ISRCTN61449514 https://doi.org/10.1186/ISRCTN61449514

Balance exercises help rehabilitation after hip fracture

Submission date
31/01/2017

Recruitment status
No longer recruiting

Registration date
03/03/2017

Overall study status
Completed

Last Edited
29/01/2019

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
Hip fracture is a major health problem that usually occurs in older people that is strongly linked with declines in mobility (movement), and independence, and quality of life. Hip fractures are usually treated through surgery but also require rehabilitation, usually done through a different types of physical therapy, in order to improve mobility and quality of life. However, there are still doubts about rehabilitation effectiveness, when it should happen after an injury and for how long, as well as which kind of techniques should be used. Therefore, the aim of this study is to compare a hospital rehabilitation program that includes a balance task-specific training with a program of general physical training in order to improve physical function, pain, activities of daily living (ADL), balance, and quality of life in subjects with hip fracture treated surgically.

Who can participate?
Adults older than 70 who have internal hip fixation surgery

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group receive standard individual physiotherapy sessions led by a physiotherapist. This involves improving movement through increasing muscle strength using exercises and modifying daily living activities. Those in the second group receive balance specific exercises. This involves performing tasks that tries to support improving their balances through specific exercises, walking, movement, and modifications of daily living activities. Participants are followed up after 12 months to assess their physical function, pain, quality of life and balance.

What are the possible benefits and risks of participating?
Participants may benefit from improving physical function, activities of daily living, balance, quality of life and pain intensity. Possible risks of participating are transient pain worsening, autonomic and sensory problems

Where is the study run from?
Scientific Institute of Lissone, Salvatore Maugeri Foundation IRCCS (Italy)

When is the study starting and how long is it expected to run for?
July 2012 to December 2015

Who is funding the study?
University Hospital of Cagliari (Italy)

Who is the main contact?
Prof Marco Monticone
mmonticone@gmail.com

Contact information

Type(s)
Scientific

Contact name
Prof Marco Monticone

Contact details
Cittadella Universitaria
Strada Statale, 554
Monserrato (Cagliari)
Italy
09042
+39 070 6753109
mmonticone@gmail.com

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Balance task-specific training contributes to improving physical function in older subjects undergoing rehabilitation following hip fracture: A randomized controlled trial.

Study objectives
An in-hospital rehabilitation program including balance task-specific training contributes to improving physical function as well as pain, activities of daily living (ADL), balance, and quality of life in older subjects with hip fracture treated surgically.

Ethics approval required

Old ethics approval format

Ethics approval(s)
University Hospital of Cagliari Independent Ethical Committee, 27/12/2016, ref: PN/2016/7626

Study design
Randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

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
Hip fracture

Interventions
Participants are randomly allocated to one of two groups. The clinicians mailed the principal investigator, who randomized the subjects to one of the two treatment programs using a list of blinded treatment codes and an automatic assignment system to conceal the allocation. The principal investigator obtaining and assessing the data and the biostatistician making the analyses, were both blinded to the treatment allocation. The clinicians, the physiotherapists, and the patients cannot be blinded. All of the subjects followed the exercise programs individually. The physiotherapists arranged 90-minute sessions five times a week for four weeks. Exercises were performed at medium intensity.

Experimental group: Those in this group perform balance task-specific exercises during standing with open and closed eyes with the goal of searching for a symmetrical load on their legs, during standing while keeping proprioceptive pillows under their feet, during standing by shrinking the support base, or maintaining the tandem position, or maintaining their position with and without the use of a proprioceptive bubble. Participants are asked to walk on a rectilinear trajectory with or without crutches, while changing speed and direction, or while performing motor-cognitive tasks such as turning their head on the right and left side following physiotherapists' inputs. Additional exercises such as moving from a sitting to a standing position, ascending/descending stairs and climbing obstacles are also performed.

Control group: This group follows general physiotherapy. This involves participants performing open kinetic chain exercises in supine position on the couch aimed at improving the range of hip motion, increasing hip and lower limb muscle strength, and maintaining the length and elasticity of thigh tissues.

During walking training, subjects of both groups are instructed to use their crutches reciprocally to regain a symmetrical gait pattern. Furthermore, ergonomic advice is provided to both groups by means of a booklet given to the patients during the first session of treatment in order to facilitate the modification of their daily living activities.

Participants are followed up after 12 months to assess their physical function, pain, quality of life, and balance.

Intervention Type
Behavioural

Primary outcome measure
Physical function is assessed using the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) at baseline, 3 weeks, and 12 months.

Secondary outcome measures
1. Pain is measured using the Pain Numerical Rating Scale at baseline, 3 weeks, and 12 months
2. Quality of Life is assessed using the Short-Form Health Survey at baseline, 3 weeks, and 12 months
3. Activities of daily living (ADL) is assessed using the Functional Independence Measure at baseline, 3 weeks, and 12 months
4. Balance is assessed using the Berg Balance Scale at baseline, 3 weeks, and 12 months

Overall study start date
01/07/2012

Completion date
31/12/2015

Eligibility

Key inclusion criteria
1. Internal fixation due to extra-capsular hip fractures such as trochanteric, subtrochanteric, pertrochanteric, intertrochanteric, basal and lateral femoral fractures in the dominant leg 7–10 days before admission to the Rehabilitation Unit
2. Good understanding of Italian
3. Age of >70 years

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
50 subjects

Key exclusion criteria
1. Previous hip and lower limbs surgery
2. Systemic illness
3. Cognitive impairment (MMSE<24)
4. Recent myocardial infarctions
5. Cerebrovascular events
6. Chronic lung or renal diseases

Date of first enrolment
01/07/2012

Date of final enrolment
31/12/2014

Locations

Countries of recruitment
Italy

Study participating centre
Scientific Institute of Lissone, Salvatore Maugeri Foundation IRCCS
Via Monsignor Bernasconi, 16
Lissone
Monza Brianza
Italy
20851

Sponsor information

Organisation
University of Cagliari

Sponsor details
Cittadella Universitaria
Strada Statale
554
Monserrato
Cagliari
Italy
09042

Sponsor type
University/education

ROR

https://ror.org/003109y17

Funder(s)

Funder type
University/education

Funder Name
University Hospital of Cagliari

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer review journal.

Intention to publish date
30/06/2017

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Marco Monticone at mmonticone@gmail.com

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/03/2018	29/01/2019	Yes	No