A falls prevention programme to improve quality of life, physical function and falls efficacy in older people receiving home help services: Study protocol for a randomised controlled trial

Last updated: 06/23-2017

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 Bjerk M, Brovold T, Skelton DA, Bergland A: **A falls prevention programme to improve quality of life, physical function and falls efficacy in older people receiving home help services: study protocol for a randomised controlled trial**. *BMC Health Services Research* 2017, **17**(1): 559. DOI: 10.1186/s12913-017-2516-5

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Abstract

Background:

Falls and fall-related injuries in older adults are associated with great burdens, both for the individuals, the health care system and the society. Previous research has shown evidence for the efficiency of exercise as falls prevention. An understudied group are older adults receiving home help services, and the effect of a falls prevention programme on health-related quality of life is unclear. The primary aim of this randomised controlled trial is to examine the effect of a falls prevention programme on quality of life, physical function and falls efficacy in older adults receiving home help services. A secondary aim is to explore the mediating factors between falls prevention and health-related quality of life.

Methods:

The study is a single-blinded randomised controlled trial. Participants are older adults, aged 67 or older, receiving home help services, who are able to walk with or without walking aids, who have experienced at least one fall during the last twelve months and who have a Mini Mental State Examination of 23 or above. The intervention group receives a programme, based on the Otago Exercise Programme, lasting twelve weeks including home visits and motivational telephone calls. The control group receives usual care. The primary outcome is health-related quality of life (SF-36). Secondary outcomes are leg strength, balance, walking speed, walking habits, activities of daily living, nutritional status and falls efficacy. All measurements are performed at baseline, following intervention at three months and at six months' follow-up. Sample size, based on the primary outcome, is set to 150 participants randomised into the two arms, including an estimated 15-20% drop out. Participants are recruited from six municipalities in Norway.

Discussion:

This trial will generate new knowledge on the effects of an exercise falls prevention programme among older fallers receiving home help services. This knowledge will be useful for clinicians, for health managers in the primary health care service and for policy makers.

Trial registration: ClinicalTrials.gov. NCT02374307. First registration, 16/02/2015.

Keywords: Falls prevention, Home help services, Elderly, Quality of life, Older adults, Exercise, Balance, Preventative care

Background

Older adults and health-related quality of life

Health-related quality of life (HRQOL) is of great interest, both with respect to individuals themselves as well as a primary concern of public health administrations and professionals. The remarkable increase in life expectancy in the twentieth century implies a need to focus on factors capable of promoting a high level of HRQOL into old age. In fact, older adults seem to prefer a high HRQOL more than longevity, and researchers have concluded that the key challenge is to preserve a high level of HRQOL rather than increase length of life [1, 2]. HRQOL is a subjective, multidimensional concept shaped by, but not entirely dependent upon, the effects of disease and treatment [3]. The WHO Quality of life (QOL) group defines QOL as "individuals` perception of their position in life in the context of the culture and value systems in which they live, and in relation to their goals, expectations, standards and concerns" [4]. Public health policies in many European countries are therefore primarily concerned with keeping older people living independently in the community with a good quality of life [5-7]. The raise in number of older adults implies more people with chronic diseases and a greater challenge for the health care system in finding effective and feasible interventions to reach this goal [5-8].

Aiming to enable older people to live at home as long as possible, the municipalities in Norway are responsible for providing services in the form of home help for older people [9]. Home help includes services that assist instrumental activities of daily living (iADL), such as vacuum cleaning, and personal activities of daily living (pADL), such as getting dressed, safety alarm services to provide assistance if they fall, and social support. The most important predictor of home care use seems to be dependency in IADL and ADL and cognitive impairment [10]. Home help receivers constitute a transitional group between independent community living older people, and people living in residential care facilities/nursing homes [11]. The combination of the increase of older people and the use of the so-called LEON ("lowest most efficient level of care") principle [6], makes this a steadily growing group in society, and can be seen as an especially vulnerable group among the older population. Moreover, as economic resources are scarce, there seems to be more focus on post-acute care instead of health promotion and prevention to maintain older adults at home [12]. To date there is no evidence-based practice standard for falls-prevention in Norwegian home care services.

Older adults and falls

Falls and fall-related injuries are common in older adults and are associated with substantial economic costs that are borne by individuals, the community, and the medical system as a whole [13, 14]. Up to 40% of all nursing home admissions have been found to relate to falls and instability [15]. Important risk factors for falling in the group of older adults are impaired balance and gait, polypharmacy and a history of falls [16]. Poor nutritional status has also been associated with an increased risk of falling, [17] and malnutrition or being in risk of malnutrition is prevalent in half of the older adults receiving home care services [18]. Common consequences of a fall are fear of falling, activity restrictions, loss of mobility and loss of independence [19]. Falling**,** or being at risk of falling also has a negative influence on QOL [20]. Hence, it can be argued that HRQOL is an important outcome in the assessment of falls-prevention programmes [21].

After several decades of research on interventions to reduce falls and fall risk factors, there is now strong evidence for the effectiveness and cost-efficiency of exercise in reducing the number of falls [14, 22-25]. An important, but yet understudied group when it comes to the effect of falls prevention programmes are older adults receiving home help services, and especially those who recently have experienced a fall [11]. Previous research has shown that falls and fear of falling are common in this population and are correlated with the amount of home care needed [11, 26]. Vikman et al. [11] concluded that future studies should have a focus on the effects of falls prevention programmes in the group of those receiving home help services. Recently it has been shown that home help receivers fell more frequently than the independent home-dwelling older population [27]. Low functional level and high home care recipient health problems were independently associated with risk of falling [27]. Fear of falling is also reported more frequently in the group of older adults receiving home help services compared to those who do not receive home care [28]. This suggests that the higher level of fear of falling could be due to a higher level of frailty in this group. Finally, it has been shown that elderly home help receivers in Sweden have a lower QOL compared to those without help and that QOL was negatively correlated with the amount of help needed [29].

Interventions to improve Quality of life

Although exercise-based falls prevention programmes have shown a clear effect on falls incidence and fall risk factors in the general older population, the evidence is still inconsistent about the effects on HRQOL and in particular related to the population of home help receivers [11, 21]. A systematic review by Vaapio et al. [21] considered the specific effect of falls prevention programmes on QOL. The review looked at twelve RCTs including older adults, but none of the studies were aimed at home help receivers. Six of these studies showed a positive effect on QOL. The interventions in these

studies ranged from exercise (two studies), information based (one study), to comprehensive geriatric assessment (one study). The review concluded that there is a lack of evidence about the potential benefits of falls prevention programmes on QOL in older people and that more research is needed.

To the authors' knowledge, only two RCTs have been examining exercise interventions aimed specifically at the population of older home help receivers [30, 31]. The first study tested a home-exercise programme and found positive results on maximum walking speed, but unfortunately the assessors were not blinded to the intervention [31]. The other study explored the effects and costs of a multifactorial, interdisciplinary team approach to falls prevention in 109 older home help receivers with a risk for falls [30]. Exercise was part of the programme, but the amount and mode of exercise varied according to individual needs. At six months, no difference in the mean number of falls between groups were found. Subgroup analyses showed that the intervention effectively reduced falls in men (75-84 years old) with a fear of falling or negative fall history, but it is unclear whether the study had sufficiently power for subgroup analyses [30]. Nevertheless, the secondary outcome of QOL significantly improved in the intervention group.

The effect of exercise interventions on HRQOL in the general older adult population have had mixed results, reporting both statistically significant positive effects as well as no significant changes [32-35]. A meta-analysis found no difference between aerobic and strength training, suggesting that the different exercise modes yielded the same effect on self-reported physical function domains of HRQOL [34]. Acree et al. [3] concluded that healthy older adults who regularly participated in physical activity of at least moderate intensity for more than one hour per week had higher HRQOL measures in both physical and mental domains than those who were less physically active. Although many intervention trials have found a positive association between exercise and HRQOL, the available data from other intervention trials conducted among older adults is inconsistent. Additionally, information of the most effective mode of exercise that may influence HRQOL is lacking [32-35]. Self-efficacy is a possible psychological mediating factor and physical function is a possible physiological mediating factor. Previous research has shown that self-efficacy beliefs can be related to well-being following exercise interventions [36, 37] and that self-efficacy can explain adherence to exercise programs [38-41]. A central concept of the self-efficacy theory is so-called performance accomplishment, i.e. mastery experiences related to certain activities [42], and this points towards testing the mediating effect also of physical function.

The primary aim of this study is to explore the effects of a falls prevention programme, lasting twelve weeks, on HRQOL in older adults receiving home help services. Effects on the secondary outcomes, physical function and falls efficacy, will also be explored. A secondary aim of this study is to explore the mediating factors between falls prevention and HRQOL.

Methods

Study design

The study is a single-blinded, pragmatic RCT comparing one intervention group with a control group. The intervention group will receive an adapted version of the Otago Exercise Programme (OEP) over twelve weeks, while the control group receives usual care. Measurements are performed at baseline, at three months and at six months. The intervention and assessments will be conducted in the participants' homes. Assessors will be blinded to group participation.

Study setting and recruitment

Six municipalities in the Oslo region have agreed to take part in the research project. Participants are recruited through consultants in the municipalities coordinating and providing home help services. The researcher visits the municipalities on a regular basis to conduct the recruitment. Additionally, health workers in the municipalities are informed about the criteria to participate and will alert about eligible participants. Eligible participants will be contacted by the researcher by telephone and asked to consent to being sent information about the study. After a week, they will be contacted again to see if they consent orally to participate. Before baseline testing, the participants must provide a written informed consent. Figure 1 presents the planned flow of participants in the study.

Inclusion and exclusion criteria

Inclusion criteria are: Individuals who 1) are 67 or older, 2) receive home help services 3) have experienced at least one fall during the last twelve months, 4) are able to walk with or without a walking aid and 5) understand Norwegian. Exclusion criteria are: 1) medical contraindications to exercise, 2) life expectancy below one year, 3) a score below 23 on the Mini Mental State Examination (MMSE) and 4) currently participating in other falls prevention programmes or trials.

Randomisation

The participants are randomly assigned at a 1:1 ratio to the intervention group and the control group. A computer-generated, permuted block randomisation scheme is used to allocate the participants. Following randomisation, the participants receive information by telephone on which group they are allocated to. See flow chart in Figure 1.

In order to optimize the rigor of the RCT and to minimize bias, a number of methodological factors have been incorporated into the design of the study. The study participants will be randomly allocated to the groups via concealed allocation, as inadequately concealed allocation has been associated with bias in RCTs [43]. Due to the nature of the intervention, it is not possible to blind the participants or the treating therapists to the allocated groups. However, all assessors are blinded to the allocated groups. In further attempts to reduce bias, data will be analysed on an intention-to-treat basis. This preserves the randomisation process and imitate the real-life situation where the possibility exists that not all participants receive the prescribed treatment.

Study intervention

The intervention performed is based on the OEP, including home visits and motivational phone calls [44]. Balance exercises comprise tasks in standing, walking backwards, stair-walking and rising from a chair. Strengthening exercises uses ankle weight cuffs to strengthen hip extension and abduction, knee flexion and extension and ankle plantar and dorsiflexion. The programme also includes warm-up exercises as movement of neck and shoulders. The OEP has been described in more detail previously [44]. This programme has been shown to be effective in reducing number of falls and number of injuries resulting from falls in addition to improving strength and balance, and maintaining falls efficacy in home-dwelling older adults [45].

In previous studies the OEP has been performed over a period of one year [45]. A meta-analysis by Sherrington et al. [46], looking at the effect of falls prevention programmes, recommend a dose of at least three hours of exercise weekly for six months. This weekly dose is attempted, but the duration of three months is shorter than in previous studies. Nevertheless, as in the original OEP, the same number of home visits and telephone calls will be made, and the participants will be encouraged to do a sufficient amount of exercise between home visits. The rational for the change in duration and frequency is both theoretical and pragmatic. Participants included for this study are frail older adults who have a fall history and who receive home help services. Previous research has shown that home help receivers fall more frequently and have a higher level of fear of falling [27, 47]. Poor health, fear of falling, depression and lack of strength are barriers for older adults in order to adhere to exercise programmes [48]. The participants in this study are thus likely to have a lower level of observance compared to more independent elderly and a duration of one year might be too long. Additionally, previous research has shown that falls prevention programmes which were considered too demanding by the participants even had a negative impact on QOL [49]. On the other hand, only receiving a few visits might not provide sufficient support which in turn could limit adherence. The

pragmatic rationale relates to the organizational structure of physiotherapy services in the primary health care. For this group of older adults an intervention of three months is within the time frame of what the physiotherapists normally can provide. Finally, previous research has shown that also falls prevention programmes with a shorter duration than six months have had a positive effect on QOL [21].

The physiotherapists visit the participants at home five times during the intervention (week 1, 2, 4, 8 and 10) for instruction and for guiding the appropriate level and progression of each exercise. This includes one additional visit compared to the first twelve weeks of the original OEP intervention [44]. Each visit will take about one hour. The first visit may take longer is initial information is given and a relationship is established. At this visit advice related to safety when performing exercises is provided to the participants, both orally and written. In between supervised sessions, participants will be encouraged to continue exercising on their own three times weekly for 30 minutes. Equipment for exercising (ankle cuff weights of 1, 1,5, 2 and 2,5 kg) is provided for each participant. The weeks between home visits, the physiotherapists call the participants to motivate them to continue exercising and to answer possible questions. As a part of the programme, the participants are also encouraged to perform at least two or more weekly walks of ≥30 minutes. The participants are provided with a written exercise booklet including illustrations. Following the intervention period, the participants to keep the exercise equipment and booklets, in order to continue exercising.

The participants in the control group will receive usual care from the primary health care service. Following reassessment, the participants will have opportunity to participate in other falls prevention programmes, for example, already existing balance exercise group classes.

Education of intervention deliverers

Workshops and meetings will be held to inform the physiotherapists participating in the project. Before starting recruitment, one full day workshop on falls prevention and OEP is held for all therapists. Following start-up of recruitment and until the end of the project one workshop will be held approximately every forth months. These last half a day and include one lecture on a topic concerning older people and time for discussion on the development of the project. Additional to the workshops, the researcher will have monthly meetings with the physiotherapists in the different municipalities. In order to make sure that the intervention is performed as intended, a fidelity checklist based on the OEP-manual has been developed. The physiotherapists use the checklist when conducting the home visits and phone calls.

Outcome measures

Following recruitment participants are assessed before they are randomised. Assessors are blinded to the participants´ group assignment. The time window between baseline assessment and start of intervention is aimed to be within two weeks, and the same time window for assessments due at three and six months. Measurements and their order are selected to avoid physical and mental fatigue of the participants. Outcome measures that are employed have established reliability and validity, as recommended by the CONSORT group [50]. In addition to improving measurement quality and outcomes, it enables direct comparisons with other studies that investigate HRQOL and can possibly contribute to meta-analyses.

At baseline the Mini Mental Statement Examination (MMSE), a measurement of ”Global cognitive function”, is performed and is used as exclusion criteria. The maximum score is 30. A score below 23 indicates cognitive impairment and these participants are excluded [51]. Sociodemographic characteristics, like age and education, are also assessed at baseline. Primary and secondary outcome measures will be performed at baseline, at three months and at six months' follow-up.

Primary outcome variable

HRQOL is the primary outcome measured by the Short Form 36 Health Survey (SF-36) [52]. This is a generic and validated questionnaire which, translated into Norwegian, is conducted as an interview [53]. The 36 items in SF-36 are grouped into eight health status scales: physical functioning, role limitations due to physical problems and due to emotional problems, bodily pain, general health perception, vitality, social functioning and mental health [52].

Secondary outcome variables

In addition to the SF36, the EQ-5D (1990 EuroQOL EQ-5D) is reported. The EQ-5D is a generic and validated questionnaire [54-57]. It describes five dimensions of HRQOL (mobility, self-care, usual activities, pain/discomfort, anxiety/depression), each of which can take one of five responses at five levels of severity (no problems/slight problems/moderate problems/severe problems/severe problems/extreme problems).

Physical function includes measures of balance, gait speed, muscle strength as well as activities of daily living. The Bergs Balance Scale is a 14-item scale, which is applied to assess static and dynamic balance in older adults [58]. Gait speed is assessed by measuring usual walking speed over four meters [59] and muscle strength is measured by the 30 seconds sit to stand test [60]. Instrumental ADL is recorded using the Norwegian Version of the Lawton IADL scale, which is a valid and reliable measure of a person's self-reported ability to perform complex activities of daily living [61].

Physical activity is measured using the "Walking habits questionnaire", a valid questionnaire for walking habits and physical activity for frailer older people [62]. This questionnaire assesses general behaviour of walking, regarding how often and for how long. The following questions are asked: "Do you take a daily walk?" (yes/no) or "If you do not take a daily walk how many times per week do you take a walk?" (never/almost never/1-2 days/3-4 days/ almost daily) and "How long does you walk generally last? (0-15 mins/15-30mins/30-60mins/ 1h-2h/>2h)". Walking time in minutes per week is calculated by taking the lowest level of days multiplied by lowest level of minutes for each response alternative [62].

Nutritional status is measured using the Mini Nutritional Assessment (MNA- elderly, Société des Produits Nestlé, S.A., Vevey, Switzerland) form. The first screening part of six questions is used which includes measurement of weight and height for calculation of BMI [63-65].

Falls efficacy is assessed using the Falls Efficacy Scale International (FES-I). This scale has shown good reliability and validity assessing concerns about falling in older adults, and is recommended for clinical trials and practise [66, 67]. It is a self-reported questionnaire, containing 16 items on different activities of daily living. Level of concern is measured on a four-point scale ranging from 1, which is not at all concerned, to 4 which is very concerned [68].

Adherence to the programme is documented through an activity diary completed by the participants and a form checked by the physiotherapists during home visits and calls. Additionally, the participants have a falls calendar where they report adverse events. Adverse events are registered in the following four categories: falls, cardiovascular events, musculoskeletal injuries and health care utilization and will be documented as "due to the intervention" or "not due to the intervention" [69].

Sample size estimation

The sample size is estimated from the primary outcome, HRQOL (SF-36). A treatment difference of 10 points between the two groups in one of the domains in SF-36 is regarded to be of statistical and clinical significance. The associated standard deviation is assumed to be around 20 points. This implies a moderate effect size [70], which can be expected as previous OEP studies have shown substantial effects on physical outcomes [45]. Moreover, a similar Norwegian study, which included older adults performing exercise following discharge from hospital, estimated the required sample size identically [71]. Given a power of 80% and level α=0.05, we aim at including 150 participants, allowing for a 15-20% dropout, to detect a difference of 10 points between groups (see Figure 1).

Statistical procedures

Statistical analysis is performed using SPSS or a similar statistical package. Descriptive data are reported for variables of interest. The data will be analysed following the intention to treat principle [72]. Prospective differences in primary and secondary outcomes and baseline characteristics between the intervention group and the control group will be assessed by t-tests for continuous and normal distributed variables and with non-parametric tests for categorical variables. Multiple linear regression modelling are used to control for confounding of between-group differences [73]. Hypotheses about mediating factors are tested through correlations, multiple regressions and bootstrapping methods exploring the correlations and explained variance of the chosen mediating factors and the changes in QOL [74]. Bootstrapping is a non-parametric method and is considered favourable with dichotomous variables (group 1 and 2) and small samples ($n < 250$) [74].

Discussion

The main purpose of the study is to evaluate the impact of OEP on HRQOL in older adults receiving home help services. We anticipate that the intervention described in this protocol will have a positive impact on the HRQOL. The tailored intervention will have a potential to promote evidence-based decision-making and empower older people receiving home help services to remain to a greater extent in charge of their own lives. We rely on a systematic approach, which corresponds with the guidance on developing and evaluating RCTs [75]. Only a few studies have included HRQOL when measuring the effect of a falls prevention programme, and most of these studies include it as a secondary outcome [21, 76]. Outcomes examining HRQOL are selected based on literature identifying a standard set of measurements in falls prevention programmes [77, 78]. SF-36 is chosen due to its good validity, reliability and responsiveness when assessing older adults [79]. This outcome is detailed and broad, but it might be putting a burden on the participants due to its length and sensitive questions. Nevertheless, estimating HRQOL is important to determine whether the effect of a falls prevention programme is significant enough to achieve clinical relevant changes and thus to justify the implementation.

Several studies have looked at the effect of exercise on HRQOL, but to the authors' knowledge, none of them have specifically focused on older adults who receive home help services and who have a fall history. Studying the relationship between exercise and HRQOL is interesting due to the potential influence of exercise on both health and wellness through improvement of HRQOL [3, 80]. However, results from previous clinical exercise trials have reported mixed effects on HRQOL following exercise [32-35, 81]. Although many studies have found a positive association between exercise and HRQOL,

available data from other trials is inconsistent and lacks information on the most effective mode of exercise that may influence HRQOL [32, 33, 71, 81]. This study can provide insight into the effect of falls preventative exercise and its applicability to home-dwelling older fallers with dependency of help from the primary health care service.

There are two ways an intervention mechanism can influence HRQOL, it can be a mediator or a moderator [82]. A mediating factor is defined as an intervening causal factor that may provide information concerning why the intervention increases HRQOL. Moderator mechanisms help us to understand for whom an intervention works [38] and can be classified as either characteristic of the person/group i.e. baseline characteristics or characteristics of the exercise protocol [38, 83]. Mediating mechanisms between HRQOL and falls-prevention programs may be both physiological, such as increased balance and strength, and psychological, such as self-efficacy [38]. A recent study provide evidence that fear is related to falls and concluded that falls self-efficacy plays a mediation role on the relationship between fear of falls and falls [84]. They recommend that any falls prevention should consider psychological covariates of falls, especially subjects' self-efficacy to reduce falls, alongside other risk factors and covariates of falls. More theoretically driven research on these mechanisms behind treatment effects have been recommended [85-87].

It is widely accepted that falls and subsequent injuries are likely to result in a substantial reduction in quality of life for the persons affected as well a substantial economic burden to the healthcare system [88]. This provision of OEP in this setting could potentially be a beneficial and cost-effective intervention for this group of frail older adults, just as it is for community-dwelling older adults. Several studies have performed analysis on cost-effectiveness of exercise programmes which have shown that it can reduce healthcare costs [14, 89]. Due to its large sample size and theoretically based intervention the present study has the potential to generate new knowledge that may improve the design of future activity programmes for older fallers receiving home help services. Since both outcome measures as well as the intervention are carried out in a clinical setting, relevance and application of study findings to clinicians is enhanced. Results from this study will be primarily of interest to, and could be used by, health care managers and clinicians. Particularly, the results will be useful in decision making to set priorities relating to prevention measures in the community, to appropriately allocate resources and to assess costs and benefits of a falls prevention programme. Finally, the results can be useful for policy makers, in order to put preventative healthcare for this group of frail older adults on the agenda.

To conclude, older people receiving home help services represent a growing and diverse group as part of the population of community-dwelling older adults. The appropriate assessment of HRQOL, the mechanisms behind the relationship between fall prevention and HRQOL, the most effective mode of exercise, as well as the clinical relevance of the results, are challenging issues which are important to address.

List of abbreviations

ADL	Activities of Daily Living
BMI	Body Mass Index
EQ-5D	European Quality of Life - 5 Dimensions
HRQOL	Health-related Quality of Life
iADL	instrumental Activities of Daily Living
LEON	lowest most efficient level of care
MMSE	Mini Mental State Examination
MNA	Mini Nutritional Assessment
OEP	Otago Exercise Programme
pADL	personal Activities of Daily Living
QOL	Quality of Life
RCT	Randomised Controlled Trial
SF-36	Short Form 36 Health Survey
WHO	World Health Organization

Declarations

Ethics approval and consent to participate

The project proposal has been approved by The Regional Committee for Medical Research Ethics in South Norway (Ref. 2014/2051). Informed consent is obtained from all participants included in the analyses, and the project is conducted according to the WMA Declaration of Helsinki.

Consent for publication

Not applicable

Availability of data and materials

The datasets generated and/or analysed during the proposed study are only available to the participating researchers due to data protection laws. Subsets or aggregation of these data will not include information that could compromise research participants' privacy. Consent can be made available from the corresponding author on reasonable request.

Competing interests

DAS is a Director of Later Life Training Ltd, a UK based non-profit organisation providing training to therapists in the effective delivery of the OEP to older adults.

Funding

This study has received no external funding. It is internally funded by the Oslo and Akershus University College.

Authors' contributions

MB and AB were involved in choosing falls prevention programme as well as outcome measures. AB was responsible for the internal grant application for this trial. MB and AB contributed to the design of the study. MB administrates the data collection and coordination of conducting the fall prevention programme. MB and AB wrote the first draft of the manuscript. TB and DAS critically revised and approved the final version of this manuscript.

Acknowledgements

Thanks to all physiotherapists and consultants working in the municipalities contributing with information on practical issues on recruitment and management of the intervention.

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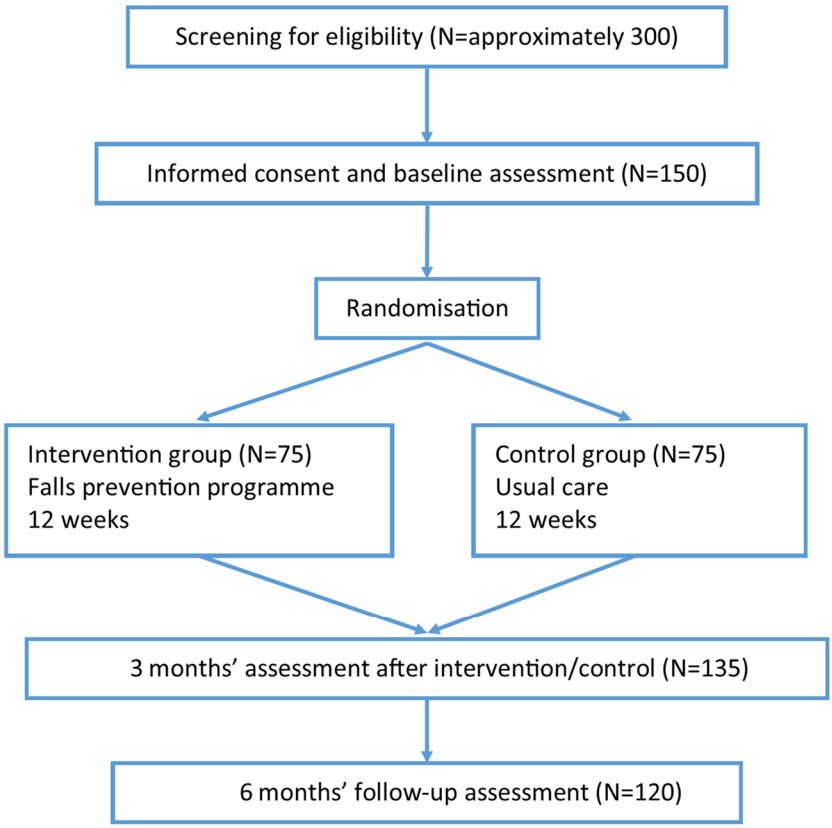

Figure 1: Planned flow of participants in the study.

SPIRIT

STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1, 2
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	2
	2b	All items from the World Health Organization Trial Registration Data Set	2
Protocol version	3	Date and version identifier	
Funding	4	Sources and types of financial, material, and other support	14
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	1, 14
	5b	Name and contact information for the trial sponsor	14
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	14
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	14
Introduction			

Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	3-5
	6b	Explanation for choice of comparators	6
Objectives	7	Specific objectives or hypotheses	5, 10-11
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	6
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	6
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	6
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	7-8
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	8, 10
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	6
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	8-10
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	6-7, 9, Figure 1

Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	10
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	6
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	6-7
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	6-7,
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	6
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	7-9
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	6
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	8-10
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	7

Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	Included in ethical approval, p.14
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	10
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	10
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	6-7
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	14
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	10, 14
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	10
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	NA
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	14
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	14

Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	6, 14
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	NA
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	Included in ethical approval, p.14
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	14
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	14
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	8
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	14
	31b	Authorship eligibility guidelines and any intended use of professional writers	
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	14
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	Included in ethical approval
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.