

# SO-HIP study

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Recruiting
<b>Health condition type</b>	-
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON24960

### Source

Nationaal Trial Register

### Health condition

hip fracture, fear of falling

## Sponsors and support

**Primary sponsor:** Academic Medical Center (AMC), University of Amsterdam (UVA), The Netherlands

**Source(s) of monetary or material Support:** Fonds Nuts OHRA  
NWO

## Intervention

## Outcome measures

### Primary outcome

patients' perceived daily functioning, assessed with the performance rating of the Canadian Occupational Performance Measure (COPM)

### Secondary outcome

level of physical activity and independence in activities of daily living, the level of sense of safety, fear of falling, self rated health and the use of health care resources at one, three and six months after the start of the rehabilitation

# Study description

## Background summary

Six nursing homes will be randomized in a three-arm stepped wedge cluster randomized trial. All nursing homes will initially provide standard care. At designated time points, nursing homes, successively and in random order, will cross over to the provision of OT and at the next time point, to sensor monitoring-enhanced OT. A total of 360 older individuals, previously living alone in the community, who after a hip fracture were admitted to a geriatric rehabilitation ward for a short-term rehabilitation, will be enrolled.

Individuals in the first intervention group (OTc) will participate in an OT rehabilitation program based on cognitive behavioral therapy (CBT) principles. In the sensor monitoring group, sensor monitoring is added to the OT CBT (OTcsm).

Participants will receive a sensor monitoring system consisting of (i) an activity monitor during nursing home stay, (ii) a sensor monitoring system at home and a (iii) a web-based feedback application. These components will be embedded in the OT. The OT consists of a weekly session with an occupational therapist during the nursing home stay followed by four home visits and four telephone consultations. The primary outcome is patient-perceived daily functioning at 6 months, assessed using the Canadian Occupational Performance Measure (COPM).

## Study objective

After hip fracture, 20-90% of older individuals experience new disabilities in activities of daily living (ADL) that affect their ability to remain living independently at home. Fear of falling hinder older persons to perform ADLs needed for good recovery. Increasing self-efficacy beliefs can reduce fear of falling and can help increase physical activity needed to recover. By goal setting, better insight in the ADLs of older persons performance an recovery after hip fracture might be enhanced. Sensor monitoring can be used as a coaching tool. Currently it is unclear how effective sensor monitoring embedded in an occupational therapist (OT)rehabilitation program is in the recovery of ADLs compared by coaching by an OT alone or care as usual.

We expect that the use of sensor monitoring, embedded in an OT-rehabilitation program in nursing homes and a follow-up at the home of the participant leads to more improvement in ADLs of older persons after a hip fracture compared to the OT coaching without sensor monitoring and usual care. This results in enhanced participation in daily activities, improvement of sense of safety and improved self-rated health related quality of life.

## Study design

four moments of measurements for all patients:

- first week nursing home (T0)

- before discharge from the nursing home to home (T1)
- T3, post- intervention, 4 months after the start of the geriatric rehabilitation
- 6 months after the start of the geriatric rehabilitation (T6)

## **Intervention**

1. care as usual (multidisciplinary rehabilitation)
2. care as usual and coaching by an OT using cognitive behavioral treatment principles concerning falls
3. care as usual and sensor monitoring added to the coaching by an OT

## **Contacts**

### **Public**

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## **Eligibility criteria**

### **Inclusion criteria**

Patients are:

- admitted to a geriatric rehabilitation ward in a nursing home after hip surgery
- 65 years and older

- living alone in the community or in a senior residence
- have a minimal-mental state examination of 15 or higher
- have an indication for a short term rehabilitation

## Exclusion criteria

- are terminally ill
- are waiting for a permanent place in a nursing home
- do not give informed consent

## Study design

### Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

### Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-04-2016
Enrollment:	280
Type:	Anticipated

## Ethics review

Positive opinion	
Date:	01-04-2016
Application type:	First submission

## Study registrations

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

ID: 43760

Bron: ToetsingOnline

Titel:

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

No registrations found.

### In other registers

Register	ID
NTR-new	NL5610
NTR-old	NTR5716
CCMO	NL54132.018.15
OMON	NL-OMON43760

## Study results