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Development and delivery of an exercise programme for falls prevention: the Prevention of Falls Injury Trial (PreFIT)

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Abstract

Objective This paper describes the development and implementation of an exercise intervention to prevent falls within The Prevention of Fall Injury Trial (PreFIT), which is a large multi-centred randomised controlled trial based in the UK National Health Service (NHS).
Design Using the template for intervention description and replication (TIDieR) checklist, to describe the rationale and processes for treatment selection and delivery of the PreFIT exercise intervention.
Participants Based on the results of a validated falls and balance survey, participants were eligible for the exercise intervention if they were at moderate or high risk of falling.
Interventions Intervention development was informed using the current evidence base, published guidelines, and pre-existing surveys of clinical practice, a pilot study and consensus work with therapists and practitioners. The exercise programme targets lower limb strength and balance, which are known, modifiable risk factors for falling. Treatment was individually tailored and progressive, with seven recommended contacts over a six-month period.

Clinical Trials Registry (ISCTRN 71002650).

Keywords: Falls; Falls prevention; Exercise; Older people; Complex intervention

Introduction

It is estimated that, annually, 30% of community dwelling people over the age of 65 years and 50% over 80 years, fall at least once [1]. The consequences can be physical and/or psychological and falls resulting in injury are a leading cause of mortality [1]. Approximately 5% of community dwelling older people who fall annually experience a fracture [2] and the estimated annual cost of fall related fractures in the UK is £2 billion [3]. Therefore, falls are an important focus of clinical and public health care [4].

Falls have a multifactorial aetiology; and there are several proposed prevention strategies. Some of the major risk factors are potentially modifiable, including impairments of gait and balance. Exercise aimed at these risk factors has been shown to reduce rate and risk of falling [5]. However, exercise programmes vary in type and mode of delivery [6,7].

Another prevention approach is Multifactorial Fall Prevention assessment (MFFP) and intervention where a broader range of fall risk factors are identified and treatment is targeted [8]. The NHS currently commits substantial funding to MFFP services and a conservative estimate of the annual cost is £34 million per year [7]. However, there is limited

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evidence of the efficacy of MFFP on preventing fall-related fractures and there have been no head-to-head comparisons of treatment options. Therefore, the National Institute of Health Research (NIHR), Health Technology Assessment (HTA) programme, commissioned a large-scale RCT to evaluate the relative effectiveness and cost effectiveness of alternative interventions for preventing fractures and falls in community dwelling older adults (ISCTRN 71002650).

The Prevention of Fall Injury Trial (PreFIT)

The design of the Prevention of Fall Injury Trial (PreFIT) is described in the trial protocol [9], but in brief, is a three-arm, pragmatic, cluster RCT, comparing advice only (control), advice with exercise and advice with MFFP, in community dwelling adults aged 70 years and over. The unit of randomisation is the general practice. Based on the outcome of a short self-completed fall and balance screening survey [10], participants with a history of falls and/or current balance problems, deemed to be at moderate or high risk of falling, were eligible for invitation to the intervention. Intervention development began in October 2010, with the first participant recruited to the pilot study in September 2011.

The Medical Research Council (MRC) recommends a description of interventions included in RCTs, its components, and rationale for inclusion [11]. Therefore, using the TIDieR checklist (Appendix B) [12], this paper describes the development and procedures for the PreFIT exercise intervention. The design of the MFFP intervention has been described elsewhere [13].

Rationale for the development the PreFIT exercise intervention

The rationale for using exercise to prevent falls is well established in the literature and clinical practice. Several exercise programmes have been developed and tested within high quality RCTs [14–16], and are published with sufficient detail to allow accurate replication.

Whilst developing the PreFIT intervention we adopted an evidence-based rationale for programme selection, including type and dose of exercise. Reflecting the pragmatic intention of the trial, the exercise programme needed to be deliverable within the budgetary and practice constraints of the NHS, and where possible, utilise high quality exercise programmes already well-embedded in NHS services. We, therefore, reviewed the current literature and existing systematic reviews of falls prevention interventions, published guidelines and pre-existing surveys of clinical practice, and carried out a pilot study and consensus work with therapists to specify the intervention.

Defining the essential elements of a fall prevention exercise programme

There is positive and consistent evidence for strength and balance exercises as a falls prevention strategy [5,6]. Individually tailored exercises are necessary to account for differing health and physical function; these should be of sufficient dose, and be progressive to ensure physiological challenges continue as fitness and functional ability improves [6].

At the time of intervention development, a Cochrane systematic review [5,17] investigating strategies to prevent falling in community dwelling older people, reported 59 RCTs examining exercise as a sole intervention. The review reported group exercise reduced fall rates by 29% and risk of falling by 25% and individual home exercise programmes (HEPs) by 32% and 22% respectively [5]. There is weak evidence suggesting that exercise interventions may reduce the risk of fall related fracture, but this observation is based on a meta-analysis of a small, selective group of trials (n = 6) [5].

A separate systematic review of 54 exercise RCTs confirmed that exercise can prevent falls [6]. Higher dose exercise *i.e.* 50 hours over the trial period was found to be most effective, recommended as at least 2 hours per week for 6-months, including moderate/high challenge balance exercise, either in groups or HEP format [6]. Exercise to improve balance is most effective if performed three times per week for 3 months [18], but for lasting effects, needs to be sustained [6,18,19]. From a public health perspective, physical activity guidelines also recommend older people engage in activities to improve strength and balance at least twice a week [20].

Strength training in falls prevention programmes has additional benefits as an effective means of improving physical functioning for older people [19,21]. Strengthening exercises should include a resistance element to overload major muscle groups *i.e.* using weights/exercise bands, be progressive and be undertaken on at least two days per week [6,19]. The American College of Sports Medicine (ACSM) promotes strength training for older adults, reporting that given adequate training, older people can make significant gains in strength in 3 to 4 months [19]. This, therefore, supports the inclusion of strength training in a 6-month intervention.

The impact of walking as a falls prevention strategy remains unclear. International fall prevention guidelines do refer to several studies incorporating a walking component [16,22] and although associated with a reduction in falls, it is difficult to evaluate the effectiveness of walking alone as they also included strength and balance exercise. There is, however, evidence suggesting walking can increase risk of falling [6,23]. Therefore, walking is considered a less important feature of falls prevention interventions, but is recommended, if safe to do so, without compromising balance re-training efforts [6].

Selecting a specific intervention

We searched the published literature, replicating the previous search strategies of the Cochrane review [5,17]. We identified several standardised programmes incorporating the essential elements of a falls prevention exercise programme, reported in sufficient detail to allow replication and/or delivered an accompanying accredited training programme. To

Table 1
Exercise prescription based on chair stand test and four test balance scale.

* Level	Criteria for prescribing strength exercises	Criteria for prescribing balance exercises
Level 1	Completed chair stand test using arms *OR* took longer than 2 minutes with arms folded (failed test). *Weights*: start with a lighter weight (*e.g.* 0.5 kg) or possibly no weight at all. *Repetitions*: consider a lower number of repetitions *e.g.* five to eight repetitions.	Failed balance test. Has difficulty with feet together stand *OR* can only achieve feet together stand. You should be selecting from *level 1* balance exercises only. *Repetitions*: aiming for 5 to 10 reps or seconds with support.
Level 2	Chair stand test successfully completed between 1 and 2 minutes *Weights*: start with a lighter weight, 0.5 kg. *Repetitions*: Aim for 8 to 10 repetitions if comfortable.	Managed some of balance test. Can achieve semi-tandem stand. Start by selecting *level 2* balance exercises and moderate per how the participant manages. *Repetitions*: aiming for one or two sets of 10 or 10 seconds or steps +/− support.
Level 3	Chair stand test successfully completed *e.g.* five stands within a minute. *Weights*: use a reasonable starting weight *e.g.* 1 kg. *Repetitions*: Prescribe either one or two sets of 10 repetitions.	Can achieve semi-tandem stand and can partially or completely hold the tandem stand. Start by selecting *both levels 2 and 3* balance exercises, and moderate per how the participant manages. *Repetitions*: aiming for one or two sets of 10 or 10 seconds or steps +/− support.
Level 4	Chair stand test successfully completed *e.g.* five rises within 30 seconds. *Weights*: use heavier starting weights *e.g.* 1 kg or 1.5 kg. *Repetitions*: You may need to prescribe more than 10 repetitions for participants to feel that the challenge has been moderately difficult.	Balance test successful. Can achieve one leg stand. Consider starting with *level 4* exercises, but moderate the prescription per how the participant manages. *Repetitions*: aiming for up to four sets of 10 or 10 seconds or steps without support.

reflect the pragmatic underpinning of the trial, information about exercise interventions already being delivered in NHS settings was considered [7,24], and three eligible programmes meeting all these criteria were shortlisted.

The exercise component of a multifactorial intervention developed by Tinetti *et al.* [14], aimed at reducing the risk of falling among community dwelling older people was considered. However, this exercise intervention is not widely used in the UK, therefore, other programmes were selected in preference.

The Falls Management Exercise Programme (FaME) is a 36-week group and home exercise programme incorporating fitness components plus specific falls management strategies such as open, closed and backward chain exercises, functional and floor work and Tai Chi adapted moves [25]. At the time of PreFIT intervention development, FaME had only been tested in one RCT of women over 65 years [15] therefore it was excluded. Since then, FaME has been evaluated against the Otago Exercise Programme, in a large primary care cluster RCT in lower risk older adults [26].

Designed specifically for falls prevention in community settings, the Otago Exercise Programme (OEP) is predominantly a HEP, incorporating individually tailored, progressive lower limb strengthening exercises using ankle weights, moderate to high challenge balance exercises and a walking plan [16]. In a series of four RCTs, the OEP was evaluated in 1016 community dwelling adults aged between 65 and 97 years and shown to reduce falls and fall related injuries by 35% [27,28].

Surveys of UK falls services indicated that 188 (81%) of those services used an exercise intervention; most commonly, the OEP or components of it (modified to remove exercises which may be unsafe if performed unsupervised) and 41% of all falls services employed either a trained OEP leader or a Postural Stability Instructor (54%) [24,29].

Given the high-quality evidence for the clinical and cost effectiveness of the OEP, the appropriateness of its components, its use in NHS settings and its ease to teach and deliver, the OEP was selected for use in PreFIT.

Description of the exercise intervention (following the TIDieR checklist)

Intervention providers

A physiotherapist qualified as an OEP leader [30], supported by members of the research team, provided a 4 hour structured training session to all therapists responsible for delivering the exercise intervention. Between November 2011 and September 2014, 24 training sessions were delivered to 84 therapists, of which, 49/84 (58%) were Physiotherapists, 8/84 (10%) were Occupational Therapists, 14/84 (17%) were Therapy Assistants and 13/84 (15%) were Exercise Specialists; all working in either NHS specialist falls prevention services, community therapy services or physiotherapy departments. Due to staffing issues, movement of staff and NHS structural changes, 26/84 (31%) of those trained did not go on to deliver the PreFIT intervention.

Training included the background to the problem of falls, current evidence for falls prevention, the rationale for the trial, theoretical and practical sessions on the OEP and trial administration procedures. Each therapist received a comprehensive manual containing a detailed account of all trial and intervention procedures. This manual will be available from http://wrap.warwick.ac.uk/86481 on completion of the trial.

Procedures

Each participant underwent an individual assessment with the therapist assigned to manage their treatment. This initial assessment took approximately 1 hour. Firstly, the therapist conducted a brief check with the participant to identify health issues that might influence participation. Then, as per the OEP, baseline strength and balance were measured using a Chair Stand Test and Four Test Balance Scale. These are simple, quick, valid and reliable tests of lower limb strength and balance [31,32]. The outcome of these tests determined the starting level of exercise prescription (Table 1); starting at a safe achievable level, whilst still experiencing a moderate intensity challenge [28].

The Chair Stand Test is a proxy measure of lower limb strength [28]. It involves timing participants whilst they perform five sit to stands [28,31,33] from a chair placed against a wall for safety. Following a demonstration by the therapist, the participant stands up and sits down five times with their arms folded (if possible). Standing nearby, the therapist supervises, using a stopwatch to record time taken to complete the test, allowing a maximum of 2 minutes [31]. If necessary, participants can use the chair arms to assist sit to stand, but regardless of time taken, these participants start at Level 1 for strength exercises.

The Four Test Balance Scale involves four increasingly difficult timed static balance tests: feet together stand, semi-tandem stand, tandem stand and single leg stand. The participant performs the test near a wall/solid object for safety, but without any assistive devices and in bare feet. The therapist supervises and times the participant and can help them assume each foot position. Progression through the four tests only continues if each stance is held for 10 seconds. If a participant cannot assume a foot position, support is needed or if there is any change of foot position, then timing and the test is stopped [28,32,33].

Walking is discussed to establish how much the participant does and if appropriate, safe ways to increase time spent walking (duration not speed), the target being 30 minutes twice a week (indoors and/or outdoors). The assessment may include consideration and assessment for walking aids.

Having selected appropriate starting levels, the therapist demonstrates and explains each prescribed exercise and observes the participant performing them, to ensure that they are confident to undertake them independently at home.

The OEP exercises are available from: http://www.acc.co.nz/PRD_EXT_CSMP/groups/external_providers/documents/publications_promotion/prd_ctrb118334.pdf [28], but in summary include:

- Warm up:
  - Five gentle exercises comprising mobility movements of the neck, shoulders, trunk, hips, knees and ankles.
- Five lower limb strength exercises:
  - Targeting knee flexors and extensors, hip abductors and ankle dorsiflexors and plantarflexors, using ankle weights and body weight as resistance.
- Twelve dynamic balance exercises:
  - Ranging from tandem stand with support (Level 1) to heel toe walking backwards with no support (Level 4). N.B. Not all 12 exercises are prescribed initially but more are added to the programme as the participant progresses (see Appendix 2).

The exercise programme takes approximately 30 minutes per session. Therapists instructed participants to exercise independently at home, completing at least three sessions per week, with a rest day in between for strengthening exercises. Adherence and compliance with exercise programmes can be challenging, especially over long periods [33]. Evidence suggests that calendars or diaries improve adherence [34], therefore, participants were encouraged to use exercise activity calendars; serving as a reminder to exercise, a prompt to self-monitor behaviour and gave therapists the opportunity to check and provide feedback on exercise performance.

We reviewed the literature to identify additional behaviour change techniques, which included action planning [35], identification of barriers to exercise and use of problem solving strategies including SMART (Specific, Measurable, Achievable, Relevant and Timely) goal setting to motivate participants to continue with the programme [36]. Participants are actively involved in the decision-making process regarding selection of exercises and goal setting; this can reinforce how best the exercises and walking plan can realistically and specifically help in maintaining activities that are important to them.

Materials

The equipment required for the exercise intervention includes a straight-backed firm chair (between 40 and 50 cm in height) and a stopwatch; both used during baseline and final assessments.

Each participant was provided with a personalised A5 exercise folder including pictures of and instructions for each exercise, as well as general exercise advice. A set of ankle weights was provided for their strengthening exercises; these were replaced with heavier weights over time to ensure progression.

After the intervention, participants were encouraged to continue with their exercise programme and a 'staying active' leaflet, designed specifically for the trial, was given to each participant. This included information about purchasing weights, the benefits of continued exercise and current exercise opportunities in their local area.

Where

Due to the pragmatic nature of the trial, location of face to face appointments varied dependent on local service provision, but included outpatient/clinic settings and home visits. Some services could deliver the intervention in groups, but the majority saw participants individually, however either was permitted.

When and how much

The supervised PreFIT exercise intervention is planned for 6 months. This is shorter than the original OEP, which lasted a year, but is likely to be longer than current usual NHS practice, where many services provide strength and balance training for up to 12 weeks [24,29]. During the 6 months, therapists arranged *a minimum* of three face-to-face appointments, either individually or in a group setting and three telephone appointments with participants. Ideally, follow up appointments occurred at 3 and 6 weeks, 3, 4 and 5 months, with a final assessment (face to face) at 6 months to repeat The Chair Stand Test and Four Test Balance Scale (seven contacts over 6-month period).

Therapists completed an exercise treatment log at each appointment. Information recorded included: exercises undertaken, weight/support used, number of repetitions or sets, participants' progress *i.e.* whether the amount of exercise increased at follow up appointments or whether strength, balance and walking improved overall (final assessment), and the number of times exercises were completed per week (self-report).

Tailoring

Tailoring is personalised and is used to ensure progression of exercise *i.e.* increasing repetitions, sets or weights or adding balance exercises to provide an on-going moderately intense challenge [28]. Tailoring occurs during the assessment and follow up appointments where exercises are individually prescribed to address deficits of strength and balance and to take account of other conditions and the preferences of the participants.

Modifications

A pilot study, involving GP practices in North Devon, determined acceptability of the exercise intervention to participants and clinicians, and feasibility of delivering the intervention in an NHS setting. Following feedback from therapists, the exercise treatment log was modified to improve and simplify data collection and to overcome challenges of organising PreFIT appointments within their normal clinical

work, we produced a scheduling tool for planning follow-up visits.

Adherence/fidelity

To determine whether the intervention was delivered as intended, each therapist underwent at least one structured observation by a research physiotherapist to assess whether they delivered the exercise intervention in accordance with the specified protocol.

Using a standardised checklist, the following items were assessed: correct exercise prescription in response to the initial assessment, effective and safe delivery of the programme including progression, adherence to the protocol *i.e.* not providing additional exercises or treatment, and completion of all paperwork. Each therapist received a written grading (satisfactory, minor concerns or serious concerns) and follow up visits were arranged if necessary.

Fidelity to the intervention will be assessed through data collected on the treatment logs, and from postal questionnaires completed by participants at different follow-up time points [9].

Discussion

Falls prevention strategies are complex interventions and published research often fails to describe trial interventions sufficiently, making it difficult to translate research findings into clinical practice. We provide a detailed overview of the PreFIT exercise intervention, using the TIDieR checklist, to ensure transparent reporting and potentially allow easier replication of this work into practice should the intervention prove effective.

PreFIT is testing an exercise intervention using an established evidence based exercise programme within a large RCT. As per the evidence and recommendations for falls prevention exercise programmes, the intervention (OEP) comprises strength and balance exercises, a walking plan and is of sufficient duration [6,16,28,37]. The PreFIT intervention is consistent with high quality, international, evidence based clinical guidelines and research [1,37,38]. The OEP is already widely used within the UK NHS, although commonly in a shorter format *i.e.* up to 12 weeks' duration [24,29]. Furthermore, the ProFouND initiative has promoted roll out across Europe, to disseminate best practice in exercise delivery [39].

The pragmatic approach taken to deliver the PreFIT exercise intervention within the constraints of busy NHS physiotherapy departments, community falls services and existing exercise therapy services has been challenging *e.g.* due to NHS structural changes, service reorganisation and staff changes. However, if shown to be effective, this 6-month intervention is feasible for delivery in both community and hospital settings and is documented to a standard promoting consistency in delivery, enabling replication in future studies and practice. The intervention is acceptable to participants and clinicians, and despite waiting list pressures, staff shortages and a constantly changing NHS, we found that it could be delivered successfully.

The effectiveness and cost-effectiveness of the PreFIT exercise intervention in comparison with advice only and a MFFP intervention, on the prevention of fractures and falls will be reported at the conclusion of the trial.

Key messages

- This article describes the rationale for a falls prevention exercise intervention within a large randomised controlled trial.
- A thorough description of the development and delivery of a complex falls prevention exercise intervention is presented.

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Conflict of interest: DAS is a Director of Later Life Training, a not for profit company that has provided specialist training for health and exercise professionals in OEP (since 2006).

Contributors: SEL, JB and SF drafted the core content of the intervention, refined by DAS. EJW coordinated study administration, acquisition of trial data and senior administrative support. JB, SF and VN delivered intervention training. SF and JB coordinated delivery of interventions. SF drafted the manuscript. SEL was chief investigator, specified the original formulation of the intervention and obtained the funding. All authors critically revised the manuscript for important intellectual content and approved the final manuscript.

Appendix A.

Collaborators:

PreFIT Study Group: Chief Investigator: Professor Sarah E Lamb. Co-investigators (Grant holders): Professor Martin Underwood, Professor Finbarr Martin, Professor Lucy Yardley, Professor Dawn Skelton, Professor Keith Willett, Professor Sandra Eldridge, Dr Tim Friede, Dr Claire Hulme, Dr Anne-Marie Slowther, Dr Sarah Duggan. Core trial team members are listed in the protocol paper [9].

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Newcastle: Lucy Flanagan, Ben Johnson, Vivienne Thompson.

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Appendix B. Supplementary data

Supplementary data associated with this article can be found, in the online version, at http://dx.doi.org/10.1016/j.physio.2017.06.004.

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