Care4Stroke+ program: Caregiver mediated exercises with e-health support for early supported discharge after acquired brain injury.

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Central nervous system vascular disorders
Study type	Interventional

Summary

ID

NL-OMON41664

Source
ToetsingOnline

Brief title
Care4Stroke+

Condition

- Central nervous system vascular disorders

Synonym
acquired brain injury, stroke

Research involving
Human

Sponsors and support

Primary sponsor: Reade, centrum voor revalidatie en reumatologie

Source(s) of monetary or material Support: Ministerie van OC&W,EvoCare,ZonMW

Intervention

Keyword: acquired brain injury, caregiver, intervention, training

Outcome measures

Primary outcome

Primary measurements of outcome: 1) Length of Stay; 2) self-reported health-status with the Stroke Impact Scale (SIS version 3.0) and 3) Self-Efficacy for patient (Sef-Efficacy for Symptom Management Scal (SESx)) and caregiver (Revised Scale for Caregiving Self-Efficacy (RSCSE)).

Secondary outcome

Secondary outcomes for included stroke patients are EuroQol-5D (EQ-5D), the Barthel Index, Rivermead Mobility Index, Berg Balance Scale, 5 meter walking speed, 6 minute walking test, Timed Up and Go Test, the Motricity Index (leg), The Fugl-Meyer assessment (leg), Nottingham Extended Activities of Daily Living and modified Rankin Scale. In order to track the daily activity, patients will wear a wireless activity monitor on the wrist one week before and after the intervention. In addition, patients keep a diary to record adherence to the exercise program and emerging complications. Caregiver burden will be evaluated with the Caregiver Strain Index and Carer Quality of Life Index. For patients and caregivers the Hospital Anxiety and Depression Scale, Fatigue Severity Scale, Family Assessment Device and Personal Opinion Questionnaire for empowerment will be used. In addition each couple will use a cost diary.

Study description

Background summary

Several systematic reviews have indicated that additional exercise therapy and repetitive task training have a significant effect on functional outcome after brain injury. Guidelines therefore conclude that patients in a rehabilitation setting should have the opportunity to get an increase of intensity of therapy. At this moment resources in rehabilitation facilities are not sufficient to meet these recommendations. A new method could be to involve caregivers (partner, family, friends) in exercise training. Previous studies suggest that this form of exercises done with a caregiver can lead to a better functional outcome for the patient and less strain for the caregiver. A critical part will be safety, adherence of the patient and caregiver and continuing support, for which innovative e-health and structured tele-rehabilitation services could be used.
In addition, a recent meta-analysis has shown that early supported discharge with additional services in the community is beneficial for optimizing the transition from the rehabilitation setting to the home situation and is cost-effective by reducing the length of stay of inpatient services, acknowledging that inpatient rehabilitation accounted for about 44% of all care costs.

Study objective

The primary aim of this study is to evaluate the feasibility, clinical effectiveness and cost effectiveness of a caregiver mediated exercises programme combined with e-health services (CARE4STROKE+) to improve self-reported health status and reduce the length of stay and costs by allowing early supported discharge of stroke patients to their own home setting.

Study design

The present study has a randomized controlled trial design.

Intervention

Participants will be allocated to either 8 weeks of the CARE4STROKE+ programme in addition to usual care or to 8 weeks of usual care.

Study burden and risks

Participants in the intervention group get a surplus of 150 minutes of exercise training a week; Caregivers will be involved and will need to allocate time to the programme as well. Care is taken to assure safe performance of the

exercises. This will be accomplished by e-health and tele-rehabilitation services and safety instructions and close guidance and coaching of a therapist. The control group will have no additional benefit or risks. Assessments will take place at baseline, after the intervention and at twelve weeks follow up. They consist of questionnaires and tests, taking approximately two hours per assessment.

Contacts

Public
Reade, centrum voor revalidatie en reumatologie

Overtoom 283
Amsterdam 1054HW
NL
Scientific
Reade, centrum voor revalidatie en reumatologie

Overtoom 283
Amsterdam 1054HW
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Patient:
1) 18 years or older
2) written informed consent
3) able to understand the Dutch language (on sufficient level to understand instructions and

complete the questionnaires)
4) knowing and able to appoint a caregiver who he/she wants to participate in the programme (with a maximum of two caregivers)
5) living independently before the acquired brain injury
6) planned to be discharged home
7) being able to follow instructions (a MMSE score > 18 points)
8) Functional Ambulation Score (FAC) < 5
9) a score of <11 on the domain 'depression' on the Hospital Anxiety and Depression Scale (HADS)
10) Motivated for CME
11) Diagnosis group of ABI caused by stroke, subarachnoid haemorrhage, trauma, status after cardiac arrest, encephalitis or postoperative status after brain tumor.Caregiver:
1) 18 years or older
2) written informed consent
3) able to understand the Dutch language (on sufficient level to understand instructions and complete the questionnaires)
4) sufficiently motivated for CME
5) a score of <11 on the domain 'depression' on the Hospital Anxiety and Depression Scale (HADS)
6) medically stable and physically able to perform the exercises together with the patient.

Exclusion criteria

For patient and caregiver:
Serious comorbidity which interferes with participation

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-02-2013
Enrollment:	176
Type:	Actual

Ethics review

Approved WMO Date:	01-11-2012
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	28-01-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	04-06-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	20-11-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	15-04-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	06-05-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	13-10-2015
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: 23243
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL34618.048.12
Other	TC=5055