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

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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

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3 be active and participative in the society. Their focus is on health promotion and disability
4 prevention. Scheduled appointments are not required and they are free of charge. Health Kiosk is
5 a nurse-led pilot primary care service environment situating in a shopping center,[17, 18].
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8 Service Centre is a modern meeting place for senior citizens with various indoor and outdoor
9 activities. A rapid health screening with tailored counselling and guidance at an easily accessible
10 environment can offer a modernized primary care concept to tackle or slow down progressive
11 but early phase health issues and disablement processes. It may also provide a unique
12 opportunity to increase PA, support physical function, and avoid falls, depressive symptoms and
13 social isolation,[17, 18].
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16 To our knowledge, this will be the first RCT to evaluate the effectiveness of health and PA
17 counselling in a community-based Health Kiosk and/or Service Centre environment to improve
18 life-space mobility and prevent falls. Another novel aspect is that we will assess simultaneously
19 changes in the ratio of falls rates and the difference in rate changes in the life-space mobility
20 outcome.
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31 **TRIAL OBJECTIVES**

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33 The primary aim of this randomized controlled trial (RCT) named “Counselling for physical
34 activity, life-space mobility and falls prevention in old age” (COSMOS) is to examine the
35 effectiveness of the community-based health and PA counselling program in increasing life-space
36 mobility and reducing the rate of falls in community-dwelling elderly people.
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41 More specifically, the COSMOS study is a 24-month effectiveness RCT with a 24-month follow-
42 up at a community-based environment to examine whether individualized health counselling with
43 a strength and balance exercise program and prescription of regular PA is effective at improving
44 life-space mobility and reducing the falls rates. Secondary aims of the study are to evaluate the
45 effects of the counselling intervention on data on fall-induced injuries and living-arrangements,
46 number of fallers, fracture risk, mean level of PA, physical performance, quality of life, mood,
47 cognition, and balance confidence. We will also evaluate the cost-effectiveness of the counselling
48 program within the community-based environment for falls and whether any of the aforementioned
49 potential benefits can be maintained two years after the end of 24-month intervention.
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Table 1. Condensed trial registration data

Data category	Information
Registry and trial identifying number	ISRCTN registry 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
Primary Contact	Dr Johanna Edgren, johanna.edgren@jyu.fi
Contact (scientific)	Dr Riku Nikander, riku.p.nikander@jyu.fi
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. 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. 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. 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. 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. 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. 5. Quality of life is assessed using The World Health Organization Quality of Life (WHOQoL) questionnaire at baseline, 12, 24 and 48 months. 6. Living-arrangements are determined by asking patients at baseline, 12, 24 and 48 months. 7. Fracture risk is assessed using the WHO Fracture Risk Assessment Tool at baseline, 12, 24 and 48 months. 8. Depressive mood is assessed using the Geriatric Depression Scale (GDS-15) at baseline, 12, 24 and 48 months. 9. Cognitive status is assessed using the Mini-Mental State Examination (MMSE) at baseline, 12, 24 and 48 months. 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. 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 2. Community-living people 3. Living in Ylöjärvi, Finland, or neighbouring municipalities 4. At least minor mobility difficulty
Target sample size	450
Participant exclusion criteria	1. Severe functional limitations (unable to walk 500 m unaided) 2. Severe cardiovascular or pulmonary disease 3. Severe progressive disease 4. Terminally ill (predicted lifetime <12 months) 5. Memory impairment (MMSE score 21 points or less) 6. Living in an institution 7. Unwilling to be randomized 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,

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3 or some other change in carrying out the task. *Minor mobility difficulty* is considered if
4 participant reports task modification in one or more of the tasks listed above.
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7 Participant *exclusion criteria* are following: 1) severe functional limitations (unable to walk 500
8 meters unaided), 2) severe cardiovascular or pulmonary disease, 3) severe progressive disease, 4)
9 terminally ill (predicted life expectancy <12 months), 5) memory impairment (MMSE score 21
10 points or less),[21], 6) living in an institution, 7) unwilling to be randomized, or 8) alcoholism
11 (AUDIT score ≥ 15),[22].
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16 **Recruitment**

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

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37 Participants will be randomly allocated into either 1) the health and PA counselling intervention
38 or 2) the sham exercise intervention (control). A computer generated randomization protocol will
39 be created by a statistician who is not part of the research team. Random allocation will be
40 stratified by sex, age (65-79 years/80 years or older) and presence or absence of falls during the
41 last 24 months. Block size of 6, 8, 10 or 12 will be randomly varied to ensure the equality of
42 group sizes (allocation ratio 1:1). Allocation results will be stored in sealed envelopes and stored
43 in locked cabin. After the baseline measurements, a researcher will open one envelope according
44 to each participant's sex, age and previous falls and then verifies to the research records, in
45 which intervention participant is allocated. Participants are not informed whether they belong to
46 the superior or control intervention (i.e. health and PA counselling versus sham exercise).
47 Allocation concealment will be ensured, as the randomisation code will only be released until the
48 end of the study. Research nurses and physiotherapists are not blinded to the group allocation
49 since limited personnel resources. The principal investigator will be blinded.
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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	<ul style="list-style-type: none"> • One legged squat • One legged sit to stand • Sideways squats • Jumping exercises 	Same strengthening exercises as in the COSMOS 1 → Repetitions and series are updated and jumping exercises are extended and more demanding
Balance exercises	<ul style="list-style-type: none"> • Same as in the D level of the Otago Exercise Program but stair climbing is replaced with squats • 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

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

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20 A number of secondary outcome measures will be assessed to clarify potential mechanism
21 underlying any reduction in fall rates during the trial, and to determine to what extent the training
22 transfers to other important outcomes.
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26 *Physical activity (PA)*: The Finnish Hookie AM 20 triaxial accelerometer will be used to
27 measure all PA over a 7-day period. The Hookie AM 20 device and related data analyses is
28 based on the UKK Institute's algorithms which has been used in three large Finnish population-
29 based cohort studies,[29, 30] and in older community dwelling individuals,[31]. A PA and
30 exercise diary will also be used during the first 24 months' period of the study. Self-reported PA
31 will also be quantified using the scale by Grimby,[32] with slight modifications,[33].
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37 *Physical performance*: An experienced research physiotherapist will conduct all physical
38 performance tests, including the Timed Up and Go-test (TUG),[34] and Short Physical
39 Performance Battery (SPPB),[35]. Handgrip strength from the dominant arm will be assessed
40 using the Jamar hand dynamometer,[36].
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45 *A fall indicator variable* (yes/no) will be formed and *fall-induced injuries* will be assessed based
46 on diaries filled daily and returned each month until 24-months after the baseline. Hospital
47 registers will also be used to verify severe injuries during the intervention and follow-up.
48
49

50 *Health-related quality of life* will be assessed using the World Health Organization Quality of
51 Life (WHOQOL) 26-item short version questionnaire, which includes questions related to
52 physical health, psychological health, social relationships and environment,[37]. *Living-*
53 *arrangements* will be determined by interview. *Fracture risk* will be assessed by WHO Fracture
54 Risk Assessment Tool (FRAX) via interview. The FRAX algorithms give the 10-year probability
55 of hip fracture and a major osteoporotic fracture (clinical spine, forearm, hip or shoulder
56 fracture),[38].
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3 *Depressive mood* will be assessed using the Geriatric Depression Scale (GDS-15),[39].
4 Participants who achieve 6 points or more on GDS-15 test will be referred to their physician for
5 follow up. *Cognitive status* will be assessed via the Mini-Mental State Examination
6 (MMSE),[21]. Participants who score 21 points or less in MMSE are excluded and referred to a
7 physician appointment.
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12 *Balance confidence* will be evaluated using the Activities-specific Balance Confidence scale
13 (ABC),[40]. *Fear of falling* will be assessed (yes/no) and measured by the Visual Analogue
14 Scale (VAS),[41]. A 100-mm long line will be used with the left end of the line (0 mm)
15 representing “no fear” and the right end (100 mm) “extreme fear”.
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19 ***Other variables***

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22 During the health examination, the research nurse will measure height and weight using standard
23 procedures. Body mass index will be calculated as body weight (kg)/height (m) squared. The
24 research nurse will also ask about any chronic and geriatric conditions, prescription
25 medication(s) and the presence of any *cardiovascular condition* using New York Heart
26 Association functional class (NYHA),[42] and perform an orthostatic test,[43]. *Alcohol*
27 *consumption* will be assessed by the AUDIT-C tool and additionally by AUDIT if the AUDIT-C
28 score is 6 or more among men and 5 or more among women,[22]. If the AUDIT score is 15 or
29 more, participants will be excluded and referred to a health care practitioner.
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35 *Self-reported physical ability* will be determined via interview and asking participants: “How
36 would you describe your physical ability?” Options are: 1) excellent, 2) good, 3) average, and 4)
37 poor. *Need of mobility assistive devices* will also be determined via interview. *Mobility difficulty*
38 will be assessed using a structured interview described earlier (see participant eligibility). As an
39 outcome measure of *adherence*, we utilize the average number and duration of exercise sessions
40 and total number and duration of exercise sessions based on daily completed and monthly
41 returned PA and exercise diaries. In addition, *perceived exertion* will be assessed using the
42 modified Borg Rating of Perceived Exertion (RPE) scale (range 0-10),[44].
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51 *Demographics* include age, sex, marital status, education, and more recent occupation, as well as
52 diet, use of spectacles, and smoking habits and whether participants have any problems related to
53 vision and hearing, will be determined by interview. *Previous falls* will also be asked at baseline:
54 “Have you fallen (and if so, how many times) during the previous year/6 months/month (without
55 substantial external force) and did you injure yourself? *Adverse events* due to interventions are
56 assessed by daily completed and monthly returned diaries and telephone interviews.
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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

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3 rates of falls, fallers, multiple fallers and fall-induced injuries (including fractures) per 100
4 person-years. Proportion of fallers between groups will be reported using incidence rate ratio
5 statistics.
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9 *Ancillary analysis* using causal modelling will be conducted to establish intervention effects in
10 people with greater adherence (per protocol analysis). Covariance analysis will be used to
11 analyze between group-differences in other continuous variables and general linear models will
12 be utilized to assess the effect of group allocation on continuous secondary outcome measures.
13
14 Logistic regression models will be used to compare the two intervention groups on dichotomous
15 outcome measures. *The explanatory factors of exercise adherence* will be investigated in a
16 longitudinal path model enabling the linking data from individual characteristics to intervention
17 effectiveness. Directed acyclic graphs are used to establish theoretical model relationships that
18 serve as basis for model development with observed data. Additionally, we model physical
19 activity trajectories and investigate individual variability among the trajectories.
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23 *Economic analyses* will be approached from the perspective of the community health care
24 provider. The health outcome measure will be cost per fall prevented over the study duration.
25
26 Costs will include intervention costs as well as fall-induced health care and community service
27 costs. Cost-utility is based on quality-adjusted life years (QALY) gained, where quality is
28 measured at 12, 24 and 48 months with the WHO quality of life (WHOQoL) index. Using mean
29 costs and QoL in each treatment arm, the intervention cost effectiveness will be assessed by
30 comparing the intervention incremental cost per a prevented fall and incremental cost per QALY
31 gained to those in the control group. The probability that the intervention is cost effective will be
32 computed based on bootstrapping the incremental cost-effectiveness ratio as described in,[47].
33
34 Cost-effectiveness acceptability curves will be plotted for various levels of willingness to pay.
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38 Where missing data is generated through the missing-at-random (MAR) mechanism, we will
39 employ the standard MAR-based likelihood specification in Mplus,[48]. A custom missing data
40 model will be used when missing data is generated by a non-random mechanism.
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45 46 47 48 49 50 51 52 53 **DATA MANAGEMENT**

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55 Once a participant has been randomly allocated, every effort will be made to follow-up the
56 participant on outcome measures until the end of the study period. Any participants who
57 discontinue or deviate from the intervention protocols or fail to complete the exercise and falls
58 diary will still be invited to complete the 12 and/or 24 follow-up measurements. Participant data
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3 are stored on a secure database in accordance with the General Data Protection Regulations
4 (2018). All collected data will be coded with unique identification numbers and stored centrally
5 on the secure database of the University of Jyväskylä, a password-protected computer or in a
6 locked filing cabinet in a secure office space, only accessible by a limited number of people. The
7 questionnaires and forms will be checked for completeness and congruity instantly when filled
8 and/or received and again before data entry onto the database. Additionally, we will regularly
9 check the data files for omissions and errors to ensure the data integrity. Trial documentation and
10 data will be archived for at least 10 years after completion of the trial after which it will be
11 destroyed. The data monitoring committee (DMC) consists of the research group members (see
12 front page). Thus, it is not independent.
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23 **TRIAL MONITORING**

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

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38 The Ethics Committee of the Tampere University Hospital has approved the procedures and
39 design of the trial (03/11/2015, ref: R15160). The COSMOS study is carried out according to the
40 guidelines of good scientific practice (Declaration of Helsinki). Any protocol modifications will
41 be reported to the Ethical Committee and to the trial registry (ISRCTN). Participants are insured
42 for intervention related harms. Moreover, we will record any adverse events from either of the
43 interventions and report serious adverse events to the ethics committee. Participants may
44 withdraw from the study for any reason at any time.
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51 The research team is committed to full disclosure of the results of the trial. Findings will be
52 reported in accordance with the CONSORT guidelines in peer reviewed journals and
53 international scientific conferences. The funder will have no role in the analysis or interpretation
54 of the trial results.
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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.

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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.

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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

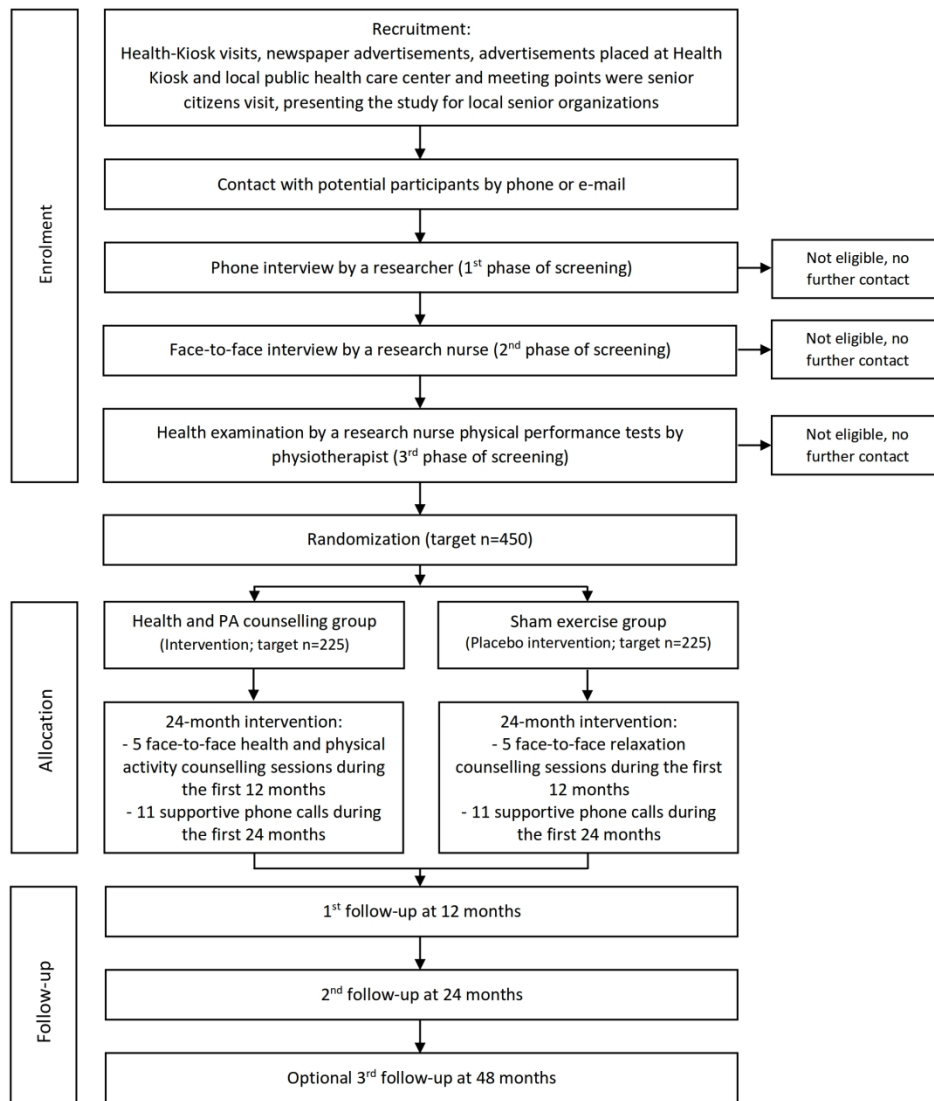
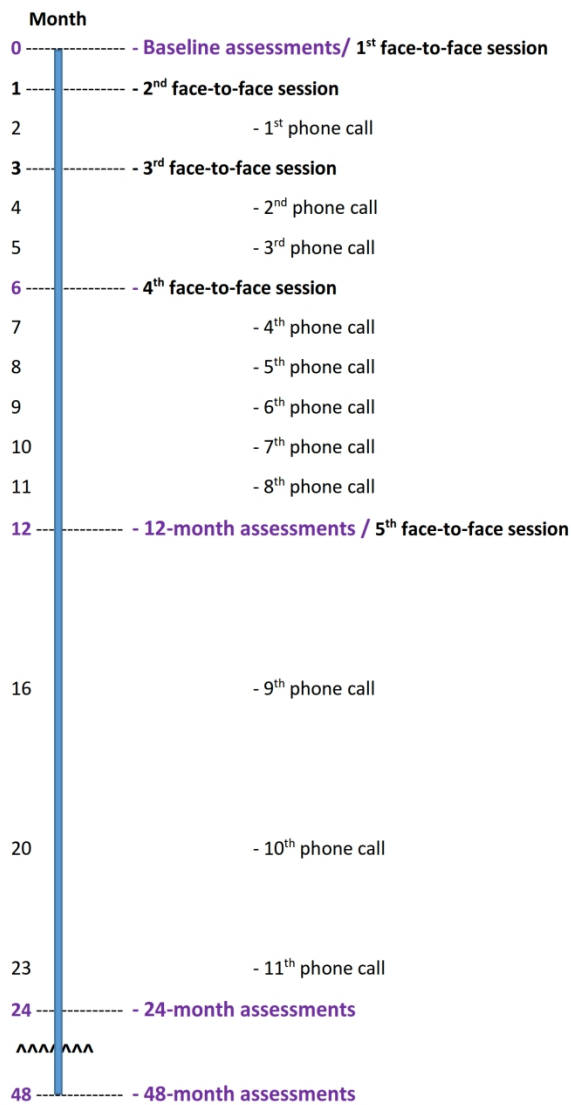


Figure 1. Flow chart of the COSMOS study, PA=physical activity

Flow chart of the COSMOS study

175x217mm (300 x 300 DPI)

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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

1	sponsor contact			
2	information			
3				
4	Roles and	#5c	Role of study sponsor and funders, if any, in study design;	16-17
5	responsibilities:		collection, management, analysis, and interpretation of	
6	sponsor and funder		data; writing of the report; and the decision to submit the	
7			report for publication, including whether they will have	
8			ultimate authority over any of these activities	
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12	Roles and	#5d	Composition, roles, and responsibilities of the coordinating	16-17
13	responsibilities:		centre, steering committee, endpoint adjudication	
14	committees		committee, data management team, and other individuals	
15			or groups overseeing the trial, if applicable (see Item 21a	
16			for data monitoring committee)	
17				
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19				
20	Background and	#6a	Description of research question and justification for	2-5
21	rationale		undertaking the trial, including summary of relevant	
22			studies (published and unpublished) examining benefits	
23			and harms for each intervention	
24				
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26				
27	Background and	#6b	Explanation for choice of comparators	11
28	rationale: choice of			
29	comparators			
30				
31				
32	Objectives	#7	Specific objectives or hypotheses	5
33				
34				
35	Trial design	#8	Description of trial design including type of trial (eg,	6,7
36			parallel group, crossover, factorial, single group),	
37			allocation ratio, and framework (eg, superiority,	
38			equivalence, non-inferiority, exploratory)	
39				
40				
41				
42	Study setting	#9	Description of study settings (eg, community clinic,	6,7
43			academic hospital) and list of countries where data will be	
44			collected. Reference to where list of study sites can be	
45			obtained	
46				
47				
48	Eligibility criteria	#10	Inclusion and exclusion criteria for participants. If	6,7-8
49			applicable, eligibility criteria for study centres and	
50			individuals who will perform the interventions (eg,	
51			surgeons, psychotherapists)	
52				
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55	Interventions:	#11a	Interventions for each group with sufficient detail to allow	6,9-11
56	description		replication, including how and when they will be	
57			administered	
58				
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1	Interventions:	#11b	Criteria for discontinuing or modifying allocated	9-11
2	modifications		interventions for a given trial participant (eg, drug dose	
3			change in response to harms, participant request, or	
4			improving / worsening disease)	
5				
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7				
8	Interventions:	#11c	Strategies to improve adherence to intervention protocols,	9-11
9	adherence		and any procedures for monitoring adherence (eg, drug	
10			tablet return; laboratory tests)	
11				
12				
13	Interventions:	#11d	Relevant concomitant care and interventions that are	9-11
14	concomitant care		permitted or prohibited during the trial	
15				
16				
17	Outcomes	#12	Primary, secondary, and other outcomes, including the	11-14
18			specific measurement variable (eg, systolic blood	
19			pressure), analysis metric (eg, change from baseline, final	
20			value, time to event), method of aggregation (eg, median,	
21			proportion), and time point for each outcome. Explanation	
22			of the clinical relevance of chosen efficacy and harm	
23			outcomes is strongly recommended	
24				
25				
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27				
28	Participant timeline	#13	Time schedule of enrolment, interventions (including any	9,
29			run-ins and washouts), assessments, and visits for	
30			participants. A schematic diagram is highly recommended	Figure 2
31			(see Figure)	
32				
33				
34				
35	Sample size	#14	Estimated number of participants needed to achieve study	15
36			objectives and how it was determined, including clinical	
37			and statistical assumptions supporting any sample size	
38			calculations	
39				
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42	Recruitment	#15	Strategies for achieving adequate participant enrolment to	8
43			reach target sample size	
44				
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46	Allocation: sequence	#16a	Method of generating the allocation sequence (eg,	8
47	generation		computer-generated random numbers), and list of any	
48			factors for stratification. To reduce predictability of a	
49			random sequence, details of any planned restriction (eg,	
50			blocking) should be provided in a separate document that	
51			is unavailable to those who enrol participants or assign	
52			interventions	
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1	Allocation	#16b	Mechanism of implementing the allocation sequence (eg,	8
2	concealment		central telephone; sequentially numbered, opaque, sealed	
3	mechanism		envelopes), describing any steps to conceal the sequence	
4			until interventions are assigned	
5				
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8	Allocation:	#16c	Who will generate the allocation sequence, who will enrol	8
9	implementation		participants, and who will assign participants to	
10			interventions	
11				
12				
13	Blinding (masking)	#17a	Who will be blinded after assignment to interventions (eg,	8
14			trial participants, care providers, outcome assessors, data	
15			analysts), and how	
16				
17				
18	Blinding (masking):	#17b	If blinded, circumstances under which unblinding is	n/a
19	emergency		permissible, and procedure for revealing a participant's	
20	unblinding		allocated intervention during the trial	
21				
22				
23				
24	Data collection plan	#18a	Plans for assessment and collection of outcome, baseline,	16-17
25			and other trial data, including any related processes to	
26			promote data quality (eg, duplicate measurements,	
27			training of assessors) and a description of study	
28			instruments (eg, questionnaires, laboratory tests) along	
29			with their reliability and validity, if known. Reference to	
30			where data collection forms can be found, if not in the	
31			protocol	
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36	Data collection plan:	#18b	Plans to promote participant retention and complete	16-17
37	retention		follow-up, including list of any outcome data to be	
38			collected for participants who discontinue or deviate from	
39			intervention protocols	
40				
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42				
43	Data management	#19	Plans for data entry, coding, security, and storage,	16-17
44			including any related processes to promote data quality	
45			(eg, double data entry; range checks for data values).	
46			Reference to where details of data management	
47			procedures can be found, if not in the protocol	
48				
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51	Statistics: outcomes	#20a	Statistical methods for analysing primary and secondary	15-16
52			outcomes. Reference to where other details of the	
53			statistical analysis plan can be found, if not in the protocol	
54				
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57	Statistics: additional	#20b	Methods for any additional analyses (eg, subgroup and	16
58	analyses		adjusted analyses)	
59				
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1	Statistics: analysis	#20c	Definition of analysis population relating to protocol non-	16
2	population and		adherence (eg, as randomised analysis), and any	
3	missing data		statistical methods to handle missing data (eg, multiple	
4			imputation)	
5				
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8	Data monitoring:	#21a	Composition of data monitoring committee (DMC);	16-17
9	formal committee		summary of its role and reporting structure; statement of	
10			whether it is independent from the sponsor and competing	
11			interests; and reference to where further details about its	
12			charter can be found, if not in the protocol. Alternatively,	
13			an explanation of why a DMC is not needed	
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18	Data monitoring:	#21b	Description of any interim analyses and stopping	n/a
19	interim analysis		guidelines, including who will have access to these interim	
20			results and make the final decision to terminate the trial	
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23	Harms	#22	Plans for collecting, assessing, reporting, and managing	17
24			solicited and spontaneously reported adverse events and	
25			other unintended effects of trial interventions or trial	
26			conduct	
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30	Auditing	#23	Frequency and procedures for auditing trial conduct, if	16-17
31			any, and whether the process will be independent from	
32			investigators and the sponsor	
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35	Research ethics	#24	Plans for seeking research ethics committee / institutional	2,17
36	approval		review board (REC / IRB) approval	
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39	Protocol	#25	Plans for communicating important protocol modifications	17
40	amendments		(eg, changes to eligibility criteria, outcomes, analyses) to	
41			relevant parties (eg, investigators, REC / IRBs, trial	
42			participants, trial registries, journals, regulators)	
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46	Consent or assent	#26a	Who will obtain informed consent or assent from potential	8
47			trial participants or authorised surrogates, and how (see	
48			Item 32)	
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51	Consent or assent:	#26b	Additional consent provisions for collection and use of	n/a
52	ancillary studies		participant data and biological specimens in ancillary	
53			studies, if applicable	
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56	Confidentiality	#27	How personal information about potential and enrolled	16-17
57			participants will be collected, shared, and maintained in	
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order to protect confidentiality before, during, and after the trial

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4	Declaration of	#28	Financial and other competing interests for principal	23
5	interests		investigators for the overall trial and each study site	
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8	Data access	#29	Statement of who will have access to the final trial	23
9			dataset, and disclosure of contractual agreements that	
10			limit such access for investigators	
11				
12				
13	Ancillary and post	#30	Provisions, if any, for ancillary and post-trial care, and for	n/a
14	trial care		compensation to those who suffer harm from trial	
15			participation	
16				
17				
18	Dissemination	#31a	Plans for investigators and sponsor to communicate trial	17
19	policy: trial results		results to participants, healthcare professionals, the	
20			public, and other relevant groups (eg, via publication,	
21			reporting in results databases, or other data sharing	
22			arrangements), including any publication restrictions	
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27	Dissemination	#31b	Authorship eligibility guidelines and any intended use of	23
28	policy: authorship		professional writers	
29				
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31	Dissemination	#31c	Plans, if any, for granting public access to the full protocol,	17,23
32	policy: reproducible		participant-level dataset, and statistical code	
33	research			
34				
35				
36	Informed consent	#32	Model consent form and other related documentation	n/a
37	materials		given to participants and authorised surrogates	
38				
39				
40	Biological specimens	#33	Plans for collection, laboratory evaluation, and storage of	n/a
41			biological specimens for genetic or molecular analysis in	
42			the current trial and for future use in ancillary studies, if	
43			applicable	
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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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Primary Subject Heading:	Public health
Secondary Subject Heading:	Rehabilitation medicine, Sports and exercise medicine
Keywords:	older people, physical activity, falls, counselling, life-space mobility, injuries

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3 1 **Counselling for physical activity, life-space mobility and falls prevention in old**
4 2 **age (COSMOS): Protocol of a randomized controlled trial (ISRCTN65406039)**

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50 45 **Word count:** 5132

51 46 **Keywords:** counselling, falls, life-space mobility, older people, physical activity

52 47 **Issue date:** 5.6.2019

53 48 **Protocol version:** revision (02)

1 ABSTRACT

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

8 **Methods and analysis:** Community-dwelling men and women (n=450) aged 65 years and over
9 with early phase mobility limitation will be recruited to a 24-month RCT with a 24-month
10 follow-up. Participants will be randomly allocated into either a health and PA counselling group
11 (intervention) or relaxation group (control intervention). All participants will receive five group
12 specific face-to-face counselling sessions and 11 phone calls. The counselling intervention will
13 include individualized health counselling, strength and balance training and guidance to regular
14 PA. The control group will receive relaxation exercises. Outcomes will be assessed at baseline,
15 12, 24, and 48 months. Primary outcomes are average life-space mobility score and falls rates.
16 Life-space mobility will be assessed by a validated questionnaire. Falls rates will be recorded
17 from fall diaries. Secondary outcomes are data on fall-induced injuries and living-arrangements,
18 number of fallers, fracture risk, mean level of PA, physical performance, quality of life, mood,
19 cognition, balance confidence, and fear of falling. Data will be analyzed using the intention-to-
20 treat principle. Cost-effectiveness of the program will be analyzed. Ancillary analyses are
21 planned in participants with greater adherence.

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

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

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27

1 STRENGTHS AND LIMITATIONS OF THE STUDY

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

1 INTRODUCTION

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

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

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

1 To our knowledge, only one previous randomized controlled trial has shown the impact of a
2 multifactorial intervention on life-space mobility in older people,[10]. It has been recommended
3 that future studies should measure mobility at both the participation and activity levels.
4 Additionally, it has been suggested that future research should include a longer follow-up period
5 to determine if the benefits of any interventions are maintained long-term (> 12 months).
6 Therefore, COSMOS will be the first randomized controlled trial to evaluate the effectiveness of
7 24-month health and physical activity counselling program in a community-based Health Kiosk
8 and/or Service Centre environment to improve life-space mobility and physical activity and
9 prevent falls, and evaluate whether any benefits are sustained after a 24-month follow-up.
10 Another novel aspect is that this study will assess simultaneously changes in the ratio of falls
11 rates and the difference in rate changes in the life-space mobility outcome.

13 TRIAL OBJECTIVES AND HYPOTHESIS

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

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

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

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1 **METHODS AND DESIGN**

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

6 **Trial design and study setting**

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

20 **Participant eligibility**

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

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

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

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

18 **Recruitment**

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

1 **Random allocation**

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

17 **Interventions**

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

28 ***Health and physical activity counselling intervention***

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

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

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

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

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

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

14 **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	<ul style="list-style-type: none"> • One legged squat • One legged sit to stand • Sideways squats • Jumping exercises 	Same strengthening exercises as in the COSMOS 1 → Repetitions and series are updated and jumping exercises are extended and more demanding
Balance exercises	<ul style="list-style-type: none"> • Same as in the D level of the Otago Exercise Program but stair climbing is replaced with squats • 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

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

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

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3 1 4) utilizing techniques learned in previous exercises to whole body relaxation, and 5) learning
4 2 consciousness of the body sensations. All exercises will be displayed on a compact disc (CD) or
5 3 via mp3-format. Additionally, written instructions will be available. During the first face-to-face
6 4 session, participants will receive the same handouts as the health and physical activity
7 5 counselling intervention members on how to avoid fall accidents in the home environment and
8 6 outdoors.

7 ***Supportive telephone calls***

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

18 19 **Outcomes**

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

25 ***Primary outcomes***

26 Daily filled and monthly returned fall diaries will be used to gather information on the *falls rates*
27 during the 24-month intervention and follow-up. A fall is defined as an unexpected event in
28 which participant comes to rest on the ground, floor or other lower level [20]. A research
29 physiotherapist will phone monthly all those participants who have reported a fall or falls or if a
30 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

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

9 ***Secondary outcomes***

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

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

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

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

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3 1 *Health-related quality of life* will be assessed using the World Health Organization Quality of
4 Life (WHOQOL) 26-item short version questionnaire, which includes questions related to
5 2 Life (WHOQOL) 26-item short version questionnaire, which includes questions related to
6 3 physical health, psychological health, social relationships and environment,[29]. *Living-*
7 4 *arrangements* will be determined by interview. *Fracture risk* will be assessed by WHO Fracture
8 5 Risk Assessment Tool (FRAX) via interview. The FRAX algorithms give the 10-year probability
9 6 of hip fracture and a major osteoporotic fracture (clinical spine, forearm, hip or shoulder
10 7 fracture),[30].

11 8 *Depressive mood* will be assessed using the Geriatric Depression Scale (GDS-15),[31].
12 9 Participants who achieve 6 points or more on GDS-15 test will be referred to their physician for
13 10 follow up. *Cognitive status* will be assessed via the Mini-Mental State Examination
14 11 (MMSE),[13]. Participants who score 21 points or less in MMSE are excluded and referred to a
15 12 physician appointment.

16 13 *Balance confidence* will be evaluated using the Activities-specific Balance Confidence scale
17 14 (ABC),[32]. *Fear of falling* will be assessed (yes/no) and measured by the Visual Analogue
18 15 Scale (VAS),[33]. A 100-mm long line will be used with the left end of the line (0 mm)
19 16 representing “no fear” and the right end (100 mm) “extreme fear”.

17 ***Other variables***

18 18 During the health examination, the research nurse will measure height and weight using standard
19 19 procedures. Body mass index will be calculated as body weight (kg)/height (m) squared. The
20 20 research nurse will also ask about any chronic and geriatric conditions, prescription
21 21 medication(s) and the presence of any *cardiovascular condition* using New York Heart
22 22 Association functional class (NYHA),[34] and perform an orthostatic test,[35]. *Alcohol*
23 23 *consumption* will be assessed by the AUDIT-C tool and additionally by AUDIT if the AUDIT-C
24 24 score is 6 or more among men and 5 or more among women,[14]. If the AUDIT score is 15 or
25 25 more, participants will be excluded and referred to a health care practitioner.

26 26 *Self-reported physical ability* will be determined via interview and asking participants: “How
27 27 would you describe your physical ability?” Options are: 1) excellent, 2) good, 3) average, and 4)
28 28 poor. *Need of mobility assistive devices* will also be determined via interview. *Mobility difficulty*
29 29 will be assessed using a structured interview described earlier (see participant eligibility). As an
30 30 outcome measure of *adherence*, we utilize the average number and duration of exercise sessions
31 31 and total number and duration of exercise sessions based on daily completed and monthly

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

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

10 **Statistical methods**

11 ***Pretrial power calculations***

12 We estimated the minimum required sample size in a simulation model including the continuous
13 and count outcomes and the mutual correlation estimated via normally distributed random
14 effects. Sample size estimation accounted for the multiple testing and the correlation between
15 outcomes,[37]. Based on previous research,[7], we assumed that the control group would have a
16 fall incidence of 131 per 100 person-years and the corresponding rate in the intervention group
17 would be 118 per 100 person-years, which corresponds to a modest relative risk reduction of
18 about 10% in favor of the intervention group. To allow some over-dispersion in the fall count,
19 the normally distributed random effect variance was set at 0.3. Based on data from the Life-
20 Space Mobility in Old Age (LISPE) study,[38], we set the mean at 64.0 (SD = 20.6) for the life-
21 space mobility score, which was increased to 70.4 in the intervention group during the follow-up
22 representing a relative increase of 10%. To obtain a conservative sample size estimate the
23 random effect correlation was set at the low value 0.10. The simulation studies were based on
24 1000 replications of the model parameters. To find the likelihood ratio test statistic significant at
25 5% significance level for the above mean difference and risk ratio simultaneously, power of 80%
26 was reached with a sample size of 346 based on equal allocation of subjects into the control and
27 intervention groups. To account for 30% attrition, the sample size was increased to 450 (225 in
28 each group). In previous intervention studies including similar components, dropout rates have
29 been approximately 15 % (Palvanen et al. 2014). We hypothesized the attrition rate to be even
30 greater, because for majority of the participants, participation involved travelling across
31 Pirkanmaa District (distances were even 100 km in each direction), and travelling costs were not
32 covered and transportation was not arranged by COSMOS.

1 ***Statistical analyses***

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

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

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

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

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3 1 comparing the intervention incremental cost per a prevented fall and incremental cost per QALY
4 gained to those in the control group. The probability that the intervention is cost effective will be
5 2 computed based on bootstrapping the incremental cost-effectiveness ratio as described in,[39].
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7 4 Cost-effectiveness acceptability curves will be plotted for various levels of willingness to pay.
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11 5 Where missing data is generated through the missing-at-random (MAR) mechanism, we will
12 6 employ the standard MAR-based likelihood specification in Mplus,[40]. A custom missing data
13 7 model will be used when missing data is generated by a non-random mechanism.
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19 9 **DATA MANAGEMENT**

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23 10 Once a participant has been randomly allocated, every effort will be made to follow-up the
24 11 participant on outcome measures until the end of the study period. Any participants who
25 12 discontinue or deviate from the intervention protocols or fail to complete the exercise and falls
26 13 diary will still be invited to complete the 12 and/or 24 follow-up measurements. Participant data
27 14 are stored on a secure database in accordance with the General Data Protection Regulations
28 15 (2018). All collected data will be coded with unique identification numbers and stored centrally
29 16 on the secure database of the University of Jyväskylä, a password-protected computer or in a
30 17 locked filing cabinet in a secure office space, only accessible by a limited number of people. The
31 18 questionnaires and forms will be checked for completeness and congruity instantly when filled
32 19 and/or received and again before data entry onto the database. Additionally, we will regularly
33 20 check the data files for omissions and errors to ensure the data integrity. Trial documentation and
34 21 data will be archived for at least 10 years after completion of the trial after which it will be
35 22 destroyed. The data monitoring committee (DMC) consists of the research group members (see
36 23 front page).
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50 25 **TRIAL MONITORING**

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53 26 A standard operation procedure has been written before launching the study and will be followed
54 27 carefully throughout the study. Regular meetings will be organized for monitoring the quality of
55 28 data collection. Senior researchers will carefully educate the personnel performing the
56 29 measurements and the same staff will engage in the data collection throughout the study.
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1 **ETHICS AND DISSEMINATION**

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

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

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

26 **PATIENT AND PUBLIC INVOLVEMENT STATEMENT**

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

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1 **AUTHORS' CONTRIBUTIONS**

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

9 **FUNDING STATEMENT**

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

12 **COMPETING INTERESTS STATEMENT**

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

17 **DATA AVAILABILITY STATEMENT**

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

22 **TABLES AND FIGURES**

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

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

25 Figure 1. Flow chart of the COSMOS study

26 Supplementary figure. Participant timeline

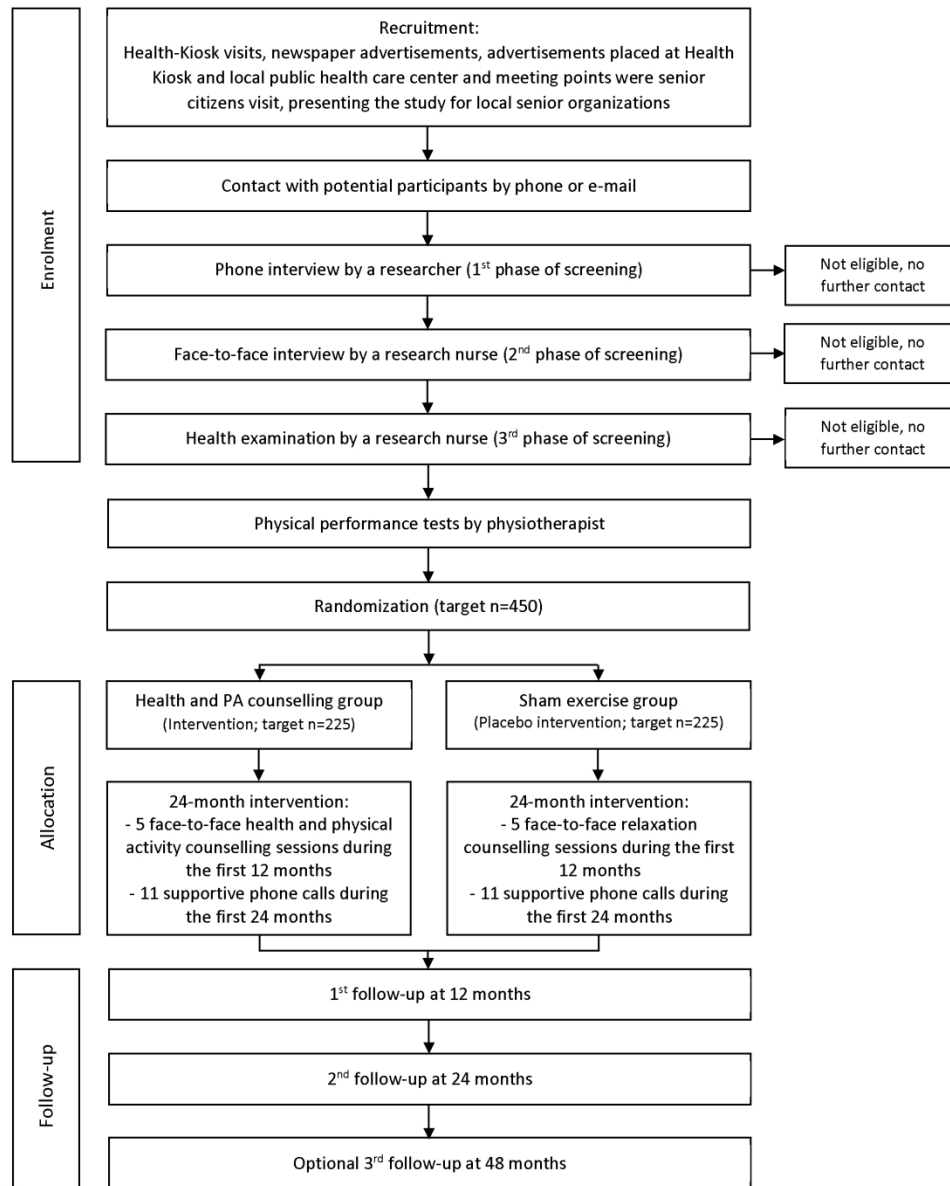
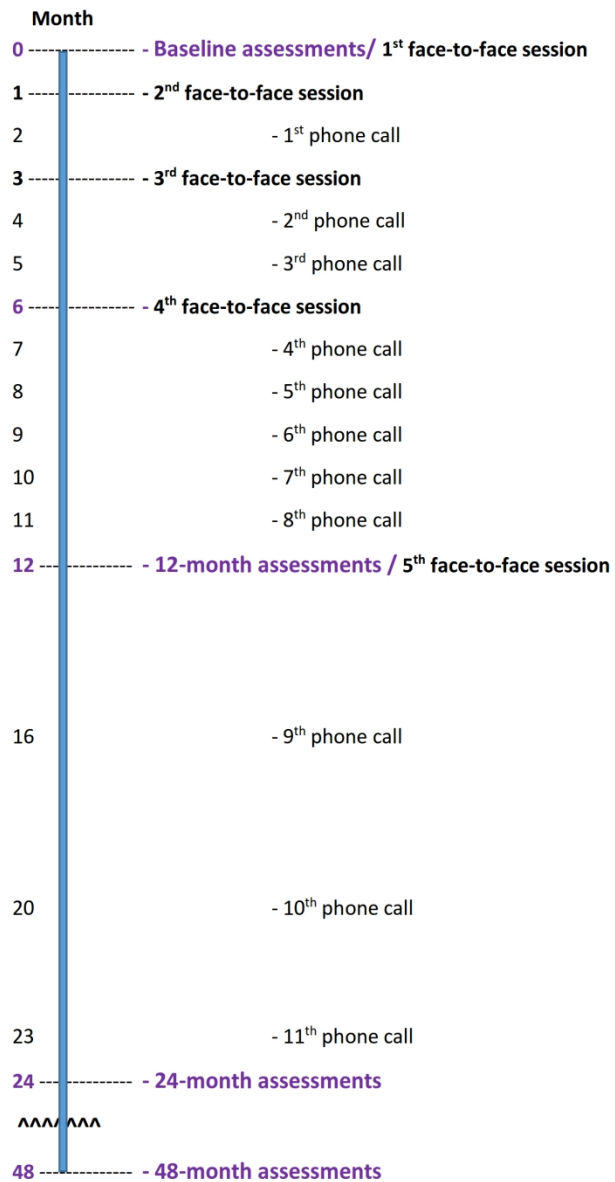


Figure 1. Flow chart of the COSMOS study

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Supplementary figure. Participant timeline

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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:

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			Page
		Reporting Item	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

1	Trial registration:	#2b	All items from the World Health Organization Trial	6
2				
3	data set		Registration Data Set	
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6	Protocol version	#3	Date and version identifier	1
7				
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9	Funding	#4	Sources and types of financial, material, and other	23
10			support	
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15	Roles and	#5a	Names, affiliations, and roles of protocol contributors	1,23
16	responsibilities:			
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18	contributorship			
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22	Roles and	#5b	Name and contact information for the trial sponsor	1,23
23	responsibilities:			
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25	sponsor contact			
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27	information			
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32	Roles and	#5c	Role of study sponsor and funders, if any, in study	17
33	responsibilities:		design; collection, management, analysis, and	
34			interpretation of data; writing of the report; and the	
35	sponsor and funder		decision to submit the report for publication, including	
36			whether they will have ultimate authority over any of	
37			these activities	
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47	Roles and	#5d	Composition, roles, and responsibilities of the	17
48	responsibilities:		coordinating centre, steering committee, endpoint	
49			adjudication committee, data management team, and	
50	committees		other individuals or groups overseeing the trial, if	
51			applicable (see Item 21a for data monitoring committee)	
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1	Background and	#6a	Description of research question and justification for	2,4-5
2				
3	rationale		undertaking the trial, including summary of relevant	
4				
5			studies (published and unpublished) examining benefits	
6				
7			and harms for each intervention	
8				
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11	Background and	#6b	Explanation for choice of comparators	10-11
12				
13	rationale: choice of			
14				
15	comparators			
16				
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18	Objectives	#7	Specific objectives or hypotheses	5
19				
20				
21				
22	Trial design	#8	Description of trial design including type of trial (eg,	6
23				
24			parallel group, crossover, factorial, single group),	
25				
26			allocation ratio, and framework (eg, superiority,	
27				
28			equivalence, non-inferiority, exploratory)	
29				
30				
31				
32	Study setting	#9	Description of study settings (eg, community clinic,	6
33				
34			academic hospital) and list of countries where data will be	
35				
36			collected. Reference to where list of study sites can be	
37				
38			obtained	
39				
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42	Eligibility criteria	#10	Inclusion and exclusion criteria for participants. If	6-7
43				
44			applicable, eligibility criteria for study centres and	
45				
46			individuals who will perform the interventions (eg,	
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48			surgeons, psychotherapists)	
49				
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51	Interventions:	#11a	Interventions for each group with sufficient detail to allow	8-11
52				
53	description		replication, including how and when they will be	
54				
55			administered	
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1	Interventions:	#11b	Criteria for discontinuing or modifying allocated	9-11
2				
3	modifications		interventions for a given trial participant (eg, drug dose	
4			change in response to harms, participant request, or	
5			improving / worsening disease)	
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11	Interventions:	#11c	Strategies to improve adherence to intervention	9-11
12				
13	adherence		protocols, and any procedures for monitoring adherence	
14			(eg, drug tablet return; laboratory tests)	
15				
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19	Interventions:	#11d	Relevant concomitant care and interventions that are	9-11
20			permitted or prohibited during the trial	
21	concomitant care			
22				
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24	Outcomes	#12	Primary, secondary, and other outcomes, including the	11-15
25			specific measurement variable (eg, systolic blood	
26			pressure), analysis metric (eg, change from baseline,	
27			final value, time to event), method of aggregation (eg,	
28			median, proportion), and time point for each outcome.	
29			Explanation of the clinical relevance of chosen efficacy	
30			and harm outcomes is strongly recommended	
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41	Participant timeline	#13	Time schedule of enrolment, interventions (including any	8,
42			run-ins and washouts), assessments, and visits for	
43			participants. A schematic diagram is highly	suppl.fig.
44			recommended (see Figure)	
45				
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51	Sample size	#14	Estimated number of participants needed to achieve	2,15
52			study objectives and how it was determined, including	
53			clinical and statistical assumptions supporting any	
54			sample size calculations	
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1	Recruitment	#15	Strategies for achieving adequate participant enrolment	7
2				
3			to reach target sample size	
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6	Allocation: sequence	#16a	Method of generating the allocation sequence (eg,	8
7	generation		computer-generated random numbers), and list of any	
8			factors for stratification. To reduce predictability of a	
9			random sequence, details of any planned restriction (eg,	
10				
11			blocking) should be provided in a separate document that	
12			is unavailable to those who enrol participants or assign	
13			interventions	
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16	Allocation	#16b	Mechanism of implementing the allocation sequence (eg,	8
17	concealment		central telephone; sequentially numbered, opaque,	
18	mechanism		sealed envelopes), describing any steps to conceal the	
19			sequence until interventions are assigned	
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23	Allocation:	#16c	Who will generate the allocation sequence, who will enrol	8
24	implementation		participants, and who will assign participants to	
25			interventions	
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33	Blinding (masking)	#17a	Who will be blinded after assignment to interventions (eg,	8
34			trial participants, care providers, outcome assessors,	
35			data analysts), and how	
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41	Blinding (masking):	#17b	If blinded, circumstances under which unblinding is	n/a
42	emergency		permissible, and procedure for revealing a participant's	
43	unblinding		allocated intervention during the trial	
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1	Data collection plan	#18a	Plans for assessment and collection of outcome,	16-17
2			baseline, and other trial data, including any related	
3			processes to promote data quality (eg, duplicate	
4			measurements, training of assessors) and a description	
5			of study instruments (eg, questionnaires, laboratory tests)	
6			along with their reliability and validity, if known.	
7				
8			Reference to where data collection forms can be found, if	
9			not in the protocol	
10				
11	Data collection plan:	#18b	Plans to promote participant retention and complete	16-17
12	retention		follow-up, including list of any outcome data to be	
13			collected for participants who discontinue or deviate from	
14			intervention protocols	
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20	Data management	#19	Plans for data entry, coding, security, and storage,	16-17
21			including any related processes to promote data quality	
22			(eg, double data entry; range checks for data values).	
23			Reference to where details of data management	
24			procedures can be found, if not in the protocol	
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30	Statistics: outcomes	#20a	Statistical methods for analysing primary and secondary	16-17
31			outcomes. Reference to where other details of the	
32			statistical analysis plan can be found, if not in the protocol	
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42	Statistics: additional	#20b	Methods for any additional analyses (eg, subgroup and	16-17
43	analyses		adjusted analyses)	
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1	Statistics: analysis	#20c	Definition of analysis population relating to protocol non-	16-17
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3	population and		adherence (eg, as randomised analysis), and any	
4				
5	missing data		statistical methods to handle missing data (eg, multiple	
6				
7			imputation)	
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11	Data monitoring:	#21a	Composition of data monitoring committee (DMC);	17
12				
13	formal committee		summary of its role and reporting structure; statement of	
14				
15			whether it is independent from the sponsor and	
16			competing interests; and reference to where further	
17			details about its charter can be found, if not in the	
18			protocol. Alternatively, an explanation of why a DMC is	
19			not needed	
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28	Data monitoring:	#21b	Description of any interim analyses and stopping	n/a
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30	interim analysis		guidelines, including who will have access to these	
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32			interim results and make the final decision to terminate	
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34			the trial	
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38	Harms	#22	Plans for collecting, assessing, reporting, and managing	18
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40			solicited and spontaneously reported adverse events and	
41				
42			other unintended effects of trial interventions or trial	
43				
44			conduct	
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48	Auditing	#23	Frequency and procedures for auditing trial conduct, if	17
49				
50			any, and whether the process will be independent from	
51				
52			investigators and the sponsor	
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54				
55	Research ethics	#24	Plans for seeking research ethics committee / institutional	2,18
56				
57	approval		review board (REC / IRB) approval	
58				
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1	Protocol	#25	Plans for communicating important protocol modifications	18
2				
3	amendments		(eg, changes to eligibility criteria, outcomes, analyses) to	
4			relevant parties (eg, investigators, REC / IRBs, trial	
5			participants, trial registries, journals, regulators)	
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11	Consent or assent	#26a	Who will obtain informed consent or assent from potential	7
12			trial participants or authorised surrogates, and how (see	
13			Item 32)	
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19	Consent or assent:	#26b	Additional consent provisions for collection and use of	n/a
20	ancillary studies		participant data and biological specimens in ancillary	
21			studies, if applicable	
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26	Confidentiality	#27	How personal information about potential and enrolled	18
27			participants will be collected, shared, and maintained in	
28			order to protect confidentiality before, during, and after	
29			the trial	
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36	Declaration of	#28	Financial and other competing interests for principal	23
37	interests		investigators for the overall trial and each study site	
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42	Data access	#29	Statement of who will have access to the final trial	23
43			dataset, and disclosure of contractual agreements that	
44			limit such access for investigators	
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49	Ancillary and post	#30	Provisions, if any, for ancillary and post-trial care, and for	n/a
50	trial care		compensation to those who suffer harm from trial	
51			participation	
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1	Dissemination	#31a	Plans for investigators and sponsor to communicate trial	18
2				
3	policy: trial results		results to participants, healthcare professionals, the	
4			public, and other relevant groups (eg, via publication,	
5			reporting in results databases, or other data sharing	
6			arrangements), including any publication restrictions	
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13	Dissemination	#31b	Authorship eligibility guidelines and any intended use of	23
14				
15	policy: authorship		professional writers	
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19	Dissemination	#31c	Plans, if any, for granting public access to the full	,23
20				
21	policy: reproducible		protocol, participant-level dataset, and statistical code	
22				
23	research			
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26	Informed consent	#32	Model consent form and other related documentation	n/a
27				
28	materials		given to participants and authorised surrogates	
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32	Biological	#33	Plans for collection, laboratory evaluation, and storage of	n/a
33				
34	specimens		biological specimens for genetic or molecular analysis in	
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37			the current trial and for future use in ancillary studies, if	
38				
39			applicable	
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 43 BY-ND 3.0. This checklist can be completed online using <https://www.goodreports.org/>, a tool made
 44 by the [EQUATOR Network](#) in collaboration with [Penelope.ai](#)
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BMJ Open

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

Journal:	<i>BMJ Open</i>
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Date Submitted by the Author:	24-Jul-2019
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Primary Subject Heading:	Public health
Secondary Subject Heading:	Rehabilitation medicine, Sports and exercise medicine
Keywords:	older people, physical activity, falls, counselling, life-space mobility, injuries

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3 1 **Counselling for physical activity, life-space mobility and falls prevention in old**
4 2 **age (COSMOS): Protocol of a randomized controlled trial (ISRCTN65406039)**

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1 ABSTRACT

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

8 **Methods and analysis:** Community-dwelling men and women (n=450) aged 65 years and over
9 with early phase mobility limitation will be recruited to a 24-month RCT with a 24-month
10 follow-up. Participants will be randomly allocated into either a health and PA counselling group
11 (intervention) or relaxation group (control intervention). All participants will receive five group
12 specific face-to-face counselling sessions and 11 phone calls. The counselling intervention will
13 include individualized health counselling, strength and balance training and guidance to regular
14 PA. The control group will receive relaxation exercises. Outcomes will be assessed at baseline,
15 12, 24, and 48 months. Primary outcomes are average life-space mobility score and falls rates.
16 Life-space mobility will be assessed by a validated questionnaire. Falls rates will be recorded
17 from fall diaries. Secondary outcomes are data on fall-induced injuries and living-arrangements,
18 number of fallers, fracture risk, mean level of PA, physical performance, quality of life, mood,
19 cognition, balance confidence, and fear of falling. Data will be analyzed using the intention-to-
20 treat principle. Cost-effectiveness of the program will be analyzed. Ancillary analyses are
21 planned in participants with greater adherence.

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

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

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1 STRENGTHS AND LIMITATIONS OF THE STUDY

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

1 INTRODUCTION

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

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

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

1 To our knowledge, only one previous randomized controlled trial has shown the impact of a
2 multifactorial intervention on life-space mobility in older people,[10]. It has been recommended
3 that future studies should measure mobility at both the participation and activity levels.
4 Additionally, it has been suggested that future research should include a longer follow-up period
5 to determine if the benefits of any interventions are maintained long-term (> 12 months).
6 Therefore, COSMOS will be the first randomized controlled trial to evaluate the effectiveness of
7 24-month health and physical activity counselling program in a community-based Health Kiosk
8 and/or Service Centre environment to improve life-space mobility and physical activity and
9 prevent falls, and evaluate whether any benefits are sustained after a 24-month follow-up.
10 Another novel aspect is that this study will assess simultaneously changes in the ratio of falls
11 rates and the difference in rate changes in the life-space mobility outcome.

13 TRIAL OBJECTIVES AND HYPOTHESIS

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

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

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

1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 47 48 49 50 51 52 53 54 55 56 57 58 59 60

1 **METHODS AND DESIGN**

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

6 **Trial design and study setting**

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

20 **Participant eligibility**

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

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

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

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

18 **Recruitment**

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

1 **Random allocation**

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

16 **Interventions**

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

27 ***Health and physical activity counselling intervention***

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

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

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

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

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

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

14 **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	<ul style="list-style-type: none"> • One legged squat • One legged sit to stand • Sideways squats • Jumping exercises 	Same strengthening exercises as in the COSMOS 1 → Repetitions and series are updated and jumping exercises are extended and more demanding
Balance exercises	<ul style="list-style-type: none"> • Same as in the D level of the Otago Exercise Program but stair climbing is replaced with squats • 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

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

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

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3 1 4) utilizing techniques learned in previous exercises to whole body relaxation, and 5) learning
4 2 consciousness of the body sensations. All exercises will be displayed on a compact disc (CD) or
5 3 via mp3-format. Additionally, written instructions will be available. During the first face-to-face
6 4 session, participants will receive the same handouts as the health and physical activity
7 5 counselling intervention members on how to avoid fall accidents in the home environment and
8 6 outdoors.

7 ***Supportive telephone calls***

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

18 19 **Outcomes**

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

25 ***Primary outcomes***

26 Daily filled and monthly returned fall diaries will be used to gather information on the *falls rates*
27 during the 24-month intervention and follow-up. A fall is defined as an unexpected event in
28 which participant comes to rest on the ground, floor or other lower level [20]. A research
29 physiotherapist will phone monthly all those participants who have reported a fall or falls or if a
30 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

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

9 ***Secondary outcomes***

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

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

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

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

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3 1 *Health-related quality of life* will be assessed using the World Health Organization Quality of
4 Life (WHOQOL) 26-item short version questionnaire, which includes questions related to
5 2 Life (WHOQOL) 26-item short version questionnaire, which includes questions related to
6 3 physical health, psychological health, social relationships and environment,[29]. *Living-*
7 4 *arrangements* will be determined by interview. *Fracture risk* will be assessed by WHO Fracture
8 5 Risk Assessment Tool (FRAX) via interview. The FRAX algorithms give the 10-year probability
9 6 of hip fracture and a major osteoporotic fracture (clinical spine, forearm, hip or shoulder
10 7 fracture),[30].

11 8 *Depressive mood* will be assessed using the Geriatric Depression Scale (GDS-15),[31].
12 9 Participants who achieve 6 points or more on GDS-15 test will be referred to their physician for
13 10 follow up. *Cognitive status* will be assessed via the Mini-Mental State Examination
14 11 (MMSE),[13]. Participants who score 21 points or less in MMSE are excluded and referred to a
15 12 physician appointment.

16 13 *Balance confidence* will be evaluated using the Activities-specific Balance Confidence scale
17 14 (ABC),[32]. *Fear of falling* will be assessed (yes/no) and measured by the Visual Analogue
18 15 Scale (VAS),[33]. A 100-mm long line will be used with the left end of the line (0 mm)
19 16 representing “no fear” and the right end (100 mm) “extreme fear”.

17 ***Other variables***

18 18 During the health examination, the research nurse will measure height and weight using standard
19 19 procedures. Body mass index will be calculated as body weight (kg)/height (m) squared. The
20 20 research nurse will also ask about any chronic and geriatric conditions, prescription
21 21 medication(s) and the presence of any *cardiovascular condition* using New York Heart
22 22 Association functional class (NYHA),[34] and perform an orthostatic test,[35]. *Alcohol*
23 23 *consumption* will be assessed by the AUDIT-C tool and additionally by AUDIT if the AUDIT-C
24 24 score is 6 or more among men and 5 or more among women,[14]. If the AUDIT score is 15 or
25 25 more, participants will be excluded and referred to a health care practitioner.

26 26 *Self-reported physical ability* will be determined via interview and asking participants: “How
27 27 would you describe your physical ability?” Options are: 1) excellent, 2) good, 3) average, and 4)
28 28 poor. *Need of mobility assistive devices* will also be determined via interview. *Mobility difficulty*
29 29 will be assessed using a structured interview described earlier (see participant eligibility). As an
30 30 outcome measure of *adherence*, we utilize the average number and duration of exercise sessions
31 31 and total number and duration of exercise sessions based on daily completed and monthly

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

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

10 **Statistical methods**

11 ***Pretrial power calculations***

12 We estimated the minimum required sample size in a simulation model including the continuous
13 and count outcomes and the mutual correlation estimated via normally distributed random
14 effects. Sample size estimation accounted for the multiple testing and the correlation between
15 outcomes,[37]. Based on previous research,[7], we assumed that the control group would have a
16 fall incidence of 131 per 100 person-years and the corresponding rate in the intervention group
17 would be 118 per 100 person-years, which corresponds to a modest relative risk reduction of
18 about 10% in favor of the intervention group. To allow some over-dispersion in the fall count,
19 the normally distributed random effect variance was set at 0.3. Based on data from the Life-
20 Space Mobility in Old Age (LISPE) study,[38], we set the mean at 64.0 (SD = 20.6) for the life-
21 space mobility score, which was increased to 70.4 in the intervention group during the follow-up
22 representing a relative increase of 10%. To obtain a conservative sample size estimate the
23 random effect correlation was set at the low value 0.10. The simulation studies were based on
24 1000 replications of the model parameters. To find the likelihood ratio test statistic significant at
25 5% significance level for the above mean difference and risk ratio simultaneously, power of 80%
26 was reached with a sample size of 346 based on equal allocation of subjects into the control and
27 intervention groups. To account for 30% attrition, the sample size was increased to 450 (225 in
28 each group). In previous intervention studies including similar components, dropout rates have
29 been approximately 15 % (Palvanen et al. 2014). We hypothesized the attrition rate to be even
30 greater, because for majority of the participants, participation involved travelling across
31 Pirkanmaa District (distances were even 100 km in each direction), and travelling costs were not
32 covered and transportation was not arranged by COSMOS.

1 ***Statistical analyses***

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

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

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

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

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3 1 comparing the intervention incremental cost per a prevented fall and incremental cost per QALY
4 gained to those in the control group. The probability that the intervention is cost effective will be
5 2 computed based on bootstrapping the incremental cost-effectiveness ratio as described in,[39].
6 3
7 4 Cost-effectiveness acceptability curves will be plotted for various levels of willingness to pay.
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11 5 Where missing data is generated through the missing-at-random (MAR) mechanism, we will
12 6 employ the standard MAR-based likelihood specification in Mplus,[40]. A custom missing data
13 7 model will be used when missing data is generated by a non-random mechanism.
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9 **DATA MANAGEMENT**

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11 10 Once a participant has been randomly allocated, every effort will be made to follow-up the
12 11 participant on outcome measures until the end of the study period. Any participants who
13 12 discontinue or deviate from the intervention protocols or fail to complete the exercise and falls
14 13 diary will still be invited to complete the 12 and/or 24 follow-up measurements. Participant data
15 14 are stored on a secure database in accordance with the General Data Protection Regulations
16 15 (2018). All collected data will be coded with unique identification numbers and stored centrally
17 16 on the secure database of the University of Jyväskylä, a password-protected computer or in a
18 17 locked filing cabinet in a secure office space, only accessible by a limited number of people. The
19 18 questionnaires and forms will be checked for completeness and congruity instantly when filled
20 19 and/or received and again before data entry onto the database. Additionally, we will regularly
21 20 check the data files for omissions and errors to ensure the data integrity. Trial documentation and
22 21 data will be archived for at least 10 years after completion of the trial after which it will be
23 22 destroyed. The data monitoring committee (DMC) consists of the research group members (see
24 23 front page).
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50 **TRIAL MONITORING**

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53 26 A standard operation procedure has been written before launching the study and will be followed
54 27 carefully throughout the study. Regular meetings will be organized for monitoring the quality of
55 28 data collection. Senior researchers will carefully educate the personnel performing the
56 29 measurements and the same staff will engage in the data collection throughout the study.
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1 **ETHICS AND DISSEMINATION**

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

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

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

26 **PATIENT AND PUBLIC INVOLVEMENT STATEMENT**

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

1 ACKNOWLEDGMENTS

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1 **AUTHORS' CONTRIBUTIONS**

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

9 **FUNDING STATEMENT**

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

12 **COMPETING INTERESTS STATEMENT**

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

17 **DATA AVAILABILITY STATEMENT**

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

22 **TABLES AND FIGURES**

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

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

25 Figure 1. Flow chart of the COSMOS study

26 Supplementary figure. Participant timeline

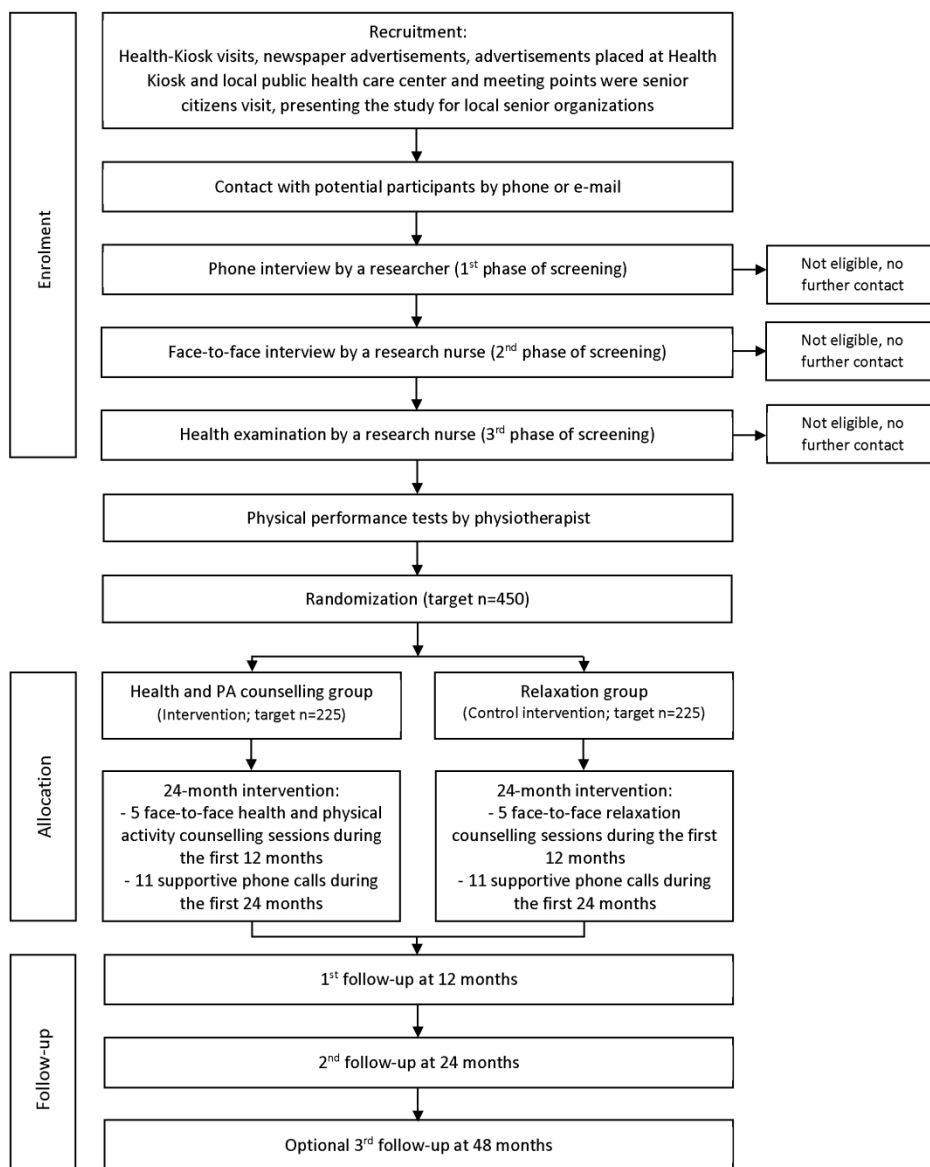
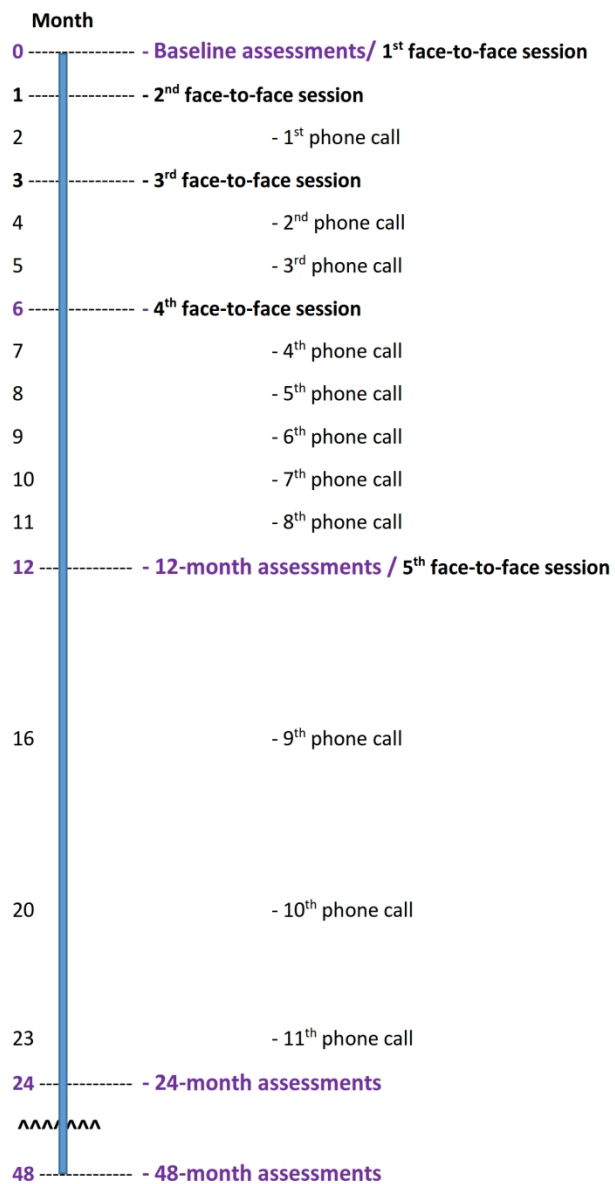


Figure 1. Flow chart of the COSMOS study

186x229mm (300 x 300 DPI)

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Supplementary figure. Participant timeline

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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

			Page
		Reporting Item	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

1	Trial registration:	#2b	All items from the World Health Organization Trial	6
2				
3	data set		Registration Data Set	
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6	Protocol version	#3	Date and version identifier	1
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9	Funding	#4	Sources and types of financial, material, and other	23
10			support	
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15	Roles and	#5a	Names, affiliations, and roles of protocol contributors	1,23
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32	Roles and	#5c	Role of study sponsor and funders, if any, in study	17
33				
34	responsibilities:		design; collection, management, analysis, and	
35			interpretation of data; writing of the report; and the	
36	sponsor and funder		decision to submit the report for publication, including	
37			whether they will have ultimate authority over any of	
38			these activities	
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47	Roles and	#5d	Composition, roles, and responsibilities of the	17
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49	responsibilities:		coordinating centre, steering committee, endpoint	
50			adjudication committee, data management team, and	
51	committees		other individuals or groups overseeing the trial, if	
52			applicable (see Item 21a for data monitoring committee)	
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1	Background and	#6a	Description of research question and justification for	2,4-5
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3	rationale		undertaking the trial, including summary of relevant	
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5			studies (published and unpublished) examining benefits	
6				
7			and harms for each intervention	
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11	Background and	#6b	Explanation for choice of comparators	10-11
12				
13	rationale: choice of			
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15	comparators			
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18	Objectives	#7	Specific objectives or hypotheses	5
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22	Trial design	#8	Description of trial design including type of trial (eg,	6
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24			parallel group, crossover, factorial, single group),	
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26			allocation ratio, and framework (eg, superiority,	
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28			equivalence, non-inferiority, exploratory)	
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32	Study setting	#9	Description of study settings (eg, community clinic,	6
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34			academic hospital) and list of countries where data will be	
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36			collected. Reference to where list of study sites can be	
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42	Eligibility criteria	#10	Inclusion and exclusion criteria for participants. If	6-7
43				
44			applicable, eligibility criteria for study centres and	
45				
46			individuals who will perform the interventions (eg,	
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48			surgeons, psychotherapists)	
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51	Interventions:	#11a	Interventions for each group with sufficient detail to allow	8-11
52				
53	description		replication, including how and when they will be	
54				
55			administered	
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1	Interventions:	#11b	Criteria for discontinuing or modifying allocated	9-11
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3	modifications		interventions for a given trial participant (eg, drug dose	
4			change in response to harms, participant request, or	
5			improving / worsening disease)	
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11	Interventions:	#11c	Strategies to improve adherence to intervention	9-11
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13	adherence		protocols, and any procedures for monitoring adherence	
14			(eg, drug tablet return; laboratory tests)	
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19	Interventions:	#11d	Relevant concomitant care and interventions that are	9-11
20			permitted or prohibited during the trial	
21	concomitant care			
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24	Outcomes	#12	Primary, secondary, and other outcomes, including the	11-15
25			specific measurement variable (eg, systolic blood	
26			pressure), analysis metric (eg, change from baseline,	
27			final value, time to event), method of aggregation (eg,	
28			median, proportion), and time point for each outcome.	
29			Explanation of the clinical relevance of chosen efficacy	
30			and harm outcomes is strongly recommended	
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41	Participant timeline	#13	Time schedule of enrolment, interventions (including any	8,
42			run-ins and washouts), assessments, and visits for	
43			participants. A schematic diagram is highly	suppl.fig.
44			recommended (see Figure)	
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51	Sample size	#14	Estimated number of participants needed to achieve	2,15
52			study objectives and how it was determined, including	
53			clinical and statistical assumptions supporting any	
54			sample size calculations	
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1	Recruitment	#15	Strategies for achieving adequate participant enrolment	7
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3			to reach target sample size	
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6	Allocation: sequence	#16a	Method of generating the allocation sequence (eg,	8
7	generation		computer-generated random numbers), and list of any	
8			factors for stratification. To reduce predictability of a	
9			random sequence, details of any planned restriction (eg,	
10			blocking) should be provided in a separate document that	
11			is unavailable to those who enrol participants or assign	
12			interventions	
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23	Allocation	#16b	Mechanism of implementing the allocation sequence (eg,	8
24	concealment		central telephone; sequentially numbered, opaque,	
25			sealed envelopes), describing any steps to conceal the	
26	mechanism		sequence until interventions are assigned	
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33	Allocation:	#16c	Who will generate the allocation sequence, who will enrol	8
34	implementation		participants, and who will assign participants to	
35			interventions	
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41	Blinding (masking)	#17a	Who will be blinded after assignment to interventions (eg,	8
42			trial participants, care providers, outcome assessors,	
43			data analysts), and how	
44				
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48	Blinding (masking):	#17b	If blinded, circumstances under which unblinding is	n/a
49	emergency		permissible, and procedure for revealing a participant's	
50			allocated intervention during the trial	
51	unblinding			
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1	Data collection plan	#18a	Plans for assessment and collection of outcome,	16-17
2			baseline, and other trial data, including any related	
3			processes to promote data quality (eg, duplicate	
4			measurements, training of assessors) and a description	
5			of study instruments (eg, questionnaires, laboratory tests)	
6			along with their reliability and validity, if known.	
7				
8			Reference to where data collection forms can be found, if	
9			not in the protocol	
10				
11	Data collection plan:	#18b	Plans to promote participant retention and complete	16-17
12	retention		follow-up, including list of any outcome data to be	
13			collected for participants who discontinue or deviate from	
14			intervention protocols	
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20	Data management	#19	Plans for data entry, coding, security, and storage,	16-17
21			including any related processes to promote data quality	
22			(eg, double data entry; range checks for data values).	
23			Reference to where details of data management	
24			procedures can be found, if not in the protocol	
25				
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30	Statistics: outcomes	#20a	Statistical methods for analysing primary and secondary	16-17
31			outcomes. Reference to where other details of the	
32			statistical analysis plan can be found, if not in the protocol	
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42	Statistics: additional	#20b	Methods for any additional analyses (eg, subgroup and	16-17
43	analyses		adjusted analyses)	
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1	Statistics: analysis	#20c	Definition of analysis population relating to protocol non-	16-17
2				
3	population and		adherence (eg, as randomised analysis), and any	
4				
5	missing data		statistical methods to handle missing data (eg, multiple	
6				
7			imputation)	
8				
9				
10				
11	Data monitoring:	#21a	Composition of data monitoring committee (DMC);	17
12				
13	formal committee		summary of its role and reporting structure; statement of	
14				
15			whether it is independent from the sponsor and	
16			competing interests; and reference to where further	
17			details about its charter can be found, if not in the	
18			protocol. Alternatively, an explanation of why a DMC is	
19			not needed	
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28	Data monitoring:	#21b	Description of any interim analyses and stopping	n/a
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30	interim analysis		guidelines, including who will have access to these	
31				
32			interim results and make the final decision to terminate	
33				
34			the trial	
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38	Harms	#22	Plans for collecting, assessing, reporting, and managing	18
39				
40			solicited and spontaneously reported adverse events and	
41				
42			other unintended effects of trial interventions or trial	
43				
44			conduct	
45				
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47				
48	Auditing	#23	Frequency and procedures for auditing trial conduct, if	17
49				
50			any, and whether the process will be independent from	
51				
52			investigators and the sponsor	
53				
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55	Research ethics	#24	Plans for seeking research ethics committee / institutional	2,18
56				
57	approval		review board (REC / IRB) approval	
58				
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1	Protocol	#25	Plans for communicating important protocol modifications	18
2				
3	amendments		(eg, changes to eligibility criteria, outcomes, analyses) to	
4			relevant parties (eg, investigators, REC / IRBs, trial	
5			participants, trial registries, journals, regulators)	
6				
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11	Consent or assent	#26a	Who will obtain informed consent or assent from potential	7
12			trial participants or authorised surrogates, and how (see	
13			Item 32)	
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19	Consent or assent:	#26b	Additional consent provisions for collection and use of	n/a
20	ancillary studies		participant data and biological specimens in ancillary	
21			studies, if applicable	
22				
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24				
25				
26	Confidentiality	#27	How personal information about potential and enrolled	18
27			participants will be collected, shared, and maintained in	
28			order to protect confidentiality before, during, and after	
29			the trial	
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36	Declaration of	#28	Financial and other competing interests for principal	23
37	interests		investigators for the overall trial and each study site	
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42	Data access	#29	Statement of who will have access to the final trial	23
43			dataset, and disclosure of contractual agreements that	
44			limit such access for investigators	
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49	Ancillary and post	#30	Provisions, if any, for ancillary and post-trial care, and for	n/a
50	trial care		compensation to those who suffer harm from trial	
51			participation	
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1	Dissemination	#31a	Plans for investigators and sponsor to communicate trial	18
2				
3	policy: trial results		results to participants, healthcare professionals, the	
4			public, and other relevant groups (eg, via publication,	
5			reporting in results databases, or other data sharing	
6			arrangements), including any publication restrictions	
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13	Dissemination	#31b	Authorship eligibility guidelines and any intended use of	23
14				
15	policy: authorship		professional writers	
16				
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18				
19	Dissemination	#31c	Plans, if any, for granting public access to the full	,23
20				
21	policy: reproducible		protocol, participant-level dataset, and statistical code	
22				
23	research			
24				
25				
26	Informed consent	#32	Model consent form and other related documentation	n/a
27				
28	materials		given to participants and authorised surrogates	
29				
30				
31				
32	Biological	#33	Plans for collection, laboratory evaluation, and storage of	n/a
33				
34	specimens		biological specimens for genetic or molecular analysis in	
35				
36				
37			the current trial and for future use in ancillary studies, if	
38				
39			applicable	
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 44 by the [EQUATOR Network](#) in collaboration with [Penelope.ai](#)
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