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# Counselling for physical activity, life-space mobility and falls prevention in old age (COSMOS): Protocol of a randomized controlled trial (ISRCTN65406039)



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# Counselling for physical activity, life-space mobility and falls prevention in old age (COSMOS): Protocol of a randomized controlled trial (ISRCTN65406039)

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## ABSTRACT

**Introduction:** The most promising way to promote active life years in old age is to promote regular participation in physical activity (PA). Maintaining lower extremity muscle function with good balance has been associated with fewer falls and the need of help from others. This article describes the design and intervention of a randomized controlled trial (RCT) investigating the effectiveness of a health and PA counselling program on life-space mobility and falls rates in community-dwelling older adults at the Health Kiosk and/or Service Centre environment.

**Methods and analysis:** Community-dwelling men and women (n=450) aged 65 years and over with early phase mobility limitation will be recruited to a 24-month RCT with a 24-month follow-up. Participants will be randomly allocated into either a health and PA counselling group (intervention) or sham exercise group (control). They receive five group specific face-to-face counselling sessions and 11 phone calls. The counselling intervention will include individualized health counselling, strength and balance training and guidance to regular PA. The control group will receive relaxation exercises. Outcomes will be assessed at baseline, 12, 24, and 48 months. Primary outcomes are average life-space mobility score and falls rates. Life-space mobility will be assessed by a validated questionnaire. Falls rates will be recorded from fall diaries. Secondary outcomes are data on fall-induced injuries and living-arrangements, number of fallers, fracture risk, mean level of PA, physical performance, quality of life, mood, cognition, balance confidence, and fear of falling. Data will be analyzed using the intention-to-treat principle. Cost-effectiveness of the program will be analyzed. Ancillary analyses are planned in participants with greater adherence.

**Ethics and dissemination:** Ethical approval was obtained from the Ethics Committee of the Tampere University Hospital (ref: R15160). Outcomes will be disseminated through publication in peer-reviewed journals and presentations international conferences.

**Trial registration:** Prospectively registered to ISRCTN (ISRCTN65406039).

## STRENGTHS AND LIMITATIONS OF THE STUDY

- This randomized controlled trial will investigate the effectiveness of a pragmatic home-based exercise program on life-space mobility and falls rates.
- The counselling protocol is delivered by nurses and physiotherapists according to current evidence-based principles to maximize long-term exercise adherence and commitment to physical activity, and to prevent falls.
- Counselling sessions take place at easily accessible community-based Health Kiosk and/or Service Centre environment.
- This will be the first randomized controlled trial to evaluate the effectiveness of health and physical activity counselling in a community-based environment to improve life-space mobility and prevent falls.
- Research nurses and research physiotherapists are not blinded to the random allocation.

## INTRODUCTION

The disablement process model by Verbrugge and Jette,[1] describes the path from pathology to disability via impairments and functional limitations. Accordingly, multiple health conditions (e.g. osteoarthritis and hypertension) may lead to physical impairments (e.g. weak leg extensor muscles), which may result in functional limitations (e.g. challenges with lower extremity function and balance). Functional limitations may finally lead to disability resulting in uncertainty to walk safely, an increased fear of falling and rate of falls, all of which can further reduce movement within a typical living area,[2, 3]. In addition, restricted life-space mobility can reduce participation in social activities, which can lead to little utilization of community amenities available. This vicious cycle can escalate as overall health and well-being of older adults deteriorates.

Developing and implementing effective strategies that prevent disability and falls among older people is an urgent public health issue since personal and societal impact from falls is enormous. Epidemiological studies have shown positive associations between PA and reduced risk for fracture through reduced risk of falls,[4-8]. However, some studies, including our previous work, suggest that regular participation in PA, especially frequent walking, may also increase older adults' fracture risk, probably due to increased exposure to fall hazards,[9-11]. Targeted exercise programs including muscle strength and balance training, such as the Otago Exercise Program, have been found to be effective at preventing falls and injurious falls among community-dwelling older adults,[12-14].

There is also evidence that older people with multiple risk factors for falls and thus at high risk of falling benefit from a multifactorial approach,[15]. For instance, a previous multifactorial trial (Chaos Falls Clinic), which included individualized 12-month falls prevention programme, in high-risk individuals aged 70 years or over reduced falls and fall-induced injuries by over 25%,[16]. Despite its effectiveness, multifactorial interventions can be expensive and labour-intensive. Less is known about other alternative health care platforms and concepts, which include low cost interventions that combine multiple preventive measures and offer these to all participants at the same concept,[15].

Community-based and easily accessible service platforms and concepts are potential for health and PA counselling since they may reach older people who already wish to change their lifestyle. In a way to reform of social and health care system in Finland and confront European megatrends such as the aging population with increasing public costs, Health Kiosks and Service Centres have been launched to enable rapid health screening and counselling to support people to

be active and participative in the society. Their focus is on health promotion and disability prevention. Scheduled appointments are not required and they are free of charge. Health Kiosk is a nurse-led pilot primary care service environment situating in a shopping center,[17, 18]. Service Centre is a modern meeting place for senior citizens with various indoor and outdoor activities. A rapid health screening with tailored counselling and guidance at an easily accessible environment can offer a modernized primary care concept to tackle or slow down progressive but early phase health issues and disablement processes. It may also provide a unique opportunity to increase PA, support physical function, and avoid falls, depressive symptoms and social isolation,[17, 18].

To our knowledge, this will be the first RCT to evaluate the effectiveness of health and PA counselling in a community-based Health Kiosk and/or Service Centre environment to improve life-space mobility and prevent falls. Another novel aspect is that we will assess simultaneously changes in the ratio of falls rates and the difference in rate changes in the life-space mobility outcome.

## TRIAL OBJECTIVES

The primary aim of this randomized controlled trial (RCT) named "Counselling for physical activity, life-space mobility and falls prevention in old age" (COSMOS) is to examine the effectiveness of the community-based health and PA counselling program in increasing life-space mobility and reducing the rate of falls in community-dwelling elderly people.

More specifically, the COSMOS study is a 24-month effectiveness RCT with a 24-month follow-up at a community-based environment to examine whether individualized health counselling with a strength and balance exercise program and prescription of regular PA is effective at improving life-space mobility and reducing the falls rates. Secondary aims of the study are to evaluate the effects of the counselling intervention on data on fall-induced injuries and living-arrangements, number of fallers, fracture risk, mean level of PA, physical performance, quality of life, mood, cognition, and balance confidence. We will also evaluate the cost-effectiveness of the counselling program within the community-based environment for falls and whether any of the aforementioned potential benefits can be maintained two years after the end of 24-month intervention.

**Table 1.** Condensed trial registration data

| Data category | Information |
|---|---|
| Registry and trial identifying number | ISRCTN registry<br>ISRCTN65406039 |
| Date of registration | 27/11/2015 |
| Recruitment status | Recruiting (start date 01/01/2016 – end date 31/3/2019) |
| Funder(s) | Academy of Finland |
| Primary sponsor | Department of Sport and Health Sciences, PL 35, 40014 University of Jyväskylä, Finland |
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| Public title | Counselling for physical activity, life-space mobility and falls prevention in old age |
| Scientific title | Physical activity counselling and exercise program targeting for increased physical activity, life-space mobility and falls prevention among community-dwelling older people: A single-center randomized controlled trial |
| Acronym | COSMOS |
| Countries of recruitment | Finland |
| Condition | Falls |
| Study design | Single-centre randomized controlled trial |
| Trial setting | Community |
| Intervention(s) | Control group: Participants will receive a placebo intervention including five face-to-face sessions of relaxation exercises. In addition, 11 supportive telephone calls will be provided.<br>Intervention group: Participants will receive five Health Kiosk-based 1.5-hour sessions including a 30-minute counselling session for motivation together with a 1-hour exercise education session. Exercise education contains strengthening exercises for lower extremity muscles. The program also includes balance, walking and stair climbing exercises and active range of movement exercises. During the sessions the exercise referral to the local community specialized gym will be also given. In addition, 11 supportive telephone calls will be provided. Safety issues of physical activity, counselling to reduce alcohol consumption and smoking, recommendation to use anti-slippery shoe devices will be advised. The total duration of the intervention is 24 months. Both groups are followed up 24 months after the intervention. |
| Primary outcome(s) | 1. Life-space mobility is assessed by a validated questionnaire at baseline, 12, 24 and 48 months.<br>2. Falls rates are assessed by daily filled and monthly returned fall diaries during the 24-month intervention. |
| Secondary outcomes | 1. Physical activity (PA): The Finnish Hookie AM 20 triaxial accelerometer will be used to measure all PA over a 7-day period. PA and exercise diary will also be used during the first 24 months' period of the study. Self-reported PA will also be quantified using the scale by Grimby with slight modifications.<br>2. Physical performance is measured using the Timed Up and Go-test (TUG), Short Physical Performance Battery (SPPB) and handgrip strength (Jamar hand dynamometer) at baseline, 12, 24 and 48 months.<br>3. Number of fallers i.e. a fall indicator variable (yes/no) based on daily filled and monthly returned fall-diaries during the 24-month intervention.<br>4. Fall-induced injuries based on daily filled and monthly returned fall-diaries during the 24-month intervention. Hospital registers are used to verify severe injuries.<br>5. Quality of life is assessed using The World Health Organization Quality of Life (WHOQoL) questionnaire at baseline, 12, 24 and 48 months.<br>6. Living-arrangements are determined by asking patients at baseline, 12, 24 and 48 months.<br>7. Fracture risk is assessed using the WHO Fracture Risk Assessment Tool at baseline, 12, 24 and 48 months.<br>8. Depressive mood is assessed using the Geriatric Depression Scale (GDS-15) at baseline, 12, 24 and 48 months.<br>9. Cognitive status is assessed using the Mini-Mental State Examination (MMSE) at baseline, 12, 24 and 48 months.<br>10. Balance confidence as a measure of fear of falling is assessed using the Activities-specific Balance Confidence scale (ABC) at baseline, 12, 24 and 48 months.<br>11. Fear of falling is assessed (yes/no) and measured by the Visual Analogue Scale (VAS). |
| Participant inclusion criteria | 1. Aged 65 years or over<br>2. Community-living people<br>3. Living in Ylöjärvi, Finland, or neighbouring municipalities<br>4. At least minor mobility difficulty |
| Target sample size | 450 |
| Participant exclusion criteria | 1. Severe functional limitations (unable to walk 500 m unaided)<br>2. Severe cardiovascular or pulmonary disease<br>3. Severe progressive disease<br>4. Terminally ill (predicted lifetime <12 months)<br>5. Memory impairment (MMSE score 21 points or less)<br>6. Living in an institution<br>7. Unwilling to be randomized<br>8. Alcoholism (AUDIT score ≥ 15) |

## METHODS AND DESIGN

This protocol article is written based on the SPIRIT reporting guidelines,[19]. The trial protocol was prospectively registered to ISRCTN (ISRCTN65406039). Condensed trial registration information is outlined in ***Table 1*** and an overview of the experimental design is illustrated in ***Figure 1.***

### Trial design and study setting

COSMOS is a pragmatic single-blinded RCT in which participants will be randomized into one of two groups: 1) the health and PA counselling intervention or 2) the relaxation intervention (control). All participants will be assessed at baseline and after 12- and 24-months. Additionally, there will be follow-up measurements at 48-months. All assessments will begin with a structured interview and health examination done by a research nurse and continue with physical performance tests carried out by a research physiotherapist. All assessments and counselling sessions will take place at the Health Kiosk of Ylöjärvi or at the Service Centre of Ylöjärvi, Finland. Ylöjärvi is a municipality of 32 000 inhabitants including suburban and rural areas. Study participants can choose themselves the place they would prefer to visit.

### Participant eligibility

The target number of participants is 450 randomly allocated to each group (n=225 each). Both men and women will be recruited. Participant *inclusion criteria* are as follows: 1) aged 65 years or over, 2) community-living people, 3) living in Pirkanmaa District, Finland, and 4) at least minor self-reported mobility difficulty.

*Mobility difficulty* will be assessed by using a structured and validated interview asking each participant about his or her ability to walk 2.0 km, walk 0.5 km, and climb up one flight of stairs,[20]. The questions are formulated as follows: “Do you have difficulty in …” with five alternative response options provided: 1) …able to manage without difficulty, 2) …able to manage with some difficulty, 3) …able to manage with great deal of difficulty, 4) …able to manage only with help of another person, and 5) …unable to manage even with help. To identify persons with minor mobility difficulty, additional questions are posed to participants who do not report task difficulty with any of the above questions. The questions concern the modification of task performance and the alternatives given are: resting in the middle of the performance, using an aid, taking support from handrails, having reduced the frequency of performing the task, having slowed down performance of the task, experiencing tiredness when performing the task,

or some other change in carrying out the task. *Minor mobility difficulty* is considered if participant reports task modification in one or more of the tasks listed above.

Participant *exclusion criteria* are following: 1) severe functional limitations (unable to walk 500 meters unaided), 2) severe cardiovascular or pulmonary disease, 3) severe progressive disease, 4) terminally ill (predicted life expectancy <12 months), 5) memory impairment (MMSE score 21 points or less),[21], 6) living in an institution, 7) unwilling to be randomized, or 8) alcoholism (AUDIT score ≥ 15),[22].

**Recruitment**

We will recruit eligible men and women during their Health-Kiosk and Service Centre visits as well as via newspaper advertisements, notice boards, community centers, and at senior events. All participants will be initially screened for eligibility over the telephone where they will have the opportunity to ask questions and have an informed discussion with research staff. Following the telephone screening, those who are eligible and are willing to participate, will receive an information letter, consent forms and reply-paid envelope. Upon receiving a signed informed consent form, a member of the research team will sign each form prior to the baseline assessments. Potential participants will be invited to the baseline assessments, where a trained research nurse confirms their eligibility with a structured interview and health examination.

**Random allocation**

Participants will be randomly allocated into either 1) the health and PA counselling intervention or 2) the sham exercise intervention (control). A computer generated randomization protocol will be created by a statistician who is not part of the research team. Random allocation will be stratified by sex, age (65-79 years/80 years or older) and presence or absence of falls during the last 24 months. Block size of 6, 8, 10 or 12 will be randomly varied to ensure the equality of group sizes (allocation ratio 1:1). Allocation results will be stored in sealed envelopes and stored in locked cabin. After the baseline measurements, a researcher will open one envelope according to each participant's sex, age and previous falls and then verifies to the research records, in which intervention participant is allocated. Participants are not informed whether they belong to the superior or control intervention (i.e. health and PA counselling versus sham exercise). Allocation concealment will be ensured, as the randomisation code will only be released until the end of the study. Research nurses and physiotherapists are not blinded to the group allocation since limited personnel resources. The principal investigator will be blinded.

## Interventions

The COSMOS study involves two interventions: 1) *health and PA counselling intervention* and 2) *sham exercise (relaxation)*. ***Supplementary figure*** describes the participant timeline. Both interventions include five face-to-face sessions taking place at week one and one, three, six, and 12 months after the baseline measurements. Both intervention programs will be updated to the next level during each face-to-face session. Participants will be provided with 11 supportive telephone calls, regardless of the intervention, which will be delivered at two, four, five, seven, eight, nine, ten, 11, 16, 20 and 23 months after baseline. The total duration of the interventions is 24 months. At the end of the first face-to-face session, physiotherapist informs the participant on how to fill out the PA and falls diary.

### *Health and physical activity counselling intervention*

Participants randomized to the health and PA counselling intervention will receive five individually tailored 1.5-hour face-to-face sessions containing a 30-minute health counselling session by a trained research nurse together with a 60-minute PA counselling session delivered by an experienced research physiotherapist.

*The health counselling* follows the motivational interviewing concept,[23] based on social cognitive theory,[24] and the trans-theoretical model,[25]. The structure of the health counselling is based on the guidelines of the IKINÄ-manual, which is a guide for preventing falls and harm from falls in older people, released by the Finnish National Institute for Health and Welfare,[26]. Accordingly, during health counselling sessions the nurse will advise participants on safety issues related to their home-environment, such as providing recommendations to use anti-slippery shoe devices during winter, and participating in regular PA. Additionally, participants in the health and PA counselling intervention receive handouts on how to avoid fall accidents in the home environment and outdoors. Moreover, health counselling sessions will include counselling for a healthy diet and recommendations to reduce alcohol consumption and smoking based on the discussions with the participant about her/his background and habits, and motivation to change,[23]. The nurse will also discuss topical and relevant health related issues with health and PA counselling intervention members i.e. managing blood pressure, medication, and depressive mood.

*The PA counselling* is based on the modified version of Otago Exercise Program (OEP, available online),[27].The OEP is an innovative model of low frequency physical activity counselling and exercise training tailored for older people and typically delivered by physiotherapist at older

people´s home. It contains four levels (A, B, C, and D) which all contain strengthening exercises for lower extremity muscles as well as balance, walking and stair climbing exercises and active range of movement exercises (e.g. neck rotations and hip and knee extensions). The exercises on each level take about 30 minutes to complete. Participants are expected to exercise three times a week at home and go for a walk at least twice a week. The participants will receive progressive illustrated instructions. Physiotherapist may modify and apply the OEP individually based on health, motivational status, and participant goals. For this study, two additional training levels (COSMOS 1 and COSMOS 2, illustrated in ***Table 2***) have been developed to ensure progression throughout the 24-month intervention for the most advanced and motivated participants.

During the PA counselling sessions, a physiotherapist will also discuss the importance of regular and diverse PA and presents the Physical Activity Pie for Older Adults (Finnish recommendations for PA among 65 years old and older) (http://www.ukkinstituutti.fi/filebank/64-physical_activity_pie.pdf). In addition, therapist will provide an exercise referral to the local community exercise facilities based on the earlier discussions with the participant about her/his background and motivation to exercise. Participants will also be provided with ankle weights (0.5–5.0 kg) for the first 12 months. Thereafter, therapist will encourage participants to attend a local gym or be involved with other community exercise facilities.

**Table 2.** Content of the COSMOS 1 and 2 levels

| | **COSMOS 1** | **COSMOS 2** |
|---|---|---|
| **Warm-up** | Same as in the Otago Exercise Program | Same as in the Otago Exercise Program |
| **Strengthening exercises** | • One legged squat<br>• One legged sit to stand<br>• Sideways squats<br>• Jumping exercises | Same strengthening exercises as in the COSMOS 1<br>➔ Repetitions and series are up-dated and jumping exercises are extended and more demanding |
| **Balance exercises** | • Same as in the D level of the Otago Exercise Program but stair climbing is replaced with squats<br>• Additionally, multitasking is incorporated into all exercises (e.g., participants count repetitions or seconds backwards). | Same balance exercises as in the COSMOS 1 level but all exercises are performed with eyes closed |

***Sham exercise intervention (control group)***

Participants randomized to the sham exercise intervention will receive five 45-minute face-to-face sessions of structured relaxation exercises instructed by a physiotherapist. We believe that offering relaxation exercises will motivate the control participants to continue in the study without increasing their PA. The relaxation program will be updated during each face-to-face session and will proceed as follows: 1) learning the diaphragmatic respiration technique, 2) learning the tension-relaxation technique, 3) utilizing tension-relaxation technique, 4) utilizing techniques learned in previous exercises to whole body relaxation, and 5) learning consciousness of the body sensations. All exercises will be performed on a compact disc (CD) or via mp3-format. Additionally, written instructions will be available. During the first face-to-face session, participants will receive the same handouts as the health and PA counselling intervention members on how to avoid fall accidents in the home environment and outdoors.

***Supportive telephone calls***

During 11 supportive telephone calls, physiotherapist will enquire about how exercise (PA or relaxing program) is progressing, has the participant fallen and ensure that the most recent fall and exercise diary is returned. Additionally, therapists will confirm or schedule the next face-to-face session or 12- and 24-month follow-up measurements when appropriate. If a participant has fallen, therapists will confirm the circumstances and consequence related to the fall/falls. For those in the health and PA counselling intervention group, the therapist will also discuss if there is a need to update the program, i.e. revise the number of repetitions and/or series or change the magnitude of the ankle weight before the next face-to-face session.

**Outcomes**

Assessments will include a comprehensive battery of tests and questionnaires on mobility, physical activity, physical function and health. The baseline assessment will take about 2 h to complete whereas 12-month and 24-month assessments will take about 1.5 h. The order of the assessments and measurements is standardized at each time point. ***Table 3*** presents the outcome and other variables, methods and schedule of the assessments in the study.

***Primary outcomes***

Daily filled and monthly returned fall diaries will be used to gather information on the *falls rates* during the 24-month intervention. A fall is defined as an unexpected event in which participant comes to rest on the ground, floor or other lower level [28]. A research physiotherapist will phone monthly all those participants who have reported a fall or falls or if a diary is not returned.

**Table 3.** Outcome and other variables, methods and schedule of the assessments

| **Continuous monitoring** | **BL** | **12-month** | **24-month** | **48-month** | **O** |
|---|---|---|---|---|---|
| **Falls rates** | | | | | **P** |
| Daily filled and monthly returned diaries | N | Y | Y | Y | |
| Number of fallers i.e. a fall indicator variable (yes/no) | | | | | S |
| Daily filled and monthly returned diaries | N | Y | Y | Y | |
| Fall-induced injuries | | | | | S |
| Daily filled and monthly returned diaries and telephone interviews | N | Y | Y | N | |
| Hospital registers are used to verify severe injuries | N | Y | Y | Y | |
| Health service use | | | | | |
| Hospital registers are used to verify severe injuries | N | Y | Y | Y | |
| Adverse events due to interventions | | | | | |
| Daily filled and monthly returned diaries and telephone interviews | N | Y | Y | N | |
| Participant adherence to the interventions | | | | | |
| Average number and duration of exercise sessions and total number and duration of exercise sessions based on daily filled and monthly returned physical activity and exercise diaries | N | Y | Y | N | |
| Perceived exertion of interventions | | | | | |
| Modified Borg scale (range 0-10) | N | Y | Y | N | |
| **Physical, cognitive and social assessments** | **BL** | **12-month** | **24-month** | **48-month** | |
| Physical activity | | | | | S |
| Hookie AM 20 triaxial accelerometer for 7 days | Y | Y | Y | N | |
| Daily filled and monthly returned physical activity and exercise diaries | N | Y | Y | N | |
| Validated questionnaire (Scale of Grimby) | Y | Y | Y | Y | |
| Physical performance | | | | | S |
| Timed Up and Go-test (TUG) | Y | Y | Y | N | |
| Short Physical Performance Battery (SPPB) | Y | Y | Y | N | |
| Jamar hand dynamometer | Y | Y | Y | N | |
| Body composition | | | | | |
| Height and weight are measured and BMI is calculated | Y | Y | Y | Y | |
| Fracture risk | | | | | S |
| World Health Organization Fracture Risk Assessment Tool (FRAX) | Y | Y | Y | Y | |
| Cardiovascular condition | | | | | |
| New York Heart Association functional class (NYHA) | Y | Y | Y | Y | |
| Orthostatic test | Y | Y | Y | N | |
| Self-reported physical ability | | | | | |
| Determined by asking | Y | Y | Y | Y | |
| Mobility difficulty | | | | | |
| Structured interview | Y | Y | Y | Y | |
| Need of mobility assistive devices | | | | | |
| Determined by asking | Y | Y | Y | Y | |
| Living arrangements | | | | | S |
| Determined by asking | Y | Y | Y | Y | |
| **Questionnaire-based assessments** | **BL** | **12-month** | **24-month** | **48-month** | |
| **Life space mobility** | | | | | **P** |
| Life-space mobility assessment (LSA) | Y | Y | Y | Y | |
| Balance confidence | | | | | S |
| Activities-specific Balance Confidence scale (ABC) | Y | Y | Y | Y | |
| Fear of falling | | | | | S |
| Determined by asking and by Visual Analogue Scale (VAS) | Y | Y | Y | Y | |
| Quality of life (QOL) | | | | | S |
| World Health Organization Quality of Life (WHOQOL) questionnaire | Y | Y | Y | Y | |
| Cognitive status | | | | | S |
| Mini-Mental State Examination (MMSE) | Y | Y | Y | Y | |
| Depressive mood | | | | | S |
| Geriatric Depression Scale (GDS-15) | Y | Y | Y | Y | |
| Alcohol consumption | | | | | |
| The Alcohol Use Disorders Identification Test (AUDIT) | Y | Y | Y | Y | |

BL=baseline, O=outcome, N=no, Y=yes, P=primary S=secondary

*Life-space mobility Assessment (LSA)* is a validated questionnaire, which measures the size of the area that a person has moved around in during the 4 weeks preceding the assessment,[2]. It correlates with observed physical performance and self-reported function,[2]. For each level of life-space (bedroom, other rooms, outside home, neighbourhood, town, beyond town) persons are asked how many days within a week they attained that level of life-space and whether they need help from another person or from assistive devices. A composite measure of life-space combines the components of life-space level attained, degree of independence, and frequency of attainment,[3].

***Secondary outcomes***

A number of secondary outcome measures will be assessed to clarify potential mechanism underlying any reduction in fall rates during the trial, and to determine to what extent the training transfers to other important outcomes.

*Physical activity (PA):* The Finnish Hookie AM 20 triaxial accelerometer will be used to measure all PA over a 7-day period. The Hookie AM 20 device and related data analyses is based on the UKK Institute's algorithms which has been used in three large Finnish population-based cohort studies,[29, 30] and in older community dwelling individuals,[31]. A PA and exercise diary will also be used during the first 24 months' period of the study. Self-reported PA will also be quantified using the scale by Grimby,[32] with slight modifications,[33].

*Physical performance*: An experienced research physiotherapist will conduct all physical performance tests, including the Timed Up and Go-test (TUG),[34] and Short Physical Performance Battery (SPPB),[35]. Handgrip strength from the dominant arm will be assessed using the Jamar hand dynamometer,[36].

*A fall indicator variable* (yes/no) will be formed and *fall-induced injuries* will be assessed based on diaries filled daily and returned each month until 24-months after the baseline. Hospital registers will also be used to verify severe injuries during the intervention and follow-up.

*Health-related quality of life* will be assessed using the World Health Organization Quality of Life (WHOQOL) 26-item short version questionnaire, which includes questions related to physical health, psychological health, social relationships and environment,[37]. *Living-arrangements* will be determined by interview. *Fracture risk* will be assessed by WHO Fracture Risk Assessment Tool (FRAX) via interview. The FRAX algorithms give the 10-year probability of hip fracture and a major osteoporotic fracture (clinical spine, forearm, hip or shoulder fracture),[38].

*Depressive mood* will be assessed using the Geriatric Depression Scale (GDS-15),[39]. Participants who achieve 6 points or more on GDS-15 test will be referred to their physician for follow up. *Cognitive status* will be assessed via the Mini-Mental State Examination (MMSE),[21]. Participants who score 21 points or less in MMSE are excluded and referred to a physician appointment.

*Balance confidence* will be evaluated using the Activities-specific Balance Confidence scale (ABC),[40] . *Fear of falling* will be assessed (yes/no) and measured by the Visual Analogue Scale (VAS),[41]. A 100-mm long line will be used with the left end of the line (0 mm) representing "no fear" and the right end (100 mm) "extreme fear".

***Other variables***

During the health examination, the research nurse will measure height and weight using standard procedures. Body mass index will be calculated as body weight (kg)/height (m) squared. The research nurse will also ask about any chronic and geriatric conditions, prescription medication(s) and the presence of any *cardiovascular condition* using New York Heart Association functional class (NYHA),[42] and perform an orthostatic test,[43]. *Alcohol consumption* will be assessed by the AUDIT-C tool and additionally by AUDIT if the AUDIT-C score is 6 or more among men and 5 or more among women,[22]. If the AUDIT score is 15 or more, participants will be excluded and referred to a health care practitioner.

*Self-reported physical ability* will be determined via interview and asking participants: "How would you describe your physical ability?" Options are: 1) excellent, 2) good, 3) average, and 4) poor. *Need of mobility assistive devices* will also be determined via interview. *Mobility difficulty* will be assessed using a structured interview described earlier (see participant eligibility). As an outcome measure of *adherence*, we utilize the average number and duration of exercise sessions and total number and duration of exercise sessions based on daily completed and monthly returned PA and exercise diaries. In addition, *perceived exertion* will be assessed using the modified Borg Rating of Perceived Exertion (RPE) scale (range 0-10),[44].

*Demographics* include age, sex, marital status, education, and more recent occupation, as well as diet, use of spectacles, and smoking habits and whether participants have any problems related to vision and hearing, will be determined by interview. *Previous falls* will also be asked at baseline: "Have you fallen (and if so, how many times) during the previous year/6 months/month (without substantial external force) and did you injure yourself? *Adverse events* due to interventions are assessed by daily completed and monthly returned diaries and telephone interviews.

## Statistical methods

### *Pretrial power calculations*

We estimated the minimum required sample size in a simulation model including the continuous and count outcomes and the mutual correlation estimated via normally distributed random effects. Sample size estimation accounted for the multiple testing and the correlation between outcomes,[45]. Based on previous research,[16], we assumed that the control group would have a fall incidence of 131 per 100 person-years and the corresponding rate in the intervention group would be 118 per 100 person-years, which corresponds to a modest relative risk reduction of about 10% in favor of the intervention group. To allow some over-dispersion in the fall count, the normally distributed random effect variance was set at 0.3. Based on data from the Life-Space Mobility in Old Age (LISPE) study,[46], we set the mean at 64.0 (SD = 20.6) for the life-space mobility score, which was increased to 70.4 in the intervention group during the follow-up representing a relative increase of 10%. To obtain a conservative sample size estimate the random effect correlation was set at the low value 0.10. The simulation studies were based on 1000 replications of the model parameters. To find the likelihood ratio test statistic significant at 5% significance level for the above mean difference and risk ratio simultaneously, power of 80% was reached with a sample size of 346 based on equal allocation of subjects into the control and intervention groups. To account for 30% attrition, the sample size was increased to 450 (225 in each group).

### *Statistical analyses*

All statistical analyses will be conducted using the Mplus software and IBM SPSS software package version 24 (IBM Corp, Armonk, New York). We will analyze the data on an intention-to-treat basis, using the data from all randomized participants despite the protocol adherence and independent of the sponsor and competing interest. Follow-up time for falls, fallers and fall-induced injuries including fractures will be calculated from the day when participant started the intervention to the end of the 24-month intervention + 24-month follow-up or withdrawal from study.

The *primary outcome analysis* is a likelihood ratio test assessing simultaneously changes in the ratio of falls rates and the difference in rate changes in the LSA outcome. The test is based on a model of the fall outcome in a negative binomial regression model, where a random effect is used to account for likely over dispersion in the fall count distribution and the intraclass correlation of the measurement time points. Descriptive information is calculated as incidence

rates of falls, fallers, multiple fallers and fall-induced injuries (including fractures) per 100 person-years. Proportion of fallers between groups will be reported using incidence rate ratio statistics.

*Ancillary analysis* using causal modelling will be conducted to establish intervention effects in people with greater adherence (per protocol analysis). Covariance analysis will be used to analyze between group-differences in other continuous variables and general linear models will be utilized to assess the effect of group allocation on continuous secondary outcome measures. Logistic regression models will be used to compare the two intervention groups on dichotomous outcome measures. *The explanatory factors of exercise adherence* will be investigated in a longitudinal path model enabling the linking data from individual characteristics to intervention effectiveness. Directed acyclic graphs are used to establish theoretical model relationships that serve as basis for model development with observed data. Additionally, we model physical activity trajectories and investigate individual variability among the trajectories.

*Economic analyses* will be approached from the perspective of the community health care provider. The health outcome measure will be cost per fall prevented over the study duration. Costs will include intervention costs as well as fall-induced health care and community service costs. Cost-utility is based on quality-adjusted life years (QALY) gained, where quality is measured at 12, 24 and 48 months with the WHO quality of life (WHOQoL) index. Using mean costs and QoL in each treatment arm, the intervention cost effectiveness will be assessed by comparing the intervention incremental cost per a prevented fall and incremental cost per QALY gained to those in the control group. The probability that the intervention is cost effective will be computed based on bootstrapping the incremental cost-effectiveness ratio as described in,[47]. Cost-effectiveness acceptability curves will be plotted for various levels of willingness to pay.

Where missing data is generated through the missing-at-random (MAR) mechanism, we will employ the standard MAR-based likelihood specification in Mplus,[48]. A custom missing data model will be used when missing data is generated by a non-random mechanism.

## DATA MANAGEMENT

Once a participant has been randomly allocated, every effort will be made to follow-up the participant on outcome measures until the end of the study period. Any participants who discontinue or deviate from the intervention protocols or fail to complete the exercise and falls diary will still be invited to complete the 12 and/or 24 follow-up measurements. Participant data

are stored on a secure database in accordance with the General Data Protection Regulations (2018). All collected data will be coded with unique identification numbers and stored centrally on the secure database of the University of Jyväskylä, a password-protected computer or in a locked filing cabinet in a secure office space, only accessible by a limited number of people. The questionnaires and forms will be checked for completeness and congruity instantly when filled and/or received and again before data entry onto the database. Additionally, we will regularly check the data files for omissions and errors to ensure the data integrity. Trial documentation and data will be archived for at least 10 years after completion of the trial after which it will be destroyed. The data monitoring committee (DMC) consists of the research group members (see front page). Thus, it is not independent.

## TRIAL MONITORING

A standard operation procedure has been written before launching the study and will be followed carefully throughout the study. Regular meetings will be organized for monitoring the quality of data collection. Senior researchers will carefully educate the personnel performing the measurements and the same staff will engage in the data collection throughout the study.

## ETHICS AND DISSEMINATION

The Ethics Committee of the Tampere University Hospital has approved the procedures and design of the trial (03/11/2015, ref: R15160). The COSMOS study is carried out according to the guidelines of good scientific practice (Declaration of Helsinki). Any protocol modifications will be reported to the Ethical Committee and to the trial registry (ISRCTN). Participants are insured for intervention related harms. Moreover, we will record any adverse events from either of the interventions and report serious adverse events to the ethics committee. Participants may withdraw from the study for any reason at any time.

The research team is committed to full disclosure of the results of the trial. Findings will be reported in accordance with the CONSORT guidelines in peer reviewed journals and international scientific conferences. The funder will have no role in the analysis or interpretation of the trial results.

## PATIENT AND PUBLIC INVOLVEMENT STATEMENT

We did not directly include patient and public involvement in this study, but we will develop the counselling program based on participant feedback.

## ACKNOWLEDGMENTS

The authors would like to thank all the trial participants. We thank also the research physiotherapists: Elina Ahlstedt-Kivelä, Paju Becker, and Eerika Tiirikainen as well as the research nurses: Anneli Peltonen, Kirsi Perkkiö, Tiina Raittinen, Laura-Emilia Vainio, and Arja Ylä-Rakkola for their valuable contribution. Additionally, authors would like to thank physician Jaakko Valvanne for his feedback on the health examination concept and psychologist Päivi Lappalainen for introducing the motivational interviewing technique to the study personnel. We thank statistician Markku Kauppinen, who created the random allocation protocol. We thank also Sirpa Ellala, Paula Pasanen-Aro, Maarit Pitkänen, Anne Santalahti, and Laura Tyyskänen at the City of Ylöjärvi for ongoing collaboration and Academy of Finland for funding the study.

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## AUTHORS' CONTRIBUTIONS

Authorship is based on the ICMJE Recommendations (2013). RN is the responsible investigator who conceived the study and will oversee the data collection. The study was conceived with input from TaR, RD, UK, TT, HS, PK, AH, SS, LK, TiR, and OT. JE and SK are responsible for managing the data collection. JE wrote this protocol manuscript, the final version of which all other authors have revised and provided input according to their area of expertise. All authors approved the final version of the manuscript.

## FUNDING STATEMENT

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## COMPETING INTERESTS STATEMENT

Riku Nikander, University of Jyväskylä and GeroCenter foundation, Jyväskylä Finland, is a co-owner of the Devisys oy, Tampere Finland, a company that produces anti-slip devices for winter conditions.

## DATA AVAILABILITY STATEMENT

De-identified participant data are available upon reasonable request from prof. Riku Nikander, riku.p.nikander@jyu.fi. Detailed IPD sharing statement is available at the ISRCTN registry (ISRCTN65406039).

## TABLES AND FIGURES

Table 1. Condensed trial registration data

Table 2. Content of the COSMOS 1 and 2 levels

Table 3. Outcome and other variables, methods and schedule of the assessments

Figure 1. Flow chart of the COSMOS study

Supplementary figure. Participant timeline

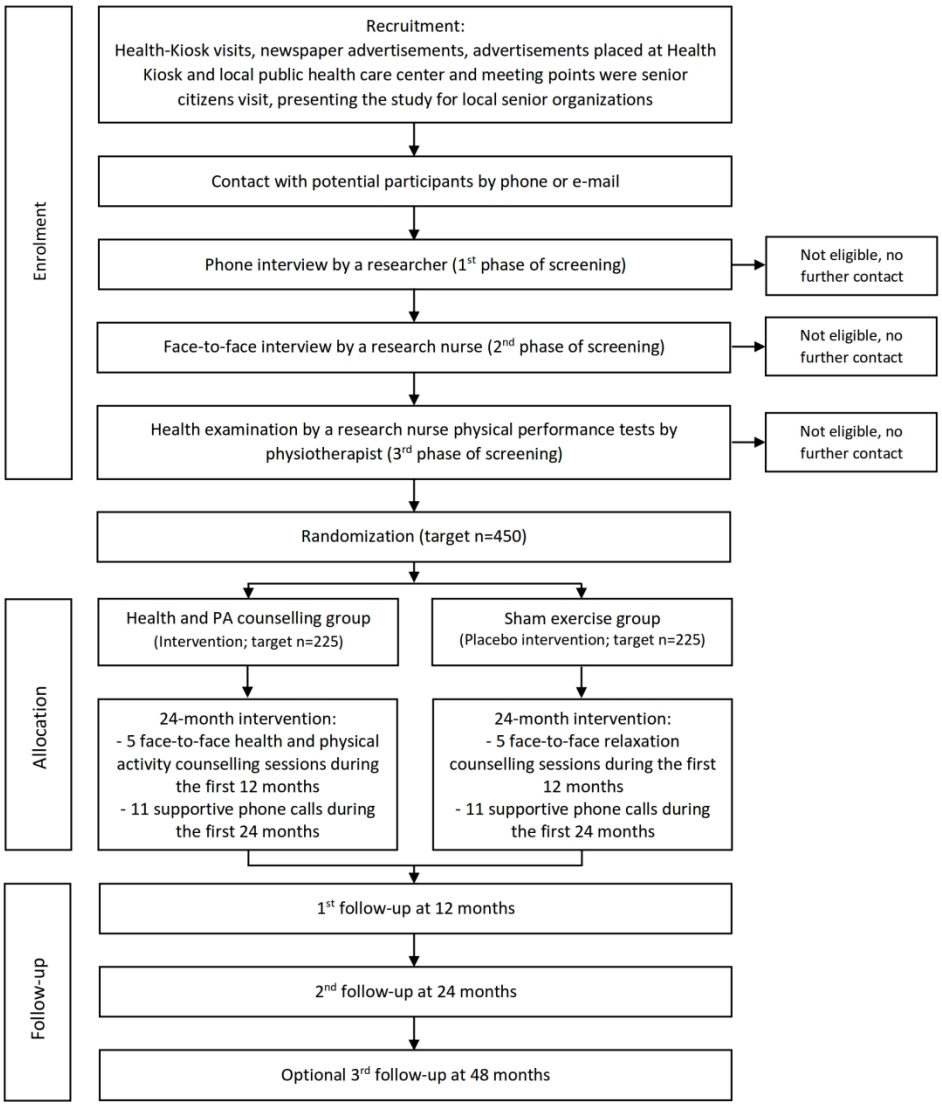


**Figure 1.** Flow chart of the COSMOS study, PA=physical activity

Flow chart of the COSMOS study

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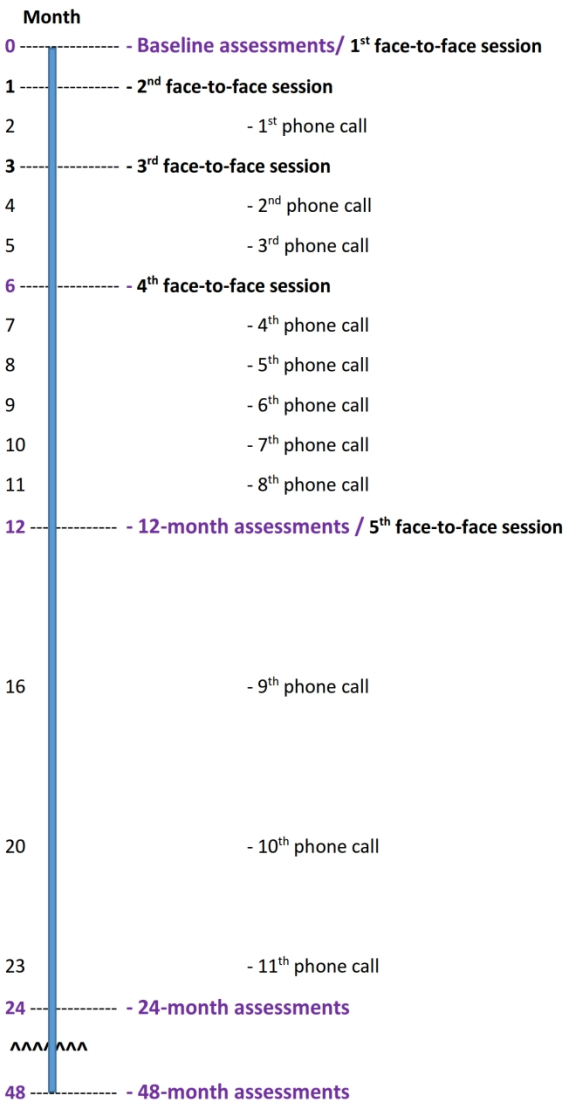


**Supplementary figure**. Participant timeline

Participant timeline

112x227mm (300 x 300 DPI)

# Reporting checklist for protocol of a clinical trial.

Based on the SPIRIT guidelines.

## Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the SPIRIT reporting guidelines, and cite them as:

Chan A-W, Tetzlaff JM, Altman DG, Laupacis A, Gøtzsche PC, Krleža-Jerić K, Hróbjartsson A, Mann H, Dickersin K, Berlin J, Doré C, Parulekar W, Summerskill W, Groves T, Schulz K, Sox H, Rockhold FW, Rennie D, Moher D. SPIRIT 2013 Statement: Defining standard protocol items for clinical trials. Ann Intern Med. 2013;158(3):200-207

| | | Reporting Item | Page Number |
|---|---|---|---|
| Title | #1 | Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym | 1 |
| Trial registration | #2a | Trial identifier and registry name. If not yet registered, name of intended registry | 2,6,7 |
| Trial registration: data set | #2b | All items from the World Health Organization Trial Registration Data Set | 6 |
| Protocol version | #3 | Date and version identifier | 1 |
| Funding | #4 | Sources and types of financial, material, and other support | 6,23 |
| Roles and responsibilities: contributorship | #5a | Names, affiliations, and roles of protocol contributors | 1,23 |
| Roles and responsibilities: | #5b | Name and contact information for the trial sponsor | 6 |

| | | | |
|---|---|---|---|
| sponsor contact information | | | |
| Roles and responsibilities: sponsor and funder | #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 | 16-17 |
| Roles and responsibilities: committees | #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) | 16-17 |
| 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 | 2-5 |
| Background and rationale: choice of comparators | #6b | Explanation for choice of comparators | 11 |
| Objectives | #7 | Specific objectives or hypotheses | 5 |
| 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, non-inferiority, exploratory) | 6,7 |
| 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 | 6,7 |
| 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) | 6,7-8 |
| Interventions: description | #11a | Interventions for each group with sufficient detail to allow replication, including how and when they will be administered | 6,9-11 |

| | | | |
|---|---|---|---|
| Interventions: modifications | #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) | 9-11 |
| Interventions: adherance | #11c | Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return; laboratory tests) | 9-11 |
| Interventions: concomitant care | #11d | Relevant concomitant care and interventions that are permitted or prohibited during the trial | 9-11 |
| 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 | 11-14 |
| 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) | 9, Figure 2 |
| 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 | 15 |
| Recruitment | #15 | Strategies for achieving adequate participant enrolment to reach target sample size | 8 |
| 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 | 8 |

| | | | |
|---|---|---|---|
| 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 | 8 |
| Allocation: implementation | #16c | Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions | 8 |
| Blinding (masking) | #17a | Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how | 8 |
| Blinding (masking): emergency unblinding | #17b | If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial | n/a |
| Data collection plan | #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 | 16-17 |
| Data collection plan: retention | #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 | 16-17 |
| 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 | 16-17 |
| Statistics: outcomes | #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 | 15-16 |
| Statistics: additional analyses | #20b | Methods for any additional analyses (eg, subgroup and adjusted analyses) | 16 |

| | | | |
|---|---|---|---|
| Statistics: analysis population and missing data | #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) | 16 |
| Data monitoring: formal committee | #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 | 16-17 |
| Data monitoring: interim analysis | #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 | n/a |
| 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 | 17 |
| Auditing | #23 | Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor | 16-17 |
| Research ethics approval | #24 | Plans for seeking research ethics committee / institutional review board (REC / IRB) approval | 2,17 |
| 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) | 17 |
| Consent or assent | #26a | Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32) | 8 |
| Consent or assent: ancillary studies | #26b | Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable | n/a |
| Confidentiality | #27 | How personal information about potential and enrolled participants will be collected, shared, and maintained in | 16-17 |

| | | | |
|---|---|---|---|
| | | order to protect confidentiality before, during, and after the trial | |
| Declaration of interests | #28 | Financial and other competing interests for principal investigators for the overall trial and each study site | 23 |
| Data access | #29 | Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators | 23 |
| 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 | n/a |
| Dissemination policy: trial results | #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 | 17 |
| Dissemination policy: authorship | #31b | Authorship eligibility guidelines and any intended use of professional writers | 23 |
| Dissemination policy: reproducible research | #31c | Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code | 17,23 |
| Informed consent materials | #32 | Model consent form and other related documentation given to participants and authorised surrogates | n/a |
| 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 | n/a |

BMJ Open

# Counselling for physical activity, life-space mobility and falls prevention in old age (COSMOS): Protocol of a randomized controlled trial (ISRCTN65406039)



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| Keywords: | older people, physical activity, falls, counselling, life-space mobility, injuries |
| | |

# Counselling for physical activity, life-space mobility and falls prevention in old age (COSMOS): Protocol of a randomized controlled trial (ISRCTN65406039)

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## ABSTRACT

**Introduction:** The most promising way to promote active life years in old age is to promote regular participation in physical activity (PA). Maintaining lower extremity muscle function with good balance has been associated with fewer falls and the need of help from others. This article describes the design and intervention of a randomized controlled trial (RCT) investigating the effectiveness of a health and PA counselling program on life-space mobility and falls rates in community-dwelling older adults at the Health Kiosk and/or Service Centre.

**Methods and analysis:** Community-dwelling men and women (n=450) aged 65 years and over with early phase mobility limitation will be recruited to a 24-month RCT with a 24-month follow-up. Participants will be randomly allocated into either a health and PA counselling group (intervention) or relaxation group (control intervention). All participants will receive five group specific face-to-face counselling sessions and 11 phone calls. The counselling intervention will include individualized health counselling, strength and balance training and guidance to regular PA. The control group will receive relaxation exercises. Outcomes will be assessed at baseline, 12, 24, and 48 months. Primary outcomes are average life-space mobility score and falls rates. Life-space mobility will be assessed by a validated questionnaire. Falls rates will be recorded from fall diaries. Secondary outcomes are data on fall-induced injuries and living-arrangements, number of fallers, fracture risk, mean level of PA, physical performance, quality of life, mood, cognition, balance confidence, and fear of falling. Data will be analyzed using the intention-to-treat principle. Cost-effectiveness of the program will be analyzed. Ancillary analyses are planned in participants with greater adherence.

**Ethics and dissemination:** Ethical approval was obtained from the Ethics Committee of the Tampere University Hospital (R15160). Outcomes will be disseminated through publication in peer-reviewed journals and presentations at international conferences.

**Trial registration:** Prospectively registered to ISRCTN (ISRCTN65406039).

## STRENGTHS AND LIMITATIONS OF THE STUDY

- This randomized controlled trial will investigate the effectiveness of a pragmatic home-based exercise program on life-space mobility and falls rates.
- The counselling protocol is delivered by nurses and physiotherapists according to current evidence-based principles to maximize long-term exercise adherence and commitment to physical activity, and to prevent falls.
- Counselling sessions take place at easily accessible community-based Health Kiosk and/or Service Centre environment.
- This will be the first randomized controlled trial to evaluate the effectiveness of health and physical activity counselling in a community-based environment to improve life-space mobility and prevent falls.
- Research nurses and research physiotherapists are not blinded to the random allocation.

## INTRODUCTION

The disablement process model by Verbrugge and Jette,[1] describes the path from pathology to disability via impairments and functional limitations. Accordingly, multiple health conditions (e.g. osteoarthritis) may lead to physical impairments (e.g. weak leg extensor muscles), which may result in functional limitations (e.g. challenges with lower extremity function and balance). Functional limitations may finally lead to disability resulting in uncertainty to walk safely, an increased fear of falling and rate of falls, all of which can further reduce movement within a typical living area,[2, 3]. In addition, restricted life-space mobility can reduce participation in social activities, which can lead to little utilization of community amenities available. This vicious cycle can escalate as overall health and well-being of older adults deteriorates.

Developing and implementing effective strategies that prevent disability and falls among older people is an urgent public health issue given our ageing population and the personal and societal impact from falls. Targeted exercise programs including muscle strength and balance training, such as the Otago Exercise Program, have been found to be effective at preventing falls and injurious falls among community-dwelling older adults,[4-6]. There is also evidence that older people with multiple risk factors for falls and thus at high risk of falling benefit from a multifactorial approach,[4]. For instance, a previous multifactorial trial (Chaos Falls Clinic), which included an individualized 12-month falls prevention programme, in high-risk individuals aged 70 years or over reduced falls and fall-induced injuries by over 25%,[7]. Despite its effectiveness, multifactorial interventions can be expensive and labour-intensive.

Community-based and easily accessible service platforms and concepts provide an opportunity potential for health and physical activity counselling since they may reach a broad range of older people who already wish to change their lifestyle. As an approach to reform the social and health care system in Finland and confront European megatrends such as the aging population with increasing public costs, community-based Health Kiosks and Service Centres have been launched to enable rapid health screening and counselling to support people to be active and participative in the society. Their focus is on health promotion and disability prevention. Scheduled appointments are not required and they are free of charge. A rapid health screening with tailored counselling and guidance at an easily accessible environment can offer a modernized primary care concept to tackle or slow down progressive but early phase health issues and disablement processes. It may also provide a unique opportunity to increase physical activity, support physical function, and avoid falls, depressive symptoms and social isolation,[8, 9].

To our knowledge, only one previous randomized controlled trial has shown the impact of a multifactorial intervention on life-space mobility in older people,[10]. It has been recommended that future studies should measure mobility at both the participation and activity levels. Additionally, it has been suggested that future research should include a longer follow-up period to determine if the benefits of any interventions are maintained long-term (> 12 months). Therefore, COSMOS will be the first randomized controlled trial to evaluate the effectiveness of 24-month health and physical activity counselling program in a community-based Health Kiosk and/or Service Centre environment to improve life-space mobility and physical activity and prevent falls, and evaluate whether any benefits are sustained after a 24-month follow-up. Another novel aspect is that this study will assess simultaneously changes in the ratio of falls rates and the difference in rate changes in the life-space mobility outcome.

## TRIAL OBJECTIVES AND HYPOTHESIS

The primary aim of this randomized controlled trial (RCT) named "Counselling for physical activity, life-space mobility and falls prevention in old age" (COSMOS) is to examine the effectiveness of a 24-month community-based health and physical activity counselling program in increasing life-space mobility and reducing the rate of falls in community-dwelling elderly people.

Secondary aims of the study are to evaluate the effects of the counselling intervention on data on fall-induced injuries and living-arrangements, number of fallers, fracture risk, mean level of physical activity, physical performance, quality of life, mood, cognition, and balance confidence. We will also evaluate the cost-effectiveness of the counselling program within the community-based environment for falls and whether any of the aforementioned potential benefits can be maintained two years after the end of 24-month intervention.

We hypothesise that 1) life-space mobility can increase and 2) fall rates can reduce via improved lower extremity ability, balance and mobility. These together enable increasing walking distances and thus support safe attendance to physical and social activities outside one's own neighbourhood or home district.

## METHODS AND DESIGN

This protocol article is written based on the SPIRIT reporting guidelines,[11] and the trial protocol was prospectively registered to ISRCTN (ISRCTN65406039). The experimental design is illustrated in ***Figure 1***.

### Trial design and study setting

COSMOS is a pragmatic single-blinded 24-month RCT with a 24-month follow-up at a community-based environment. Participants will be randomized into one of two groups: 1) a health and physical activity counselling intervention or 2) a relaxation intervention (control). All participants will be assessed at baseline and after 12- and 24-months. Additionally, there will be follow-up assessments at 48-months. All assessments will begin with a structured interview and health examination performed by a research nurse and followed by physical performance tests carried out by a research physiotherapist. All assessments and intervention sessions will take place at the Health Kiosk of Ylöjärvi or at the Service Centre of Ylöjärvi, Finland. Health Kiosk is a nurse-led pilot primary care service environment situated in a shopping center,[8, 9]. Service Centre is a modern meeting place for senior citizens with various indoor and outdoor activities. Ylöjärvi is a municipality of 32 000 inhabitants including suburban and rural areas. Study participants can choose themselves the place they would prefer to visit.

### Participant eligibility

The target number of participants is 450 who will be randomly allocated to each group (n=225 each). Both men and women will be recruited. Participant *inclusion criteria* are as follows: 1) aged 65 years or over, 2) community-living people, 3) living in Pirkanmaa District, Finland, and 4) at least minor self-reported mobility difficulty.

*Mobility difficulty* will be assessed by using a structured and validated interview asking each participant about his or her ability to walk 2.0 km, walk 0.5 km, and climb up one flight of stairs,[12]. The questions are formulated as follows: “Do you have difficulty in …” with five alternative response options provided: 1) …able to manage without difficulty, 2) …able to manage with some difficulty, 3) …able to manage with great deal of difficulty, 4) …able to manage only with help of another person, and 5) …unable to manage even with help. To identify

persons with minor mobility difficulty, additional questions are posed to participants who do not report task difficulty with any of the above questions. The questions concern the modification of task performance and the alternatives given are: resting in the middle of the performance, using an aid, taking support from handrails, having reduced the frequency of performing the task, having slowed down performance of the task, experiencing tiredness when performing the task, or some other change in carrying out the task. *Minor mobility difficulty* is considered if participant reports task modification in one or more of the tasks listed above.

Participant *exclusion criteria* are following: 1) severe functional limitations (unable to walk 500 meters unaided), 2) severe cardiovascular or pulmonary disease, 3) severe progressive disease, 4) terminally ill (predicted life expectancy <12 months), 5) memory impairment (MMSE score 21 points or less),[13], 6) living in an institution, 7) unwilling to be randomized, or 8) alcoholism (AUDIT score ≥ 15),[14]. Severe cardiovascular and severe pulmonary disease is defined as, conditions which are currently either unstable or contraindications for physical exercise and/or need immediate medical attention. Severe progressive disease is defined as, conditions such as neoplasm and amyotrophic lateral sclerosis (ALS), which have poor prognosis and presumably poor response or no response to physical exercise.

**Recruitment**

We will recruit eligible men and women during their Health-Kiosk and Service Centre visits as well as via newspaper advertisements, notice boards, community centers, and at senior events. All participants will be initially screened for eligibility over the telephone (age, living arrangements, and place of residence) where they will have the opportunity to ask questions and have an informed discussion with research staff. Following the telephone screening, those who are eligible and are willing to participate, will receive an information letter, consent forms and reply-paid envelope. Upon receiving a signed informed consent form, a member of the research team will sign each form prior to the baseline assessments. Potential participants will be invited to the baseline assessments, where a trained research nurse confirms their eligibility with a structured interview and health examination.

## Random allocation

Participants will be randomly allocated into either 1) the health and physical activity counselling intervention or 2) the relaxation intervention (control group). A computer generated randomization protocol will be created by a statistician who is not part of the research team. Random allocation will be stratified by sex, age (65-79 years/80 years or older) and presence or absence of falls during the last 24 months. Block size of 6, 8, 10 or 12 will be randomly varied to ensure the equality of group sizes (allocation ratio 1:1). Allocation results will be stored in sealed envelopes and stored in locked cabin. After the baseline measurements, a researcher will open one envelope according to each participant's sex, age and previous falls, and then verify with the research records, which intervention the participant is allocated. Participants are informed whether they belong to the health and physical activity counselling or relaxation group. Allocation concealment will be ensured, as the randomisation code will only be released at the completion of the study. Research nurses and physiotherapists are not blinded to the group allocation due to limited financial and personnel resources. The principal investigator will be blinded.

## Interventions

The COSMOS study involves two interventions: 1) health and physical activity counselling, and 2) a relaxation intervention (control group). ***Supplementary figure*** describes the participant timeline. Both interventions include five face-to-face sessions taking place at week one and one, three, six, and 12 months after the baseline measurements. During each face-to-face session, a physiotherapist will provide instructions for the next level of the program. Participants will be provided with 11 supportive telephone calls by a physiotherapist, regardless of the intervention, which will be delivered at two, four, five, seven, eight, nine, ten, 11, 16, 20 and 23 months after baseline. The total duration of the interventions is 24 months. At the end of the first face-to-face session, the physiotherapist informs the participant on how to fill out the physical activity and falls diary.

### *Health and physical activity counselling intervention*

Participants randomized to the health and physical activity counselling intervention will receive five individually tailored 1.5-hour face-to-face sessions containing a 30-minute health

counselling session by a trained research nurse together with a 60-minute physical activity counselling session delivered by an experienced research physiotherapist.

*The health counselling* follows the motivational interviewing concept,[15] based on the Social Cognitive Theory,[16] and the trans-theoretical model,[17]. The structure of the health counselling is based on the guidelines of the IKINÄ-manual, which is a guide for preventing falls and harm from falls in older people, released by the Finnish National Institute for Health and Welfare,[18]. Accordingly, during health counselling sessions the nurse will advise participants on safety issues related to their home-environment, such as providing recommendations to use anti-slippery shoe devices during winter, and participating in regular physical activity. Additionally, participants in the health and physical activity counselling intervention will receive handouts on how to avoid fall accidents in the home environment and outdoors. Moreover, health counselling sessions will include counselling on a healthy diet and recommendations to reduce alcohol consumption and smoking based on discussions with eahc participant about her/his background and habits, and motivation to change,[15]. The nurse will also discuss topical and relevant health related issues with health and physical activity counselling intervention members i.e. managing blood pressure, medication, and depressive mood.

*The physical activity counselling* is based on the modified version of the Otago Exercise Program (OEP, available online),[19].The OEP is an innovative model of low frequency physical activity counselling and exercise training tailored for older people and typically delivered by a physiotherapist at older people´s home. It contains four levels (A, B, C, and D) which all contain strengthening exercises for lower extremity muscles as well as balance, walking and stair climbing exercises and active range of movement exercises (e.g. neck rotations and hip and knee extensions). The exercises on each level take about 30 minutes to complete. Participants are expected to exercise three times a week at home and go for a walk at least twice a week for 30 minutes. Walking exercise can also be broken into smaller periods e.g. three ten-minute bouts.

The physiotherapist may modify and apply the OEP individually based on health, motivational status, and participant goals. The participants will receive progressive illustrated instructions and will be provided with ankle weights (0.5–5.0 kg) for the first 12 months. Thereafter, therapist will encourage participants to attend a local gym or be involved with other community exercise facilities. For this study, two additional training levels (COSMOS 1 and COSMOS 2, illustrated in ***Table 1***) have been developed to ensure progression throughout the 24-month intervention.

During the physical activity counselling sessions, a physiotherapist will also discuss the importance of regular and diverse physical activity and presents the Physical Activity Pie for Older Adults (Finnish recommendations for physical activity among 65 years old and older) (http://www.ukkinstituutti.fi/filebank/64-physical_activity_pie.pdf). In addition, therapist will provide an exercise referral to a local community exercise facilities based on the earlier discussions with the participant about her/his background and motivation to exercise. When participant receives a referral to a community-based exercise program, the physiotherapist will instruct him/her to replace one of the weekly Otago, COSMOS or walking exercises with corresponding exercise. For instance, participant may replace the Otago strength exercise with gym training or by attending a strength-training group. Correspondingly, participant may replace Otago balance exercise with yoga, Pilates, Tai Chi, or other guided balance exercise. Walking exercises can also be replaced e.g. with swimming or other aerobic exercise format.

**Table 1.** Content of the COSMOS 1 and 2 levels

| | **COSMOS 1** | **COSMOS 2** |
|---|---|---|
| **Warm-up** | Same as in the Otago Exercise Program | Same as in the Otago Exercise Program |
| **Strengthening exercises** | • One legged squat<br>• One legged sit to stand<br>• Sideways squats<br>• Jumping exercises | Same strengthening exercises as in the COSMOS 1<br>➔ Repetitions and series are up-dated and jumping exercises are extended and more demanding |
| **Balance exercises** | • Same as in the D level of the Otago Exercise Program but stair climbing is replaced with squats<br>• Additionally, multitasking is incorporated into all exercises (e.g., participants count repetitions or seconds backwards). | Same balance exercises as in the COSMOS 1 level but all exercises are performed with eyes closed |

***Relaxation intervention (control group)***

Participants randomized to the relaxation intervention will receive five 45-minute face-to-face sessions of structured relaxation exercises instructed by a physiotherapist. We believe that offering relaxation exercises will motivate the control participants to continue in the study without increasing their physical activity. The relaxation program will be updated during each face-to-face session and will proceed as follows: 1) learning the diaphragmatic respiration technique, 2) learning the tension-relaxation technique, 3) utilizing tension-relaxation technique,

4) utilizing techniques learned in previous exercises to whole body relaxation, and 5) learning consciousness of the body sensations. All exercises will be displayed on a compact disc (CD) or via mp3-format. Additionally, written instructions will be available. During the first face-to-face session, participants will receive the same handouts as the health and physical activity counselling intervention members on how to avoid fall accidents in the home environment and outdoors.

***Supportive telephone calls***

During 11 supportive telephone calls, the physiotherapist will enquire about how exercise (physical activity or relaxing program) is progressing, has the participant fallen and ensure that the most recent fall and exercise diary is returned. Additionally, therapists will confirm or schedule the next face-to-face session or 12- and 24-month follow-up measurements when appropriate. If a participant has fallen, therapists will confirm the circumstances and consequence related to the fall/falls. For those in the health and physical activity counselling group, the therapist will also discuss if there is a need to update the program, i.e. revise the number of repetitions and/or series or change the magnitude of the ankle weight before the next face-to-face session. In addition, any barriers to exercise that have come up from the participants will be addressed.

**Outcomes**

Assessments will include a comprehensive battery of tests and questionnaires on mobility, physical activity, physical function and health. The baseline assessment will take about 2 h to complete whereas 12-month and 24-month assessments will take about 1.5 h. The order of the assessments and measurements is standardized at each time point. ***Table 2*** presents the outcome and other variables, methods and schedule of the assessments in the study.

***Primary outcomes***

Daily filled and monthly returned fall diaries will be used to gather information on the *falls rates* during the 24-month intervention and follow-up. A fall is defined as an unexpected event in which participant comes to rest on the ground, floor or other lower level [20]. A research physiotherapist will phone monthly all those participants who have reported a fall or falls or if a diary is not returned.

**Table 2.** Outcome and other variables, methods and schedule of the assessments

| **Continuous monitoring** | **BL** | **12-month** | **24-month** | **48-month** | **O** |
|---|---|---|---|---|---|
| **Falls rates** | | | | | **P** |
| Daily filled and monthly returned diaries | N | Y | Y | Y | |
| Number of fallers i.e. a fall indicator variable (yes/no) | | | | | S |
| Daily filled and monthly returned diaries | N | Y | Y | Y | |
| Fall-induced injuries | | | | | S |
| Daily filled and monthly returned diaries and telephone interviews | N | Y | Y | N | |
| Hospital registers are used to verify severe injuries | N | Y | Y | Y | |
| Health service use | | | | | |
| Hospital registers are used to verify severe injuries | N | Y | Y | Y | |
| Adverse events due to interventions | | | | | |
| Daily filled and monthly returned diaries and telephone interviews | N | Y | Y | N | |
| Participant adherence to the interventions | | | | | |
| Average number and duration of exercise sessions and total number and duration of exercise sessions based on daily filled and monthly returned physical activity and exercise diaries | N | Y | Y | N | |
| Perceived exertion of interventions | | | | | |
| Modified Borg scale (range 0-10) | N | Y | Y | N | |
| **Physical, cognitive and social assessments** | **BL** | **12-month** | **24-month** | **48-month** | |
| Physical activity | | | | | S |
| Hookie AM 20 triaxial accelerometer for 7 days | Y | Y | Y | N | |
| Daily filled and monthly returned physical activity and exercise diaries | N | Y | Y | N | |
| Validated questionnaire (Scale of Grimby) | Y | Y | Y | Y | |
| Physical performance | | | | | S |
| Timed Up and Go-test (TUG) | Y | Y | Y | N | |
| Short Physical Performance Battery (SPPB) | Y | Y | Y | N | |
| Jamar hand dynamometer | Y | Y | Y | N | |
| Body composition | | | | | |
| Height and weight are measured and BMI is calculated | Y | Y | Y | Y | |
| Fracture risk | | | | | S |
| World Health Organization Fracture Risk Assessment Tool (FRAX) | Y | Y | Y | Y | |
| Cardiovascular condition | | | | | |
| New York Heart Association functional class (NYHA) | Y | Y | Y | Y | |
| Orthostatic test | Y | Y | Y | N | |
| Self-reported physical ability | | | | | |
| Determined by asking | Y | Y | Y | Y | |
| Mobility difficulty | | | | | |
| Structured interview | Y | Y | Y | Y | |
| Need of mobility assistive devices | | | | | |
| Determined by asking | Y | Y | Y | Y | |
| Living arrangements | | | | | S |
| Determined by asking | Y | Y | Y | Y | |
| **Questionnaire-based assessments** | **BL** | **12-month** | **24-month** | **48-month** | |
| **Life space mobility** | | | | | **P** |
| Life-space mobility assessment (LSA) | Y | Y | Y | Y | |
| Balance confidence | | | | | S |
| Activities-specific Balance Confidence scale (ABC) | Y | Y | Y | Y | |
| Fear of falling | | | | | S |
| Determined by asking and by Visual Analogue Scale (VAS) | Y | Y | Y | Y | |
| Quality of life (QOL) | | | | | S |
| World Health Organization Quality of Life (WHOQOL) questionnaire | Y | Y | Y | Y | |
| Cognitive status | | | | | S |
| Mini-Mental State Examination (MMSE) | Y | Y | Y | Y | |
| Depressive mood | | | | | S |
| Geriatric Depression Scale (GDS-15) | Y | Y | Y | Y | |
| Alcohol consumption | | | | | |
| The Alcohol Use Disorders Identification Test (AUDIT) | Y | Y | Y | Y | |

BL=baseline, O=outcome, N=no, Y=yes, P=primary S=secondary

*Life-space mobility Assessment (LSA)* is determined from a validated questionnaire, which measures the size of the area that a person has moved around in during the 4 weeks preceding the assessment,[2]. It correlates with observed physical performance and self-reported function,[2]. For each level of life-space (bedroom, other rooms, outside home, neighbourhood, town, beyond town) persons are asked how many days within a week they attained that level of life-space and whether they need help from another person or from assistive devices. A composite measure of life-space combines the components of life-space level attained, degree of independence, and frequency of attainment,[3].

***Secondary outcomes***

A number of secondary outcome measures will be assessed to clarify potential mechanism underlying any reduction in fall rates or increased life-space mobility during the trial, and to determine to what extent the training transfers to other important outcomes.

*Physical activity:* The Finnish Hookie AM 20 triaxial accelerometer will be used to measure all physical activity over a 7-day period. The Hookie AM 20 device and related data analyses is based on the UKK Institute's algorithms which has been used in three large Finnish population-based cohort studies,[21, 22] and in older community dwelling individuals,[23]. A physical activity and exercise diary will also be used during the first 24 months' period of the study. Self-reported physical activity will also be quantified using a modified version of the scale by Grimby,[24, 25].

*Physical performance*: An experienced research physiotherapist will conduct all physical performance tests, including the Timed Up and Go-test (TUG),[26] and Short Physical Performance Battery (SPPB),[27]. Handgrip strength from the dominant arm will be assessed using the Jamar hand dynamometer,[28].

*A fall indicator variable* (yes/no) will be formed. Additionally, *fall-induced injuries* will be assessed based on diaries filled daily and returned each month until 24-months after the baseline. Hospital registers will also be used to verify severe injuries (i.e. fractures and head injuries) during the intervention and follow-up. Injuries will be categorized as follows: 1) soft tissue bruises and contusions, 2) wounds and lacerations, 3) bone fractures, 4) joint distortions and dislocations, 5) head injuries other than fractures, and 6) other injuries. Additionally, all injuries will be categorized based on medical contact and/or treatment.

*Health-related quality of life* will be assessed using the World Health Organization Quality of Life (WHOQOL) 26-item short version questionnaire, which includes questions related to physical health, psychological health, social relationships and environment,[29]. *Living-arrangements* will be determined by interview. *Fracture risk* will be assessed by WHO Fracture Risk Assessment Tool (FRAX) via interview. The FRAX algorithms give the 10-year probability of hip fracture and a major osteoporotic fracture (clinical spine, forearm, hip or shoulder fracture),[30].

*Depressive mood* will be assessed using the Geriatric Depression Scale (GDS-15),[31]. Participants who achieve 6 points or more on GDS-15 test will be referred to their physician for follow up. *Cognitive status* will be assessed via the Mini-Mental State Examination (MMSE),[13]. Participants who score 21 points or less in MMSE are excluded and referred to a physician appointment.

*Balance confidence* will be evaluated using the Activities-specific Balance Confidence scale (ABC),[32] . *Fear of falling* will be assessed (yes/no) and measured by the Visual Analogue Scale (VAS),[33]. A 100-mm long line will be used with the left end of the line (0 mm) representing “no fear” and the right end (100 mm) “extreme fear”.

***Other variables***

During the health examination, the research nurse will measure height and weight using standard procedures. Body mass index will be calculated as body weight (kg)/height (m) squared. The research nurse will also ask about any chronic and geriatric conditions, prescription medication(s) and the presence of any *cardiovascular condition* using New York Heart Association functional class (NYHA),[34] and perform an orthostatic test,[35]. *Alcohol consumption* will be assessed by the AUDIT-C tool and additionally by AUDIT if the AUDIT-C score is 6 or more among men and 5 or more among women,[14]. If the AUDIT score is 15 or more, participants will be excluded and referred to a health care practitioner.

*Self-reported physical ability* will be determined via interview and asking participants: “How would you describe your physical ability?” Options are: 1) excellent, 2) good, 3) average, and 4) poor. *Need of mobility assistive devices* will also be determined via interview. *Mobility difficulty* will be assessed using a structured interview described earlier (see participant eligibility). As an outcome measure of *adherence*, we utilize the average number and duration of exercise sessions and total number and duration of exercise sessions based on daily completed and monthly

returned physical activity and exercise diaries. In addition, *perceived exertion* will be assessed using the modified Borg Rating of Perceived Exertion (RPE) scale (range 0-10),[36].

*Demographics* include age, sex, marital status, education, and most recent occupation, as well as diet, use of spectacles, and smoking habits and whether participants have any problems related to vision and hearing, will be determined by interview. *Previous falls* will also be asked at baseline: "Have you fallen (and if so, how many times) during the previous year/6 months/month (without substantial external force) and did you injure yourself? *Adverse events* due to interventions are assessed by daily completed and monthly returned diaries and telephone interviews.

## Statistical methods

### *Pretrial power calculations*

We estimated the minimum required sample size in a simulation model including the continuous and count outcomes and the mutual correlation estimated via normally distributed random effects. Sample size estimation accounted for the multiple testing and the correlation between outcomes,[37]. Based on previous research,[7], we assumed that the control group would have a fall incidence of 131 per 100 person-years and the corresponding rate in the intervention group would be 118 per 100 person-years, which corresponds to a modest relative risk reduction of about 10% in favor of the intervention group. To allow some over-dispersion in the fall count, the normally distributed random effect variance was set at 0.3. Based on data from the Life-Space Mobility in Old Age (LISPE) study,[38], we set the mean at 64.0 (SD = 20.6) for the life-space mobility score, which was increased to 70.4 in the intervention group during the follow-up representing a relative increase of 10%. To obtain a conservative sample size estimate the random effect correlation was set at the low value 0.10. The simulation studies were based on 1000 replications of the model parameters. To find the likelihood ratio test statistic significant at 5% significance level for the above mean difference and risk ratio simultaneously, power of 80% was reached with a sample size of 346 based on equal allocation of subjects into the control and intervention groups. To account for 30% attrition, the sample size was increased to 450 (225 in each group). In previous intervention studies including similar components, dropout rates have been approximately 15 % (Palvanen et al. 2014). We hypothesized the attrition rate to be even greater, because for majority of the participants, participation involved travelling across Pirkanmaa District (distances were even 100 km in each direction), and travelling costs were not covered and transportation was not arranged by COSMOS.

***Statistical analyses***

All statistical analyses will be conducted using the Mplus software and IBM SPSS software package version 24 (IBM Corp, Armonk, New York). We will analyze the data on an intention-to-treat basis, using the data from all randomized participants despite the protocol adherence and independent of the sponsor and competing interest. Follow-up time for falls, fallers and fall-induced injuries including fractures will be calculated from the day when participant started the intervention to the end of the 24-month intervention + 24-month follow-up or withdrawal from study.

The *primary outcome analysis* is a likelihood ratio test assessing simultaneously changes in the ratio of falls rates and the difference in rate changes in the LSA outcome. The test is based on a model of the fall outcome in a negative binomial regression model, where a random effect is used to account for likely over dispersion in the fall count distribution and the intraclass correlation of the measurement time points. Descriptive information is calculated as incidence rates of falls, fallers, multiple fallers and fall-induced injuries (including fractures) per 100 person-years. Proportion of fallers between groups will be reported using incidence rate ratio statistics.

*Ancillary analysis* using causal modelling will be conducted to establish intervention effects in people with greater adherence (per protocol analysis). Covariance analysis will be used to analyze between group-differences in other continuous variables and general linear models will be utilized to assess the effect of group allocation on continuous secondary outcome measures. Logistic regression models will be used to compare the two intervention groups on dichotomous outcome measures. *The explanatory factors of exercise adherence* will be investigated in a longitudinal path model enabling the linking data from individual characteristics to intervention effectiveness. Directed acyclic graphs are used to establish theoretical model relationships that serve as basis for model development with observed data. Additionally, we model physical activity trajectories and investigate individual variability among the trajectories.

*Economic analyses* will be approached from the perspective of the community health care provider. The health outcome measure will be cost per fall prevented over the study duration. Costs will include intervention costs as well as fall-induced health care and community service costs. Cost-utility is based on quality-adjusted life years (QALY) gained, where quality is measured at 12, 24 and 48 months with the WHO quality of life (WHOQoL) index. Using mean costs and QoL in each treatment arm, the intervention cost effectiveness will be assessed by

comparing the intervention incremental cost per a prevented fall and incremental cost per QALY gained to those in the control group. The probability that the intervention is cost effective will be computed based on bootstrapping the incremental cost-effectiveness ratio as described in,[39]. Cost-effectiveness acceptability curves will be plotted for various levels of willingness to pay.

Where missing data is generated through the missing-at-random (MAR) mechanism, we will employ the standard MAR-based likelihood specification in Mplus,[40]. A custom missing data model will be used when missing data is generated by a non-random mechanism.

## DATA MANAGEMENT

Once a participant has been randomly allocated, every effort will be made to follow-up the participant on outcome measures until the end of the study period. Any participants who discontinue or deviate from the intervention protocols or fail to complete the exercise and falls diary will still be invited to complete the 12 and/or 24 follow-up measurements. Participant data are stored on a secure database in accordance with the General Data Protection Regulations (2018). All collected data will be coded with unique identification numbers and stored centrally on the secure database of the University of Jyväskylä, a password-protected computer or in a locked filing cabinet in a secure office space, only accessible by a limited number of people. The questionnaires and forms will be checked for completeness and congruity instantly when filled and/or received and again before data entry onto the database. Additionally, we will regularly check the data files for omissions and errors to ensure the data integrity. Trial documentation and data will be archived for at least 10 years after completion of the trial after which it will be destroyed. The data monitoring committee (DMC) consists of the research group members (see front page).

## TRIAL MONITORING

A standard operation procedure has been written before launching the study and will be followed carefully throughout the study. Regular meetings will be organized for monitoring the quality of data collection. Senior researchers will carefully educate the personnel performing the measurements and the same staff will engage in the data collection throughout the study.

## ETHICS AND DISSEMINATION

The Ethics Committee of the Tampere University Hospital has approved the procedures and design of the trial (03/11/2015, ref: R15160). The COSMOS study is carried out according to the guidelines of good scientific practice (Declaration of Helsinki). Any protocol modifications will be reported to the Ethical Committee and to the trial registry (ISRCTN). Participants are insured for intervention related harms. Moreover, we will record any adverse events from either of the interventions and report serious adverse events to the ethics committee. Participants may withdraw from the study for any reason at any time.

The research team is committed to full disclosure of the results of the trial. Findings will be reported in accordance with the CONSORT guidelines in peer reviewed journals and international scientific conferences. The funder will have no role in the analysis or interpretation of the trial results. The study results will also be disseminated to the participants. Two information sessions will be organized to the study participants when the data of the primary outcomes has been analysed.

The research environment of the COSMOS trial is unique, because the trial is conducted at a Health Kiosk and/or a Service Centre, which are new easily accessible, free of charge counselling concepts, targeted and tailored for elderly people. This allows extending the study further to investigate the effectiveness of the counselling and exercise referral to promote actual mobility and to prevent fractures as a primary endpoint, which, according to our knowledge, has not been done before. If proven safe and effective in the population setting, the counselling/referral-concept could also be modified and extended to investigate other health hazards such as elderly people experiencing memory complaints or cognitive impairments and/or people having early depressive signs to meet their hazards early for effective prevention and/or treatment.

## PATIENT AND PUBLIC INVOLVEMENT STATEMENT

We did not directly include patient and public involvement in this study, but we will develop the counselling program based on participant feedback.

## ACKNOWLEDGMENTS

The authors would like to thank all the trial participants. We thank also the research physiotherapists: Elina Ahlstedt-Kivelä, Paju Becker, and Eerika Tiirikainen as well as the research nurses: Anneli Peltonen, Kirsi Perkkiö, Tiina Raittinen, Laura-Emilia Vainio, and Arja Ylä-Rakkola for their valuable contribution. Additionally, authors would like to thank physician Jaakko Valvanne for his feedback on the health examination concept and psychologist Päivi Lappalainen for introducing the motivational interviewing technique to the study personnel. We wish to thank statistician Markku Kauppinen, who created the random allocation protocol. We thank also Sirpa Ellala, Paula Pasanen-Aro, Maarit Pitkänen, Anne Santalahti, and Laura Tyyskänen at the administration of the City of Ylöjärvi for ongoing collaboration and the Academy of Finland for funding the study.

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## AUTHORS' CONTRIBUTIONS

Authorship is based on the ICMJE Recommendations (2013). RN is the responsible investigator who conceived the study and will oversee the data collection. The study was conceived with input from TaR, RD, UK, TT, HS, PK, AH, SS, LK, TiR, and OT. JE and SK are responsible for managing the data collection. JE wrote this protocol manuscript, the final version of which all other authors have revised and provided input according to their area of expertise. All authors approved the final version of the manuscript.

## FUNDING STATEMENT

This work was supported by the Academy of Finland (grant number 289523).

## COMPETING INTERESTS STATEMENT

Riku Nikander, University of Jyväskylä and GeroCenter foundation, Jyväskylä Finland, is a co-owner of the Devisys oy, Tampere Finland, a company that produces anti-slip devices for winter conditions.

## DATA AVAILABILITY STATEMENT

De-identified participant data are available upon reasonable request from prof. Riku Nikander, riku.p.nikander@jyu.fi. Detailed IPD sharing statement is available at the ISRCTN registry (ISRCTN65406039).

## TABLES AND FIGURES

Table 1. Content of the COSMOS 1 and 2 levels

Table 2. Outcome and other variables, methods and schedule of the assessments

Figure 1. Flow chart of the COSMOS study

Supplementary figure. Participant timeline

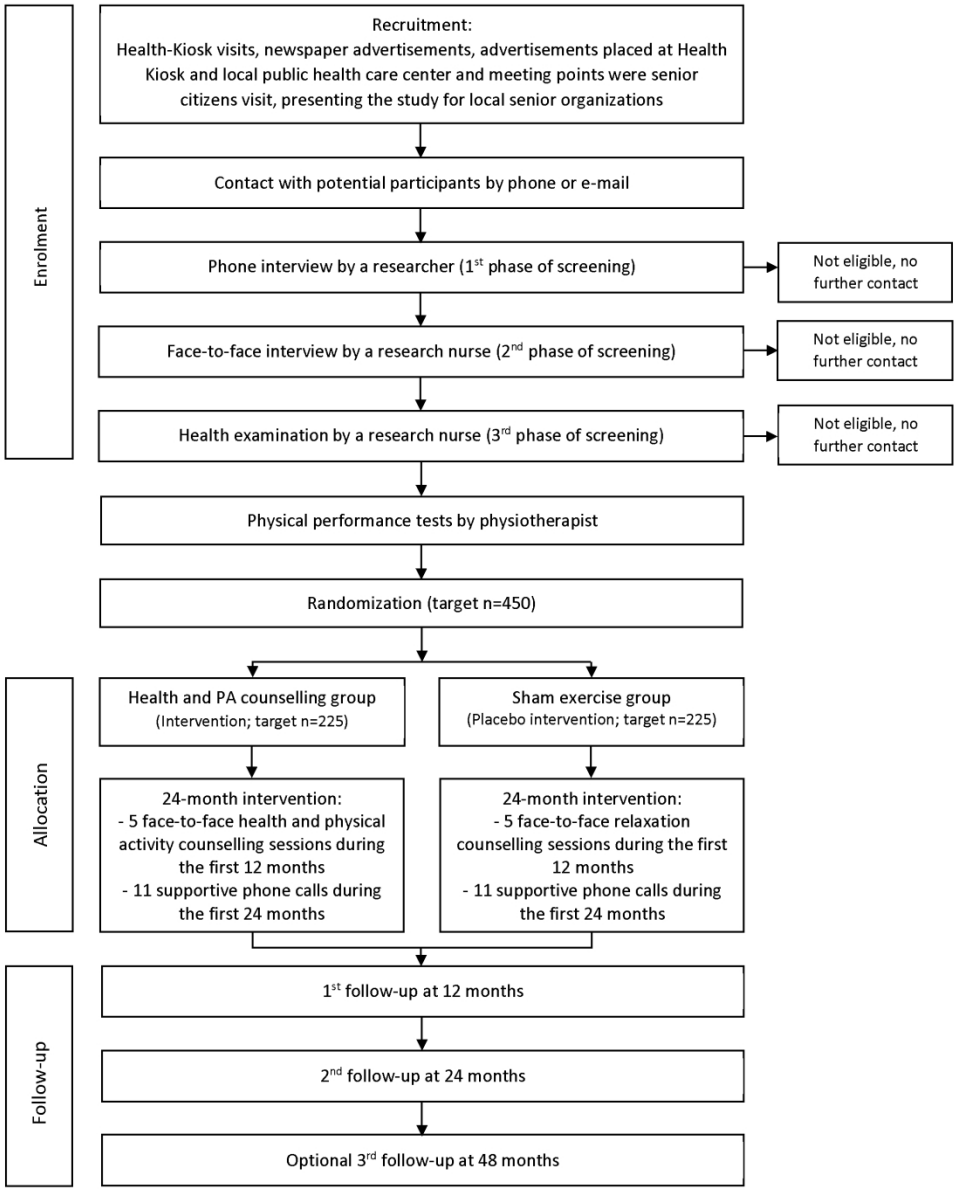


Figure 1. Flow chart of the COSMOS study

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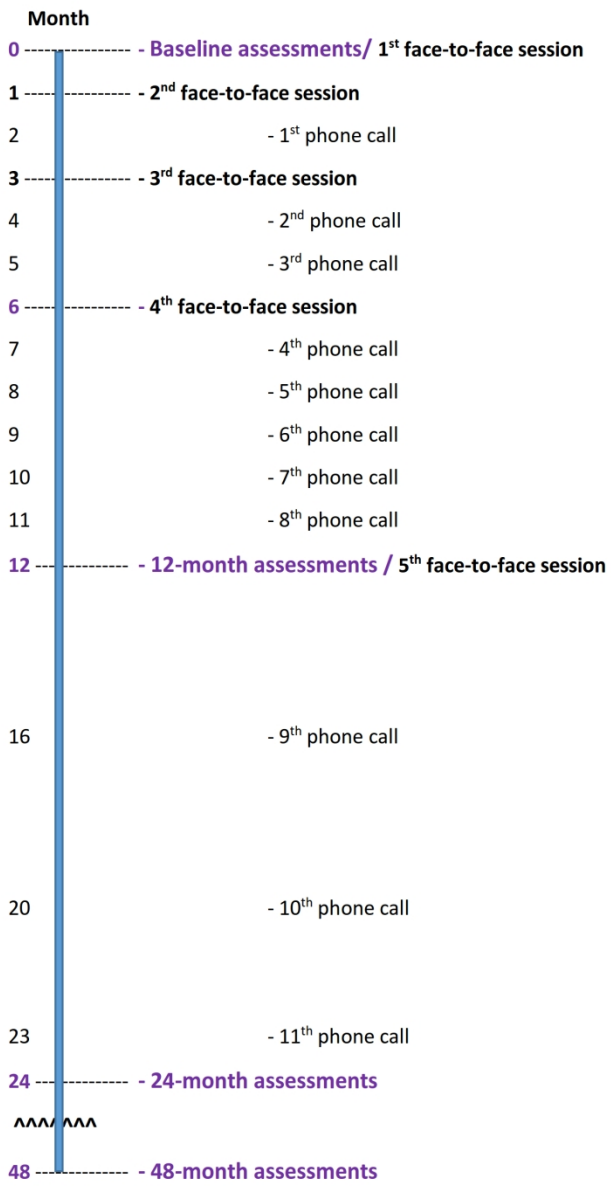


Supplementary figure. Participant timeline

350x663mm (96 x 96 DPI)

# Reporting checklist for protocol of a clinical trial.

Based on the SPIRIT guidelines.

## Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the SPIRIT reporting guidelines, and cite them as:

Chan A-W, Tetzlaff JM, Altman DG, Laupacis A, Gøtzsche PC, Krleža-Jerić K, Hróbjartsson A, Mann H, Dickersin K, Berlin J, Doré C, Parulekar W, Summerskill W, Groves T, Schulz K, Sox H, Rockhold FW, Rennie D, Moher D. SPIRIT 2013 Statement: Defining standard protocol items for clinical trials. Ann Intern Med. 2013;158(3):200-207

| | | Reporting Item | Page Number |
|---|---|---|---|
| Title | #1 | Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym | 1 |
| Trial registration | #2a | Trial identifier and registry name. If not yet registered, name of intended registry | 2,6 |

| | | | |
|---|---|---|---|
| Trial registration: data set | #2b | All items from the World Health Organization Trial Registration Data Set | 6 |
| Protocol version | #3 | Date and version identifier | 1 |
| Funding | #4 | Sources and types of financial, material, and other support | 23 |
| Roles and responsibilities: contributorship | #5a | Names, affiliations, and roles of protocol contributors | 1,23 |
| Roles and responsibilities: sponsor contact information | #5b | Name and contact information for the trial sponsor | 1,23 |
| Roles and responsibilities: sponsor and funder | #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 | 17 |
| Roles and responsibilities: committees | #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) | 17 |

| | | | |
|---|---|---|---|
| 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 | 2,4-5 |
| Background and rationale: choice of comparators | #6b | Explanation for choice of comparators | 10-11 |
| Objectives | #7 | Specific objectives or hypotheses | 5 |
| 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, non-inferiority, exploratory) | 6 |
| 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) | 6-7 |
| Interventions: description | #11a | Interventions for each group with sufficient detail to allow replication, including how and when they will be administered | 8-11 |

| | | | |
|---|---|---|---|
| Interventions: modifications | #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) | 9-11 |
| Interventions: adherance | #11c | Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return; laboratory tests) | 9-11 |
| Interventions: concomitant care | #11d | Relevant concomitant care and interventions that are permitted or prohibited during the trial | 9-11 |
| 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 | 11-15 |
| 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) | 8, suppl.fig. |
| 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 | 2,15 |

| | | | |
|---|---|---|---|
| Recruitment | #15 | Strategies for achieving adequate participant enrolment to reach target sample size | 7 |
| 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 | 8 |
| 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 | 8 |
| Allocation: implementation | #16c | Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions | 8 |
| Blinding (masking) | #17a | Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how | 8 |
| Blinding (masking): emergency unblinding | #17b | If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial | n/a |

| | | | |
|---|---|---|---|
| Data collection plan | #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 | 16-17 |
| Data collection plan: retention | #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 | 16-17 |
| 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 | 16-17 |
| Statistics: outcomes | #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 | 16-17 |
| Statistics: additional analyses | #20b | Methods for any additional analyses (eg, subgroup and adjusted analyses) | 16-17 |

| | | | |
|---|---|---|---|
| Statistics: analysis population and missing data | #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) | 16-17 |
| Data monitoring: formal committee | #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 | 17 |
| Data monitoring: interim analysis | #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 | n/a |
| 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 | 18 |
| Auditing | #23 | Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor | 17 |
| Research ethics approval | #24 | Plans for seeking research ethics committee / institutional review board (REC / IRB) approval | 2,18 |

| | | | |
|---|---|---|---|
| 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) | 18 |
| Consent or assent | #26a | Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32) | 7 |
| Consent or assent: ancillary studies | #26b | Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable | n/a |
| 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 | 18 |
| Declaration of interests | #28 | Financial and other competing interests for principal investigators for the overall trial and each study site | 23 |
| Data access | #29 | Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators | 23 |
| 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 | n/a |

| | | | |
|---|---|---|---|
| Dissemination policy: trial results | #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 | 18 |
| Dissemination policy: authorship | #31b | Authorship eligibility guidelines and any intended use of professional writers | 23 |
| Dissemination policy: reproducible research | #31c | Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code | ,23 |
| Informed consent materials | #32 | Model consent form and other related documentation given to participants and authorised surrogates | n/a |
| 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 | n/a |

BMJ Open

# Counselling for physical activity, life-space mobility and falls prevention in old age (COSMOS): Protocol of a randomized controlled trial (ISRCTN65406039)



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| | |

# Counselling for physical activity, life-space mobility and falls prevention in old age (COSMOS): Protocol of a randomized controlled trial (ISRCTN65406039)

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## ABSTRACT

**Introduction:** The most promising way to promote active life years in old age is to promote regular participation in physical activity (PA). Maintaining lower extremity muscle function with good balance has been associated with fewer falls and the need of help from others. This article describes the design and intervention of a randomized controlled trial (RCT) investigating the effectiveness of a health and PA counselling program on life-space mobility and falls rates in community-dwelling older adults at the Health Kiosk and/or Service Centre.

**Methods and analysis:** Community-dwelling men and women (n=450) aged 65 years and over with early phase mobility limitation will be recruited to a 24-month RCT with a 24-month follow-up. Participants will be randomly allocated into either a health and PA counselling group (intervention) or relaxation group (control intervention). All participants will receive five group specific face-to-face counselling sessions and 11 phone calls. The counselling intervention will include individualized health counselling, strength and balance training and guidance to regular PA. The control group will receive relaxation exercises. Outcomes will be assessed at baseline, 12, 24, and 48 months. Primary outcomes are average life-space mobility score and falls rates. Life-space mobility will be assessed by a validated questionnaire. Falls rates will be recorded from fall diaries. Secondary outcomes are data on fall-induced injuries and living-arrangements, number of fallers, fracture risk, mean level of PA, physical performance, quality of life, mood, cognition, balance confidence, and fear of falling. Data will be analyzed using the intention-to-treat principle. Cost-effectiveness of the program will be analyzed. Ancillary analyses are planned in participants with greater adherence.

**Ethics and dissemination:** Ethical approval was obtained from the Ethics Committee of the Tampere University Hospital (R15160). Outcomes will be disseminated through publication in peer-reviewed journals and presentations at international conferences.

**Trial registration:** Prospectively registered to ISRCTN (ISRCTN65406039).

## STRENGTHS AND LIMITATIONS OF THE STUDY

- This randomized controlled trial will investigate the effectiveness of a pragmatic home-based exercise program on life-space mobility and falls rates.
- The counselling protocol is delivered by nurses and physiotherapists according to current evidence-based principles to maximize long-term exercise adherence and commitment to physical activity, and to prevent falls.
- Counselling sessions take place at easily accessible community-based Health Kiosk and/or Service Centre environment.
- This will be the first randomized controlled trial to evaluate the effectiveness of health and physical activity counselling in a community-based environment to improve life-space mobility and prevent falls.
- Research nurses and research physiotherapists are not blinded to the random allocation.

## INTRODUCTION

The disablement process model by Verbrugge and Jette,[1] describes the path from pathology to disability via impairments and functional limitations. Accordingly, multiple health conditions (e.g. osteoarthritis) may lead to physical impairments (e.g. weak leg extensor muscles), which may result in functional limitations (e.g. challenges with lower extremity function and balance). Functional limitations may finally lead to disability resulting in uncertainty to walk safely, an increased fear of falling and rate of falls, all of which can further reduce movement within a typical living area,[2, 3]. In addition, restricted life-space mobility can reduce participation in social activities, which can lead to little utilization of community amenities available. This vicious cycle can escalate as overall health and well-being of older adults deteriorates.

Developing and implementing effective strategies that prevent disability and falls among older people is an urgent public health issue given our ageing population and the personal and societal impact from falls. Targeted exercise programs including muscle strength and balance training, such as the Otago Exercise Program, have been found to be effective at preventing falls and injurious falls among community-dwelling older adults,[4-6]. There is also evidence that older people with multiple risk factors for falls and thus at high risk of falling benefit from a multifactorial approach,[4]. For instance, a previous multifactorial trial (Chaos Falls Clinic), which included an individualized 12-month falls prevention programme, in high-risk individuals aged 70 years or over reduced falls and fall-induced injuries by over 25%,[7]. Despite its effectiveness, multifactorial interventions can be expensive and labour-intensive.

Community-based and easily accessible service platforms and concepts provide an opportunity potential for health and physical activity counselling since they may reach a broad range of older people who already wish to change their lifestyle. As an approach to reform the social and health care system in Finland and confront European megatrends such as the aging population with increasing public costs, community-based Health Kiosks and Service Centres have been launched to enable rapid health screening and counselling to support people to be active and participative in the society. Their focus is on health promotion and disability prevention. Scheduled appointments are not required and they are free of charge. A rapid health screening with tailored counselling and guidance at an easily accessible environment can offer a modernized primary care concept to tackle or slow down progressive but early phase health issues and disablement processes. It may also provide a unique opportunity to increase physical activity, support physical function, and avoid falls, depressive symptoms and social isolation,[8, 9].

To our knowledge, only one previous randomized controlled trial has shown the impact of a multifactorial intervention on life-space mobility in older people,[10]. It has been recommended that future studies should measure mobility at both the participation and activity levels. Additionally, it has been suggested that future research should include a longer follow-up period to determine if the benefits of any interventions are maintained long-term (> 12 months). Therefore, COSMOS will be the first randomized controlled trial to evaluate the effectiveness of 24-month health and physical activity counselling program in a community-based Health Kiosk and/or Service Centre environment to improve life-space mobility and physical activity and prevent falls, and evaluate whether any benefits are sustained after a 24-month follow-up. Another novel aspect is that this study will assess simultaneously changes in the ratio of falls rates and the difference in rate changes in the life-space mobility outcome.

## TRIAL OBJECTIVES AND HYPOTHESIS

The primary aim of this randomized controlled trial (RCT) named "Counselling for physical activity, life-space mobility and falls prevention in old age" (COSMOS) is to examine the effectiveness of a 24-month community-based health and physical activity counselling program in increasing life-space mobility and reducing the rate of falls in community-dwelling elderly people.

Secondary aims of the study are to evaluate the effects of the counselling intervention on data on fall-induced injuries and living-arrangements, number of fallers, fracture risk, mean level of physical activity, physical performance, quality of life, mood, cognition, and balance confidence. We will also evaluate the cost-effectiveness of the counselling program within the community-based environment for falls and whether any of the aforementioned potential benefits can be maintained two years after the end of 24-month intervention.

We hypothesise that 1) life-space mobility can increase and 2) fall rates can reduce via improved lower extremity ability, balance and mobility. These together enable increasing walking distances and thus support safe attendance to physical and social activities outside one's own neighbourhood or home district.

## METHODS AND DESIGN

This protocol article is written based on the SPIRIT reporting guidelines,[11] and the trial protocol was prospectively registered to ISRCTN (ISRCTN65406039). The experimental design is illustrated in ***Figure 1***.

### Trial design and study setting

COSMOS is a pragmatic single-blinded 24-month RCT with a 24-month follow-up at a community-based environment. Participants will be randomized into one of two groups: 1) a health and physical activity counselling intervention or 2) a relaxation intervention (control). All participants will be assessed at baseline and after 12- and 24-months. Additionally, there will be follow-up assessments at 48-months. All assessments will begin with a structured interview and health examination performed by a research nurse and followed by physical performance tests carried out by a research physiotherapist. All assessments and intervention sessions will take place at the Health Kiosk of Ylöjärvi or at the Service Centre of Ylöjärvi, Finland. Health Kiosk is a nurse-led pilot primary care service environment situated in a shopping center,[8, 9]. Service Centre is a modern meeting place for senior citizens with various indoor and outdoor activities. Ylöjärvi is a municipality of 32 000 inhabitants including suburban and rural areas. Study participants can choose themselves the place they would prefer to visit.

### Participant eligibility

The target number of participants is 450 who will be randomly allocated to each group (n=225 each). Both men and women will be recruited. Participant *inclusion criteria* are as follows: 1) aged 65 years or over, 2) community-living people, 3) living in Pirkanmaa District, Finland, and 4) at least minor self-reported mobility difficulty.

*Mobility difficulty* will be assessed by using a structured and validated interview asking each participant about his or her ability to walk 2.0 km, walk 0.5 km, and climb up one flight of stairs,[12]. The questions are formulated as follows: “Do you have difficulty in …” with five alternative response options provided: 1) …able to manage without difficulty, 2) …able to manage with some difficulty, 3) …able to manage with great deal of difficulty, 4) …able to manage only with help of another person, and 5) …unable to manage even with help. To identify

persons with minor mobility difficulty, additional questions are posed to participants who do not report task difficulty with any of the above questions. The questions concern the modification of task performance and the alternatives given are: resting in the middle of the performance, using an aid, taking support from handrails, having reduced the frequency of performing the task, having slowed down performance of the task, experiencing tiredness when performing the task, or some other change in carrying out the task. *Minor mobility difficulty* is considered if participant reports task modification in one or more of the tasks listed above.

Participant *exclusion criteria* are following: 1) severe functional limitations (unable to walk 500 meters unaided), 2) severe cardiovascular or pulmonary disease, 3) severe progressive disease, 4) terminally ill (predicted life expectancy <12 months), 5) memory impairment (MMSE score 21 points or less),[13], 6) living in an institution, 7) unwilling to be randomized, or 8) alcoholism (AUDIT score ≥ 15),[14]. Severe cardiovascular and severe pulmonary disease is defined as, conditions which are currently either unstable or contraindications for physical exercise and/or need immediate medical attention. Severe progressive disease is defined as, conditions such as neoplasm and amyotrophic lateral sclerosis (ALS), which have poor prognosis and presumably poor response or no response to physical exercise.

**Recruitment**

We will recruit eligible men and women during their Health-Kiosk and Service Centre visits as well as via newspaper advertisements, notice boards, community centers, and at senior events. All participants will be initially screened for eligibility over the telephone (age, living arrangements, and place of residence) where they will have the opportunity to ask questions and have an informed discussion with research staff. Following the telephone screening, those who are eligible and are willing to participate, will receive an information letter, consent forms and reply-paid envelope. Upon receiving a signed informed consent form, a member of the research team will sign each form prior to the baseline assessments. Potential participants will be invited to the baseline assessments, where a trained research nurse confirms their eligibility with a structured interview and health examination.

## Random allocation

Participants will be randomly allocated into either 1) the health and physical activity counselling intervention or 2) the relaxation intervention (control group). A computer generated randomization protocol will be created by a statistician who is not part of the research team. Random allocation will be stratified by sex, age (65-79 years/80 years or older) and presence or absence of falls during the last 24 months. Block size of 6, 8, 10 or 12 will be randomly varied to ensure the equality of group sizes (allocation ratio 1:1). Allocation results will be stored in sealed envelopes and stored in locked cabin. After the baseline measurements, a researcher will open one envelope according to each participant's sex, age and previous falls, and then verify with the research records, which intervention the participant is allocated. Participants are informed whether they belong to the health and physical activity counselling or relaxation group. Allocation concealment will be ensured, as the randomisation code will only be released at the completion of the study. Research nurses and physiotherapists are not blinded to the group allocation due to limited financial and personnel resources. The principal investigator will be blinded.

## Interventions

The COSMOS study involves two interventions: 1) health and physical activity counselling, and 2) a relaxation intervention (control group). ***Supplementary figure*** describes the participant timeline. Both interventions include five face-to-face sessions taking place at week one and one, three, six, and 12 months after the baseline measurements. During each face-to-face session, a physiotherapist will provide instructions for the next level of the program. Participants will be provided with 11 supportive telephone calls by a physiotherapist, regardless of the intervention, which will be delivered at two, four, five, seven, eight, nine, ten, 11, 16, 20 and 23 months after baseline. The total duration of the interventions is 24 months. At the end of the first face-to-face session, the physiotherapist informs the participant on how to fill out the physical activity and falls diary.

### *Health and physical activity counselling intervention*

Participants randomized to the health and physical activity counselling intervention will receive five individually tailored 1.5-hour face-to-face sessions containing a 30-minute health

counselling session by a trained research nurse together with a 60-minute physical activity counselling session delivered by an experienced research physiotherapist.

*The health counselling* follows the motivational interviewing concept,[15] based on the Social Cognitive Theory,[16] and the trans-theoretical model,[17]. The structure of the health counselling is based on the guidelines of the IKINÄ-manual, which is a guide for preventing falls and harm from falls in older people, released by the Finnish National Institute for Health and Welfare,[18]. Accordingly, during health counselling sessions the nurse will advise participants on safety issues related to their home-environment, such as providing recommendations to use anti-slippery shoe devices during winter, and participating in regular physical activity. Additionally, participants in the health and physical activity counselling intervention will receive handouts on how to avoid fall accidents in the home environment and outdoors. Moreover, health counselling sessions will include counselling on a healthy diet and recommendations to reduce alcohol consumption and smoking based on discussions with eahc participant about her/his background and habits, and motivation to change,[15]. The nurse will also discuss topical and relevant health related issues with health and physical activity counselling intervention members i.e. managing blood pressure, medication, and depressive mood.

*The physical activity counselling* is based on the modified version of the Otago Exercise Program (OEP, available online),[19].The OEP is an innovative model of low frequency physical activity counselling and exercise training tailored for older people and typically delivered by a physiotherapist at older people´s home. It contains four levels (A, B, C, and D) which all contain strengthening exercises for lower extremity muscles as well as balance, walking and stair climbing exercises and active range of movement exercises (e.g. neck rotations and hip and knee extensions). The exercises on each level take about 30 minutes to complete. Participants are expected to exercise three times a week at home and go for a walk at least twice a week for 30 minutes. Walking exercise can also be broken into smaller periods e.g. three ten-minute bouts.

The physiotherapist may modify and apply the OEP individually based on health, motivational status, and participant goals. The participants will receive progressive illustrated instructions and will be provided with ankle weights (0.5–5.0 kg) for the first 12 months. Thereafter, therapist will encourage participants to attend a local gym or be involved with other community exercise facilities. For this study, two additional training levels (COSMOS 1 and COSMOS 2, illustrated in ***Table 1***) have been developed to ensure progression throughout the 24-month intervention.

During the physical activity counselling sessions, a physiotherapist will also discuss the importance of regular and diverse physical activity and presents the Physical Activity Pie for Older Adults (Finnish recommendations for physical activity among 65 years old and older) (http://www.ukkinstituutti.fi/filebank/64-physical_activity_pie.pdf). In addition, therapist will provide an exercise referral to a local community exercise facilities based on the earlier discussions with the participant about her/his background and motivation to exercise. When participant receives a referral to a community-based exercise program, the physiotherapist will instruct him/her to replace one of the weekly Otago, COSMOS or walking exercises with corresponding exercise. For instance, participant may replace the Otago strength exercise with gym training or by attending a strength-training group. Correspondingly, participant may replace Otago balance exercise with yoga, Pilates, Tai Chi, or other guided balance exercise. Walking exercises can also be replaced e.g. with swimming or other aerobic exercise format.

**Table 1.** Content of the COSMOS 1 and 2 levels

| | **COSMOS 1** | **COSMOS 2** |
|---|---|---|
| **Warm-up** | Same as in the Otago Exercise Program | Same as in the Otago Exercise Program |
| **Strengthening exercises** | • One legged squat<br>• One legged sit to stand<br>• Sideways squats<br>• Jumping exercises | Same strengthening exercises as in the COSMOS 1<br>➔ Repetitions and series are up-dated and jumping exercises are extended and more demanding |
| **Balance exercises** | • Same as in the D level of the Otago Exercise Program but stair climbing is replaced with squats<br>• Additionally, multitasking is incorporated into all exercises (e.g., participants count repetitions or seconds backwards). | Same balance exercises as in the COSMOS 1 level but all exercises are performed with eyes closed |

***Relaxation intervention (control group)***

Participants randomized to the relaxation intervention will receive five 45-minute face-to-face sessions of structured relaxation exercises instructed by a physiotherapist. We believe that offering relaxation exercises will motivate the control participants to continue in the study without increasing their physical activity. The relaxation program will be updated during each face-to-face session and will proceed as follows: 1) learning the diaphragmatic respiration technique, 2) learning the tension-relaxation technique, 3) utilizing tension-relaxation technique,

4) utilizing techniques learned in previous exercises to whole body relaxation, and 5) learning consciousness of the body sensations. All exercises will be displayed on a compact disc (CD) or via mp3-format. Additionally, written instructions will be available. During the first face-to-face session, participants will receive the same handouts as the health and physical activity counselling intervention members on how to avoid fall accidents in the home environment and outdoors.

***Supportive telephone calls***

During 11 supportive telephone calls, the physiotherapist will enquire about how exercise (physical activity or relaxing program) is progressing, has the participant fallen and ensure that the most recent fall and exercise diary is returned. Additionally, therapists will confirm or schedule the next face-to-face session or 12- and 24-month follow-up measurements when appropriate. If a participant has fallen, therapists will confirm the circumstances and consequence related to the fall/falls. For those in the health and physical activity counselling group, the therapist will also discuss if there is a need to update the program, i.e. revise the number of repetitions and/or series or change the magnitude of the ankle weight before the next face-to-face session. In addition, any barriers to exercise that have come up from the participants will be addressed.

**Outcomes**

Assessments will include a comprehensive battery of tests and questionnaires on mobility, physical activity, physical function and health. The baseline assessment will take about 2 h to complete whereas 12-month and 24-month assessments will take about 1.5 h. The order of the assessments and measurements is standardized at each time point. ***Table 2*** presents the outcome and other variables, methods and schedule of the assessments in the study.

***Primary outcomes***

Daily filled and monthly returned fall diaries will be used to gather information on the *falls rates* during the 24-month intervention and follow-up. A fall is defined as an unexpected event in which participant comes to rest on the ground, floor or other lower level [20]. A research physiotherapist will phone monthly all those participants who have reported a fall or falls or if a diary is not returned.

**Table 2.** Outcome and other variables, methods and schedule of the assessments

| **Continuous monitoring** | **BL** | **12-month** | **24-month** | **48-month** | **O** |
|---|---|---|---|---|---|
| **Falls rates** | | | | | **P** |
| Daily filled and monthly returned diaries | N | Y | Y | Y | |
| Number of fallers i.e. a fall indicator variable (yes/no) | | | | | S |
| Daily filled and monthly returned diaries | N | Y | Y | Y | |
| Fall-induced injuries | | | | | S |
| Daily filled and monthly returned diaries and telephone interviews | N | Y | Y | N | |
| Hospital registers are used to verify severe injuries | N | Y | Y | Y | |
| Health service use | | | | | |
| Hospital registers are used to verify severe injuries | N | Y | Y | Y | |
| Adverse events due to interventions | | | | | |
| Daily filled and monthly returned diaries and telephone interviews | N | Y | Y | N | |
| Participant adherence to the interventions | | | | | |
| Average number and duration of exercise sessions and total number and duration of exercise sessions based on daily filled and monthly returned physical activity and exercise diaries | N | Y | Y | N | |
| Perceived exertion of interventions | | | | | |
| Modified Borg scale (range 0-10) | N | Y | Y | N | |
| **Physical, cognitive and social assessments** | **BL** | **12-month** | **24-month** | **48-month** | |
| Physical activity | | | | | S |
| Hookie AM 20 triaxial accelerometer for 7 days | Y | Y | Y | N | |
| Daily filled and monthly returned physical activity and exercise diaries | N | Y | Y | N | |
| Validated questionnaire (Scale of Grimby) | Y | Y | Y | Y | |
| Physical performance | | | | | S |
| Timed Up and Go-test (TUG) | Y | Y | Y | N | |
| Short Physical Performance Battery (SPPB) | Y | Y | Y | N | |
| Jamar hand dynamometer | Y | Y | Y | N | |
| Body composition | | | | | |
| Height and weight are measured and BMI is calculated | Y | Y | Y | Y | |
| Fracture risk | | | | | S |
| World Health Organization Fracture Risk Assessment Tool (FRAX) | Y | Y | Y | Y | |
| Cardiovascular condition | | | | | |
| New York Heart Association functional class (NYHA) | Y | Y | Y | Y | |
| Orthostatic test | Y | Y | Y | N | |
| Self-reported physical ability | | | | | |
| Determined by asking | Y | Y | Y | Y | |
| Mobility difficulty | | | | | |
| Structured interview | Y | Y | Y | Y | |
| Need of mobility assistive devices | | | | | |
| Determined by asking | Y | Y | Y | Y | |
| Living arrangements | | | | | S |
| Determined by asking | Y | Y | Y | Y | |
| **Questionnaire-based assessments** | **BL** | **12-month** | **24-month** | **48-month** | |
| **Life space mobility** | | | | | **P** |
| Life-space mobility assessment (LSA) | Y | Y | Y | Y | |
| Balance confidence | | | | | S |
| Activities-specific Balance Confidence scale (ABC) | Y | Y | Y | Y | |
| Fear of falling | | | | | S |
| Determined by asking and by Visual Analogue Scale (VAS) | Y | Y | Y | Y | |
| Quality of life (QOL) | | | | | S |
| World Health Organization Quality of Life (WHOQOL) questionnaire | Y | Y | Y | Y | |
| Cognitive status | | | | | S |
| Mini-Mental State Examination (MMSE) | Y | Y | Y | Y | |
| Depressive mood | | | | | S |
| Geriatric Depression Scale (GDS-15) | Y | Y | Y | Y | |
| Alcohol consumption | | | | | |
| The Alcohol Use Disorders Identification Test (AUDIT) | Y | Y | Y | Y | |

BL=baseline, O=outcome, N=no, Y=yes, P=primary S=secondary

*Life-space mobility Assessment (LSA)* is determined from a validated questionnaire, which measures the size of the area that a person has moved around in during the 4 weeks preceding the assessment,[2]. It correlates with observed physical performance and self-reported function,[2]. For each level of life-space (bedroom, other rooms, outside home, neighbourhood, town, beyond town) persons are asked how many days within a week they attained that level of life-space and whether they need help from another person or from assistive devices. A composite measure of life-space combines the components of life-space level attained, degree of independence, and frequency of attainment,[3].

***Secondary outcomes***

A number of secondary outcome measures will be assessed to clarify potential mechanism underlying any reduction in fall rates or increased life-space mobility during the trial, and to determine to what extent the training transfers to other important outcomes.

*Physical activity:* The Finnish Hookie AM 20 triaxial accelerometer will be used to measure all physical activity over a 7-day period. The Hookie AM 20 device and related data analyses is based on the UKK Institute's algorithms which has been used in three large Finnish population-based cohort studies,[21, 22] and in older community dwelling individuals,[23]. A physical activity and exercise diary will also be used during the first 24 months' period of the study. Self-reported physical activity will also be quantified using a modified version of the scale by Grimby,[24, 25].

*Physical performance*: An experienced research physiotherapist will conduct all physical performance tests, including the Timed Up and Go-test (TUG),[26] and Short Physical Performance Battery (SPPB),[27]. Handgrip strength from the dominant arm will be assessed using the Jamar hand dynamometer,[28].

*A fall indicator variable* (yes/no) will be formed. Additionally, *fall-induced injuries* will be assessed based on diaries filled daily and returned each month until 24-months after the baseline. Hospital registers will also be used to verify severe injuries (i.e. fractures and head injuries) during the intervention and follow-up. Injuries will be categorized as follows: 1) soft tissue bruises and contusions, 2) wounds and lacerations, 3) bone fractures, 4) joint distortions and dislocations, 5) head injuries other than fractures, and 6) other injuries. Additionally, all injuries will be categorized based on medical contact and/or treatment.

*Health-related quality of life* will be assessed using the World Health Organization Quality of Life (WHOQOL) 26-item short version questionnaire, which includes questions related to physical health, psychological health, social relationships and environment,[29]. *Living-arrangements* will be determined by interview. *Fracture risk* will be assessed by WHO Fracture Risk Assessment Tool (FRAX) via interview. The FRAX algorithms give the 10-year probability of hip fracture and a major osteoporotic fracture (clinical spine, forearm, hip or shoulder fracture),[30].

*Depressive mood* will be assessed using the Geriatric Depression Scale (GDS-15),[31]. Participants who achieve 6 points or more on GDS-15 test will be referred to their physician for follow up. *Cognitive status* will be assessed via the Mini-Mental State Examination (MMSE),[13]. Participants who score 21 points or less in MMSE are excluded and referred to a physician appointment.

*Balance confidence* will be evaluated using the Activities-specific Balance Confidence scale (ABC),[32] . *Fear of falling* will be assessed (yes/no) and measured by the Visual Analogue Scale (VAS),[33]. A 100-mm long line will be used with the left end of the line (0 mm) representing “no fear” and the right end (100 mm) “extreme fear”.

***Other variables***

During the health examination, the research nurse will measure height and weight using standard procedures. Body mass index will be calculated as body weight (kg)/height (m) squared. The research nurse will also ask about any chronic and geriatric conditions, prescription medication(s) and the presence of any *cardiovascular condition* using New York Heart Association functional class (NYHA),[34] and perform an orthostatic test,[35]. *Alcohol consumption* will be assessed by the AUDIT-C tool and additionally by AUDIT if the AUDIT-C score is 6 or more among men and 5 or more among women,[14]. If the AUDIT score is 15 or more, participants will be excluded and referred to a health care practitioner.

*Self-reported physical ability* will be determined via interview and asking participants: “How would you describe your physical ability?” Options are: 1) excellent, 2) good, 3) average, and 4) poor. *Need of mobility assistive devices* will also be determined via interview. *Mobility difficulty* will be assessed using a structured interview described earlier (see participant eligibility). As an outcome measure of *adherence*, we utilize the average number and duration of exercise sessions and total number and duration of exercise sessions based on daily completed and monthly

returned physical activity and exercise diaries. In addition, *perceived exertion* will be assessed using the modified Borg Rating of Perceived Exertion (RPE) scale (range 0-10),[36].

*Demographics* include age, sex, marital status, education, and most recent occupation, as well as diet, use of spectacles, and smoking habits and whether participants have any problems related to vision and hearing, will be determined by interview. *Previous falls* will also be asked at baseline: "Have you fallen (and if so, how many times) during the previous year/6 months/month (without substantial external force) and did you injure yourself? *Adverse events* due to interventions are assessed by daily completed and monthly returned diaries and telephone interviews.

## Statistical methods

### *Pretrial power calculations*

We estimated the minimum required sample size in a simulation model including the continuous and count outcomes and the mutual correlation estimated via normally distributed random effects. Sample size estimation accounted for the multiple testing and the correlation between outcomes,[37]. Based on previous research,[7], we assumed that the control group would have a fall incidence of 131 per 100 person-years and the corresponding rate in the intervention group would be 118 per 100 person-years, which corresponds to a modest relative risk reduction of about 10% in favor of the intervention group. To allow some over-dispersion in the fall count, the normally distributed random effect variance was set at 0.3. Based on data from the Life-Space Mobility in Old Age (LISPE) study,[38], we set the mean at 64.0 (SD = 20.6) for the life-space mobility score, which was increased to 70.4 in the intervention group during the follow-up representing a relative increase of 10%. To obtain a conservative sample size estimate the random effect correlation was set at the low value 0.10. The simulation studies were based on 1000 replications of the model parameters. To find the likelihood ratio test statistic significant at 5% significance level for the above mean difference and risk ratio simultaneously, power of 80% was reached with a sample size of 346 based on equal allocation of subjects into the control and intervention groups. To account for 30% attrition, the sample size was increased to 450 (225 in each group). In previous intervention studies including similar components, dropout rates have been approximately 15 % (Palvanen et al. 2014). We hypothesized the attrition rate to be even greater, because for majority of the participants, participation involved travelling across Pirkanmaa District (distances were even 100 km in each direction), and travelling costs were not covered and transportation was not arranged by COSMOS.

***Statistical analyses***

All statistical analyses will be conducted using the Mplus software and IBM SPSS software package version 24 (IBM Corp, Armonk, New York). We will analyze the data on an intention-to-treat basis, using the data from all randomized participants despite the protocol adherence and independent of the sponsor and competing interest. Follow-up time for falls, fallers and fall-induced injuries including fractures will be calculated from the day when participant started the intervention to the end of the 24-month intervention + 24-month follow-up or withdrawal from study.

The *primary outcome analysis* is a likelihood ratio test assessing simultaneously changes in the ratio of falls rates and the difference in rate changes in the LSA outcome. The test is based on a model of the fall outcome in a negative binomial regression model, where a random effect is used to account for likely over dispersion in the fall count distribution and the intraclass correlation of the measurement time points. Descriptive information is calculated as incidence rates of falls, fallers, multiple fallers and fall-induced injuries (including fractures) per 100 person-years. Proportion of fallers between groups will be reported using incidence rate ratio statistics.

*Ancillary analysis* using causal modelling will be conducted to establish intervention effects in people with greater adherence (per protocol analysis). Covariance analysis will be used to analyze between group-differences in other continuous variables and general linear models will be utilized to assess the effect of group allocation on continuous secondary outcome measures. Logistic regression models will be used to compare the two intervention groups on dichotomous outcome measures. *The explanatory factors of exercise adherence* will be investigated in a longitudinal path model enabling the linking data from individual characteristics to intervention effectiveness. Directed acyclic graphs are used to establish theoretical model relationships that serve as basis for model development with observed data. Additionally, we model physical activity trajectories and investigate individual variability among the trajectories.

*Economic analyses* will be approached from the perspective of the community health care provider. The health outcome measure will be cost per fall prevented over the study duration. Costs will include intervention costs as well as fall-induced health care and community service costs. Cost-utility is based on quality-adjusted life years (QALY) gained, where quality is measured at 12, 24 and 48 months with the WHO quality of life (WHOQoL) index. Using mean costs and QoL in each treatment arm, the intervention cost effectiveness will be assessed by

comparing the intervention incremental cost per a prevented fall and incremental cost per QALY gained to those in the control group. The probability that the intervention is cost effective will be computed based on bootstrapping the incremental cost-effectiveness ratio as described in,[39]. Cost-effectiveness acceptability curves will be plotted for various levels of willingness to pay.

Where missing data is generated through the missing-at-random (MAR) mechanism, we will employ the standard MAR-based likelihood specification in Mplus,[40]. A custom missing data model will be used when missing data is generated by a non-random mechanism.

## DATA MANAGEMENT

Once a participant has been randomly allocated, every effort will be made to follow-up the participant on outcome measures until the end of the study period. Any participants who discontinue or deviate from the intervention protocols or fail to complete the exercise and falls diary will still be invited to complete the 12 and/or 24 follow-up measurements. Participant data are stored on a secure database in accordance with the General Data Protection Regulations (2018). All collected data will be coded with unique identification numbers and stored centrally on the secure database of the University of Jyväskylä, a password-protected computer or in a locked filing cabinet in a secure office space, only accessible by a limited number of people. The questionnaires and forms will be checked for completeness and congruity instantly when filled and/or received and again before data entry onto the database. Additionally, we will regularly check the data files for omissions and errors to ensure the data integrity. Trial documentation and data will be archived for at least 10 years after completion of the trial after which it will be destroyed. The data monitoring committee (DMC) consists of the research group members (see front page).

## TRIAL MONITORING

A standard operation procedure has been written before launching the study and will be followed carefully throughout the study. Regular meetings will be organized for monitoring the quality of data collection. Senior researchers will carefully educate the personnel performing the measurements and the same staff will engage in the data collection throughout the study.

## ETHICS AND DISSEMINATION

The Ethics Committee of the Tampere University Hospital has approved the procedures and design of the trial (03/11/2015, ref: R15160). The COSMOS study is carried out according to the guidelines of good scientific practice (Declaration of Helsinki). Any protocol modifications will be reported to the Ethical Committee and to the trial registry (ISRCTN). Participants are insured for intervention related harms. Moreover, we will record any adverse events from either of the interventions and report serious adverse events to the ethics committee. Participants may withdraw from the study for any reason at any time.

The research team is committed to full disclosure of the results of the trial. Findings will be reported in accordance with the CONSORT guidelines in peer reviewed journals and international scientific conferences. The funder will have no role in the analysis or interpretation of the trial results. The study results will also be disseminated to the participants. Two information sessions will be organized to the study participants when the data of the primary outcomes has been analysed.

The research environment of the COSMOS trial is unique, because the trial is conducted at a Health Kiosk and/or a Service Centre, which are new easily accessible, free of charge counselling concepts, targeted and tailored for elderly people. This allows extending the study further to investigate the effectiveness of the counselling and exercise referral to promote actual mobility and to prevent fractures as a primary endpoint, which, according to our knowledge, has not been done before. If proven safe and effective in the population setting, the counselling/referral-concept could also be modified and extended to investigate other health hazards such as elderly people experiencing memory complaints or cognitive impairments and/or people having early depressive signs to meet their hazards early for effective prevention and/or treatment.

## PATIENT AND PUBLIC INVOLVEMENT STATEMENT

We did not directly include patient and public involvement in this study, but we will develop the counselling program based on participant feedback.

## ACKNOWLEDGMENTS

The authors would like to thank all the trial participants. We thank also the research physiotherapists: Elina Ahlstedt-Kivelä, Paju Becker, and Eerika Tiirikainen as well as the research nurses: Anneli Peltonen, Kirsi Perkkiö, Tiina Raittinen, Laura-Emilia Vainio, and Arja Ylä-Rakkola for their valuable contribution. Additionally, authors would like to thank physician Jaakko Valvanne for his feedback on the health examination concept and psychologist Päivi Lappalainen for introducing the motivational interviewing technique to the study personnel. We wish to thank statistician Markku Kauppinen, who created the random allocation protocol. We thank also Sirpa Ellala, Paula Pasanen-Aro, Maarit Pitkänen, Anne Santalahti, and Laura Tyyskänen at the administration of the City of Ylöjärvi for ongoing collaboration and the Academy of Finland for funding the study.

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## AUTHORS' CONTRIBUTIONS

Authorship is based on the ICMJE Recommendations (2013). RN is the responsible investigator who conceived the study and will oversee the data collection. The study was conceived with input from TaR, RD, UK, TT, HS, PK, AH, SS, LK, TiR, and OT. JE and SK are responsible for managing the data collection. JE wrote this protocol manuscript, the final version of which all other authors have revised and provided input according to their area of expertise. All authors approved the final version of the manuscript.

## FUNDING STATEMENT

This work was supported by the Academy of Finland (grant number 289523).

## COMPETING INTERESTS STATEMENT

Riku Nikander, University of Jyväskylä and GeroCenter foundation, Jyväskylä Finland, is a co-owner of the Devisys oy, Tampere Finland, a company that produces anti-slip devices for winter conditions.

## DATA AVAILABILITY STATEMENT

De-identified participant data are available upon reasonable request from prof. Riku Nikander, riku.p.nikander@jyu.fi. Detailed IPD sharing statement is available at the ISRCTN registry (ISRCTN65406039).

## TABLES AND FIGURES

Table 1. Content of the COSMOS 1 and 2 levels

Table 2. Outcome and other variables, methods and schedule of the assessments

Figure 1. Flow chart of the COSMOS study

Supplementary figure. Participant timeline

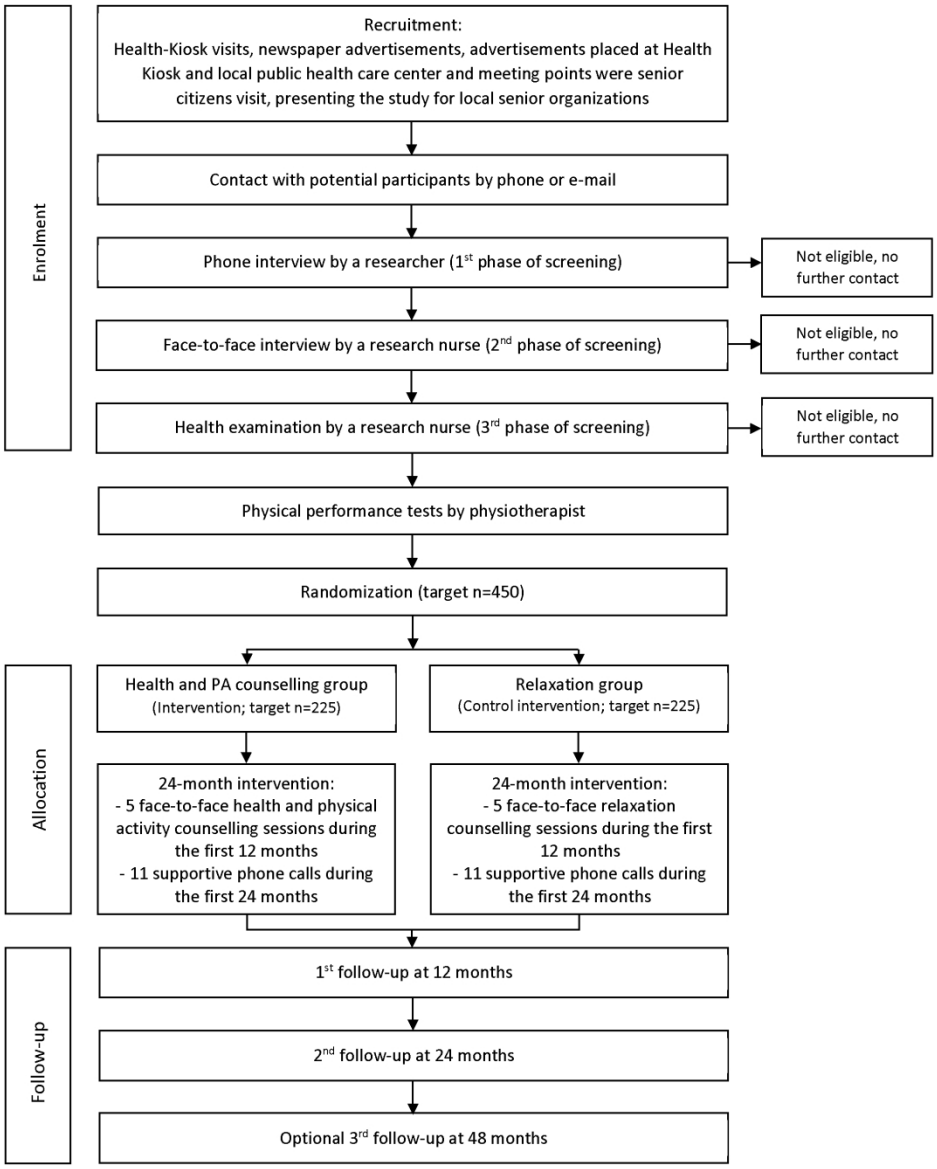
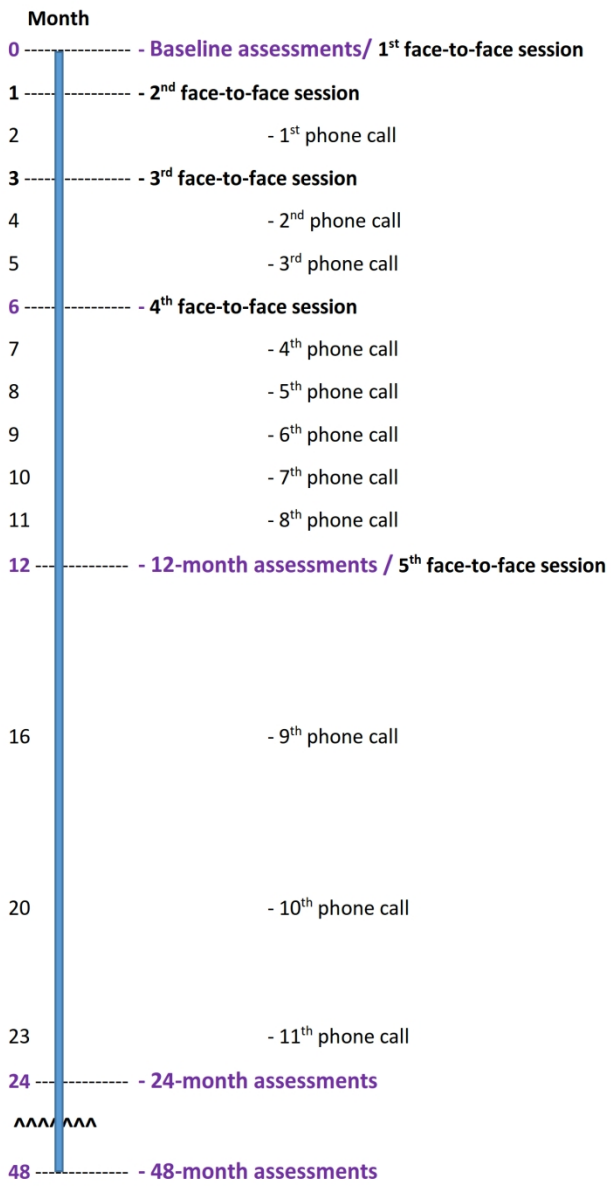



Figure 1. Flow chart of the COSMOS study

186x229mm (300 x 300 DPI)




Supplementary figure. Participant timeline

350x663mm (96 x 96 DPI)

# Reporting checklist for protocol of a clinical trial.

Based on the SPIRIT guidelines.

## Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the SPIRIT reporting guidelines, and cite them as:

Chan A-W, Tetzlaff JM, Altman DG, Laupacis A, Gøtzsche PC, Krleža-Jerić K, Hróbjartsson A, Mann H, Dickersin K, Berlin J, Doré C, Parulekar W, Summerskill W, Groves T, Schulz K, Sox H, Rockhold FW, Rennie D, Moher D. SPIRIT 2013 Statement: Defining standard protocol items for clinical trials. Ann Intern Med. 2013;158(3):200-207

| | | Reporting Item | Page Number |
|---|---|---|---|
| Title | #1 | Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym | 1 |
| Trial registration | #2a | Trial identifier and registry name. If not yet registered, name of intended registry | 2,6 |

| | | | |
|---|---|---|---|
| Trial registration: data set | #2b | All items from the World Health Organization Trial Registration Data Set | 6 |
| Protocol version | #3 | Date and version identifier | 1 |
| Funding | #4 | Sources and types of financial, material, and other support | 23 |
| Roles and responsibilities: contributorship | #5a | Names, affiliations, and roles of protocol contributors | 1,23 |
| Roles and responsibilities: sponsor contact information | #5b | Name and contact information for the trial sponsor | 1,23 |
| Roles and responsibilities: sponsor and funder | #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 | 17 |
| Roles and responsibilities: committees | #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) | 17 |

| | | | |
|---|---|---|---|
| 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 | 2,4-5 |
| Background and rationale: choice of comparators | #6b | Explanation for choice of comparators | 10-11 |
| Objectives | #7 | Specific objectives or hypotheses | 5 |
| 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, non-inferiority, exploratory) | 6 |
| 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) | 6-7 |
| Interventions: description | #11a | Interventions for each group with sufficient detail to allow replication, including how and when they will be administered | 8-11 |

| | | | |
|---|---|---|---|
| Interventions: modifications | #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) | 9-11 |
| Interventions: adherance | #11c | Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return; laboratory tests) | 9-11 |
| Interventions: concomitant care | #11d | Relevant concomitant care and interventions that are permitted or prohibited during the trial | 9-11 |
| 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 | 11-15 |
| 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) | 8, suppl.fig. |
| 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 | 2,15 |

| | | | |
|---|---|---|---|
| Recruitment | #15 | Strategies for achieving adequate participant enrolment to reach target sample size | 7 |
| 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 | 8 |
| 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 | 8 |
| Allocation: implementation | #16c | Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions | 8 |
| Blinding (masking) | #17a | Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how | 8 |
| Blinding (masking): emergency unblinding | #17b | If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial | n/a |

| | | | |
|---|---|---|---|
| Data collection plan | #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 | 16-17 |
| Data collection plan: retention | #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 | 16-17 |
| 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 | 16-17 |
| Statistics: outcomes | #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 | 16-17 |
| Statistics: additional analyses | #20b | Methods for any additional analyses (eg, subgroup and adjusted analyses) | 16-17 |

| | | | |
|---|---|---|---|
| Statistics: analysis population and missing data | #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) | 16-17 |
| Data monitoring: formal committee | #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 | 17 |
| Data monitoring: interim analysis | #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 | n/a |
| 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 | 18 |
| Auditing | #23 | Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor | 17 |
| Research ethics approval | #24 | Plans for seeking research ethics committee / institutional review board (REC / IRB) approval | 2,18 |

| | | | |
|---|---|---|---|
| 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) | 18 |
| Consent or assent | #26a | Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32) | 7 |
| Consent or assent: ancillary studies | #26b | Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable | n/a |
| 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 | 18 |
| Declaration of interests | #28 | Financial and other competing interests for principal investigators for the overall trial and each study site | 23 |
| Data access | #29 | Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators | 23 |
| 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 | n/a |

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| Dissemination policy: trial results | #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 | 18 |
| Dissemination policy: authorship | #31b | Authorship eligibility guidelines and any intended use of professional writers | 23 |
| Dissemination policy: reproducible research | #31c | Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code | ,23 |
| Informed consent materials | #32 | Model consent form and other related documentation given to participants and authorised surrogates | n/a |
| 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 | n/a |