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Counselling for physical activity, life-space mobility and falls prevention in old age

Submission date
10/11/2015

Recruitment status
No longer recruiting

Registration date
27/11/2015

Overall study status
Completed

Last Edited
22/10/2020

Condition category
Injury, Occupational Diseases, Poisoning

[X] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Falls are one of the leading causes of death and injury in people over the age of 65. Studies have shown that getting more exercise can help to lower the risk of falls by improving balance, coordination and strength. Many older people find it difficult to get enough exercise, and so actively encouraging and promoting regular participation in physical activity (PA) is especially important. Being able to safely move around outside the home is important part of long-term independence in old age. There are a range of services and activities available in the community to promote health and well-being, however many older people are unable to access these. It has been found that the many older people tend to stay in areas they know well. Life-space mobility is a way of measuring the size of the area that a person has moved around in over the last month (i.e. home, yard, neighbourhood, town and beyond town). Many people feel that if they go beyond this “comfort zone” then they are more likely to have a fall and injure themselves, greatly limiting their independence. In order to try to help people with a limited area of mobility, health kiosks have been set up in public places. A health kiosk is a place which is easily accessible locally, that can provide easily accessible healthcare. The aim of this study is to find out whether offering individual counselling sessions to older people at a health kiosk is an effective and cost-effective way of encouraging older people to become more active.

Who can participate?
Adults aged 65 or over with minor mobility difficulty

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group take part in 5 hour-long individual counselling sessions. During these sessions participants are taught about strengthening their leg muscles, balance, walking, stair climbing, and active range of movement exercises, as well as a referral to a community specialised gym. The participants are also given advice about safety issues and the importance of a healthy lifestyle. Those in the second group are given placebo (dummy) exercises involving relaxation and mindfulness (being aware of yourself and everything around you), as well as written material about the importance of exercise.

What are the possible benefits and risks of participating?
Participants may experience benefits to their health such as lowering the risk of developing health problems such as heart disease and diabetes. Physical activity could also help them to do more day-to-day and reduce their risk of falls in the long-run. Risks of participating are small however when people increase their level of physical activity, there is a risk of sore muscles and falls.

Where is the study run from?
The Ylöjärvi Health Kiosk and the Service Centre of Ylöjärvi (Finland)

When is the study starting and how long is it expected to run for?
September 2015 to December 2018

Who is funding the study?
Academy of Finland (Finland)

Who is the main contact?
1. Dr Johanna Edgren (Public)
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2. Dr Riku Nikander (Scientific)
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Contact information

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Public

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Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

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

Study objectives
1. The Health Kiosk environment incorporating targeted counselling and referral to an evidence-based exercise program will improve physical and muscle performance and mobility, decrease falls and fall-related injuries and improve overall PA levels and health-related quality of life
2. The Health Kiosk environment will represent a cost-effective model for preventing falls and will increase the number of participants capable of independent living post intervention and two years after the end of the 24-month intervention

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Regional Ethics Committee of the Expert Responsibility area of Tampere University Hospital, 03/11/2015, ref: R15160

Study design
Single-centre randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet.

Health condition(s) or problem(s) studied
Falls

Interventions
Participants are randomly allocated to one of two groups:

Current interventions as of 04/01/2019:
Control group: Participants will receive a sham exercise intervention including five 45-minute face-to-face sessions of relaxation exercises. Exercise program will be up dated during each face-to-face session and each exercise is provided on CD or via mp3 format. In addition, 11 supportive telephone calls will be provided.

Intervention group: There will be five face-to-face 1.5-hour sessions including a 30-minute health counselling session for motivation together with a 1-hour exercise education session. The health counselling contains the safety issues of home environment and physical activity, counselling for healthy diet, and counselling to reduce alcohol consumption and smoking. The exercise education is based on the Otago Program. It contains strengthening exercises for lower extremity muscles as well as balance, walking, stair climbing, and active range of movement (for example, neck rotations and hip and knee extensions) exercises. During the sessions the exercise referral to the local community exercise facilities will be also given. The participants will receive progressive illustrated instructions. In addition, 11 supportive telephone calls will be provided.

The total duration of the interventions is 24 months. Both groups are followed up 24 months after the intervention.

Previous interventions from 04/05/2018 to 04/01/2019:
Control group: Participants will receive a placebo intervention including five face to face sessions of mindfulness relaxation exercises. Exercise program will be up dated during each face to face session and each exercise is provided on CD.

Intervention group: There will be 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 (for example, neck rotations and hip and knee extensions). During the sessions the

exercise referral to the local community specialized gym will be also given. The participants will receive a progressive written exercise program with schematic drawings. In addition, 11 supportive telephone calls will be provided. The 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.

Previous interventions from 30/08/2016 to 04/05/2018:
Control group: Participants will receive a placebo intervention including five face to face sessions of mindfulness relaxation exercises. Exercise program will be up dated during each face to face session and each exercise is provided on CD.

Intervention group: There will be five Health Kiosk-based 1-hour sessions including a 20-minute counselling session for motivation together with a 40-minute 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 (for example, neck rotations and hip and knee extensions). During the sessions the exercise referral to the local community specialized gym will be also given. The participants will receive a progressive written exercise program with schematic drawings. In addition, 11 supportive telephone calls will be provided. The 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.

Original text:
Control group: Participants will receive a placebo intervention including one-time group session of mindfulness relaxation exercises and a written exercise program.

Intervention Type
Other

Primary outcome measure
Current primary outcome measures as of 04/02/2019:
1. Life-space mobility assessed by a validated questionnaire (Life-spece mobility measures mobility based on distance through which a person reports moving during the 4 weeks preceding the assessment. Questions establish movement to specific life-space levels ranging from within one’s dwelling to beyond one’s town) at baseline, 12, 24 and 48 months.
2. Falls rates: daily filled and monthly returned fall-diaries will be used to collect information on falls and fall-related injuries and registers will be used to verify severe injuries at baseline, 12, 24 and 48 months.

Previous primary outcome measures:
1. Life-space mobility assessed by a validated questionnaire (Life-spece mobility measures mobility based on distance through which a person reports moving during the 4 weeks preceding the assessment. Questions establish movement to specific life-space levels ranging from within one’s dwelling to beyond one’s town) at baseline, 12, 24 and 48 months

2. Number of falls and fall-related injuries: monthly collected fall-diaries will be used to collect information on falls and fall-related injuries and registers will be used to verify severe injuries at baseline, 12, 24 and 48 months

Secondary outcome measures

Current secondary outcome measures as of 04/02/2019:
1. Physical activity is assessed using a Finnish Hookie AM 20 triaxial accelerometer for 7 days and physical activity diary for 4 weeks at baseline, 12, 24 and 48 months.
2. Physical performance is measured using the Timed Up and Go-test (TUG), Short Physical Performance Battery (SPPB) and Jamar hand dynamometer at baseline, 12, 24 and 48 months.
3. Number of fallers (a fall indicator variable: yes/no) will be assessed based on diaries filled daily and returned each month until 24-months after the baseline.
4. Fall-induced injuries will be assessed based on diaries filled daily and returned each month until 24-months after the baseline.
5. Health-related 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 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),[40]. A 100mm long line will be used with the left end of the line (0mm) representing “no fear” and the right end (100mm) “extreme fear”.

Previous secondary outcome measures as of 04/05/2018:
1. Physical activity is assessed using a Finnish Hookie AM 20 triaxial accelerometer for 7 days and physical activity diary for 4 weeks at baseline, 12, 24 and 48 months
2. Physical performance is measured using the Timed Up and Go-test (TUG) , Short Physical Performance Battery (SPPB) and Jamar hand dynamometer at baseline, 12, 24 and 48 months
3. Quality of life is measured using The World Health Organization Quality of Life (WHOQOL) questionnaire at baseline, 12, 24 and 48 months
4. Living-arrangements are determined by asking patients at baseline, 12, 24 and 48 months
5. Number of fallers based on monthly collected fall-diaries at baseline, 12, 24 and 48 months
6. Fracture risk is assessed using the WHO Fracture Risk Assessment Tool at baseline, 12, 24 and 48 months
7. Mental status is assessed using the Geriatric Depression Scale (GDS-15) at baseline, 12, 24 and 48 months
8. Cognitive status is assessed using the Mini-Mental State Examination (MMSE) at baseline, 12, 24 and 48 months
9. 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

Previous secondary outcome measures:
1. Physical activity is assessed using a Finnish Hookie AM 20 triaxial accelerometer for 7 days and physical activity diary for 4 weeks at baseline, 12, 24 and 48 months
2. Physical performance is measured using the Timed Up and Go-test (TUG) , Short Physical Performance Battery (SPPB) and Jamar hand dynamometer at baseline, 12, 24 and 48 months

3. Quality of life is measured using The World Health Organization Quality of Life (WHOQOL) questionnaire at baseline, 12, 24 and 48 months
4. Living-arrangements are determined by asking patients at baseline, 12, 24 and 48 months
5. Falls rate is measured using a short risk profile interview (i.e. “Have you fallen (and if so, how many times) during the previous year (without substantial external force)?) at baseline, 12, 24 and 48 months
6. Fracture risk is assessed using the WHO Fracture Risk Assessment Tool at baseline, 12, 24 and 48 months
7. Mental status is assessed using the Geriatric Depression Scale (GDS-15) at baseline, 12, 24 and 48 months
8. Cognitive status is assessed using the Mini-Mental State Examination (MMSE) at baseline, 12, 24 and 48 months

Overall study start date
01/09/2015

Completion date
30/06/2021

Eligibility

Key inclusion criteria
Current participant inclusion criteria as of 04/02/2019:
1. Aged 65 years or over
2. Community-living people
3. Living in Ylöjärvi, Finland, or neighbouring municipalities
4. At least minor mobility difficulty
5. Living in Pirkanmaa distrcit.

Previous participant inclusion criteria as of 30/08/2016
1. Aged 65 years or over
2. Community-living people
3. Living in Ylöjärvi, Finland, or neighbouring municipalities
4. At least minor mobility difficulty

Previous 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
5. History of fall(s)

Participant type(s)
Healthy volunteer

Age group
Senior

Sex
Both

Target number of participants
450 (225+225)

Key exclusion criteria
Current participant exclusion criteria as of 30/08/2016
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)

Previous 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

Date of first enrolment
01/01/2016

Date of final enrolment
30/06/2019

Locations

Countries of recruitment
Finland

Study participating centre
The Ylöjärvi Health Kiosk
Elotie 1
Ylöjärvi
Finland
33470

Study participating centre
The Service Centre of Ylöjärvi
Rantajätkantie 2 B
Ylöjärvi
Finland
33470

Sponsor information

Organisation
University of Jyväskylä

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Sponsor type
University/education

Website
https://www.jyu.fi/en

ROR
https://ror.org/05n3dz165

Funder(s)

Funder type
Research council

Funder Name
Academy of Finland (Suomen Akatemia)

Alternative Name(s)
Suomen Akatemia, Finlands Akademi, Academy of Finland, AKA

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Finland

Results and Publications

Publication and dissemination plan
The research results will be published in high-class scientific journals such as Journal of the American Medical Association (JAMA), British Medical Journal (BMJ) or Journal of the American Geriatrics Society. In 2017, we will report the results from the baseline data and results from the follow up data in 2019.

As of 04/05/2018, the researchers intended to publish the study protocol by 31/01/2019.

Intention to publish date
30/06/2019

Individual participant data (IPD) sharing plan
The datasets generated during and/or analyzed during the current study will be available upon request from Dr Riku Nikander, riku.p.nikander@jyu.fi
The datasets generated during and/or analyzed during the current study will also be stored in a publically available repository: Dataverse platform (https://dvn.jyu.fi/dvn/).
Data will be available from 5/2019 until 2029 (at least 10 years from the end of data collection) for research and/or education purposes for research collaborators as soon as the data will be collected and if the primary research group who has collected the data do not intend to utilize the requested data. Data will be available for secondary (ancillary) analyses. The primary research group will accomplish analyses of RCT design. Data will be provided only anonymized based on the Finnish legislation of personal data and statement given by the Regional Ethics Committee of the Expert Responsibility area of Tampere University Hospital. An informed consent has been obtained from participants when enrolled on the study.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	24/09/2019	22/10/2020	Yes	No