The SO-HIP study, Effectiveness of sensor monitoring in an occupational therapy rehabilitation program for older persons after hip fracture: design of a three-arm stepped wedge cluster randomized trial

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

Summary

ID

NL-OMON43760

Source
ToetsingOnline

Brief title
The SO-HIP study

Condition

- Fractures

Synonym
physical and daily functioning after hip fracture

Research involving

Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: fonds nuts ohra; 150.000 euro

Intervention

Keyword: Hip fracture, Occupational Therapy, Sensor monitoring, Stepped wedge cluster randomized trial

Outcome measures

Primary outcome

The primary outcome is patients* perceived daily functioning, assessed with the performance rating of the Canadian Occupational Performance Measure (COPM). The primary analysis for effectiveness will be the between-group differences of the COPM rating at 6 months after randomization.

Secondary outcome

The secondary outcome measures are the 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 postoperatively.

Study description

Background summary

After hip fracture, 20-90% of older persons experience new disabilities in activities of daily living (ADL) that affect their ability to remain living independently at home. Fear of falling hinders 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 and recovery

after hip fracture might be enhanced. New technologies such as 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 to coaching by an OT alone or care as usual

Study objective

The primary objective is to study the effect of sensor monitoring embedded in an OT rehabilitation program for older persons after hip fracture on recovery of daily functioning, 6 months after the start of rehabilitation, as compared to coaching by an OT without sensor monitoring and care as usual. The secondary objectives are:
-to investigate the effect of the intervention on physical activities and activities of daily living, 1, 3 and 6 months after the start of the rehabilitation.
-to investigate the effect of the intervention on sense of safety, fear of falling and health-related quality of life, 1, 3 and 6 months after the start of the rehabilitation.
-to investigate the effect of the intervention on the use of healthcare resources 1, 3 and 6 months after the start of the rehabilitation.

Study design

A sequential double hybrid stepped wedge cluster randomized trial with the nursing homes (clusters) as the units of randomization. All clusters will start with the usual care at the beginning of the study. At each time point (after three months), a cluster crosses over from usual care to coaching by an OT and at the next time point to sensor monitoring embedded in an OT coaching-program. The study will be conducted in two separate phases: a feasibility study and a main study.
Randomization: Nursing homes will be randomized via web-based central randomization, and determines the sequence in which a nursing home will start the three interventions. Each sequence contains all three interventions, albeit with different durations.

Intervention

All patients receive multidisciplinary rehabilitation as care as usual. On top of the usual care, patients in the first intervention group receive an OT rehabilitation program, using cognitive behavioral treatment (CBT) principles concerning falls consisting of five steps: 1) to educate being physical active and to stimulate physical activity and exercises, 2) to ascertain the amount of movement and physical activity during the day and give feedback 3) to set realistic goals for the performance of daily activities 4) to plan these activities and 5) to evaluate progress. The coaching consists of a weekly

session with an occupational therapist during nursing home stay followed by 4 home visits and 4 telephone consultations. In the sensor monitoring group, sensor monitoring is added to the OT coaching program. Patients receive a sensor monitoring system consisting of (i) a wearable activity monitor during the stay in the nursing home, (ii) a wireless sensor monitoring system at home and a (iii) a web-based feedback application. These components will be embedded in the coaching program. This coaching approach too, consists of a weekly session with an occupational therapist during nursing home stay followed by 4 home visits and 4 telephone consultations
Usual care: Usual care consists of a multidisciplinary rehabilitation program as per nursing home, by a multidisciplinary rehabilitation team. The focus of the rehabilitation will be PT. If needed, some of the patients receive rehabilitation at home or at an outside rehabilitation ward of the nursing home. The amount of OT given by the nursing homes will be different varying from none to a few sessions.
Follow up: Patients are followed-up until six months after the start of geriatric rehabilitation in a nursing home

Study burden and risks

In the sensor monitoring group, sensor monitoring is added to the OT coaching program. Patients receive a sensor monitoring system consisting of (i) a wearable activity monitor during the stay in the nursing home, (ii) a wireless sensor monitoring system at home and a (iii) a web-based feedback application. This coaching approach too, consists of a weekly session with an occupational therapist during nursing home stay followed by 4 home visits and 4 telephone consultations.

There are four moments of measurements for all participants: at baseline, before discharge nursing home to home and three and six months after start of the rehabilitation in the nursing home.
The outcome measurements are non-invasive and the last two measurements will take place at the patient*s home.
There are no foreseeable risks associated with the intervention or measurements for the study.

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) admitted to a nursing home after hip fracture surgery;
2) 65 years and older;
3) have an indication for a short -term rehabilitation in a nursing home;
4) living alone in the community or in a senior recidence;
5) have approval from the attending nursing home physician for inclusion.

Exclusion criteria

1) are terminally ill;
2) are waiting for a permanent place in a nursing home
3) do not give informed consent.
4) have severe cognitive impairment (MMSE score < 15)

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	20-10-2015
Enrollment:	360
Type:	Actual

Medical products/devices used

Generic name:	sensor monitoring system
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	19-10-2015
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	22-04-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	07-06-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	08-06-2016

Application type:	Amendment
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: 24960
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL54132.018.15
OMON	NL-OMON24960