# A randomised controlled trial to improve outcomes of hip fracture patients with fear of falling in geriatric rehabilitation

No registrations found.

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| **Ethical review** | Positive opinion |
| **Status** | Recruiting |
| **Health condition type** | - |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON20252

**Source**
NTR

**Brief title**
FIT-HIP

**Health condition**

- Fear of falling (valangst)
- Hip fracture (heupfractuur)
- Geriatric rehabilitation (geriatrische revalidatie)

### Sponsors and support

**Primary sponsor:** Leiden University Medical Center (LUMC)
Department of Public Health and Primary Care (PHEG)
**Source(s) of monetary or material Support:** ZonMw (as part of the program "Huisartsgeneeskunde en Ouderengeneeskunde")
Project number: 839120004

### Intervention

## Outcome measures

### Primary outcome

1.Mean difference in The Tinetti Performance Oriented Mobility Assessment (POMA) score at discharge from GR (or at a maximum of 3 months of admittance to GR), compared between FIT-HIP intervention and usual care.
The POMA is a measure of mobility function (gait and balance).

2. Mean difference in the Falls Efficacy Scale International (FES-I) score at discharge from GR (or at a maximum of 3 months of admittance to GR), compared between FIT-HIP intervention and usual care. The FES-I is a measure of fear of falling.

### Secondary outcome

A. Effect evaluation:

Mean differences for the following parameters at discharge from GR will be compared between FIT-HIP intervention and usual care:

1. Functional status (Barthel index, Functional Ambulation Categories). Time points: discharge. Follow up 1 and 2 (Barthel index).

2. Quality of life (EuroQOL five dimensions questionnaire).
Time points: discharge, follow up 1 and 2.

Also the following parameters will be compared between FIT-HIP intervention and usual care:

3. Number of falls (Fall calendar). Time points: discharge, follow up 1 and 2.

4. Mortality rate.

5. Discharge destination after rehabilitation. Time point: discharge.

(“Home” = living address prior to the fracture. Any other discharge destination is labelled as “other”)

6. Participation after discharge from GR (Utrechtse Schaal voor Evaluatie van Revalidatie – Participatie). Time points: follow up 1 and 2.

B. Process evaluation
In accordance with the theory of Saunders and using a mixed-method approach (self-administered questionnaire and qualitative group interviews), fidelity; completeness; exposure; satisfaction; reach; recruitment and context will be evaluated as part of the process evaluation.

C. Economic evaluation
The economic evaluation consists of a cost analysis and a cost-utility analysis, both with a six-month time horizon after discharge from GR. Costs will be measured from a healthcare perspective. In the cost-utility analysis, the difference in healthcare costs between the strategies will be compared to the difference in Quality-Adjusted Life Years (QALYs, calculated using the Dutch EQ-5D tariff and the visual analogue scale for health). Estimated healthcare costs will include the costs of the FIT-HIP intervention (estimated from the study registration) and other healthcare utilization (estimated using quarterly questionnaires filled out by the patients). Other healthcare utilization will include general practitioners, other consultations, home care, informal care, hospitalization, and residential care. A cost-price analysis will be performed for the FIT-HIP intervention; other healthcare will be valued using standard prices.

# Study description

**Background summary**

Rationale: Annually in the Netherlands 15.000 elderly patients (55 years or older) are admitted to hospital because of a hip fracture. Of these patients, approximately 3500-5000 are discharged to a skilled nursing home to take part in an inpatient geriatric rehabilitation program (GR). The functional prognosis after a hip fracture is poor with a 1 year mortality rate of 20-30%. A great deal of the patients experience permanent functional disability, with only 40% recovering to their pre-fracture functional state. Factors that influence functional outcome are pre-fracture functional state (activities in daily living and walking function), age, sex, cognitive function, depression and fear of falling. Fear of falling possibly has a greater effect on functional outcome than pain or depression. Currently there are no programs known available aimed at reducing fear of falling among hip fracture patients admitted to geriatric rehabilitation units.

Objective: To determine the effects, feasibility and costs of a multi-component cognitive behavioural intervention for reducing fear of falling and associated activity restriction in hip fracture patients admitted for geriatric rehabilitation.

Study design: Cluster randomised controlled trial, with blinding of patients and outcome assessors.

Study population: Hip fracture patients aged 65 years or older, admitted to a geriatric rehabilitation unit for rehabilitation.
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Main exclusion criteria: factors interfering with learnability (diagnosis of dementia or score on the 'hetero-anamnesis list cognition' > 1, suggesting pre-morbid cognitive problems, major psychiatric disease, insufficient mastery of Dutch language), limited life expectancy, patients with a pathological hip fracture and patients with a pre-fracture Barthelindex score < 15.

Intervention: The control group receives care as usual, as embedded in the care pathway geriatric rehabilitation for hip fracture patients. The intervention group receives the FIT-HIP intervention integrated in the usual care. The FIT-HIP intervention consists of various elements of cognitive behaviour therapy (guided exposure, psycho-education, cognitive restructuring and relapse prevention). This will be combined with exercise training in the physiotherapy sessions.

Main study parameters/endpoints:
Effect evaluation: Reduction in the fear of falling, measured with the Falls Efficacy Scale International (FES-I). Improvement in mobility measured by the Tinetti Performance Oriented Mobility Assessment (POMA).
Process evaluation: Within the framework of the process evaluation, fidelity; completeness; exposure; satisfaction; reach; recruitment and context will be evaluated by quantitative and qualitative analysis.

Economic evaluation: Cost analysis (from a healthcare perspective) and cost-utility analysis (comparing healthcare costs to Quality-Adjusted Life Years).

**Study objective**

Treatment of fear of falling in hip fracture patients in GR, using the FIT-HIP intervention, will lead to reduction of fear of falling and therefore to an improvement of mobility function (gait and balance), in comparison to patients with fear of falling who do not receive this treatment.

**Study design**

- Baseline measurements: first week of admission to GR

- Discharge measurements: last week of admission to GR

- Follow up 1: 3 months after discharge from GR

- Follow up 2: 6 months after discharge from GR

**Intervention**

The control group receives care as usual, as embedded in the care pathway geriatric rehabilitation for hip fracture patients. The intervention group receives the FIT-HIP intervention integrated in the usual care. The FIT-HIP intervention consists of various elements of cognitive behaviour therapy (guided exposure, psycho-education, cognitive restructuring, relapse prevention). This will be combined with exercise training in the physiotherapy sessions.

# Contacts

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# Eligibility criteria

## Inclusion criteria

Main inclusion criteria:

- Aged 65 years or older

- Admitted to a geriatric rehabilitation (GR) unit for rehabilitation due to a hip fracture

- Concerned to fall. This is measured by the one item fear of falling question (answering ‘positively’ in the category sometimes, often or very often)

## Exclusion criteria

- The patient has a condition interfering with learning ability, such as:

1. A diagnosis of dementia or score on the 'hetero-anamnesis list cognition' > 1, suggesting pre-morbid cognitive problems

2. A major psychiatric disease

3. Insufficient mastery of Dutch language

- The patient has a limited life expectancy

- The patient has a pathological hip fracture

- Pre-fracture Barthel-index score < 15 (as a measure of ADL dependency)

# Study design

## Design

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|---|---|
| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Double blinded (masking used) |
| Control: | N/A , unknown |

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 09-03-2016 |
| Enrollment: | 165 |
| Type: | Anticipated |

## Ethics review

Positive opinion

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| Date: | 07-03-2016 |
| Application type: | First submission |

## Study registrations

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

No registrations found.

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

No registrations found.

### In other registers

| Register | ID |
|---|---|
| NTR-new | NL5573 |
| NTR-old | NTR5695 |
| Other | 839120004 : ZonMW |

## Study results