ISRCTN53680197 https://doi.org/10.1186/ISRCTN53680197

Mobility recovery after hip fracture: physical activity and rehabilitation program among community-dwelling hip fracture patients

Submission date	Recruitment status
24/09/2009	No longer recruiting
Registration date	**Overall study status**
03/03/2010	Completed
Last Edited	**Condition category**
11/06/2020	Injury, Occupational Diseases, Poisoning

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Study website
https://www.jyu.fi/sport/laitokset/tutkimusyksikot/sgt/en

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
Physical activity and rehabilitation program among community-dwelling hip fracture patients: a single centre randomised controlled trial

Acronym
ProMo

Study objectives
This study investigates the effects of a rehabilitation program on mobility and functional capacity of older community-dwelling people operated for hip fracture.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical Committee of the Jyväskylä Central Hospital Board approved on the 18th August 2007 and 22nd August 2008.

Study design
Single centre randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

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
Collum or pertrochanter fracture

Interventions
Intervention group:
Individually tailored physical rehabilitation program aiming to restore mobility (ProMo). The purpose of the intervention is to restore mobility after hip fracture. The one year intervention starts within one month (at least six weeks after discharged from the health care centre. ProMo

is a multicomponent rehabilitation protocol consisting of individual progressive home exercise program and counselling/management sessions for physical activity promotion and pain and fear of falling management. Usage and satisfaction with assistive devices for walking will also be discussed.

Control group:
Usual care. The control group is instructed to follow the guidelines provided by the hospital and healt care centre.

The total duration of the intervention is 12 months. The subjects (both intervention and control groups) will be followed up for 12 months after the intervention.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
The short term primary outcome (at 3 and 6 months) is Short Physical Performance Battery (SPPB) including habitual walking speed, chair rise and balance tests. One year primary outcome will be mobility limitation and disability.

Secondary outcome measures
Measured at baseline, 3, 6 and 12 months:
1. Maximal and habitual walking speed over 10 metres
2. Isometric muscle strength for knee extension and leg extension power, assessed from both sides
3. Functional balance, assessed by Berg Balance Scale
4. Fear of falling, assessed by Activities-specific Balance Confidence scale
5. Pain, assessed by Visual Analogue Scale (VAS) and questionnaire
6. Functional capacity, assessed by validated questionnaire
7. Level of physical activity, assessed by a questionnaire
8. Information concerning use of formal and informal care
9. Bone density and geometry measured for lower leg
10. Depressive mood (Beck Depression Inventory [BDI])

Measured at baseline, 6 and 12 months:
11. Bone density and geometry measured for arm

Measured at baseline, 3, 6 and 12 months and 24 months (12 month follow-up):
12. Form of dwelling, collected by a questionnaire and health and social service registers

Overall study start date
01/01/2008

Completion date
30/06/2012

Eligibility

Key inclusion criteria
Over 60-year-old community-dwelling men and women operated for hip fracture at the local hospital during 2008 - 2009 and living in the city of Jyväskylä or neighbouring municipalities

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
42 per group (total: 84)

Total final enrolment
81

Key exclusion criteria
1. Living in an institution
2. Confined to bed at the time of the fracture
3. Severe memory problems (min-mental state examination [MMSE] less than 19)
4. Severe cardiovascular or pulmonary disease
5. Severe progressive disease (i.e., neoplasm, amyotrophic lateral sclerosis [ALS])
6. Unwillingness to participate

Date of first enrolment
01/01/2008

Date of final enrolment
30/06/2012

Locations

Countries of recruitment
Finland

Study participating centre
Rautpohjank 8a
Jyvaskyla
Finland
40700

Sponsor information

Organisation
Ministry of Education (Finland)

Sponsor details
PL 29
Valtioneuvosto
Helsinki
Finland
00023

Sponsor type
Government

Website
http://www.minedu.fi/OPM/?lang=en

ROR
https://ror.org/02w52zt87

Funder(s)

Funder type
Government

Funder Name
Ministry of Education (Finland)

Funder Name
The Social Insurance Institution of Finland (Kela) (Finland)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/12/2012		Yes	No
Results article	results	01/12/2013		Yes	No
Results article	results	01/05/2014		Yes	No
Results article	results	01/04/2015		Yes	No
Results article	results	09/06/2020	11/06/2020	Yes	No