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Promotion of physical activity and mobility among older people with musculoskeletal disorders

Submission date
26/01/2016

Recruitment status
No longer recruiting

Registration date
27/01/2016

Overall study status
Completed

Last Edited
16/02/2023

Condition category
Musculoskeletal Diseases

[X] Prospectively registered

[X] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

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 (mobility) is important part of long-term independence in old age. Musculoskeletal disorders (problems with the muscles and /or joints because of injury or long-term illnesses such as arthritis) are increasingly common in adults over 60. Studies have shown that when a person is hospitalized because of a musculoskeletal disorder affecting their legs and/or back, they can become very inactive during their hospital stay. This can lead to problems “getting back into” physical activity and causes mobility issues in the future. There is currently a lack of evidence about the effectiveness of combining physical activity promotion programs (to encourage people to become more active) with rehabilitative exercise training (exercises designed to help restore movement) among older adults who have been recently discharged from the hospital. The aim of this study is to find out whether a home-based physical activity promotion program can help improve the level of physical activity and mobility in older adults who are recovering from a musculoskeletal disorder affecting the legs or back.

Who can participate?

Adults over 60 years old who do not live in nursing homes and have been admitted to and discharged from hospital because of a musculoskeletal disorder affecting their legs or back.

What does the study involve?

Participants are randomly allocated to one of two groups. Those in the first group continue to receive their usual care, and do not take part in any extra exercise for the 6 month study period. Those in the second group also continue to receive their usual care however they also take part in the personalised home-based rehabilitation program for 6 months. This program is given by a trained physiotherapist, and involves a combination of counselling and leg exercises which get progressively harder. At the start of the study and then again after 3, 6 and 12 months, all

participants have their level of physical activity measured using an accelerometer (device to measure how much they move) and complete a number of questionnaires in order to assess their mobility, independence and mental faculties.

What are the possible benefits and risks of participating?
All participants benefit from receiving information about their physical performance, and participants who receive the personalized rehabilitation program my benefit from improved mobility. There is a small risk that participants may fall or become injured during exercise.

Where is the study run from?
Palokka Health Centre and Kyllö Health Centre in Jyväskylä (Finalnd)

When is the study starting and how long is it expected to run for?
February 2016 to February 2018

Who is funding the study?
1. National Institute for Health and Welfare (Finland)
2. Social Insurance Institution of Finland (Finland)
3. Ministry of Social Affairs and Health (Finland)

Who is the main contact?
1. Professor Riku Nikander (scientific)
2. Mrs Katri Turunen (public)

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Program to Promote Physical Activity and mobility recovery in older people hospitalized for musculoskeletal disorders: A single-centre randomized controlled trial

Acronym
ProPA

Study objectives
The 6-month individually targeted multi-component intervention will increase the level of physical activity and restores mobility of older adults compared to controls receiving standard /usual care.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Ethics Committee of the Central Finland Health Care District, 03/02/2015, ref: 3U/2014

Study design
Single-centre randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Home

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Musculoskeletal disorders in lower extremities or back

Interventions
Participants are randomly allocated to one of two groups.

Intervention group: Participants receive standard/usual care, as well as an individually targeted multi-component home-based program that aims to increase physical activity and restore mobility. The six-month intervention comprises goal-directed physical activity promotion (counselling and management sessions for physical activity promotion and mobility goal attainment), progressive lower extremity physical exercise program, and supported physical and social activity sessions. The intervention will start at home following hospital discharge, baseline measurements and randomization. It will be coordinated and delivered by a physiotherapist and supported by of a lay volunteer person.

Control group: Participants continue to receive standard/usual care, and are instructed to follow the instructions provided by the Health Centre-Hospital. Total duration of the intervention is six months.

Participants in both groups will be followed up for 12 months after baseline.

Intervention Type
Behavioural

Primary outcome measure
1. Level of physical activity and inactivity is objectively assessed using the accelerometer at baseline, 3 and 6 months
2. Level of physical activity is measured using validated self-reporting questionnaires at baseline, 3, 6 and 12 months
3. Mobility is assessed using the Short Physical Performance Battery and self-reporting at baseline, 3, 6 and 12 months

Secondary outcome measures
1. Life space mobility is assessed by Birmingham Life-Space Assessment (LSA) at baseline, 3, 6 and 12 months
2. Social participation and autonomy is assessed using the Impact on Participation and Autonomy (IPA) questionnaire at baseline, 6 and 12 months
3. Fear of falling assessed using the Falls Efficacy Scale International (FES) questionnaire at baseline, 3, 6 and 12 months
4. Pain is assessed using the modified Brief Pain Inventory at baseline, 3, 6 and 12 months
5. Depressive mood assessed is measured using the Centre for Epidemiologic Studies Depression Scale (CES-D) at baseline, 3, 6 and 12 months
6. Perceived barriers to indoor and outdoor physical activity is assessed using checklists for perceived environmental barriers to outdoor mobility (PENBOM; 15 items) and perceived environmental facilitators for outdoor mobility (PENFOM; 16 items) as well as self-reporting at baseline, 3, 6 and 12 months

7. Memory are assessed using Mini-Mental State Examination (MMSE) at baseline, 3, 6 and 12 months
8. Executive function is assessed using the Trail Making test at baseline, 3, 6 and 12 months
9. Use of formal and informal care is assessed through self-reporting (formal health care will be varified from the registers of Health Centre-Hosptials) at 3, 6 and 12 months
9. Hand grip strength from the dominant hand with a hand-held dynamometer at baseline, 3, 6 and 12 months

Overall study start date
01/02/2016

Completion date
28/02/2018

Eligibility

Key inclusion criteria
1. Aged 60 years and over
2. Community-dwelling
3. Admitted and thereafter discharged to home from Health Centre-Hospital because of musculoskeletal disorder, such as orthopedic surgery of lower extremity (i.e. hip fracture, joint replacement) or some other musculoskeletal event or condition of lower extremity or back (i.e. fall, aggravated arthritis, osteoporotic fracture and/or back pain)

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
We will recruit 60 participants per group, i.e. in total 120 participants.

Total final enrolment
117

Key exclusion criteria
1. Living in an institution
2. Confined to bed at time of recruitment
3. Severe memory problems (mini-mental state examination (MMSE) less than 21
4. Severe cardiovascular or pulmonary disease
5. Severe progressive disease (i.e., neoplasm, ALS, Parkinson disease).
6. Alcoholism
7. Unwillingness to participate

Date of first enrolment
01/02/2016

Date of final enrolment
31/10/2017

Locations

Countries of recruitment
Finland

Study participating centre
Palokka Health Centre
Ritopohjantie 25
Jyväskylä
Finland
40270

Study participating centre
Kyllö Health Centre
Keskussairaalantie 20
Jyväskylä
Finland
40620

Sponsor information

Organisation
GeroCenter Foundation for Aging Research and Development

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Sponsor type
Research organisation

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Welfare

Funder Name
Social Insurance Institution of Finland

Funder Name
Ministry of Social Affairs and Health (for Kuopio University Hospital Catchment Area)

Results and Publications

Publication and dissemination plan
Results will be published in peer-reviewed international scientific journals prioritizing open access series.

Intention to publish date
30/10/2019

Individual participant data (IPD) sharing plan
The datasets generated and/or analyzed during the present study are not available as they contain information that could compromise research participant privacy/consent (the tightened privacy policy in EU). The main results will be published by the research group.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/04/2020	07/04/2020	Yes	No
Protocol article		21/11/2017	16/02/2023	Yes	No
Results article	Secondary subgroup analysis	21/03/2021	16/02/2023	Yes	No