

Combined clinical and home rehabilitation for stroke patients: a pilotstudy into the implementation of a new treatment protocol.

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The objective of the pilotstudy is to develop and evaluate a new combined clinical and home rehabilitation research protocol for stroke patients. This pilotstudy will focus on the (re)learning of ADL and mobility skills. Important questions are:-Is...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON30599

Source

ToetsingOnline

Brief title

Combined clinical and home rehabilitation for stroke patients

Condition

- Other condition

Synonym

cerebrovascular accident, stroke

Health condition

neurologische aandoeningen: nl cerebro vasculair accident (CVA)

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen

Source(s) of monetary or material Support: Stichting Beatrixoord

Intervention

Keyword: clinical rehabilitation, home care services, rehabilitation, stroke

Outcome measures

Primary outcome

Primary study parameters are activities of daily living (ADL) and mobility.

Secondary outcome

Secondary study parameters are length of stay in the rehabilitation centre, mood, fatigue, stress and satisfaction.

Study description

Background summary

Stroke patients often experience difficulties in transferring skills acquired in the clinical setting to their home-setting. Therefore context-specific and task-specific training is very important.

Simulation of the home-setting in the rehabilitation centre appears to be difficult. Research has demonstrated that compared with conventional care, early supported discharge services are associated to be effective to independency concerning ADL and mobility.

For some patients early supported discharge is not possible because of the amount of care and therapy that is needed. These patients are considered for clinical rehabilitation in the CvR UMCG location Beatrixoord. To be sure that these patients will be able to profit by the benefits of home rehabilitation, we will execute a pilotstudy which consists of a combination of clinical and home rehabilitation for stroke patients.

It might be possible that a combination of clinical and home rehabilitation will provide earlier independence concerning ADL and mobility as compared with clinical rehabilitation. A consequence could be a reduction in length of stay in the rehabilitation centre and lower costs.

Study objective

The objective of the pilotstudy is to develop and evaluate a new combined clinical and home rehabilitation research protocol for stroke patients. This pilotstudy will focus on the (re)learning of ADL and mobility skills.

Important questions are:

- Is it possible to optimize the contents of the combined clinical and home-based rehabilitation program?
- Which are the similarities and differences between the contents and the theoretical starting points of the new combined rehabilitation program and the care-as-usual?
- Is it possible to sharpen the selection criteria?
- Which instruments can be used to objectivate the intended change and possible secondary effects?

If the treatment protocol is useful this pilotstudy will be continued in an RCT.

Study design

A single subject design is used.

Intervention

The intervention consists of a combined clinical and home rehabilitation program for stroke patients. Besides the rehabilitation that is given in the rehabilitation centre, patients will travel two times a week (two times three hours) to their homes for rehabilitation at home. This pilotstudy will focus on the (re)learning of ADL and mobility skills.

Study burden and risks

Compared with the care-as-usual, patients that will participate in the pilotstudy will receive rehabilitation at home for two days a week. This could be a burden for the patient but the benefit is that context-specific training is possible this way. To take notice of the fatigue which will arise from travelling by car. patients have to live in a range of twenty kilometres from the CvR UMCG location Beatrixoord.

Only patients that are physically, mentally as well as emotionally capable of being treated at home will be able to participate.

If the patient isn't capable of being treated at home as a result of physical, emotional or mental problems, participation in the pilotstudy will be ended.

As a result of the combined rehabilitation program the partner/ caregiver will be relieved by the stay in the rehabilitation centre because stroke patients often have serious motor and/or cognitive impairments.

Because a part of the rehabilitation takes place in the home setting, the partner can intensively participate during rehabilitation. Home rehabilitation can give a quicker and better insight in the possibilities and limitations of a life with a partner suffering from stroke. For the patient and his/her partner, the change from staying in the rehabilitation centre to discharge at home will be easier. The moments when the patient will be tested and also the number of instruments that are used in the pilotstudy hardly differ from the care-as-usual.

Contacts

Public

Universitair Medisch Centrum Groningen

Dilgtweg 5
9751 ND
Nederland

Scientific

Universitair Medisch Centrum Groningen

Dilgtweg 5
9751 ND
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- The patient has had a stroke.
- It's the first stroke.

- The patient is at least 18 years and capacitate and competent.
- The patient is staying in the rehabilitation centre and receives clinical rehabilitation.
- The medical situation of the patient is stable.
- The patient can pay attention to a task.
- The patient is able to sit for at least three hours in a chair.
- The patient is able to make (eventually with some help) a transfer into en out of a car.
- It is possible to move into and through the house with a wheelchair.
- Before the stroke the patient was functioning independent (in the domain of activities of daily living and mobility).
- The patient (and the partner) is motivated for the combined rehabilitation program.
- The patient lives in a range of twenty kilometres from the CvR UMCG location Beatrixoord.
- The patient can understand a commision (AAT: score $\geq 6-9$).

Exclusion criteria

- The patient isn't motivated for the combined rehabilitation program.
- Discharge to home isn't possible.
- The patient and/or partner can't understand the Dutch language.
- Co-morbity, like a psychiatric disease, a malignant and/or progressive disease.
- The patient isn't able to travel home (mental and physical).
- There are no goals in the domain of ADL and mobility to be worked on at home.

Study design

Design

Study phase:	2
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	12-04-2007
Enrollment:	8
Type:	Actual

Ethics review

Approved WMO

Date: 22-02-2007

Application type: First submission

Review commission: METC Universitair Medisch Centrum Groningen (Groningen)

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	NL16014.042.07