Functional gait rehabilitation in elderly following a fall-related hip fracture using the C-Mill: an RCT

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Fractures
Study type	Interventional

Summary

ID

NL-OMON35571

Source
ToetsingOnline

Brief title
Effectiveness of C-Mill training following hip fracture

Condition

- Fractures

Synonym
fractured hip, hip fracture

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit
Source(s) of monetary or material Support: This study is part of a larger researchprogram entitled 'Steps to follow and obstacles to avoid in speeding up functional

gait rehabilitation'

Intervention

Keyword: Falling, Gait adaptability, Hip fracture in elderly, Treadmill

Outcome measures

Primary outcome

Measures of balance, gait and mobility include the main study parameters. The Performance Oriented Mobility Assessment (POMA), a widely used tool for assessing mobility and fall risk in older people, is the main outcome measure in the current study.

Secondary outcome

Secondary study parameters are fall incidence and fear of falling.

Study description

Background summary

Thirty percent of all community-living people over 65 years of age fall each year and fall incidence is even higher in older populations in nursing, rehabilitation and hospital care facilities and in elderly who previously experienced an injurious fall. Most falls are caused by trips and slips during walking and often external factors, like obstacles, are involved. Gait-related falls are thus very common events in elderly and put a large strain on the health and well-being of older adults.
Safe gait requires continuous stepadjustments in order to, for example, negotiate in uneven terrain or to avoid obstacles. Earlier research reported that the ability to adjust gait during walking is often impaired in elderly.
C-Mill training is specifically developed to practice stepadjustments during walking. The effectiveness of C-Mill training, i.e. treadmill walking with a specific emphasis on functional walking ability via constant and irregular gait modulations, obstacle crossing and speeding-up and slowing-down, on walking ability, fall incidence and fear of falling has not been studied thus far

Study objective

The main objective of this study is to examine the effectiveness of C-Mill training over other training for improving walking ability in elderly recovering from a fall-related hip fracture. Secondary objective is to examine the effectiveness of C-Mill training, compared to other training, for reducing fall incidence and fear of falling

Study design

The current study regards a single-blind randomized controlled trial.

Intervention

Walking ability, fall incidence and fear of falling in a group of participants receiving 6 weeks of C-Mill training, will be compared with that of two control groups receiving either 6 weeks of dose-matched treadmill walking without a focus on training gait adjustments or dose-matched conventional physiotherapy. C-Mill training and regular treadmill walking are provided 2 or 3 times per week in groups of 2 patients for 40 minutes and are supplemented with conventional physiotherapy to the frequency of 5 times per week. The control group receiving conventional physiotherapy is only provided with conventional physiotherapy with a frequency of 5 times per week as well.

Study burden and risks

In order to reduce fall incidence in the elderly, it is import to gather evidence on the effectiveness of intervention programs and the underlying mechanisms.
The risks of participating in the current study are considered to be very low. Patients of Solis Zorggroep have already been provided with regular treadmill walking and C-Mill therapy in addition to conventional therapy. Thus, beside randomisation little will change in terms of provided therapy.
Measures of walking ability performed in the current study will be conducted as part of regular therapy, thus require no extra time of the participant. Completing various questionnaires during pre-intervention, post-intervention and retention assessments after 1 and 12 months follow up requires 30 - 50 minutes of extra time of the participant. Reporting fall incidence requires maximal 5 minutes per day for a period of one year.
In short, the only burden of participating in the current study is the time investment. That is, participation requires 4 times 30 - 50 minutes and maximal 5 minutes per day for a period of one year.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. Fall related hip fracture
2. Age * 65 years
3. Functional Ambulation Category * 2
4. Expected duration of therapy: * 6 weeks
5. Simple instructions must be understood and executed

Exclusion criteria

1. Patient may not bear weight on the leg
2. Moderate or severe cognitive impairment (a score below 18 at the Mini Mental State Examination)
3. Severe visual deficits
4. Contraindication to physical activity
5. Activity tolerance below 40 minutes with rest intervals

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	20-01-2012
Enrollment:	120
Type:	Actual

Ethics review

Approved WMO Date:	05-12-2011
Application type:	First submission
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 26710

Source: NTR
Title:

In other registers

Register	ID
CCMO	NL37842.029.11
OMON	NL-OMON26710