

Fear of Falling Intervention in Hip Fracture Geriatric Rehabilitation: a Cluster Randomised Controlled Trial

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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.

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

Summary

ID

NL-OMON43792

Source

ToetsingOnline

Brief title

FIT-HIP

Condition

- Other condition
- Anxiety disorders and symptoms

Synonym

concerned to fall, fear of falling

Health condition

orthopedisch (heupfractuur) en als toevoeging bij psychische stoornis: verandering in lichamelijke activiteit

Research involving

Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum, afdeling Public Health en Eerstelijngeneeskunde (PHEG)

Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: fear of falling, geriatrics, hip fracture, rehabilitation

Outcome measures

Primary outcome

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: This consists of a cost-effectiveness analysis. The health

care costs consist of intervention costs and general health care costs such as

costs for the rehabilitation, hospital administrations, use of physiotherapy

and home care.

Secondary outcome

- Functional status (activities of daily living; measured with the Barthel

Index and Functional Ambulation Categories),

- Participation (Utrechtse Schaal voor de Evaluatie van Revalidatie-

Participatie- subscale/ question 2)

- Quality of life (EQ5D)

- Fall frequency (measured by self registration fall calendars)
- Discharge destination

Study description

Background summary

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 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.

Study 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

Blinded cluster randomised controlled trial.

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 and cognitive restructuring). This will be combined with exercise training in the physiotherapy sessions.

Study burden and risks

The FIT-HIP intervention consists of cognitive behavioural therapy and is not associated with additional health risk for the patient. Potential benefits of the FIT-HIP intervention are reduction of fear of falling and a better functional recovery (gait / mobility) during the rehabilitation. The burden of participation is time: approximately 75 minutes at admission to and at discharge from geriatric rehabilitation (interview/self administered questionnaires and functional testing of mobility). The follow up consists of a self-administered questionnaire (duration +/- 35 min), sent to the home address by post, two times after discharge from geriatric rehabilitation. In a selection of patients (N=20) from the intervention group, a qualitative group interview will be performed to assess feasibility of the intervention (duration +/- 1 hour).

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

- Aged 65 years or older
- Admitted to a geriatric rehabilitation 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

Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	09-03-2016
Enrollment:	150
Type:	Actual

Ethics review

Approved WMO

Date: 09-09-2015

Application type: First submission

Review commission: METC Leiden-Den Haag-Delft (Leiden)
metc-ldd@lumc.nl

Approved WMO

Date: 26-01-2016

Application type: Amendment

Review commission: METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO

Date: 28-01-2016

Application type: Amendment

Review commission: METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO

Date: 23-02-2016

Application type: Amendment

Review commission: METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO

Date: 23-03-2016

Application type: Amendment

Review commission: METC Leiden-Den Haag-Delft (Leiden)
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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
CCMO	NL54171.058.15