# Effectiveness of C-Mill training following hip fracture.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

# **Summary**

## ID

NL-OMON26710

Source NTR

**Brief title** FARE

#### **Health condition**

Elderly, hip fracture, falling, gait adaptability Ouderen, heupfractuur, vallen, loopspecifiek aanpassingsvermogen

## **Sponsors and support**

**Primary sponsor:** - Research Institute MOVE, Faculty of Human Movement Sciences, VU University Amsterdam, The Netherlands

- Amsterdam Rehabilitation Research Center | Reade, Amsterdam, The Netherlands **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

### **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. Other measurements include

- 1. Functional Ambulation Category (FAC) Score;
- 2. Elderly Mobility Scale (EMS);
- 3. Nottingham Extended Activities of Daily Living (NEADL);
- 4. Hip Disability and Ostheoarthrisis Score (HOOS);
- 5. 10m walk test (10MWT);
- 6. 10m walk test with cognitive dual task;
- 7. 10m walk test with obstacle avoidance;
- 8. Timed Up and Go (TUG);
- 9. Trail Making Test (TMT).

#### Secondary outcome

Secondary study parameters are fall incidence and fear of falling. Fall incidence is monitored monthly post intervention, for a period of one year. Fear of falling is assessed using the Falls Efficacy Scale-International (FES-I).

# **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 step adjustments 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 slowingdown, on walking ability, fall incidence and fear of falling has not been studied thus far.

The aim 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.

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 dosematched conventional physiotherapy. It is hypothesized that C-Mill training is superior to regular treadmill walking and conventional physiotherapy in improving walking ability and reducing fall incidence and fear of falling.

#### **Study objective**

Falls are common in elderly and often result in adverse consequences. 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 slowingdown, on walking ability, fall incidence and fear of falling has not been studied thus far.

It is hypothesized that C-Mill training is superior to regular treadmill walking and conventional physiotherapy in improving walking ability and reducing fall incidence and fear of falling in elderly residing in inpatient rehabilitation care after a fall-related hip fracture.

#### Study design

- 1. Pre-intervention (week 1);
- 2. Post intervention (week 7);
- 3. Retention (4 weeks post-intervention);
- 4. 12 month follow-up;
- 5. Fall incidence is monitored monthly for a period of 1 year.

#### Intervention

1. C-Mill training, i.e. treadmill training with a specific emphasis on training gait adaptability: 2-3 times a week 40 minutes in groups of 2 patients for 6 consecutive weeks. The C-Mill

training sessions are supplemented with conventional physiotherapy to a frequency of 5 times a week;

2. Regular treadmill training : 2-3 times a week 40 minutes in groups of 2 patients for 6 consecutive weeks. Treadmill training sessions are supplemented with conventional physiotherapy to a frequency of 5 times a week;

3. Control group: Conventional physiotherapy, 5 times a week for 6 consecutive weeks.

Dose-matched control groups:

C-Mill and treadmill training sessions replace a similar dose of conventional therapy to create dose-matched control groups, i.e. all groups receive therapy with equal duration and frequency.

# Contacts

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# **Eligibility criteria**

## **Inclusion criteria**

1. Fall related hip fracture;

2. Age > 65 years;

- 3. FAC > 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

## Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	16-01-2012
Enrollment:	120
Туре:	Anticipated

# **Ethics review**

Positive opinionDate:03-01-2Application type:First sull

03-01-2012 First submission

# **Study registrations**

## Followed up by the following (possibly more current) registration

ID: 35571 Bron: ToetsingOnline Titel:

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

No registrations found.

# In other registers

Register	ID
NTR-new	NL3074
NTR-old	NTR3222
ССМО	NL37842.029.11
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON35571

# **Study results**

Summary results N/A