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# Randomised controlled trial (RCT) study design for a large-scale municipal fall prevention exercise programme in community-living older women: study protocol for the Kuopio Fall Prevention Study (KFPS)

Tommi Vilpunaho,[1] Heikki Kröger,[1,2] Risto Honkanen,[1] Heli Koivumaa-Honkanen,[3,4] Joonas Sirola,[1,2] Virpi Kuvaja-Köllner,[5] Reijo Sund,[1] Toni Rikkonen[1]

For numbered affiliations see end of article.

**Correspondence to**
Tommi Vilpunaho;
tommiv@student.uef.fi

## ABSTRACT

**Introduction** Falls are a substantial health problem in seniors, causing fractures and being the leading cause of fatal injuries. The benefits of physical activity in fall prevention have been shown in randomised controlled trials (RCTs) in small cohorts (eg, ≤200 persons), but there is a gap between the known health effects of exercise and the large-scale implementation of effective activity in communities. Mental health and subjective well-being (SWB) should also be studied since they are strongly related to healthy ageing. Thus far, the proven efficacy of communal strategies to reduce falls and improve healthy ageing is sparse.

**Methods and analysis** In 2016, a 2-year RCT was launched in Kuopio, Finland to estimate the efficacy of a large, population-based, fall prevention exercise programme in community-living older women (born 1932–1945). Both the intervention and control group (n=457+457) receive health education. The intervention group is also offered free 6-month supervised training courses (weekly gym training and Taiji sessions), followed by a free 6-month unsupervised use of exercise facilities, as well as unsupervised low-cost exercise is also offered for another 12 months. During the whole 24-month follow-up, controls are free to pursue all their normal physical activities. Both study groups undergo the study measurements three times. Outcome measures include recording of falls, injuries, bone mineral density, changes in health and functional status and cognitive performance, deaths and SWB. Finally, the cost-effectiveness and cost–utility analysis will be conducted from the societal view. The main analyses comparing outcomes between study groups will be conducted using the intention to treat principle.

**Ethics and dissemination** The study has been reviewed and approved by the Research Ethics Committee of the Hospital District of North Savo. All regulations and measures of ethics and confidentiality are handled in accordance with the Declaration of Helsinki.

**Trial registration number** NCT02665169; Pre-results.

## Strengths and limitations of this study

► This protocol paper presents a large-scale, population-based, group exercise intervention programme on fall prevention, functional ability and subjective well-being in older women.
► The study enables the acquisition of high-quality long-term background data to produce valid strategies for fall prevention and related cost–utility.
► The study and its results are assumed to be applicable among middle-large cities in developed countries with similar service structures.
► Women unable to follow the exercise programme due to disability were not included to the study.
► Blinding was not possible in respect to participants.

## INTRODUCTION

The number of senior citizens (aged ≥65) is estimated to increase from 1.0 to 1.5 million in Finland (total population 5.5 million in 2018) between 2012 and 2031 and the majority of these are women.[1 2] Falls are a considerable health problem in seniors, with around one-third falling annually and women being at a higher risk than men.[3] Falls often lead to fractures and hospitalisation and are the leading cause of fatal injury.[4] Thus, fall prevention is an important issue that drives communities to maintain the functional ability of seniors in several ways including counselling and exercises for fall prevention. These approaches require the systematic evaluation of their implementation in municipal settings.

Previously, strength and balance exercises, including Taiji (Tai Chi), have been shown to be effective in the prevention of falls among seniors. Exercise may have

more favourable effects in fall prevention when exercise programmes contain balance-challenging components and comprise more than 3 hours per week of exercise.[5] Three approaches seem to reduce fall risk: (1) multiple component group exercises, (2) Taiji as a group exercise and (3) individually prescribed multiple component home exercise. However, professional supervision is recommended to seniors and minimise adverse effects of strength training.[5 6] In addition, there have been a number of encouraging results varying from short-term studies and small physical activity trials in intensively supervised settings.[7 8] Regular physical activity is one of the most important links between health, independent functioning and subjective well-being (SWB).[9 10]

The benefits of physical activity have been shown in several studies,[11–13] but there is a gap between known exercise health effects in controlled environments and the large-scale implementation of exercise for seniors in communities. Long-term (mental and physical) health and lifestyle data on large population-based exercise interventions would help to estimate the applicability of these measures at the community level and in health policy decisions. Existing long-term follow-up data prior to exercise intervention may improve fall prevention estimates by allowing health behaviour and morbidity trajectories from the menopause to old age to be considered.

Comorbidities, functional decline and fear of falling impair SWB in old age. Conversely, exercise may have a beneficial effect on the above-mentioned factors.[9 10] Even light habitual exercise seems to improve well-being.[10] Taiji and multifactorial training are correlated to a reduced fear of falling, while high-intensity strength or endurance training has been shown to reduce depression.[14–18] There is also promising evidence that exercise may improve the ability to perform activities of daily living in people with dementia.[19] Physical activity programmes are efficient in the promotion of mental health and seem to be effective in the treatment of depression,[20–22] although the long-term benefits of exercise on old age depression are uncertain, indicating the need for high-quality randomised controlled trials (RCTs). To evaluate the effects of exercise on mental health and SWB more long-term studies with large, population-based samples are needed to establish recommendations on intensity, duration and the nature of exercise for this purpose. In addition, trials using services that are accessible to a wide range of senior citizens are needed to estimate the effect of a group exercise programme on mental health and fear of falling at the population level.

SWB is one of the main indicators of mental health.[23] In exercise interventions, SWB and personality factors can be expected to also play role as a predictor, not only as an outcome. Among community-dwelling older adults, recent studies have reported lifetime anxiety disorders to be associated with and depressive symptoms to be predictive of falls.[24 25] Based on these findings, the importance of addressing intrinsic fall risk in fall prevention strategies[26] and the inclusion of assessments of depression in national guidelines for fall risk assessments and quality indicators for fall prevention[25] is emphasised. Also our previous results show that SWB predicts falls,[27] but previously SWB has been shown to predict injurious deaths independent of health status and health behaviour in a large 20-year Finnish general population cohort study.[28]

Knowledge on the cost-effectiveness of community-based fall prevention with exercise is sparse. For the efficient use of resources, interventions might need to be targeted at high-risk groups.[14] Some studies have suggested that fall prevention in physical exercise programmes with different methods, for example, minimally supervised monthly exercise classes or supervised weekly group training classes, can be cost saving.[29–31] Incremental cost-effectiveness ratios of fall prevention programmes have been evaluated for example in terms of the reduction of overall falls and medical care following injurious falls, the avoidance of mobility deterioration and an increase in quality-adjusted life years (QALYs).[29 31] However, methodological variations make comparison of fall prevention programmes difficult and little is known about the overall effect at the community level. Follow-up before and after the intervention provides information about the stability of trial effects. In addition, it allows more exact cost-effectiveness and cost–utility estimations at the population level.

Participation bias among seniors in exercise interventions has been recognised in several studies.[32–34] Certain characteristics of invited individuals may affect their willingness and ability to participate. For example, socioecological factors (eg, age, marital status, education level), health state indicators (eg, physical activity, mobility, frailty) and subjective health and mental statuses (eg, SWB, depression symptoms) have all been identified as having an impact on the recruitment of seniors.[32–34]

In conclusion, falls, frailty, fear of falling and SWB have been recognised as important outcomes among seniors. There is limited evidence of the proven efficacy of prevention strategies to tackle falls and improve SWB. Group exercise and its effects on these outcomes needs further clarification at the community level. Therefore, large, population-based RCTs on seniors with long-term background data on risk factors (eg, Kuopio Osteoporosis Risk Factor and Prevention (OSTPRE) study's data described in Methods section) may provide a more exact and comprehensive estimation of the effects of physical exercise on these outcomes. Also, the cost-effectiveness of such fall prevention programmes can, thus, be evaluated. In addition, it is important to detect seniors' characteristics affecting willingness to participate in exercise interventions, as it benefits future recruitment strategies.

In this paper, the protocol for the ongoing exercise-RCT (Kuopio Fall Prevention Study, KFPS) assessing the efficacy of a large, population-based fall prevention programme in community-living older women is described.

**Table 1** Three research perspectives of Kuopio Fall Prevention Study and their respective subjects and measures

| Perspective | Subjects | Measures |
|---|---|---|
| 1. Health | 1.1 Falls and injuries | Fall rate |
| | | Fall-related injury and treatment |
| | | Risk factors of falling |
| | 1.2 Functional capacity and cognition skills | Changes in functional and cognitive status |
| | 1.3 Body composition and bone strength | Changes in bone mineral density, fat and lean mass |
| | 1.4. Subjective well-being | QoL, life satisfaction and effects on mood and personality |
| 2. Society | 2.1 Health and social care | Use of health and social services |
| | 2.2 Cost–utility analysis | Cost–utility of municipal services |
| | 2.3 Subjective well-being | Loneliness, stress and fear of falling |
| | | Changes in SWB |
| 3. Epidemiology | 3.1 Previous lifestyle, medical history and SWB | Medical history, lifestyle and SWB predicting trial compliance and health outcomes. |
| | | Post hoc analysis of OSTPRE 25-year follow-up data. |

OSTPRE, Osteoporosis Risk Factor and Prevention Study; QoL, quality of life; SWB, subjective well-being.

## METHODS AND ANALYSIS
### Objectives and hypotheses of the KFPS
The main objective of the KFPS study is to estimate the effects of exercise at the population level from three different perspectives: (1) Health: falls and injuries, body composition, bone strength and functional capacity, cognition skills and SWB; (2) Society: health and social care, cost–utility analysis and SWB and (3) Epidemiology: previous lifestyle, medical history and SWB (table 1). The primary outcomes of KFPS are: (1) fall rate and fall related injuries and (2) SWB (quality of life (QoL), life satisfaction, mood affects, personality features and fear of falling). Secondary outcomes are: (1) cost-effectiveness (per fall/fracture) and cost–utility (per quality-adjusted years); (2) changes in body composition, functional capacity and cognitive ability, and (3) risk factor identification (25-year lifestyle history affecting compliance and outcomes).

The main hypotheses of KFPS are: (1) the free use of facilities activates seniors in municipal sport activities, and (2) strength and balance exercise lowers fall risk and fear of falling, while better SWB results in reduction of health and social service usage. However, SWB and lifestyle history has a significant effect on compliance, perceived health effects and cost-effectiveness of the municipal services provided.
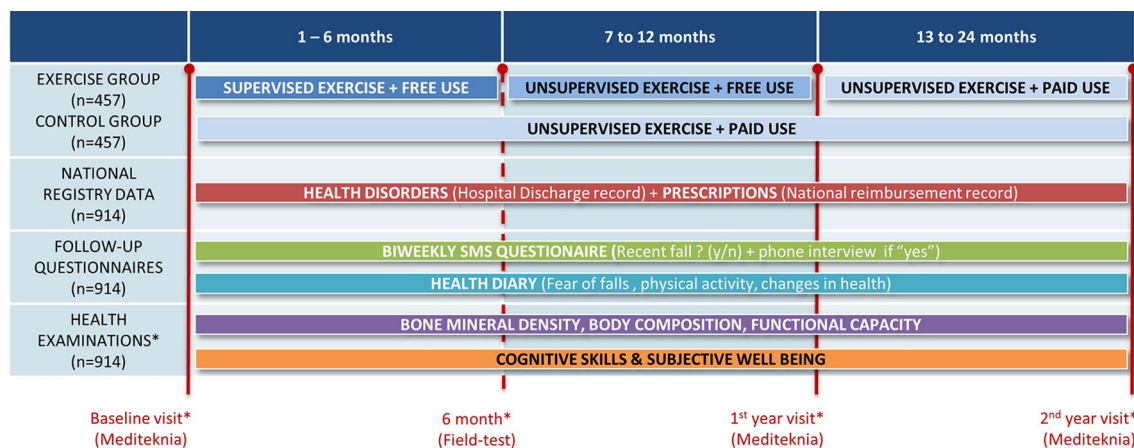
### Study design
The KFPS is based on the OSTPRE cohort, which was used to recruit women into the fall prevention trial. OSTPRE is a population-based prospective cohort study, which was commenced in 1989 by including all women born in 1932–1941 and residing in Kuopio Province, Finland (n=14 220).[35] It investigates genetic and acquired factors associated with falls, fractures and bone loss in postmenopausal women. An enquiry into the health status, medications and lifestyle factors for fractures and falls has been administered to the entire cohort at 5-year

intervals. A stratified random sample of 3222 women has been followed more intensively with clinical measurements. Data from the OSTPRE study are used in the KFPS study. A detailed description of the OSTPRE project can be found at http://www.uef.fi/en/web/kmru/ostpre.

In 2016, based on information from the OSTPRE-study follow-up data, an exercise RCT (KFPS) was launched to estimate the effect of exercise intervention in prevention of falls and the promotion of well-being and healthy ageing in older women in cooperation with the municipality of Kuopio in Finland. Both the intervention group and control group receive education on fall prevention and health as well as a brochure introducing free or low-cost exercise opportunities arranged by the city of Kuopio. The intervention group is offered a free 6-month supervised training course with successive 6-month free exercise without supervision. The second year includes unsupervised low-cost exercise for another 12 months. Thus, the total follow-up time is 24 months (figure 1). During the follow-up, controls are free to pursue their normal physical activities without intervention.

The study is performed in the Clinical Research Centre of the University of Eastern Finland (UEF), Kuopio Campus, at the Kuopio Musculoskeletal Research Unit (KMRU, Mediteknia). Both study groups visit KMRU three times: at baseline, and at the 12 months and 24 months follow-ups. On these occasions visits are blinded from the research staff and both study groups undergo similar measurements (dual X-ray absorptiometry (DXA) body composition, functional tests). Clinical measurements at baseline were done on average within 14 days prior to the start of the intervention and before polling into exercise or control group. A primary outcome, the falls, are counted from monthly self-reports and a weekly single message system (SMS) question (yes/no). In addition, fractures, injuries and deaths are monitored, although the study is not powered for fracture and mortality outcomes.

**Figure 1** Overview of the KFPS study design and methods. KFPS, Kuopio Fall Prevention Study.

All women in the intervention group have by now already completed their initial 6 month supervised and the successive 6-month non-supervised exercise period. Also, the 12-month follow-up visits have been completed by now for both study groups. After that, the study protocol continues with annual clinical measurements and gathering of observational data (figure 1). Follow-up measurements at the 24-month time point will be accomplished in 2019. Analyses for outcome measures will be performed using the 12 months and 24 months data. Reporting and implementation of the study results will start in 2020.

### Patient and public involvement statement

Patients and the public were not involved in the study design or conduct of the study. Annually, a public event for the study cohort is organised, where the audience have an opportunity to comment on the study composition. All study participants get the results from the DXA, cognitive tests and functional tests right after each visit. After the completion of the 2-year follow-up measurements in autumn 2019 the study population will be invited to an occasion where main results of the trial will be presented. In addition, these results will be presented in local and national press/media. National guidelines for fall prevention will also be checked against the results of this study.

### Participants and randomisation

Initial eligibility criteria for the study were: (1) women born 1932–1941; (2) living within a reasonable distance (≤10 km) of Kuopio city centre; (3) ability to attend the exercise sessions twice a week for the first 6 months and (4) adequate health (self-ambulatory and no unstable angina pectoris, severe pulmonary disease or moderate to severe dementia). All women meeting eligibility criteria 1 and 2 were asked about their willingness to take part into the 2-year exercise trial with a mailed invitation letter. After the initial invitation, the number of women attending the study was lower than expected. An additional group of women within the same area, born in 1942–1945, was approached to reach an adequate sample size. Altogether, between January 2016 and March 2017,

an information letter concerning the study was mailed to a total of 4262 women, born between 1932 and 1945. In preliminary screening, out of 1600 respondents, women unable to fulfil eligibility criteria 3 and 4 were excluded, leaving 914 women in total (21.4% of all women invited) into randomisation at baseline (figure 2). This includes a subsample of 582 women belonging to the long-term OSTPRE cohort (born from 1932 to 1941) and 332 women recruited from the second round (born from 1942 to 1945).

The recruitment and baseline measurements were successfully completed in April 2017. The final sample has been block randomised using computer-generated random numbers into the intervention (n=457) and control (n=457) groups. A randomised allocation sequence was generated by a data analyst under the guidance of a senior professional statistician. After the baseline measurements were completed and informed consent was received, each participant was allocated to either intervention or control group as shown by the next randomisation code in the allocation sequence. Randomisation codes remained hidden for the study nurses until the actual recruitment took place. An allocation ratio of 1:1 was used. Outcome data collection and recording as well as analyses will be blinded at the study group level throughout the trial whenever possible.

### Interventions
#### Health education

Education concerning fall prevention and lifestyle was given twice during the first year to the entire study population. This included a written educational brochure about falls and oral information concerning nutrition, home safety issues and exercise-related lifestyle factors. Both groups have also been given information about introductory courses and free and low-cost recreational activities organised for seniors by the city of Kuopio.

#### Physical exercise intervention

The physical exercise intervention aims to increase muscle strength, improve balance and increase mobility. Strength and resistance exercises have been shown to
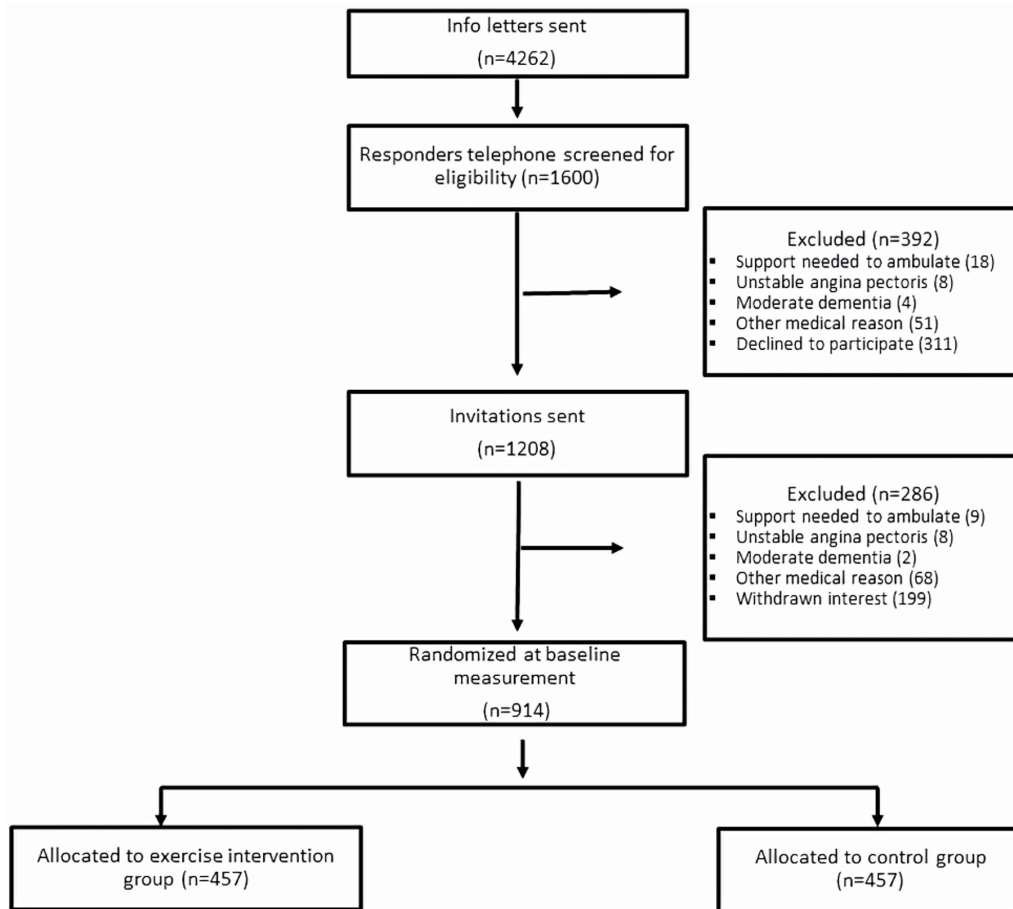
**Figure 2** Flow chart of recruitment and participation in the KFPS study. KFPS, Kuopio Fall Prevention Study.

improve seniors' functional capacity [11–13], while Taiji has been shown to be useful for improving balance and preventing falls even in more challenging cases, including Parkinson's disease with an established fear of falling.[36]

The intervention group's initial 6-month supervised exercise course was designed to introduce women to basic training techniques and establish their knowledge of strength training and Taiji. It had two main training modes, that is, a progressive gym training course and a Taiji basic course for seniors. Both courses were performed once a week, 1-hour sessions each, totalling two exercises (2 hours) per week. After the supervised courses, the same protocol was supposed to be followed for another 6-month period independently. The unsupervised training period did not include additional support from the study. The women were encouraged to use the free use of communal premises and to continue their physical routines, based on Taiji and gym exercise protocols they were familiarised with at beginning. However, no compulsory training routine was required. Controls were, after being given the study material and education, on their own in respect to their subsequent physical activity, but their physical activity was monitored with a self-reported questionnaire and activity diary.

Supervisors for the strength exercise protocol at the gym were two trained professional physiotherapists. Taiji

sessions were supervised by a full-time professional Taiji teacher with 20-year previous teaching experience in the subject. Both protocols were planned and familiarised to instructors on site. The Taiji protocol was designed in collaboration with the instructor.

*The senior gym training course*

The senior gym training course aimed to familiarise study subjects with safe and correct techniques for weight training and devices. The gym training protocol was based on circuit training with stack weight devices, enabling the training of a large group simultaneously. Free weights were not used; the strength exercise was performed using fixed equipment to minimise the risk of injury and to lower the learning curve for correct workout techniques. The first four visits were mainly dedicated to familiarising the group with proper techniques, individual starting loads and the proper use of equipment. Thereafter, the training was focused on large muscle groups, including lower limbs (quadriceps/hamstring), back (lower and upper) and an abdominal midsection. Additional workout for arms and chest was included, but not prioritised. Workout weight was determined individually, based on the results of previous visits and a theoretical one repetition maximum (Borg's scale). The initial number of repetitions was between 12 and 15 per set, with a total

of 3 sets for each workout move and allowing 2 min of rest between them. The number of repetitions was lowered to 8–12 after 6 weeks (online supplementary appendix 1). The estimated training intensities as one repetition maximum per set (%1 RM) for the initial 6-week strength endurance period and for the following 12-week hypertrophy period were 70%–65% and 80%–70%, respectively. The warm-up section included light stretching. The programme protocol and exercises varied during the 6-month introductory period, to maintain the stimuli and to establish women's personal know-how for their individual workout routines. After 6 months, women were encouraged to continue the exercises independently.

### The Taiji introduction course

The Taiji introduction course aimed to reduce falls by improving coordination, balance and range of movement. The 6-month protocol was progressive, starting from the basic techniques, body weight shifting and range of moves that eventually enable independent and personal training. Priority was given to practical and applicable Taiji elements optimised for seniors, and to improve their postural balance, lower limb muscle strength and coordination. The course programme was established in cooperation with a professional Taiji instructor (online supplementary appendix 2). A combination of elements similar to the previous research-based Taiji training regimen[37] were implemented accordingly. The implementation and applicability of Taiji in communal use among seniors will also be investigated. While Taiji does not require any special equipment or facilities for seniors to carry out their routines, women were encouraged to continue, independently or in self-paid Taiji groups, after the first supervised 6 months passed.

### Criteria for discontinuing allocated interventions

Trial participants were assumed to participate in the whole intervention. A participant's intervention was discontinued if her health state changed significantly (new or worsening severe disease, inability to participate in exercise intervention, need for continuous support to ambulate) or if a participant discontinued by withdrawal of consent.

Any reported adverse events and unintended effects of trial interventions were collected from participants by study nurses and assessed individually. In the case of severe adverse effects, the principal investigator could have discontinued the trial.

### Procedures for monitoring adherence

Participants' adherence to interventions was expected to improve by providing free use of Kuopio city premises for the first year. Adherence was monitored with biweekly SMS questionnaires/calls, self-administered diaries and during the 6-month supervised exercise course and during the annual clinical measurements. In case of participant's inability to confirm an appointment, study nurse contacted the person by telephone.

### Cooperation with the city, use of premises and costs
#### Use of premises and costs

The permission to use Kuopio city premises free in this study has been granted by the municipal board. The city provided the use of facilities, including a weight room and a gymnastic hall for Taiji sessions. While the intervention used public municipal sport and activity facilities, it investigated the effect of free and supervised exercise, followed by independent use on individual and societal aspects. Access to the municipal exercise premises was monitored with a personal electronic key card 'Healthy Kuopio' which allowed the initial 12-month free access for the first year. Its renewal for the second year cost €65 and was obtainable from various municipal offices to anyone with a pensioner status. Use of the key card in any municipal recreational premises created an electronic record of the visit.

#### Utilisation of premises and study flow in practice

The intervention group of 457 women was divided into 15–18-person groups, which was optimal regarding the supervision and the amount of exercise devices available. Altogether 27 exercise intervention groups were formed to cover the sample size. The municipal premises were in use for the study during midday, between 10:00 and 14:00 hours. During this time, four groups underwent a 1-hour training sessions (approximately 50 min +10 min for briefing, changes, etc). After the initial 6-month supervised period, all groups had their free-of-charge period activated for another 6 months. Altogether, the study protocol consecutively used the premises for over 2 years from the start of the first exercise group to the last.

### Outcome measures
#### Preliminary enquiry and OSTPRE follow-up data (post hoc)

The OSTPRE 25-year enquiry, with a question about the willingness to participate in the exercise RCT (KFPS) was sent to the whole OSTPRE cohort alive in April 2014, out of which 2250 were Kuopio residents. Altogether, 1310 women were eligible for the study, out of which 558 were successfully recruited as a subsample. The OSTPRE questionnaire data from the previous 25 years (1989–2014) will be used to investigate the factors predicting exercise intervention compliance and health outcomes in this subsample. Primarily, questions concerning lifestyle (nutrition, physical activity), socioeconomic situation, history of chronic health disorders and previous DXA-scan results (bone mass, body composition changes) that were questioned in 5-year intervals during the OSTPRE follow-up will be used.

#### Recording of falls through SMS questionnaire

The intervention and control groups (including dropouts) are currently being questioned biweekly for falls by phone with a simple SMS question (yes/no) when applicable. Positive reports are being contacted with phone calls and verified for details of falls. Falls are defined according to WHO International ICD diagnosis codes by

including all falls on the same level, on stairs and from height. In this study, any self-reported minor or major accident and medically diagnosed injury related to fall, slip fall or falling from a height below 1 m is considered as a 'fall-related injury' if sensation of pain or soreness is reported in the phone interview following the fall report. The biweekly SMS is being regarded as the golden standard for fall recording. Approximately, 1000 individual falls have been registered and verified by phone interview so far.

## Self-administered diary

The self-administered diary is returned every 6 months, where recent falls and leisure time physical activity are being reported. The first fall, number of falls and the falls requiring medical attention are being recorded. Medical records (Hospital discharge and The Social Insurance Institution of Finland) will be cross-checked for falls, fractures and medical history. Additionally, the participants self-record falls with a diary, including information about date, time, place of occurrence, mechanism and cause of falling, place of treatment and hospitalisation. By using the same diary, leisure time exercise events, causes of non-participation and changes in health status and medication will be monitored.

## Well-being and cognitive performance

Several aspects of cognition are evaluated at the baseline and at 12-month and 24-month follow-ups to measure their changes throughout the follow-up period and to identify aspects of SWB that predict favourable outcomes in exercise intervention or are most effected by exercise intervention among ageing women. The following psychometric scales or questions were used: (1) QoL (EuroQol-5D Health Questionnaire[38]; Life Quality Scale (from the Finnish Health 2000—survey)[39]); (2) Life satisfaction (Life Satisfaction Scale; Satisfaction with Life Scale[40]); (3) Depressive symptoms (Prime-MD screen; shortened version (six questions) of Geriatric Depression Scale-15[41]); (4) Loneliness (De Jong Gierveld Loneliness Scale (11-item))[42] (5) Perceived Stress[43]; (6) Resilience (Brief Resilience Coping Scale)[44]; (7) Personality screen[45]; (8) Personality features, that is, hostility and optimism (Life Orientation Test[46]); (9) Cognition (Mini-Mental State Examination[47]).

## Clinical measurements

During each visit, a participant's weight, height and waist circumference are measured. The participant is also asked about possible changes in body weight in last 3 months. The order of physical measurements taken during a visit is single leg stance test, squat test, isometric leg extension strength, grip strength, DXA scan, Timed Up and Go test (TUG), body sway test.

### Dual X-ray absorptiometry

Bone mineral density (BMD) measurements are performed at total body and the left proximal femur (or right if the left femur contains artefacts such as prosthesis). Composition measurements including fat mass and lean mass are performed at total body. Both scans are performed with DXA (Lunar iDXA, GE, Madison, Wisconsin, USA). Quality controls are followed according to the manufacturer.

### Functional tests

The functional tests include six items: (1) single leg stance test (two attempts): eyes open with better foot, time measured (continuing for 30 s, result <3 s is considered as a fail); 2) squat test: that is, ability to squat down to touch the floor with fingertips: (a) not able at all; (b) able to squat down completely; (c) able to get up from squat down-position without support (result: able/unable); (3) isometric leg extension strength (HUR Labs, Jyväskylä) (three repetitions/both legs): sitting on chair one leg stabilised with strap to chair, maximum effort to extend the stabilised leg (result in Newtons); (4) maximal grip strength with handheld dynamometer (Jamar, Sammons-Preston, Illinois, USA) (three repetitions): dominant hand grip strength (result in kilograms); (5) TUG (one attempt): time for a person rising from the chair, walking at normal speed to 3 m mark, turning, walking back to the chair and returning to the seated position (result in seconds)[48] and (6) computerised body sway analysis (HUR Labs BT3, Jyväskylä) (four measurements, 30 s each): standing on platform (a) normal stance, foot in V-position with eyes open; (b) normal stance, foot in V-position with eyes shut; (c) semitandem stance with eyes open and (d) semitandem stance with eyes shut (result in square millimetres of sway).

## Sarcopenia and frailty assessment

Sarcopenia is assessed according to The European Working Group on Sarcopenia in Older People (EWGSOP) as presence of both low muscle mass and low muscle function (strength or performance) with increased risk of disability, poor QoL and death. The EWGSOP2 recommends use of (1) low muscle strength, (2) low muscle quantity and quality or (3) low muscle performance for the diagnosis.[49] Measurements for sarcopenia diagnosis are performed during each study visit.

Frailty is a more comprehensive phenotype of a fragile old person than sarcopenia and is defined operationally as meeting three out of the next five: (1) unintentional weight loss, (2) self-reported exhaustion, (3) weakness (low grip strength), (4) slow walking speed and/or (5) low physical activity.[50] In the study, all except walking speed are recorded (changes in weight, grip strength, TUG-test, self-administered diaries).

## The cost-effectiveness

The cost-effectiveness analysis is based on standard methods.[51 52] It is carried out in two different settings. The first investigates whether the intervention is cost-effective for fall prevention compared with control group. The second is cost–utility analysis, which use QALYs gained as outcome. The results will be presented in cost

per QALY. The viewpoint of the analyses is a societal view, which is regarded as the most comprehensive view. The subanalysis will also be performed from the municipal perspective, since the city of Kuopio has a substantial contribution to these services.

### Study power and sample size
#### Fall rate and OSTPRE study data
A primary outcome is falling. The entire OSTPRE-study cohort has been questioned for fall history in the preceding 12 months at 5-year intervals, most recently in 2014. At the 20-year questionnaire (in 2009), 35.0% of the OSTPRE women reported a fall during the last 12 months. Of these, 54.2% had fallen at least twice or more. Recent meta-analysis has reported very heterogeneous drop-out rates depending on factors such as geographic location, demography, duration and intensity of the protocol.[14] Original estimation of the drop-outs, based on this meta-analysis, was set to 20% for the intervention group and 16% for the control group.

#### Death rates
Annual mortality in Finland from 2011 to 2012 was 2.5% for women aged 75–79 years.[4] Respondents of the OSTPRE cohort have had lower mortality than the national average. Therefore, the cumulative mortality was estimated to have been 10% for the last 5 years (n=2502–2250).

#### Summary of group sizes and study power
The estimation was, with a 5% error margin, that 341 women in both groups would be required to give 80% power for detecting 31% fall reduction within a 30% general fall incidence during the 12-month follow-up. With a 3% annual mortality and 20% to 16% drop-out percentages for intervention and control samples, respectively, the estimated group sizes would be (341/0.77)+(341/0.81)=442+420. Adjusted for 80% compliance with mixed effects, the total group size was estimated to be 1078. However, the total final study population of 914 women (457 for each study group) presents an adequate sample size due to the significantly lower than estimated drop-out rate and a higher number of falls.

### Statistical analysis
The intervention and control groups will be compared using the $X^2$ test for dichotomous variables and the t-test for continuous variables. Respectively, in multivariable analyses, logistic and linear regression will be used. In the analyses of longitudinal repeated measures and differences in changes of variable values, linear mixed regression models will be used. Subgroup analyses will be conducted using interaction terms in regression models. Rates will be calculated by dividing the number of events by follow-up time in person-years or in multivariable cases by using Poisson regression. For outcomes that can be located in time, Kaplan-Meier curves and Cox proportional hazards model will be used. For the analyses, 95% CIs will be provided. In the case of multiple comparisons, Bonferroni correction will be used.

In the main analyses, participants will be included in the groups as they are randomised (intention-to-treat principle). Additional analysis will be conducted using the observed exercise status (by protocol analysis). In the analyses of rates and event histories, drop-outs will be considered as censored observations. Reasons for drop-outs will be reported. In addition to the analysis of available cases, additional analyses where missing data are imputed using modern methods or derived from linked register data will also be performed.

### Data management
Data management in the project will be organised by KMRU. The data will be stored in secured data servers located at the UEF and managed by a named data manager. Data generated in the project will be curated by project collaborators, and national healthcare records will be integrated into centralised data storage. Data versions will be controlled and backed up by authorised personnel. The secure sharing of information and study data is done between project partners and collaborators. New data will be accessible for all when possible, considering possible ethical and privacy issues.

A data monitoring committee was not implemented due to lack of competing or conflicting interests.

## ETHICS AND DISSEMINATION
### Equality and ethical issues
Equity and the distribution of different socioeconomic aspects are well balanced among the study cohort. The sample consists of all women within the same age group, living in the same geographical region, from a variety of socioeconomic backgrounds. Although the study involves only women, they are at the highest risk of osteoporosis and fractures in Finland. The first year of the intervention is free for the intervention group and thereafter expenses for the next 12 months are reasonable for all socioeconomic classes (approximately €65). Only the intervention group will receive supervised exercise and free use of the premises, while controls are free to pursue all their physical activities. The annual expense for controls to obtain similar access without supervision remains equal (at €65) and therefore does not exclude them from pensioners' privileges within the community. However, double-blinded RCT exercise intervention of this magnitude would not be sustainable on a community level.

UEF provides the insurance for participants according to the Finnish Patient Injuries Act.

### Dissemination
The study researchers will publish the articles according to International Committee of Medical Journal Editors (ICMJE) recommendations.[53] According to the publication and data policy of the UEF, all research information produced by this project will be made available for the

scientific community and society as a whole. New results will be presented to the general public through UEF's Communications and Media Relations department and UEF web pages. Publications will be made available for shared use by depositing copies of publications in the open-access repository of the university (green route). When applicable, research results will be published in peer-reviewed journals, which are scientifically high in quality and which carry out a reliable scientific review process for research papers. Anonymised data are planned to be dispensed to the scientific community in an appropriate open-access data repository.

## GENERALISABILITY

Cohort effect of the younger women born in 1942–1945 compared with OSTPRE cohort women born in 1932–1941 is possible. Six years in age may make a difference, that is, less old age frailty and dementia. However, controls for this younger group were selected from the same younger population group.

Although the KFPS study is limited to older women, the results are considered to be applicable to males as well, as the study protocol does not require any gender-based adjustments. In the recent exercise study among older adults, no differences in attendance and drop-out rates between the genders were found, and relative muscle increase as well as strength and function improvement were similar between men and women.[54]

The study allows the estimation of municipal resources on health and SWB in seniors. The study enables the high-quality long-term population-based data to produce meaningful answers for fall prevention strategies with corresponding cost–utility analysis. In addition, the study generates more exact data for guidelines and applicable clinical recommendations to Finnish communities and municipalities. Since major cities in Finland provide similar services, results can be used in national strategies. The study is one of the largest exercise interventions conducted for this age group. It provides results that have potential to act as a reference study for future strategies for middle-large cities in countries with similar service structures.

## LIMITATIONS OF THE STUDY

The KFPS study cohort is limited to older women in a Finnish middle-large municipality. The initial risk of under-recruitment has become obsolete. However, another acknowledged risk is that this exercise programme will increase other physical activities, which do not reduce but may in fact increase the occurrence of falls or related fractures.[10] For that purpose, falls on the way to study protocol exercises, exposure and exposure time for walking and other selected forms of physical activity will be controlled with a set of questions applied at the study enquiries and phone interviews. By using the Fall Risk by Exposure method, the amount of physical activity as a measure of exposure to falls or fractures can be estimated. This will decrease the potential additional effect due to increased physical activity. In addition, the trend of the control group increasing their physical activity will be monitored with questionnaires, interviews during three clinic visits and by checking the records of municipal and health service usage.

## DISCUSSION

In this article, a protocol for a group exercise RCT on functional ability, sarcopenia and frailty, fall risk and SWB in older women is presented. Fall prevention programmes for older people, including, for example, behavioural instructions and exercise interventions, have been shown to reduce falls.[55 56] The generalisability of evidence for exercise efficacy could remain limited and cost-effectiveness might turn out to be negative. However, the expectation is that the population-based KFPS trial with better generalisability will be effective and prevent functional decline, improve SWB and decrease the use of healthcare services. Also, the cost-effectiveness and cost–utility of large-scale fall prevention programmes at the community level will be estimated. Active and cost-effective integration of the seniors into physical activities is vital for successful strategies in ageing Europe. The KFPS study will acquire new information on these topics.

**Author affiliations**
[1]Kuopio Musculoskeletal Research Unit (KMRU), University of Eastern Finland - Kuopio Campus, Finland
[2]Department of Orthopaedics, Traumatology and Hand Surgery, Kuopio University Hospital, Finland
[3]Institute of Clinical Medicine (Psychiatry), University of Eastern Finland - Kuopio Campus, Finland
[4]Department of Psychiatry, Kuopio University Hospital, Finland
[5]Department of Health and Social Management, University of Eastern Finland - Kuopio Campus, Finland

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