

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

Submission date
24/09/2009

Recruitment status
No longer recruiting

Prospectively registered

Protocol

Registration date
03/03/2010

Overall study status
Completed

Statistical analysis plan

Results

Last Edited
11/06/2020

Condition category
Injury, Occupational Diseases, Poisoning

Individual participant data

Plain English Summary

Not provided at time of registration

Study website

<https://www.jyu.fi/sport/laitokset/tutkimusyksikot/sgt/en>

Contact information

Type(s)

Scientific

Contact name

Dr Sarianna Sipilä

Contact details

Rautpohjank 8a

Jyvaskyla

Finland

40700

-

sarianna.sipila@jyu.fi

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 hypothesis

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

Condition

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 health 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

Overall study end date

30/06/2012

Eligibility

Participant 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

Participant 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

Recruitment start date

01/01/2008

Recruitment end date

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