 7 studies, 8 interventions, $I^2 = 67\%$, Table 2). Similarly, the trials testing longer exercise interventions of >12 months in duration resulted in a reduction in rate and risk of falling (RaR 0.88, 95% CI 0.82 to 0.94, 8 studies, 2943 participants, $I^2 = 51\%$, Table 2) and (RR 0.91, 95% CI 0.85 to 0.98, 1727 participants, 5 studies, $I^2 = 0\%$, Table 2).

Duration of follow-up

Overall, the exercise interventions in studies whereby participants were followed-up for up to 24-months after randomisation showed a 21% reduction in rate of falls (RaR 0.79, 95% CI 0.70 to 0.88; 5929 participants, 20 studies, 24 interventions, $I^2 = 64\%$, Table 2) and 17% reduction in risk of falling (RR 0.83, 95% CI 0.75 to 0.93, 4442 participants, 16 studies, 19 interventions, $I^2 = 59\%$, Table 2). However, the three studies with follow-up beyond 24 months found no effect on rate (RaR 0.80, 95% CI 0.60 to 1.06; 321 participants, 3 studies, $I^2 = 0\%$, Table 2) or risk of falling (RR 0.79, 95% CI 0.61 to 1.03; 248 participants, 2 studies, $I^2 = 0\%$, Table 2).

Discussion

This systematic review of exercise interventions for falls prevention found evidence that exercise programmes have sustained benefits on falls reduction over time. This meta-analysis of 24 studies found that exercise interventions can reduce rate and risk of falling in community-dwelling older people beyond a year when compared to a control intervention. The overall long-term reduction in rate of falls was 21% (range 12% to 29%), based on 23 studies involving 6250 participants, and risk of falling was reduced by 17% (range 8% to 24%), (18 studies; 4690 participants).

Using the ProFaNE taxonomy classification, gait, balance and functional training exercises [13], are the most frequently used and considered the most effective type of exercises to include in a falls prevention programme [36]. In this review, 20/24 (83%) of the studies included this category of exercise

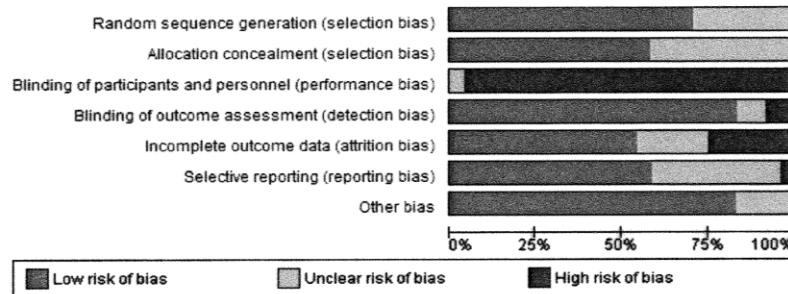


Fig. 2. Risk of bias graph.

Table 2
A summary of the effects of exercise on rate and risk of falling.

Characteristic	No. of studies	Rate ratios (95% confidence interval)	No. of studies	Risk ratios (95% confidence interval)
Effect of exercise on:				
Rate of falls beyond 12 months	23	0.79 (0.71 to 0.88)		
Risk of falling beyond 12 months			18	0.83 (0.76 to 0.92)
Type of exercise				
Multiple component exercise	14	0.82 (0.74 to 0.91)	8	0.91 (0.85 to 0.96)
Gait/balance/functional training and strength/resistance exercises	4	0.99 (0.83 to 1.17)	1	0.99 (0.87 to 1.13)
Gait/balance/functional training and strength/resistance and flexibility exercises	3	0.76 (0.62 to 0.93)	3	0.87 (0.79 to 0.95)
Gait/balance/functional training and strength/resistance and flexibility and 3D exercises	3	0.65 (0.43 to 0.99)	2	0.53 (0.15 to 1.84)
Gait/balance/functional training and strength/resistance and 3D exercises	1	0.95 (0.78 to 1.16)		
Gait/balance/functional training and strength/resistance and endurance exercises	1	0.68 (0.40 to 1.16)		
Gait/balance/functional training and strength/resistance exercises and general physical activity	2	0.82 (0.63 to 1.06)	1	0.94 (0.62 to 1.42)
Gait/balance/functional training and general physical activity	1	0.93 (0.80 to 1.08)		
Gait/balance/functional training and 3D exercises and general physical activity	1	0.52 (0.16 to 1.70)	1	0.68 (0.19 to 2.43)
Single component exercise	10	0.65 (0.48 to 0.87)	11	0.74 (0.60 to 0.90)
Gait/balance/functional training	5	0.45 (0.28 to 0.74)	6	0.60 (0.33 to 1.12)
3D exercises	2	0.79 (0.50 to 1.25)	2	0.84 (0.73 to 0.96)
General physical activity	2	0.91 (0.63 to 1.31)	2	0.83 (0.58 to 1.18)
Strength/resistance exercises	1	0.54 (0.15 to 2.02)	1	0.47 (0.14 to 1.60)
Duration of exercise intervention				
<6-months	6	0.79 (0.72 to 0.87)	5	0.89 (0.77 to 1.03)
6 to 12 months	9	0.67 (0.56 to 0.80)	8	0.64 (0.49 to 0.83)
>12 months	8	0.88 (0.82 to 0.94)	5	0.91 (0.85 to 0.98)
Duration of follow-up				
12 to 24 months	20	0.79 (0.70 to 0.88)	16	0.83 (0.75 to 0.93)
>24 months	3	0.80 (0.60 to 1.06)	2	0.79 (0.61 to 1.03)

intervention. When incorporated in multiple exercise component interventions, gait, balance and functional training exercises reduced rate and risk of falling by 18% and 9%, respectively. When tested as single component interventions, gait, balance and functional training programmes [9,32–35] were found to reduce rate of falls (55%) but not risk of falling. 3D (Tai Chi) interventions [18,20] were the only single component interventions to significantly reduce risk of falling

(16%). Single interventions of strength/resistance exercises and general physical activities i.e. walking, were not found to be effective in reducing rate or risk of falling.

These findings support the recommendations by Sherrington *et al.* [36] for the essential components to include in falls prevention exercise programmes. Gait, balance and functional training exercises (with an emphasis on balance exercises) are an essential element of either a single or multi

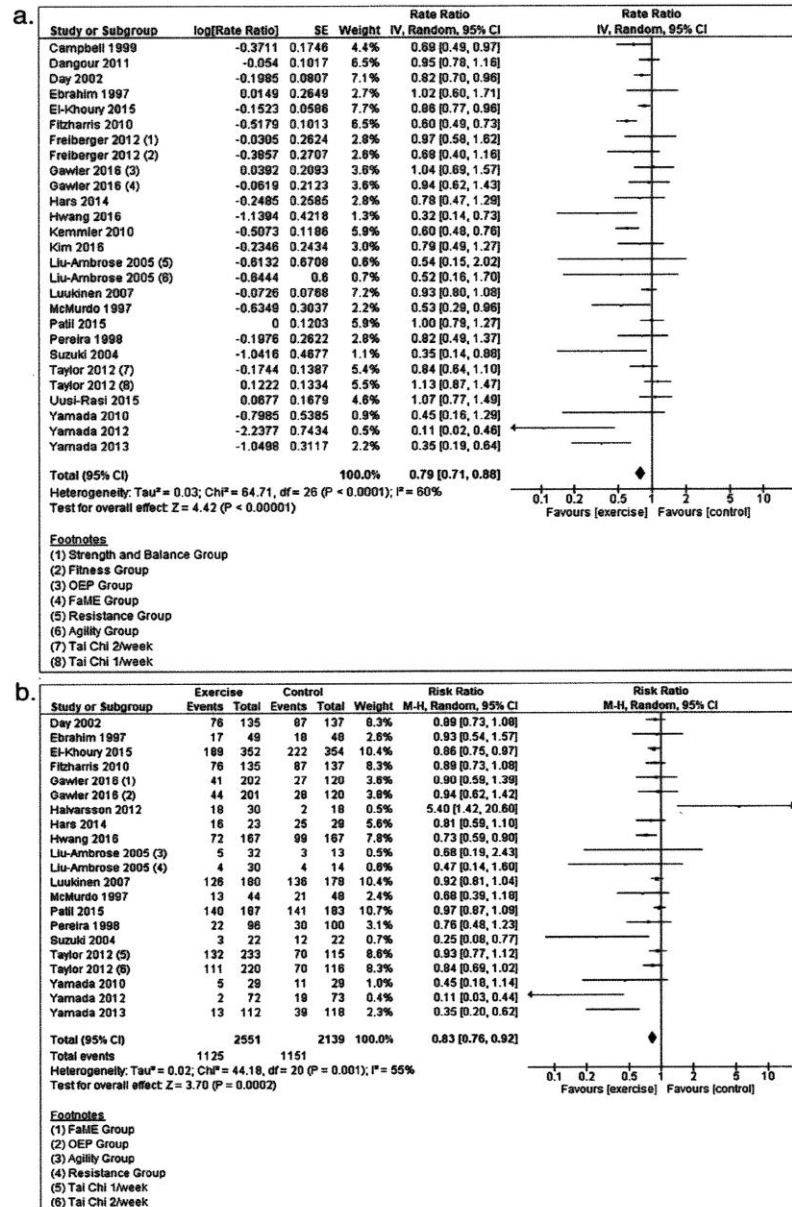


Fig. 3. (a) Exercise vs control, outcome 1, rate of falling. (b) Exercise vs control, outcome 2, risk of falling.

component falls prevention exercise intervention. This review suggests that this category of exercise also has long-term benefits on falls prevention.

This review found that the various falls prevention interventions being tested may have slightly different long-term effects, impacting on rate of falls and number of fallers dif-

ferently, and therefore, this must be taken into account when designing interventions. The ProFANE expert group [7] recommend that falls prevention trials include rate and risk of falling as key outcomes, both of which were examined in this review. These outcomes are clinically important as every fall carries a risk of injury, therefore, interventions that reduce rate of falls have clinical and economic significance. From a public health perspective, delaying time to first fall by reducing risk of falling is also an important clinical outcome [4].

Our results support the recommendations by Sherrington *et al.* [6] regarding the essential components to include in falls prevention exercise programmes. Gait, balance and functional training exercises (with an emphasis on balance exercises) are an essential element of either a single or multiple exercise component falls prevention exercise intervention. Our review findings suggest that this type of exercise also has long-term benefits on falls prevention.

Similarly, our review findings concur with recommendations that falls prevention exercise interventions should be of at least six months duration [36]. We found that exercise interventions delivered over a longer duration, lasting from six months to a year, reduced rate and risk of falling by a third. However, in a survey of 231 NHS falls prevention services, programme length varied in the 188 (81%) services providing an exercise intervention, ranging from programmes lasting two to 24 weeks, with a mean exercise programme length of only eight weeks (SD 3 weeks) [37]. In our review, the pooled results of shorter interventions such as those delivered in NHS settings (<6 months), did reduce rate of falls (21%) but were not found to reduce risk of falling.

Overall, the pooled results of the 21 exercise interventions in studies following up participants for up to 24 months had a 21% and 16% reduction on rate and risk of falling respectively. This is despite different durations of intervention and time to follow-up data collection. Only three studies followed up participants for more than two years [8,9,24]. Of these, two studies followed participants up to four years and one to 10-years. When data were pooled, there was no evidence that these interventions had any long-term effect on falling. Individually, the studies did suggest an effect on rate and risk of falling long-term, as they found that those in the intervention arms experienced fewer falls beyond two years compared with those in the control arms, but these results were not statistically significant when pooled.

Study limitations

The findings of the review are limited by and should be interpreted with caution due to the moderate to substantial statistical and clinical heterogeneity of the included studies. There is a risk that the effects of exercise on rate and risk of falling may be overestimated because of methodological weaknesses in nearly half of the included studies.

Although the interventions were grouped using the ProFANE taxonomy, the content of exercise programmes was

diverse, and studies also varied widely in terms of mode and duration of delivery. It was not possible to evaluate finer level detail, such as extent of participant attendance, adherence or quality of prescribed exercise e.g. whether individually or group-delivered sessions.

There was variability in the methods used to collect outcome data to capture falls. Over half of studies used the gold standard prospective falls diaries/calendars but nine studies used retrospective self-report which rely upon memory recall of past events, possibly resulting in recall bias [12]. However, the sensitivity analyses by data collection method did not change the direction or magnitude of estimate of effect.

The majority of the included participants were female (79%). Although women are more likely to fall compared to men, gender specific differences in falls risk do exist and this along with these other limitations must be taken into consideration when generalising the results to the wider population and in the design of falls prevention interventions [38].

Finally, the quantity of studies following-up trial participants beyond two years was limited, with only three studies collecting data in the longer term. There may be other broader health-related benefits from older adults undertaking exercise programmes, such as improvements in cardiovascular function or psychological health. Although long-term follow-up is rarely used as a primary outcome in the falls prevention field, the effectiveness, safety and the economics of falls prevention interventions could be judged more fully in light of the knowledge gained from longer term follow-up of clinical trials.

Conclusion

There is evidence that certain types of falls prevention exercise programmes have long-term effects on falling and these effects may be sustained up to two years after an exercise intervention. The impact of exercise interventions on falls appear to decline after two years, although few studies undertake follow-up beyond this timeframe. Future studies should consider performing long-term follow-up to fully understand the sustained health benefits from falls prevention interventions delivered to community-dwelling older adults.

Key messages

- There is a shortage of data relating to the possible long-lasting effects of falls prevention exercise interventions for older adults.
- Previous systematic reviews have assessed the effect of falls prevention exercise programmes for up to 12-months; this review evaluates the sustained effect of falls prevention exercise programmes beyond a year.
- This review provides evidence of the long-term effect of certain falls prevention exercise interventions.

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Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at <https://doi.org/10.1016/j.physio.2018.09.002>.

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Appendix 1a - Search strategy

1. falls.mp. or exp falling/
2. accidental falls.mp.
3. fall*.mp.
4. 1 or 2 or 3
5. exp accident prevention/ or exp prevention/ or exp primary prevention/ or prevention.mp.
6. prevent*.mp.
7. 5 or 6
8. 4 and 7
9. exp exercise/ or exercise.mp.
10. exercise therapy.mp. or exp kinesiotherapy/
11. physical activity.mp. or exp physical activity/
12. motor activity.mp. or exp motor activity/
13. (exercis* or activit*).mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading]
14. 9 or 10 or 11 or 12 or 13
15. 8 and 14
16. (long term or long-term).mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading]
17. 1(follow up or follow-up).mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading]
18. 16 and 17
19. 15 and 18
20. clinical study.mp. or exp clinical study/
21. clinical trial/
22. controlled clinical trial.mp. or exp controlled clinical trial/
23. meta-analysis/
24. randomized controlled trial/
25. systematic review.mp. or exp "systematic review"/
26. 20 or 21 or 22 or 23 or 24 or 25

27.18 and 25

Appendix 2 - What enables older people to continue with their falls prevention exercises? A qualitative systematic review

Open access

Research


BMJ Open What enables older people to continue with their falls prevention exercises? A qualitative systematic review

Susanne Finnegan,¹ Julie Bruce,¹ Kate Seers²

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¹Warwick Clinical Trials Unit, University of Warwick, Coventry, UK

²RCN RI, Royal College of Nursing Research Institute, Warwick Medical School, University of Warwick, Coventry, UK

Correspondence to
Susanne Finnegan;
susanne.finnegan@warwick.ac.uk

ABSTRACT

Objectives To review the qualitative literature that explores the barriers and facilitators to continued participation in falls prevention exercise after completion of a structured exercise programme.

Design A systematic literature review with thematic synthesis of qualitative studies exploring older adults' experiences of continued participation in falls prevention exercise.

Data sources Comprehensive searches were conducted in MEDLINE, PSYCHinfo, AMED, ASSIA, CINAHL and EMBASE from inception until November 2017. Additional studies were identified via searches of reference lists and citation tracking of relevant studies.

Eligibility criteria Qualitative or mixed methods studies exploring experiences of community-dwelling older adults (65 years and over) participation in a falls prevention exercise programme including their experience of ongoing participation in exercise after the completion of a structured exercise programme.

Data extraction and synthesis Key characteristics including aim, participant characteristics, method of data collection, underpinning qualitative methodology and analytical approach were extracted and independently checked. Thematic synthesis was used to integrate findings.

Results From 14 studies involving 425 participants, we identified three descriptive themes: identity, motivators/deterrents and nature of the intervention and one overarching analytical theme: agency.

Conclusions Older people have their own individual and meaningful rationale for either continuing or stopping exercise after completion of a structured falls prevention exercise programme. Exploring these barriers and facilitators to continued exercise is key during the intervention phase. It is important that health care professionals get to know the older person's rationale and offer the best evidence-based practice and support to individuals, to ensure a smooth transition from their structured intervention towards longer-term exercise-related behaviour.

PROSPERO registration number CRD42017082637.

INTRODUCTION

Falls remain a global health problem for older people. The WHO recognises falling as the second leading cause of accidental or unintentional injury-related death worldwide.¹ Thus,

Strengths and limitations of this study

- A systematic review of qualitative data examining the barriers and facilitators to ongoing falls prevention exercise after completion of an exercise programme.
- The methods used ensured that the identified themes were grounded in the data.
- The Critical Appraisal Skills Program (CASP) qualitative checklist was used to assess the trustworthiness, transparency and relevance of the included studies and GRADE-Confidence in the Evidence from Reviews of Qualitative Research (CERQual) was used to assess the credibility of our findings.
- The CASP tool does not claim to be a definitive guide for critical appraisal and there was variability in CASP scores.

intervening to prevent falls is an international priority.

Falls prevention exercise programmes including moderate intensity strength and balance training are effective at reducing rate and risk of falling in older adults,^{2,3} but exercise needs to be maintained to have a lasting effect.³ Falls prevention exercise programmes in both research and health settings tend to be of short duration (<6 months),⁴ and uptake and retention to these programmes is challenging.⁵

Numerous quantitative and qualitative studies have been undertaken to understand the reasons behind the problems with uptake and adherence to these structured programmes.⁶⁻⁹ There is, however, lack of information about exercise behaviours in the longer term, after completion of falls prevention programmes. To promote lifelong behaviour change and long-term commitment to exercise among older people, it is important to understand the barriers and facilitators to adherence, not only during delivery of structured exercise interventions, but also once the intervention has been delivered.

The aim of this systematic review of qualitative evidence was to explore the barriers and facilitators to continued participation in

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falls prevention exercise once structured falls prevention programmes come to an end.

METHOD

A qualitative systematic review involves systematically searching for primary qualitative studies which can be integrated using methods such as thematic synthesis.^{10 11} The Enhancing transparency in reporting the synthesis of qualitative research (ENTREQ) checklist was used to guide the reporting of this review.¹²

Search strategy and selection criteria

Comprehensive searches were conducted in MEDLINE, PSYCHinfo, AMED, ASSIA, CINAHL and EMBASE from inception until November 2017. The search strategies are included in online supplementary file 1. We performed a manual search of reference lists and citation tracking of relevant studies to identify additional papers. The search was restricted to studies published in the English language. Qualitative studies and mixed methods studies that clearly report the qualitative findings separately were included if participants were community dwelling and at least 65 years old or the mean reported age of participants was 65 years or over. Inclusion criteria included studies examining both individual (home-based) or group-based falls prevention exercise programmes with an aim to explore older adults' experiences of ongoing participation in falls prevention exercise after the completion of a structured exercise programme. This included: (1) continuing in a new falls prevention exercise group; (2) continuation of falls prevention exercises independently at home, based on the exercise intervention; or (3) continuing with other/new types of exercise to replace the falls prevention exercises. Studies were excluded if they included participants living in residential or nursing homes, did not include qualitative data collection methods for example, interviews or focus groups and did not generate data about ongoing participation in exercise post-intervention.

Quality appraisal

The Critical Appraisal Skills Program (CASP) qualitative checklist was used to assess the trustworthiness, transparency and relevance of the included studies.¹³ The tool does not claim to be a definitive guide for critical appraisal but focuses on the key principles underpinning qualitative research.¹² Studies were not excluded based on the CASP scores, but the information from the assessments were used in the discussion of the overall review.

To complement the CASP checklist we also applied the GRADE-Confidence in the Evidence from Reviews of Qualitative Research (CERQual).^{14 15} To ensure a review of this type reasonably represents the area of interest, CERQual provides a systematic and transparent framework for assessing confidence in individual review findings. This framework consists of four components: (1) methodological limitations, (2) coherence, (3) adequacy of data and (4) relevance.

Pairs of review authors (SF and JB/KS) independently assessed each study for quality and credibility and resolved any disagreements through discussion.

Data extraction

Key characteristics of included studies were extracted by SF and independently checked by JB and KS. Any discrepancies were resolved via discussion. For each study, the following were extracted: author, year of publication, country of origin, stated aim, participant characteristics, method of data collection, underpinning qualitative methodology and analytical approach. Relevant text and illustrative participant quotations from the findings and discussion sections of each study were extracted and discussed before being entered verbatim into NVIVO V.11 to assist in organising the text for analysis.

Data synthesis and analysis

We used thematic synthesis to integrate findings.¹¹ This involved three overlapping, non-linear phases: (1) line by line coding of the findings, (2) organisation of codes into descriptive themes and (3) construction of analytical themes.¹¹

One reviewer (SF) performed line by line coding of the primary studies, recording and translating the concepts of participants' experiences of ongoing exercise from one study into another, constantly comparing codes between studies and organising these codes into descriptive themes. KS double coded 20% of studies, there was broad agreement on the codes and themes and no new codes or themes emerged. As per Thomas and Harden's recommendations,¹¹ the descriptive themes and sub-themes were based on the original findings of the included studies. All studies were re-read and reviewed multiple times to ensure that pertinent data were integrated into the descriptive themes appropriately. To 'go beyond' the content of the original studies and construct analytical themes, the review authors discussed the descriptive themes and used mind mapping to create a schematic to expand and explain the themes from the primary studies by identifying cross-cutting conceptual links.

Mind mapping involved using diagrams to visually structure ideas and discussion points about the potential concepts coming from the data. This process enabled the themes to be organised and structured in a more coherent way.

Patient and public involvement

There was no patient or public involvement in the development of this manuscript.

RESULTS

Literature search results

In total, 69 full-text articles were retrieved for review, of which 14 studies were included, involving 425 participants (figure 1).

Study characteristics are described in table 1.

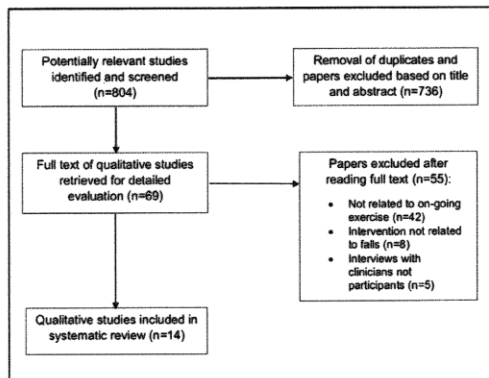


Figure 1 Flow diagram of search and study selection process.

All the exercise interventions in the included studies were group-based exercise programmes. They were delivered as either stand-alone exercise programmes or within a broader multi-factorial falls prevention programme. The aim of two studies was primarily examining issues with the uptake of falls prevention programmes but also explored older people's ideas and suggestions for future programmes and what might be involved in a successful programme including ongoing participation.^{16 17} The studies were undertaken in six countries: seven in the UK,^{18–24} four in Australia/New Zealand,^{25–28} and one each in Norway,²⁹ Denmark¹⁶ and Hong Kong.¹⁷ One study restricted participant inclusion to men only,²⁷ and all studies included community-dwelling adults aged 65 and over (range 65–94 years).

Quality of reporting

There was some variability in the CASP scores (table 2).

All 14 studies clearly described the aim, selected qualitative research as the appropriate methodology and design to undertake the research and gave a clear statement of their findings. However, only 2/14 (14%) studies adequately described or considered the relationship between the researcher and the participants; therefore, potential individual researcher biases were not reported. All studies sought ethical approval from a research ethics committee for their research.

Table 3 is a summary of qualitative findings based on the four components of the GRADE-CERQual framework.

For each descriptive theme, studies were assessed for methodological limitations, coherence, adequacy and relevance. We are moderately confident in the themes of identity and motivators/deterrents; thus, it is likely that these review findings are a reasonable representation of the phenomenon of interest. We have high confidence in the nature of the intervention theme, meaning it is highly likely that this finding is a reasonable representation of the phenomenon of interest.¹⁴

Synthesis

In identifying the barriers and facilitators to ongoing participation in falls prevention exercise, one overarching analytical theme encapsulating three descriptive themes with sub-themes were derived from the findings of the original 14 studies; they are presented here with narrative exemplars. A schema of the themes was developed using mind mapping and is presented in figure 2.

Descriptive themes

Theme 1: identity

This theme and sub-themes describe how the participant's perception of self or their own identity affected their continued participation in exercise.

'Fallers'

Even though these older adults had all participated in a falls prevention exercise programme, often they did not identify themselves as 'fallers' despite having had a fall. Preventing falls was rarely described as a reason for continued exercise:

A decrease in the likelihood of a fall was infrequently mentioned...also related to this was the perception that the participant was not at risk of falls, possibly in part due to their level of health and fitness, and also in part due to their participation in alternate forms of physical activity²⁵

Participants were asked about their attitudes to health service falls prevention interventions...views varied from 'being prepared to try' or 'go along with it', to obvious reluctance...they felt they were not yet in need²¹

Instead, rather than preventing falls, participants described improvements in strength and balance and increased confidence in relation to overall independence, functional improvements and quality of life as important reasons for continued exercise:

A number of benefits were expressed among the participants, including balance improvement...higher confidence in activities of daily living, and greater happiness¹⁷

The results showed that motivating factors to adhere to recommended exercise were perceived prospects of staying independent, maintaining current health status, and improving physical balance and the ability to walk²⁹

'I'm not old'

Increased age is a risk factor for falling and although the participants identified a link between risk of falling and older age, some did not identify themselves as being old. However, some also did not think of age as a barrier to ongoing exercise:

'...they did not readily identify with the population that they perceived to be the target of the intervention, that is, 'people who fall' or 'old people'²⁵

Table 1 Characteristics of included studies

Author/year	Country	Aim	Participants	Data collection	Underpinning methodology	Analysis
Ballinger and Clemson 2006 ²³	Australia	To investigate perspectives of older people about a falls prevention programme.	Nine women and two men; median age: 76 years (n=11).	Semistructured interviews.	Grounded theory.	Grounded theory analysis.
De Groot and Fagerström 2011 ²⁹	Norway	To describe the motivating factors and barriers for older adults to adhere to falls prevention group exercise.	Five women and five men; mean age: 83 years (range 71–91 years) (n=10).	Semistructured interviews.	None described.	Descriptive content analysis developed by Matternud. ⁴³
Dickinson <i>et al</i> 2011 ¹⁸	UK	To explore older people's views and experiences of fall prevention interventions including the barriers and facilitators to uptake and participation.	187 older people including 30 Chinese and 32 South Asian mean age: 75 years (n=187).	17 focus groups (n=122) and 65 semi-structured interviews.	Grounded theory.	A constant comparative approach drawing on Grounded theory.
Evron 2009 ¹⁶	Denmark	To gain new knowledge about barriers to participation in hospital-based falls assessment.	Eight women and two men (refusers); mean age: 81 years (range 70–87 years). Eight women and two men (accepters); mean age: 86 years (range 78–94 years) (n=20).	Semistructured interviews.	Phenomenological approach was used in the interview process.	Thematic analysis.
Haas and Haines 2014 ⁴⁶	Australia	To examine the acceptability and impact on sustained participation in falls prevention activities and health behaviours since programme completion.	16 women and seven men from culturally and linguistically diverse backgrounds; median age 84 years (n=23).	Semistructured telephone interviews.	None described.	Content analysis using a framework approach.
Hawley 2009 ¹⁹	UK	A study to investigate the links between social interaction and continuation of home exercise.	Nine older people (n=9).	Unstructured interviews.	Grounded theory.	Grounded theory analysis.
Hawley-Hague <i>et al</i> 2017 ⁴⁰	UK	An evaluation of strength and balance programmes delivered in the community including transition to long-term community exercise classes.	nine men and 19 women from three Community Otago groups and two Active Always groups. Mean age: 81.2 (range 70–91).	Five focus groups.	None described.	Thematic analysis.
Liddle <i>et al</i> 2017 ²⁷	Australia	To explore the experiences and perspectives of older men regarding fall risk and prevention.	11 men ranging from 64 to 82 years (n=11).	Interview study.	None described.	Grounded theory analysis.

Continued

Table 1 Continued

Author/year	Country	Aim	Participants	Data collection	Underpinning methodology	Analysis
Moody <i>et al</i> 2012 ³⁸	New Zealand	To present participants' perceptions of the benefits and delivery of a water-based exercise programme on falls risk and physical function.	13 women and four men; mean age: 78 years (range 68–89 years) (n=17).	Four focus groups and one semi-structured interview.	None described.	General inductive approach.
Peach <i>et al</i> 2017 ⁴¹	UK	To explore the perceptions of older people with mild dementia and mild cognitive impairment, and their family carers, about falling, falls risk and the acceptability of falls prevention interventions.	Dyads of 20 patients aged 70–93 years (13 men and seven women) and 21 carers (10 spouses, 9 children, 1 friend and 1 grandchild) (n=41).	Semi-structured interviews held with dyad.	None described.	Thematic analysis.
Robinson <i>et al</i> 2014 ²²	UK	To involve older people and physiotherapists in the development of acceptable strategies to promote uptake and adherence with an exercise-based falls prevention programme.	Eight women and four men; mean age: 79 years (n=12).	Focus groups.	None described.	Framework analysis.
Stathi <i>et al</i> 2010 ³³	UK	To investigate the processes associated in engaging older adults in a 12 month research-based exercise programme and continued physical activity.	14 women and 7 men; mean age: 76 years (n=21).	Semi-structured interviews.	None described.	Principles of interpretive qualitative analysis.
Vernon and Floss 2008 ⁴⁴	UK	To explore older people's experiences in relation to access and acceptability of local community based postural stability exercise classes.	20 women and 2 men; age ranged from 65 to 94 but only 17 reinterviewed (n=22).	In-depth interviews.	None described.	Not clear.
Wong <i>et al</i> 2011 ¹⁷	Hong Kong	To identify characteristics of participants in a falls prevention programme and factors related to participation.	Nine women and four men; mean age: 76 years (n=13).	Focus groups x3.	None described.	Content analysis.



Table 2 CASP scoring results

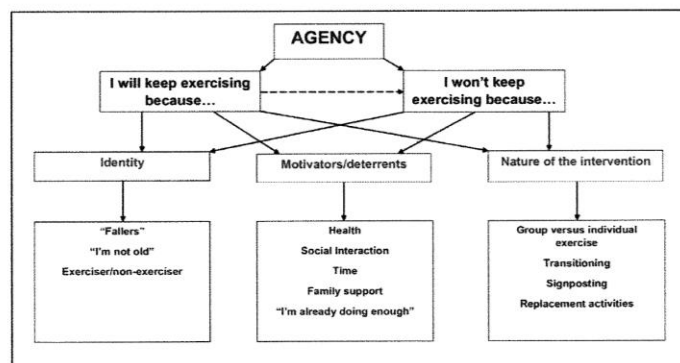
Reviewer	Study	Clear aim	Appropriate for qualitative research	Appropriate design	Appropriate recruitment strategy	Data collection	Relationship between researcher and participant	Ethical issues considered	Rigorous data analysis	Clear statement of findings
1	Ballinger <i>et al</i> ²⁵	Yes	Yes	Yes	Yes	Yes	No	Can't tell	Yes	Yes
2		Yes	Yes	Yes	Yes	Yes	No	Can't tell	Yes	Yes
1	De Groot and Fagerström ²⁹	Yes	Yes	Yes	Yes	Yes	Can't tell	Yes	Yes	Yes
2		Yes	Yes	Yes	Yes	Yes	Can't tell	Yes	Yes	Yes
1	Dickinson <i>et al</i> ¹⁸	Yes	Yes	Yes	Yes	Can't tell	Can't tell	Can't tell	Yes	Yes
2		Yes	Yes	Yes	Yes	Can't tell	Can't tell	Can't tell	Yes	Yes
1	Evron <i>et al</i> ¹⁶	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
2		Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
1	Haas and Haines ²⁶	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
2		Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
1	Hawley ¹⁹	Yes	Yes	Yes	Can't tell	Can't tell	Can't tell	Can't tell	Yes	Yes
2		Yes	Yes	Yes	Can't tell	Can't tell	Can't tell	Can't tell	Yes	Yes
1	Hawley-Hague <i>et al</i> ²⁰	Yes	Yes	Yes	Yes	Yes	Can't tell	Yes	Yes	Yes
3		Yes	Yes	Yes	Yes	Yes	Can't tell	Yes	Yes	Yes
1	Liddle <i>et al</i> ²⁷	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes
3		Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes
1	Moody <i>et al</i> ²³	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes
3		Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes
1	Peach <i>et al</i> ²¹	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes
3		Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes
1	Robinson <i>et al</i> ²²	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes
3		Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes
1	Stathi <i>et al</i> ²³	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes
3		Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes
1	Vernon and Ross ²⁴	Yes	Yes	Yes	Yes	Yes	No	Yes	No	Yes
3		Yes	Yes	Yes	Yes	Yes	No	Yes	No	Yes
1	Wong <i>et al</i> ¹⁷	Yes	Yes	Yes	Yes	Yes	No	Yes	No	Yes
3		Yes	Yes	Yes	Yes	Yes	No	Yes	No	Yes
	% of yes*	100	100	100	92	85	15	77	85	100

CASP, Critical Appraisal Skills Program.

Table 3 GRADE-CERQual summary of qualitative findings table

Review finding	Studies contributing to the review finding	Methodological limitations	Coherence	Adequacy	Relevance	Assessment of confidence
Identity	17, 19–21, 23, 25, 26, 28	Moderate methodological limitations (five studies with none or minor limitations and three with moderate limitations [unclear recruitment strategy, data collection methods, ethical considerations, insufficient rigorous data analysis and no reflexivity]).	Minor concerns about coherence (some concerns about the fit between data from two of the primary studies and the review finding).	Minor concerns about adequacy (seven studies that together offered moderately rich data and one study offering thin data).	Minor concerns about relevance (three studies focused solely on exercise interventions and five studies on falls prevention interventions involving exercise).	Moderate
Motivators/deterrents	18–29	Moderate methodological limitations (eight studies with none or minor limitations and four with moderate limitations [unclear recruitment strategy, data collection methods, ethical considerations, insufficient rigorous data analysis and no reflexivity]).	Minor concerns about coherence (some concerns about the fit between data from one of the primary studies and the review finding).	None or very minor concerns about adequacy (twelve studies that together offered rich data).	None or very minor concerns about relevance (six studies focused solely on exercise interventions and six studies on falls prevention interventions involving exercise).	Moderate
Nature of the intervention	16, 18, 20–25, 28	Minor methodological limitations (seven studies with none or minor limitations and two study with moderate methodological limitations [unclear recruitment strategy, data collection methods and ethical considerations, insufficient rigorous data analysis no reflexivity]).	Minor concerns about coherence (some concerns about the fit between data from two of the primary studies and the review finding).	Minor concerns about adequacy (eight studies that together offered moderately rich data and one study offering thin data).	Minor concerns about relevance (four studies focused solely on exercise interventions and five studies on falls prevention interventions involving exercise).	High

CERQual, Confidence in the Evidence from Reviews of Qualitative Research.

**Figure 2** A diagram of descriptive and analytical themes.

'They linked greater fall risk to getting old, but they did not see themselves as old. Being old was associated with the idea of not doing anything, an idea which they rejected. Creating busy lives demonstrated they were not sitting around and therefore were not old'²⁷

Exerciser/non-exerciser

Older adults have a variety of attitudes and perceptions about what exercise means. The way they identified with exercise and their attitudes towards exercise impacted on how and why they either continued or discontinued with their exercises. The reasons to continue as an exerciser were for the perceived benefits to independence and general health and function. They also described an increase in confidence and ability to exercise because of taking part in their intervention:

'Participants are driven to be active in an attempt to achieve further independence or maintain the independence they have already achieved'¹⁹

Intrinsic motivators predominantly revolved around the notion held by participants that exercise in general was good for them. They anticipated that the exercise would be beneficial to them for 'keeping fit', and 'keeping young'²⁶

The improved levels of confidence and competence empowered some participants to meet the challenge of moving from a highly supervised environment to a more standard exercise environment²³

Non-exercisers were able to clearly define reasons for no longer participating in exercise and justified this by labelling themselves to explain their reasons:

Those participants who were no longer exercising reported that they were too lazy, not in the right mood, no longer needed to exercise, did not enjoy exercising on their own or preferred another activity such as walking²⁶

However, others gave a variety of reasons why they had found it difficult to maintain an exercise regime, including 'being the sort of person who hates exercise', ill health, lack of interest, being too busy and laziness²⁵

Theme 2: motivators/deterrents

This theme describes some of the issues that motivated participants to continue exercising after the end of the programme and in contrast, the deterrents which influenced some to stop exercising.

Health

Health benefits, maintaining health and preventing deterioration of health were all described as motivators to continued exercise. Preventing falls was seldom mentioned as a health benefit or motivator:

A number of functional health benefits were reported by the older people as a result of participating in

an exercise-based falls prevention programme and these motivated them to continue with the prescribed exercise-regime²²

When patients who became active were asked about their motivation to change their behaviour, the leading response was their own belief that exercise was important to their health¹⁹

Conversely, health issues were also cited as a barrier to ongoing exercise:

One barrier to ongoing participation was that of illness²⁸

The physical barriers were health-related factors leading to dizziness, feeling shaky, pain, drowsiness, and reduced strength and endurance. The psychological barriers described were depression...²⁹

Social interaction

Linked closely to an individual's preferences for group exercise, the social benefits of participating in group exercise frequently acted as a facilitator to continued participation, even though the transition to new groups could prove challenging. The social element related to being in the company of others, support from other group members and the instructor and the pleasure and enjoyment that this brought with it:

For some participants, social interaction was the main goal.... A social setting is an important factor to stimulate exercise on a regular basis²⁹

The reasons given for continuing to exercise included... appreciation of the sociability involved in exercising²⁴

From community Otago to long-term maintenance in an Active Always class, it was...often a lot of the same group members which made participants feel more reassured and comfortable²⁰

Participants exercising independently missed social interaction:

Continuing to do exercises at home independently was often discussed as being less enjoyable²⁶

Time

Time was a recurring factor affecting long-term commitment to exercise. As a barrier, participants described a lack of time or being too busy to continue to exercise:

Perhaps a more surprising reason for not attending an intervention was that older people, although retired, often had other commitments, so found it difficult to attend regular interventions. Time pressures, due to caring responsibilities were another constraint¹⁸

Men who had stopped doing the exercises cited competing activities that took priority²⁷

Conversely, for those who did continue to exercise, participants found ways to overcome issues with time by

integrating their exercises into everyday life and fitting them into their routine; this acted as an important facilitator:

Incorporating the exercise into their daily routine also proved a popular strategy among the older people²²

Others who maintained their exercise regime adopted such strategies as viewing the exercises as a necessary regular chore and repeatedly reminding themselves of the obligation to carry them out, so that they felt guilty if the routine was missed²⁵

...changes in their everyday schedule to accommodate the new and more active lifestyle²³

Family support

As well as encouragement from their exercise instructors, participants described support and encouragement from others, usually family members. This was a facilitator to ongoing exercise:

This support was either family or spouse support, someone within the home encouraging them to keep going or close family support encouraging them to be active¹⁹

For the participants who had finished the course... one person repeated some of the exercises with another friend from the group. Another person... had a carer who helped her do the exercises at home...²⁴

However, the 'support' of family members sometimes became a barrier to ongoing exercise as the responsibility became too burdensome for carers. Another issue was relatives' concerns for safety which led to activity restriction and was a major source of frustration for participants:

Several relatives described trying to prompt patients to exercise, but without success. Indeed, the need to remind patients, or monitor their exercise engagement, could constitute an unwelcome obligation²¹

Although most participants felt that they were supported by professionals or family to be active, some participants did find that at times they were restricted. This tended to be when concern for safety turned into restrictive behaviour. This restriction of activity led to feelings of frustration and a sense of loss...¹⁹

'I'm already doing enough'

Participants were committed to ongoing exercise until they felt their health status had improved to the level they perceived to be successful or they had achieved the goals that were meaningful to them, after which their commitment waned:

Previously practiced exercises were recognised to have been beneficial, but were discontinued once the need had passed, or only practised occasionally, as the habit had 'just drifted off somewhere' or exercise

sheets were 'filed away'. Participants reported that they were currently 'doing enough' exercise through 'normal' activity...²¹

...the reason for this lack of adherence to home exercise was that a level of independence was reached at which the benefits of home exercise no longer traded off against the risks (eg, fear of falling, injury, pain)¹⁹

...related to this was the perception that the participant was already fit, strong and healthy and that their existing physical activities were sufficient to maintain this²⁶

Theme 3: nature of the intervention

This theme describes the practical and real-world experiences of older people participating in falls prevention exercise programmes.

Group-based programmes versus individual exercise

All the included studies involved older people who had participated in structured group exercise hence it was not possible to make comparisons with interventions directed at individuals exercising independently. For some, being part of a group was a facilitator to continue to exercise.

...exercising together with others gave them pleasure and had motivated them to continue exercising in the municipality²⁹

For the participants who had finished the course of exercise classes, one person repeated some of the exercises they had been taught along with another friend from the group²⁴

However, the group environment made some older adults feel uncomfortable and uneasy. For some, the experience of group exercise was a barrier to ongoing participation after completion of the programme:

Despite such observations, however, the older people indicated that they preferred to exercise at home²²

Barriers were... unpleasant experience during previous exercise group sessions²⁹

Transitioning

Despite their wish to continue to exercise, at the end of group interventions, some participants described the difficulty in transitioning from one exercise format to another. This included transitioning from their existing established group to a new exercise group or moving to exercising independently. For those keen to continue with group exercise, the main barriers to ongoing participation were identifying an appropriate local group to attend, difficulty obtaining information about new exercise opportunities and potential financial implications:

Difficulties were also caused when a fixed programme of exercise came to an end. Many participants who attended regularly exercise-based falls interventions found them to be beneficial and would have liked the classes to have continued for longer or to have had

the opportunity to join a follow-on class. Often there were no suitable classes to which people could progress which affected motivation¹⁸

They were put off by not knowing where to access appropriate exercise in the community, or because they felt awkward and out of place in public places: e.g. feeling 'like an old lady' in the gym²¹

They did not want to use money on exercise programmes...¹⁶

Signposting

This transitional period over to a new exercise group highlights the significant role of the instructor or healthcare professional (HCP) leading the programme, not only during the intervention but as it comes to an end. The provision of appropriate, up-to-date and relevant information about other groups or new exercise opportunities was considered a facilitator:

The provision of informational support in the form of 'exit routes' to other exercise opportunities facilitated them to continue exercise. They praised the exercise class leaders' support during the transitional phase, and the available information about exercise choices in their local community²³

...that ongoing input from a healthcare professional in an educational or advisory capacity would enhance feelings of self-efficacy and promote ongoing adherence²²

...the health professional suggested that the participant could maintain their exercises by attending a Community Otago class. Motivation to attend could also be related to an existing relationship that had been established with the instructor... this relationship helped transfer through from rehabilitation into long-term maintenance²⁰

Replacement activities

For those who were unable to find a new group or those wishing to exercise independently, they sometimes took it on themselves or worked with their instructors to find practical ways to continue exercising. This did mean, however, that not everyone continued with the specific falls prevention exercises they were prescribed, choosing to exercise in different ways:

Participants seemed more likely to walk as a regular form of ongoing exercise than performing exercises specific to falls prevention. This was perhaps because walking was seen as functional and necessary (for example, to get to/from the shops)²⁶

Participants referred to engaging in a wide range of leisure activities and hobbies which often involved activity and social engagement [including bowls, visiting friends and family, trips out, holidays, sewing, gardening, golf, walking, doing crosswords and puzzles, going into town, bus trips, reading, dancing, church-going]²¹

Analytical themes

One overarching analytic theme encapsulating these descriptive themes emerged from the studies of older adults' views: agency. Agency can be defined as an individual's ability to act independently and to make their own free choices and decisions.^{30,31} This ability is influenced by the individual's belief structure which has formed through their own aims and experiences as well as the views and perceptions of society and the structure of the environment that the individual is in.^{30,32}

Therefore, in this instance, the participants' agency influenced their decision to continue exercising. Using their agency, these older people established their own identity and ascertained their own motivators or deterrents to continued exercise based on the nature of the exercise intervention.

DISCUSSION

Uptake of and adherence to falls prevention exercise programmes is often poor and research has been undertaken to establish the reasons for this.^{9,33,34} However, there is lack of evidence about the barriers and facilitators to ongoing exercise when falls prevention programmes come to an end. It is important to consider these factors to promote behaviour change over the longer term.

This review systematically searched and synthesised the literature to identify perceptions of older people who have completed falls prevention exercise programmes. The analytical and descriptive themes identified provide a deeper understanding of what motivated or discouraged them from continuing exercising. All the included studies involved older adults who had participated in group exercise, thus, the review findings apply to this population.

The analytical theme emerging from this review is agency; that is an individual's ability to choose whether to continue to exercise based on their own beliefs, experiences and those of society and the environment they are in.³⁰⁻³²

The choice to continue to exercise after participation in a falls prevention exercise programme appears to be a dichotomy; participants either do exercise, or they don't. Although, as a caveat to this and highlighted in the 'I'm already doing enough' theme, after time, some people who do continue initially, stop once they achieve what they perceive to be successful personal goals.^{19,21}

Opting to continue to exercise seems to be an active process and older adults construct their own story as to why it is important for them to continue.^{19,23,26} In contrast, discontinuing tends to be a more passive process; although older people still create their own story, and do not necessarily choose to be passive but exercise is just not a priority for them.^{25,26} Frequently, despite recognising the potential benefits of exercising, those who stop exercising had a clear rationale for doing so including 'health issues', 'too lazy', 'hate exercise' or 'too busy'. To make exercise more of a priority for these 'non-exercisers' and

to continue to motivate 'exercisers', HCPs need to understand all of their stories.

Older people have a clear sense of identity. Our findings are consistent with previous studies, highlighting that older adults feel that negative images and stereotypes often related to old age and falling did not fit with their identity.³⁵⁻³⁷ Instead, they perceive themselves as independent and capable people who can care for themselves, are not and do not wish to be reliant on or become a burden to others and act accordingly to maintain their independence.^{25,27} Older people use their agency in deciding how to maintain their independence and these decisions may or may not include exercising.³⁸

Thus, our review highlights a potential mismatch between priorities of the older person compared with those of HCPs delivering falls prevention interventions which typically involve strength and balance exercises. Rather than specifically preventing falls (goal of HCPs), most older adults reported being motivated to exercise to maintain or prevent deterioration of physical and mental health and remain functionally independent.^{17,29} However, although willing to continue to exercise, older adults frequently opt for other forms of exercise after group programmes.^{21,26} A potential reason for this is the lack of availability of appropriate community based groups to move on to.^{18-21,23,28} Alternatively, as they do not identify themselves as 'fallers', they stop their strength and balance exercises and replace these with walking, as this is perceived to be more important for maintaining functional independence.^{17,29} This supports earlier work by McInnes and colleagues.³³ HCPs need to promote ongoing strength and balance exercises as another way of meeting desired goals ensuring that older people understand the reasons for and potential benefits of these specific exercises during the supervised exercise phase. Commonly identified motivators to continued exercise such as maintaining independence^{19,26,29} and social interaction/engagement^{19,20,24,29} should be used by HCPs to promote continued exercise; appealing to these motivators while finding strategies to overcome barriers, especially during the transition period at the end of structured programmes.

This review highlights that behaviour change is an important factor to consider in the promotion of lifelong exercise. However, very few falls prevention programmes incorporate motivational-volitional behaviour change techniques and there is some uncertainty about which strategies might motivate older adults to undertake or continue with falls prevention exercises.^{39,40}

There are a few feasibility studies of falls prevention exercise programmes incorporating behaviour change strategies. Fleig and colleagues³⁹ used habit formation and helped participants with goal setting and action planning to facilitate ongoing exercise. At 6 months, participants showed an increase in action control (awareness of standards, self-monitoring and self-regulatory effort), action planning and automaticity (the degree to which the behaviour becomes habitual). They also reported

an appreciation for interdisciplinary nature of the programme, and information on motivational techniques and habit formation.

McMahon and colleagues⁴¹ combined motivational and physical components of a falls prevention programme. The motivational component including social network support, motivational support and empowering education resulted in significantly improved behaviour and health outcomes in the intervention group. These studies show the potential benefit of incorporating behaviour change techniques into falls prevention exercise programmes, but larger UK based clinical trials, with adequate follow-up, are needed to provide evidence of long-term effectiveness.

This review highlights the importance of HCPs getting to know the stories of individuals participating in falls prevention exercise programmes. Similar to studies exploring uptake and adherence to exercise,⁴² this review revealed that choosing to continue or stop exercising was influenced by a combination of factors including identity, health, social interaction and type of exercise. These findings give meaning to the participants' agency, encapsulating both the barriers and facilitators to ongoing exercise. It is important to identify these motivators and deterrents during the intervention phase and behavioural change strategies appear to have potential, alongside educational elements in the programmes, to help participants incorporate exercise into everyday life.

Strengths and limitations

To the best of our knowledge, this is the first systematic review of qualitative data examining the barriers and facilitators to ongoing falls prevention exercise after completion of an exercise programme.

Although we considered searching for grey literature, due to challenges of time this was not undertaken in a systematic manner. There is no main database for the identification of grey literature, unlike MEDLINE, EMBASE and other biomedical, social and psychological databases. We are familiar with internet-based information sites, including the System for Grey Literature in Europe which organises grey literature by subject area. However, these sites are challenging as they tend to lack advanced search and export features. Some also require subscription fees. We therefore acknowledge that this is a limitation of the review.

In relation to the synthesis, it is possible that other reviewers may have generated different themes, but the authors repeatedly read and reread the original studies to ensure themes were grounded in the data. To ensure trustworthiness in the data and findings of the review, CASP was used to assess transparency and relevance of the included studies and GRADE-CERQual tools were used to assess the credibility of our findings. Despite some methodological limitations in the primary studies, we have moderate to high confidence in the findings.

The descriptive and analytic themes illustrate what enables older people to continue with their falls prevention



exercises. However, information about ongoing participation in exercise is limited as even in the included studies it was not the sole focus of the primary research. Since the participants in the included studies had all been through group-based falls prevention interventions there is a lack of information regarding older people's perspectives and experiences of individual (home-based) falls prevention exercise interventions. These people may have different experiences and, therefore, this is another area that needs further investigation.

CONCLUSION

Older people have their own individual and meaningful rationale for continuing or stopping exercise after the end of their falls prevention programme. Exploring these barriers and facilitators to continued exercise appears to be important during the intervention phase. It is important that HCPs get to know the older person's rationale and offer the best evidence-based practice and support to individuals, ensuring a smooth transition from structured interventions to independent exercise with sustained behaviour change. Enabling older people to continue with lifelong exercise requires understanding the place of exercise in their life and helping them to integrate it into their daily life, while keeping it relevant to them and their story.

Contributors SF, JB and KS conceived the idea for this systematic review. SF designed and conducted the literature searches. SF, JB and KS conducted data extraction, analysis and interpretation. SF wrote the first draft of the manuscript and all authors contributed to subsequent revisions and have agreed on the final version of the manuscript.

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Appendix 2a - Search strategy

1. Falls.mp. or exp falling/
2. Fall*.mp
3. 1 or 2
4. Exp prevention/ or exp primary prevention/ or exp accident prevention/ or prevention.mp
5. Prevent*.mp
6. 4 or 5
7. 3 and 6
8. Exp exercise/ or exercise.mp
9. Physical activity.mp. or exp physical activity/
10. Motor activity.mp or exp motor activity/
11. (exercis* or activit*).mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading word]
12. 8 or 9 or 10 or 11
13. 7 and 12
14. 1(patient* adj6 (complan* or participat* or satisf* or adher* or refus* or attitude* or experience* or perception* or engage*)).mp. [mp=abstract, heading words, title]
15. (patient* AND (complan* or participat* or satisf* or adher* or refus* or attitude* or experience* or perception* or engage*)).mp. [mp=abstract, heading words, title]
16. 14 or 15
17. 13 and 16
18. Longitudinal studies.mp. or exp longitudinal study/
19. (long term or long-term).mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading word]
20. (follow up or follow-up).mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading word]
21. 18 or 19 or 20
22. 17 and 21

- 23. Qualitative studies.mp or exp qualitative research/
- 24. Phenomenology.mp or exp phenomenology/
- 25. Ethnography.mp or exp ethnography/
- 26. Grounded theory.mp or exp grounded theory/
- 27. Narrative.mp. or exp narrative/
- 28. 23 or 24 or 25 or 26 or 27
- 29. 22 and 28

Appendix 3 - Extended follow-up study pack



- date -

- Address of participant –

Dear XXXX,

The Prevention of Fall Injury Trial (PreFIT) – A follow-up study

Thank you very much for taking part in the PreFIT study. You may remember that the aim of PreFIT was to find out the best ways to help people over the age of 70 years remain fit and active, and to prevent falls and fractures.

We recruited 9,821 people from across England. You took part and completed questionnaires about your general health and balance. Due to the large number of people involved, the trial is still on-going, with the results of the main study due in 2018.

We write to ask if you would help us by completing one more questionnaire. We would like to find out whether there has been any change to your general health, balance and quality of life over the last few years.

We enclose an information sheet which includes more details about why this additional survey is important and what is involved. Please feel free to discuss this with family or friends or a member of the study team before you make up your mind about taking part.

If you would like take part, please sign the consent form, complete the reply slip and questionnaire (enclosed) and return them all in the freepost envelope provided. Although you have already given consent to participate in PreFIT, we need separate consent for this extra questionnaire.

/ Continued

Warwick Medical School University of
Warwick Coventry CV4 7AL UK
T Freephone 0800 634 0439
F +44 (0)24 7657 4657
www.warwick.ac.uk



~ 2 ~

If you do not wish to take part in the study, please complete the reply slip and return in the freepost envelope and we will not contact you any further.

Thank you in advance for your help. Please do not hesitate to contact us if you have any queries. If you would like to speak to the Trial Coordinator, Mrs Emma Withers, please call her on (Freephone) 0800 634 0439 or email PreFIT@warwick.ac.uk

Yours sincerely,



Emma Withers
PreFIT Trial Coordinator
Warwick Clinical Trials Unit





Follow-up Questionnaire Reply Slip

Patient ID _____

Contact Details *Participant Name*
 Participant Address

Please tick one of the following options and return this form in the FREEPOST envelope provided:

- I am happy to complete the follow-up questionnaire**
(please return your completed questionnaire using the FREEPOST envelope provided)

- I do not wish to complete the questionnaire please do not contact me further**
(please return this reply slip and the blank questionnaire using the FREEPOST envelope provided)



PARTICIPANT INFORMATION SHEET

We are inviting you to take part in follow-up research for the Prevention of Fall Injury Trial (PreFIT). Before you decide if you want to take part, please read the information in this leaflet. You can talk about this research with other people if you wish.

Firstly, thank you for participating in PreFIT. The aim of PreFIT has been to investigate how the NHS can best help people aged over 70 to retain good balance and function and avoid problems like falls and fractures. Due to the large number of people involved, the trial is still on-going, with the results of the main study due in 2018.

What is the purpose of this project?

The purpose of this follow-up project is to find out if your health, balance, activity and quality of life, have changed since taking part in the last survey. We are writing to everyone who took part in the PreFIT study to ask if you would complete a further questionnaire so we can compare changes in your health and balance over time.

What will I be asked to do if I take part in the project?

If you would like to take part in the project please sign the enclosed consent form and complete the questionnaire (approximately 30 minutes to complete) and then return both in the freepost envelope provided. Although you gave consent to take part in the original PreFIT study, we need separate consent as this is an extra follow-up study.

A signed consent form will also give us permission to collect relevant information from your medical records which are held by NHS Digital (formerly the Health and Social Care Information Centre). An authorised researcher would securely provide NHS Digital with your name, date of birth and NHS number to access your records to get the information we need. This may include Hospital Episode Statistics (HES) which are data about visits to hospitals in England. NHS Digital will also provide us with information about study participants who may have passed away since the start of the study, including date and cause of death.

Additionally, we would like to interview a small number of people (approximately 30) about their experience of being involved in PreFIT and their physical activity and general health (please see page 10 of the questionnaire). We are also asking if, at a later date, you would consider completing a diary about falls for one month, recording if you have any falls each day.

Do I have to take part in this project?

No. It is up to you to decide if you want to take part. If you decide not to take part, the healthcare you receive will not be affected in any way. If you agree to take part, you can withdraw from the project at any time without having to give a reason.

What are the possible risks of taking part?

We do not think that there are any risks associated with taking part in any part of this project.

ISRCTN71002650

What are the possible benefits of taking part?

The findings from this project will help healthcare professionals understand possible long term effects of different treatments to help older people stay healthy and active.

Who will know that I am taking part?

The only other people who will know that you are taking part are members of the project team.

Will my details be kept confidential?

Yes. All information collected during the project will be kept confidential at all times and in compliance with the Data Protection Act 1998. All information is stored in a secure place and only selected personnel involved in the study will have access to it.

Where will I find information about the project?

Information about the project can be found on our website www.warwick.ac.uk/go/prefit.

What will you do with the findings of the project?

The findings of this project will be reported to the NHS and published in relevant medical journals. We will also present the findings at conferences to health and social care professionals and other relevant groups, such as Age UK.

Who is organising and paying for the project?

The study is being co-ordinated by The University of Warwick, led by Professor Sarah Lamb. The Dunhill Medical Trust (which is a member of the Association of Medical Research Charities (AMRC)) funds some elements of this follow up research. Derbyshire Ethics Committee has reviewed the study.

What if I want to complain?

If you wish to make a complaint, please contact: **Head of Research Governance**, Registrar's Office, University House, University of Warwick, Coventry CV4 8UW (Tel: 024 7657 4774) or email researchgovernance@Warwick.ac.uk

How can I contact the project team?

If you have any questions about the project, or your involvement in it, either now or in the future, do please contact the project team either by telephone Freephone: 0800 634 0439, email prefit@warwick.ac.uk or in writing:

Freepost RSLT-KRZA-SURK
Emma Withers – PreFIT Trial Coordinator
PreFIT Study
Warwick Clinical Trials Unit
University of Warwick
Gibbet Hill
Coventry CV4 7AL

Thank you for taking the time to read this information sheet

ISRCTN71002650

ID No: *Please add ID Label here*

FOLLOW-UP QUESTIONNAIRE CONSENT FORM

If you would like to take part in this follow-up research, please read this consent form, then, if you agree with each of the four statements, please **sign, date, and print your name in the space provided** at the bottom of the form.

Please return the top copy of the form (white page) using the freepost envelope provided, and keep the second copy (pink page) for your records.

Thank you.

I confirm that:

1. I have read and understand the Patient Information Sheet (dated XXXX, version XXXX). I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.
2. I understand my participation is voluntary and I am free to withdraw at any time, without having to give a reason and without my medical care or legal rights being affected.
3. I understand that individuals from the research team may look at sections of my medical notes and information held by NHS Digital where it is relevant to my taking part in this research. This may include:
 - **Hospital Episode Statistics (HES)**, which are data about visits to hospitals in England
 - **Data about deaths (including date and cause of death)** supplied by the Office for National Statistics and held by NHS Digital
4. I agree to take part in this follow-up research.

Signature: _____

Print Name: _____

Date: _____

PARTICIPANT ID:



FollowUp Questionnaire

Freepost RSLT-KRZA-SURK
Emma Withers - PreFIT Trial CoOrdinator
PreFIT Study
Warwick Clinical Trials Unit
University of Warwick
Gibbet Hill
Coventry
CV4 7AL

Freephone : 0800 634 0439
Fax : 024 7657 4657
E-mail : prefit@warwick.ac.uk

Warwick
Medical School
CLINICAL TRIALS UNIT

ISRCTN 71002650 Extended FollowUp CRF-V1_01 03 2017

Please enter the date you are completing this questionnaire

--	--	--	--	--	--	--	--	--	--

Section 1 - There are three questions in this section.

This section is about your walking and any falls you have had in the last 12 months.

- 1.1 In the last 12 months, have you had any fall including a slip or trip; following which you have come to rest on the ground, floor, or lower level? Yes No

If yes, how many times have you fallen within the last 12 months?

- 1.2 Have you had any broken bones in the last 12 months as a result of falling? Yes No

If yes, how many broken bones have you had within the last 12 months as a result of falling.

- 1.3 On average, how many hours a day did you spend walking?
(Please cross (X) one)

- None
- Less than an hour
- More than 1 but less than 2 hours
- 2-4 hours
- More than 4 hours

Section 2 There are seven questions in this section. Please answer all questions, placing a cross within one box for each question. This section is about your balance and physical activity. Please cross (X) the most appropriate answer.

2.1 Do you have difficulties balancing whilst walking on a level surface?

Never

Sometimes

Often

Very Often

Always

2.2 Are you able to get out and about on foot outside the house?

Unaided

With a stick/support only

With help only

I can't get out at all

2.3 Over the past week, how often did you do any exercises for your muscle strength

Never

1-2 days

3 or more days

2.4 Over the past week, how often did you do any exercises for your balance (for example standing on one leg, sideways walking, heel toe walking)?

Never

1-2 days

3 or more days

2.5 Over the past week, how often did you engage in other exercise or recreational activities such as brisk walking, dancing, swimming, tennis, bowls or other similar activities?

- Never Go to question 2.7
- 1-2 days
- 3 or more days

2.6 In the past week, on average, how many hours per day did you engage in these exercises or recreational activities?

- Less than 1 hour
- More than 1 but less than 2 hours
- 2—4 hours
- More than 4 hours

2.7 In the last 12 months, how much difficulty did you have with the following activities, without the help of another person? (please cross (X) one box per line)

	No difficulty	A little difficulty	Some difficulty	A lot of difficulty	Unable to perform
a. Getting in/out of a bath	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b. Moving from bed to a chair	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c. Getting to the toilet	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
d. Dressing	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
e. Eating	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Section 3 There are five questions in this section.

The following questions are about your general health **at the moment**. By placing a cross in one box in each group below, please indicate which statement best describes your own health state **today**.

Please place a cross within one box for each question

3.1 Mobility

I have no problems in walking about

I have some problems in walking about

I am confined to bed

3.2 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

3.3 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

3.4 Pain / Discomfort

I have no pain or discomfort

I have moderate pain or discomfort

I have extreme pain or discomfort

3.5 Anxiety / Depression

I am not anxious or depressed

I am moderately anxious or depressed

I am extremely anxious or depressed

Section 4 There are 16 questions in this section. Please answer all questions, placing a cross within one box for each question.

This section is about your physical strength and ability to perform certain tasks.

Over the **past 12 months** have you experienced any of the following?

4.1 A sudden loss of balance?

Rarely or never

Sometimes

Often

Very often

4.2 Weakness in your arms?

Rarely or never

Sometimes

Often

Very often

4.3 Weakness in your legs?

Rarely or never

Sometimes

Often

Very often

4.4 Feeling dizzy or faint when you stand up quickly?

Rarely or never

Sometimes

Often

Very often

4.5 Had a loss of appetite?

Rarely or never

Sometimes

Often

Very often

4.6 Had any unexplained weight loss?

Rarely or never

Sometimes

Often

Very often

4.7 Had any difficulty paying attention to what is going on around you?

Rarely or never

Sometimes

Often

Very often

4.8 Had trouble finding the right word?

Rarely or never

Sometimes

Often

Very often

4.9 Had difficulty remembering things?

Rarely or never

Sometimes

Often

Very often

4.10 Find you forget where you put things?

Rarely or never

Sometimes

Often

Very often

4.11 Do you have difficulty reading the newspaper?

Rarely or never

Sometimes

Often

Very often

4.12 Do you have difficulty recognising a friend across the street?

Rarely or never

Sometimes

Often

Very often

4.13 Do you have difficulty reading signs at night?

Rarely or never

Sometimes

Often

Very often

4.14 Do you have any difficulty hearing a conversation over the phone?

Rarely or never

Sometimes

Often

Very often

4.15 Do you have any difficulty hearing a normal conversation?

Rarely or never

Sometimes

Often

Very often

4.16 Do you have any difficulty hearing a conversation in a noisy room

Rarely or never

Sometimes

Often

Very often

Section 5

There is one question in this section.
Please place a cross within one box for the question.

5.1 Compared to 12 months ago, how would you rate your health in general now?

- Much better now
- Somewhat better now
- About the same
- Somewhat worse now
- Much worse now

Section 6 There are two questions in this section.
Please place a cross within one box for each question.

6.1 We would like to interview a small number of people to find out more about the experience of being involved in the PreFIT Study.

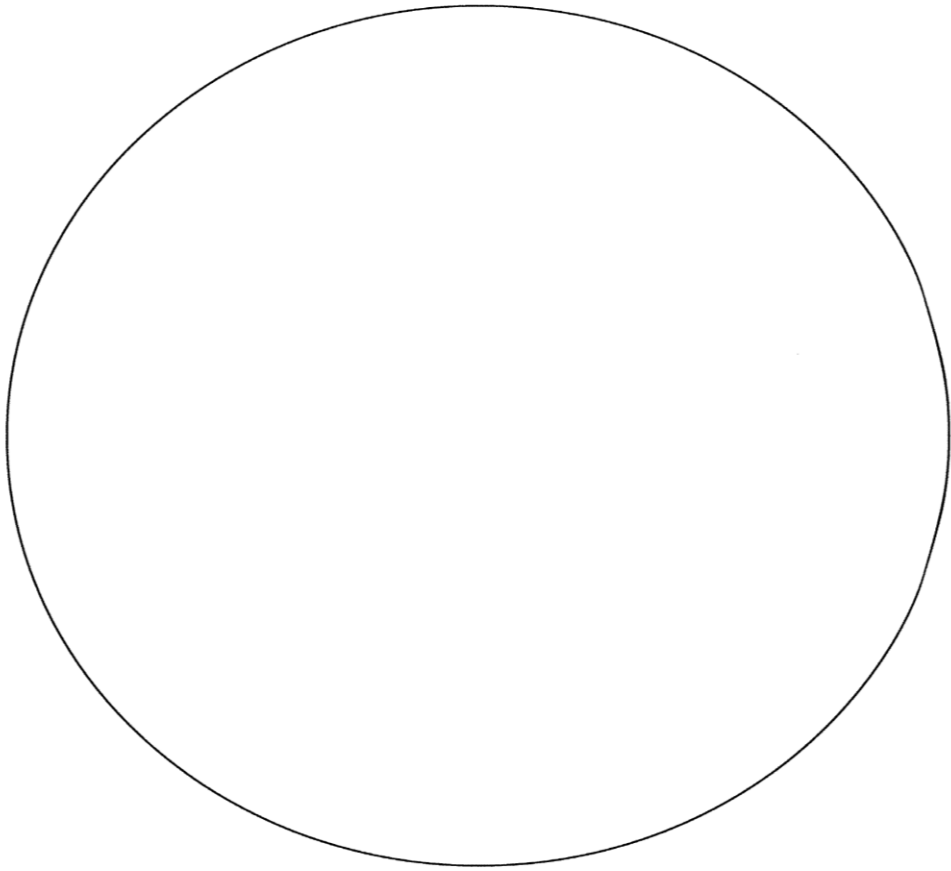
	Yes	No
Would you be interested in being approached for an interview?	<input type="checkbox"/>	<input type="checkbox"/>
We will contact you if you are selected to take part.		

6.1 Would you be willing to complete a 1 month fall diary?

	<input type="checkbox"/>	<input type="checkbox"/>
We will contact you if you are selected to take part.		

Section 7 There is one question in this section.

Below you will see a large circle. Please could you draw numbers in this circle to make it look like the face of a clock? Then could you draw the hands of the clock to read "10 past 11."



For Office use only:



Please Turn Over

You have now completed the questionnaire. Thank you.

Please check that you have completed all sections and then return your completed questionnaire in the freepost envelope provided.

If there is anything else that you would like to tell us, please feel free to write any notes for the research team on this page.

THANK YOU VERY MUCH FOR YOUR TIME.

Appendix 4 - Falls diaries



WARWICK
CLINICAL TRIALS UNIT

Date Participant ID

Participant details

Dear XXXX,

The Prevention of Fall Injury Trial (PreFIT) – 1-month Falls Diary

Thank you for your interest in completing a falls diary. We appreciate your continued contribution to this research.

The aim of this part of the study is to capture the number of falls you are having on a day to day basis. We ask that you complete one diary – for 1-month (similar to those you completed as part of the main PreFIT study) to record if you have had any falls, slips or trips in which you have lost your balance and landed on the ground, floor or other lower level.

You indicated on your last questionnaire that you were happy to be contacted about completing a 1-month falls diary; therefore, we have enclosed an information sheet which includes more details about what is involved. Please feel free to discuss this information with family or friends or a member of the study team before you make your mind up about taking part.

If you are willing to take part, please complete the diary and return it to us at the end of May 2018 (Freepost). Please note that a returned, completed diary indicates that you consent for us to use this data in our analysis.

Thank you in advance for your help. If you have any questions about how to complete the diary please telephone the study office on Freephone number 0800 634 0439 or email PreFIT@warwick.ac.uk

Yours sincerely,



Susanne Finnegan
Research Fellow
Warwick Clinical Trials Unit

Enclosed:
Patient Information Sheet
Falls Diary (Freepost)

PreFIT_falls diary_cover letter_V3 19 07 17

AVAILABLE IN LARGE PRINT ON REQUEST



PARTICIPANT INFORMATION SHEET

The Prevention of Fall Injury Trial (PreFIT) – 1-month Falls Diary

We are inviting you to complete a falls diary for one month in relation to the Prevention of Fall Injury Trial (PreFIT). Before you decide if you want to take part, please read the information in this leaflet. Please feel free to discuss this information with family or friends or a member of the study team before you make your mind up about taking part.

Thank you for participating in the PreFIT trial. The aim of PreFIT has been to investigate how the NHS can best help people aged over 70 to retain good balance and function and avoid problems like falls and fractures. Due to the large number of people involved, the trial is still on-going, with the results of the main study due in 2018.

What is the purpose of collecting falls diary data?

Using falls diaries or calendars is considered to be a high-quality method of collecting the number of falls that an individual has. Therefore, the purpose of collecting this extra falls data is to capture the number of falls you are having on a day to day basis and thus obtain an accurate account of the number of falls occurring during the period of one month. This data will be compared with information from any previous falls diaries that you have completed as part of the PreFIT study.

Why have I been chosen?

You have been invited because you took part in the PreFIT study and indicated on your last questionnaire that you were willing to complete a 1-month falls diary.

What will I have to do if I do take part?

We ask that you complete a diary (like those you completed as part of the main PreFIT study) to record if you have had any falls, slips or trips in which you have lost your balance and landed on the ground, floor or other lower level. Please start the diary on the 1st May 2018. We would like you to record the number of times you have fallen each day – using a “0” for none, “1” for one fall and so on. At the end of the month, please post the completed diary back to us (Freepost – no envelope required). The return of a completed diary indicates that you consent for us to use this data in our analysis.

If you report many falls, a member of the team may telephone you to check on all the reported incidents.

Do I have to take part?

No. If you decide not to take part, the healthcare you receive will not be affected in any way. If you agree to take part, you can change your mind at any time and withdraw from completing the falls diary without having to give a reason.

What are the possible risks of taking part?

We do not believe that there are any particular risks associated with completing a falls diary, although we do acknowledge the time commitment that may be involved.

PreFIT Falls Diary Information Sheet V2_19 07 17

AVAILABLE IN LARGE PRINT ON REQUEST

What are the possible benefits of taking part?

Although there may not be any direct benefits to you, the information gained from participants of a clinical trial such as PreFIT, may improve future care for people who have problems with balance and are at risk of falling in the future.

Who will know that I am taking part?

The only people who will know that you are taking part are members of the project team.

Will my details be kept confidential?

Yes. All information collected during the project will be kept confidential and in compliance with the Data Protection Act 1998. All information will be stored in a secure place, and only selected authorised personnel will have access to it. All documentation and data will be archived for ten years after completion of this project.

What will you do with the findings of the study?

The findings of this project will be published in relevant health journals. We will also present the findings widely at conferences to health and social care professionals and other relevant groups, such as Age UK.

Who is organising and paying for the project?

The PreFIT study is being co-ordinated by The University of Warwick, led by Professor Sarah Lamb.

The Dunhill Medical Trust (which is a member of the Association of Medical Research Charities [AMRC]) is funding Susanne Finnegan to undertake this collection of falls diary data as part of her PhD (Life After Falls prevention Therapy involving ExeRcise – LAFTER).

East Midlands – Derby Research Ethics Committee has reviewed and approved the study.

What if I want to make a complaint?

If you wish to make a complaint, please contact: **Head of Research Governance**, Registrar's Office, University House, University of Warwick, Coventry CV4 8UW (Tel: 024 7657 4774) or email researchgovernance@Warwick.ac.uk

How can I contact the project team?

If you have any questions about the project, or your involvement in it, either now or in the future, do please contact the project team either by telephone **Freephone: 0800 634 0439**, email prefit@warwick.ac.uk or in writing to: Freepost LAFTER STUDY

Thank you for taking the time to read this information sheet



For each day this month, please write the number of times you had any fall, including a slip or trip, in which you lost your balance and landed on the floor or ground or lower level. If you did not have a fall, please write '0'.

March 2018

Participants ID «TNO»

Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
			1	2	3	4
5	6	7	8	9	10	11
12	13	14	15	16	17	18
19	20	21	22	23	24	25
26	27	28	29	30	31	

At the end of March (when this card is complete) please post it back to us.
There is no need for you to add your name or any postage.

For Office Use Only: - Number of Falls

2

ISRCTN71002650

PreFIT Extended Follow-up Falls Diary_V3_19 07 17

Appendix 5 - Ethical approval for follow-up study



Health Research Authority

East Midlands - Derby Research Ethics Committee

The Old Chapel
Royal Standard Place
Nottingham
NG1 6FS

Please note: This is the favourable opinion of the REC only and does not allow the amendment to be implemented at NHS sites in England until the outcome of the HRA assessment has been confirmed.

07 April 2017

Emma Withers
PROSPER Trial Coordinator
Warwick Clinical Trials Unit
Warwick Medical School University
Coventry
CV4 7 AL

Dear Emma Withers

Study title:	Prevention of Fall Injury Trial
REC reference:	10/H0401/36
Amendment number:	8
Amendment date:	01 March 2017
IRAS project ID:	40999

The above amendment was reviewed by the Sub-Committee in correspondence.

Ethical opinion

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

Approved documents

The documents reviewed and approved at the meeting were:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Letters of invitation to participant [PreFIT_Follow-up_Invitation Letter]	1	01 March 2017
Notice of Substantial Amendment (non-CTIMP)	8	01 March 2017
Other [Extended FollowUp CRF]	1	01 March 2017

Participant consent form [PreFIT_Follow-up_Consent_Form]	1	01 March 2017
Participant information sheet (PIS) [PreFIT_Follow Up_PIS]	1	01 March 2017
Research protocol or project proposal [PreFIT_Protocol for extended follow-up]	1	01 March 2017

Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

Working with NHS Care Organisations

Sponsors should ensure that they notify the R&D office for the relevant NHS care organisation of this amendment in line with the terms detailed in the categorisation email issued by the lead nation for the study.

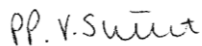
Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

We are pleased to welcome researchers and R & D staff at our Research Ethics Committee members' training days – see details at <http://www.hra.nhs.uk/hra-training/>

10/H0401/36:	Please quote this number on all correspondence
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Yours sincerely



Mr Peter Korczak (Chair)
Chair

E-mail: NRESCommittee.EastMidlands-Derby@nhs.net

Enclosures: List of names and professions of members who took part in the review

*Copy to: Mrs Ceri Jones
Professor Sarah Lamb, University of Warwick
Dr Peter Hedges*

East Midlands - Derby Research Ethics Committee

Attendance at Sub-Committee of the REC meeting on 06 April 2017

Committee Members:

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Mr Peter Korczak (Chair)	Consultant Maxillofacial Surgeon	Yes	
Mrs Janet Mallett	Retired Nurse	Yes	

Also in attendance:

<i>Name</i>	<i>Position (or reason for attending)</i>
Miss Victoria Strutt	REC Manager

Appendix 6 - Interview study pack

	
Date	Participant ID
Participant details	Participant ID
Dear XXXX,	
The Prevention of Fall Injury Trial (PreFIT) – an interview study	
Thank you for your interest in this interview study. The aim of the study is to investigate your experience of participating in the PreFIT trial, as well as any physical activity and exercise you do and how this affects your health.	
You indicated on your last questionnaire that you were happy to be approached about the interview study; therefore, we have enclosed an information sheet which includes more detail about what is involved. Please feel free to discuss this information with family or friends or a member of the study team before you make your mind up about taking part.	
If you are willing to take part in this interview study, please complete the enclosed consent form and return it in the freepost envelope provided. A member of the research team will then contact you to arrange a convenient time to visit you at your home or telephone you to complete the interview, which may take up to 60 minutes.	
Thank you in advance for your help. Please do not hesitate to contact us if you have any queries. If you would like to speak the Trial Coordinator, Mrs. Emma Withers, please call her on Freephone number 0800 634 0439 or email PreFIT@warwick.ac.uk .	
Yours sincerely,	
	
Susanne Finnegan Warwick Clinical Trials Unit University of Warwick	
Enclosed: Participant Information Sheet Consent Form Prepaid envelope	
PreFIT Interview Study Invitation Letter_V1_15 06 17	

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PARTICIPANT INFORMATION SHEET

The Prevention of Fall Injury Trial (PreFIT) - An Interview Study

We are inviting you to take part in an interview study related to the Prevention of Fall Injury Trial (PreFIT). Before you decide if you want to take part, please read the information in this leaflet. Please feel free to discuss this information with family or friends or a member of the study team before you make your mind up about taking part.

Firstly, thank you for participating in the PreFIT trial. The aim of PreFIT has been to investigate how the NHS can best help people aged over 70 to retain good balance and function and avoid problems like falls and fractures. Due to the large number of people involved, the trial is still on-going, with the results of the main study due in 2018.

What is the purpose of this interview study?

The purpose of this interview study is to find out about your experience of being involved in the PreFIT study. We are also interested in your experiences of physical activity and exercise and their effect on your general health and quality of life.

Why have I been chosen?

You have been invited because you took part in the PreFIT study and indicated on your last questionnaire that you were willing to be approached about the interview study. We plan to interview about 30 people, thus, not everyone who expresses an interest will be contacted.

What will I have to do if I do take part?

If you would like to take part, please initial and sign the enclosed consent form and return it in the freepost envelope provided. A member of the research team will contact you to arrange a convenient time for the interview. The interview will take place in your own home or over the telephone, whichever you prefer, and will take up to one hour. However, we can arrange to conduct a shorter interview or talk on several occasions for a shorter duration if you wish.

We will be audio recording the interview. The only people to listen to the recording will be members of the research team and a transcriber who will type the interview so that the data can be analysed; your name and any information that could identify you will be removed. With your permission, anonymous quotes from your transcript might be used in PreFIT publications. The file of the audio recording will be deleted at the end of the study.

Do I have to take part?

No. If you decide not to take part, the healthcare you receive will not be affected in any way. If you agree to take part, you can withdraw from the interview study at any time without having to give a reason.

What are the possible risks of taking part?

We do not believe that there are any particular risks associated with taking part in an interview, although we do acknowledge the extra time commitment that may be involved. We

AVAILABLE IN LARGE PRINT ON REQUEST

also appreciate that some people may find it difficult to talk about some topics. We will not ask you to talk about anything that you are not comfortable with and you may halt the interview at any time.

What are the possible benefits of taking part?

Although there may not be any direct benefits to you, the information gained from participants of a clinical trial such as PreFIT, may improve future care for people who have problems with balance and are at risk of falling in the future.

Who will know that I am taking part?

The only people who will know that you are taking part are members of the project team.

Will my details be kept confidential?

Yes. All information collected during the project will be transferred securely to Warwick Clinical Trials Unit and kept confidential and in compliance with the Data Protection Act 1998. All information will be stored in a secure place, and only selected authorised personnel will have access to it. With your permission, anonymous quotes from your transcript might be used in PreFIT publications. All documentation and data will be archived for ten years after completion of this project.

What will you do with the findings of the study?

The findings of this project will be published in relevant health journals. We will also present the findings widely at conferences to health and social care professionals and other relevant groups, such as Age UK.

Who is organising and paying for the project?

The PreFIT study is being co-ordinated by The University of Warwick, led by Professor Sarah Lamb.

The Dunhill Medical Trust (which is a member of the Association of Medical Research Charities [AMRC]) is funding Susanne Finnegan to undertake this interview study as part of her PhD (Life After Falls prevention Therapy involving ExeRcise – LAFTER).

East Midlands – Derby Research Ethics Committee has reviewed and approved the study.

What if I want to make a complaint?

If you wish to make a complaint, please contact: **Head of Research Governance**, Registrar's Office, University House, University of Warwick, Coventry CV4 8UW (Tel: 024 7657 4774) or email researchgovernance@Warwick.ac.uk

How can I contact the project team?

If you have any questions about the project, or your involvement in it, either now or in the future, do please contact the project team either by telephone **Freephone: 0800 634 0439**, email prefit@warwick.ac.uk or in writing to: Freepost LAFTER STUDY

Thank you for taking the time to read this information sheet



Please add ID Label here

ID No:

The Prevention of Fall Injury Trial (PreFIT) – An interview study

CONSENT FORM

If you would like to take part in this interview study, please read this consent form, then, if you agree with each of the five statements, **please INITIAL each box, then sign, date, and print your name in the space provided** at the bottom of the form.

Thank you.

I confirm that:

- 1. I have read and understand the information sheet (V2, dated 11/07/2017). I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.
- 2. I understand that my participation is voluntary and that I am free to withdraw at any time, without having to give a reason and without my medical care or legal rights being affected.
- 3. I give permission for the interview to be audio digitally-recorded. I understand that audio recordings will be securely transferred to the University of Warwick for transcription/analysis.
- 4. I give permission for anonymous quotes from my interview to be used in the reporting and dissemination of this study.
- 5. I agree to take part in the interview study.

Signature: _____ Date: _____ Print name: _____

Researcher signature: _____ Date: _____ Print name: _____

Interview Schedule for the Prevention of Fall Injury Trial (PreFIT)

This qualitative study will involve individual interviews. Please ensure all participants have read the Patient Information Sheet (PIS) and signed a consent form before their interview.

1. Interview Schedule: Experience of the PreFIT study and effects of physical activity/exercise on general health and quality of life.

Reminder – Purpose of Individual Interviews

- 1) To explore participants' experiences of being involved in the PreFIT study.
- 2) To explore what physical activity/exercise the participants are currently undertaking and its effects.
- 3) To identify whether participants physical activity/exercise has changed since participation in PreFIT, and if so, how, and what effect has it had?
- 4) To explore participants' views on the barriers and facilitators to physical activity/exercise.

Before switching on the audio-recorder

Background information – why this interview

"This interview is to help us understand your experience of taking part in the PreFIT study."

Confidentiality

"Before we start talking, I would like to assure you that everything that you say will remain confidential. Your doctor, nurse or any other health professional will not see or hear any of the information that is shared here. If we do use anything that you have said, such as in a report or journal article, it will be made anonymous so that you cannot be identified."

Any questions at this stage?

"Do you have any questions before we switch on the recorder and start?"

Switch on the audio-recorder

Interviewees will be encouraged to speak openly and freely about what their experience of the exercise intervention was and how the intervention has affected them.

Indicative questions and prompts are given below (these questions are flexible and not all questions will be appropriate or asked of all participants):

Indicative Questions	Prompt
Can you tell me what made you take part in the PreFIT study? What were your thoughts and feelings when you were asked? What was it like for you?	Had you had any falls prior to taking part? Have you had any since?

Have you ever had any falls or problems with your balance? Can you tell me about what happened when you fell?	To what extent do falls interfere with your life? Have you ever had any treatment (other than the PreFIT intervention) to help with your balance or falls?
Did you have to do any exercises as part of the study? If yes, what did you think of the exercises? How did they make you feel?	How did you find doing them? a) Was there anything easy or hard about doing them? b) How did you manage with finding the time to do them? c) Did you like doing them?
If no, would you have been interested in doing exercises? Why?	Did you receive the Age UK Staying Steady leaflet? How did you find the exercise/physical activity information in the leaflet? Was it any help to you?
Can you tell me what does exercise or physical activity mean to you?	What do you think of/picture when someone talks about exercise or physical activity?
Can you tell me what effect you think exercise/physical activity has on health?	How does it affect/how has it affected your risk of falling?
Do you currently do <i>any</i> exercise/physical activity? If yes, can you tell me about the type of exercise you do. Why do you do this exercise? If no, can you tell me why you don't do any exercise?	Are you including gardening, walking etc. or specific types of exercise?
Do you still do any of the exercises you were given as part of PreFIT? Which ones do you do? Why?	Have you altered them? If so, how and why?
Can you tell me about anything that helped you stick with the PreFIT exercises?	What made you want to keep exercising?
Can you tell me about anything that made it difficult for you to carry on with or start the PreFIT exercises?	How do these difficulties affect your health/life?
What, if anything, prevents you from doing more exercise/physical activity?	What would make it easier for you to be more active?
Has the amount or type of exercise/physical activity you do changed since you got involved in the PreFIT study? Why?	What effect has this had on your health/life?
What messages would you give to other people who fall or have problems with their balance?	

What messages would you give to other people who are thinking about taking part in a research project?	
--	--

Rounding off

[Suggested dialogue]

“Is there something else that you think is important that I haven’t asked you or you would like to discuss? Is there something that you think we should have talked about but haven’t?”

Thank you

Thank individuals for their help with the study. We very much appreciate their time.

Appendix 7 - Ethical approval for interview study



Health Research Authority

East Midlands - Derby Research Ethics Committee

The Old Chapel
Royal Standard Place
Nottingham
NG1 6FS

Please note: This is the favourable opinion of the REC only and does not allow the amendment to be implemented at NHS sites in England until the outcome of the HRA assessment has been confirmed.

24 August 2017

Susanne Finnegan
Research Fellow
Warwick Clinical Trials Unit
Warwick Medical School
University of Warwick
Warwick Clinical Trials Unit
Gibbet Hill Campus
Coventry
CV4 7AL

Dear Susanne Finnegan,

Study title:	Prevention of Fall Injury Trial
REC reference:	10/H0401/36
Amendment number:	9
Amendment date:	14 July 2017
IRAS project ID:	40999

The above amendment was reviewed on 22 August 2017 by the Sub-Committee in correspondence.

Ethical opinion

Decision: No ethical issues.

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

Approved documents

The documents reviewed and approved at the meeting were:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Covering letter on headed paper [Covering Letter_09 08 2017.docx]		09 August 2017
Interview schedules or topic guides for participants [PreFIT_Interview Study_Interview schedule_V1_15 06 17.docx]	1	15 June 2017

Letters of invitation to participant [PreFIT_Interview Study_Invitation letter_V1_15 06 17.docx]	1	15 June 2017
Notice of Substantial Amendment (non-CTIMP) [AmendmentForm_ReadyForSubmission.pdf]	9	14 July 2017
Other [PreFIT_cover letter_falls diary_V3_19 07 17.docx]	3	19 July 2017
Other [PreFIT Extended Follow Up_Falls Diary_V3_19 07 17.pdf]	3	19 July 2017
Participant consent form [PreFIT_Interview Study_Consent Form_V2_11 07 17.docx]	2	11 July 2017
Participant information sheet (PIS) [PreFIT_Falls Diary_PIS_V2_19 07 17_.docx]	2	19 July 2017
Participant information sheet (PIS) [PreFIT_Interview Study_PIS_V2_11 07 17.docx]	2	11 July 2017
Research protocol or project proposal [PreFIT_Protocol Addendum_interview study and falls diary_V3_19 07 2017.docx]	3	19 July 2017

Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

Working with NHS Care Organisations

Sponsors should ensure that they notify the R&D office for the relevant NHS care organisation of this amendment in line with the terms detailed in the categorisation email issued by the lead nation for the study.

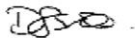
Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

We are pleased to welcome researchers and R & D staff at our Research Ethics Committee members' training days – see details at <http://www.hra.nhs.uk/hra-training/>

10/H0401/36:	Please quote this number on all correspondence
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Yours sincerely



PP
Dr John S Fenlon
Chair

E-mail: NRESCCommittee.EastMidlands-Derby@nhs.net

Enclosures: List of names and professions of members who took part in the review

*Copy to: Mrs Ceri Jones,
Professor Sarah Lamb,
Dr Peter Hedges*

East Midlands - Derby Research Ethics Committee

Attendance at Sub-Committee of the REC meeting on 22 August 2017

Committee Members:

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Dr John S Fenlon (Chair)	Statistical Consultant	Yes	
Mrs Janet Mallett	Retired Nurse	Yes	

Also in attendance:

<i>Name</i>	<i>Position (or reason for attending)</i>
Miss Daniella Sarno	REC Assistant

Appendix 8 - Reflections on the interview process

Interview 6: I really liked the question posed to me by the participant – “What did you expect to find when you arrived?” She was referring to the expectations and presumptions that people or society have about “old people” and what we picture when we talk about people in their 80’s. This will be something that I keep with me and think about during the next batch of interviews.

And in reality, none of the participants have been what people might think they should be like. I don’t think I have too many preconceptions about older people because of my work with older people and the variety of older people that I have met but I know that I do build up a picture of the participants when I talk to them on the phone to arrange the interviews and this picture doesn’t always match reality, so I guess I do have more preconceptions than I thought.

The interviews are definitely getting easier but it is still a challenge to keep quiet and let the participants tell their story – the physio in me still wants to butt in at times to ask questions that might be more appropriate in a clinical setting – especially in environments where there is a lot of equipment/walking aids etc. where my preconceptions can lead me to think there are problems where they might not be any, but I am getting better at putting that to one side and really listening to the participant’s story. I discussed this with a physio colleague who also does qualitative interviewing and she felt the same – at times she feels the urge to ask about things that would be important clinically but are not so important in the context of the research we are doing. Context is so important for phenomenology!

I am definitely using the interview schedule a lot less and am following up on relevant points with more prompts and more natural conversation to get as much detail as I can, so I guess I am listening a lot more than the first couple of interviews where I was so intent on asking the right questions in the hope of hearing the “right” thing to answer my research question. Maybe I do have a lot more preconceptions than I first realised – waiting to hear the right thing surely means that I thought that these people were going to tell me certain things - and to some extent some of the things I might have expected have

come up but there is also a lot of information that I didn't even think about or ever expect to hear and I need to concentrate on all of it to get a clear picture of the participants stories.

From this particular interview transcript some really interest ideas have come to my mind and need exploring in further interviews. I really want to think about this idea of a real fall versus a fall that isn't real. What definitions are there? Is it related to injurious versus non-injurious? Or is it that there was a reason for the fall versus no reason? What do my participants mean by real falls? Lots to think about...

