CAREgiver participation to improve intensity of training after stroke, a pilot study of a new intervention.

No registrations found.

Ethical review	Positive opinion
Status	Suspended
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23243

Source
NTR

Brief title
CARE4STROKE pilot

Health condition

Stroke, Caregiver mediated exercises,
beroerte, oefenen met een naaste

Sponsors and support

Primary sponsor: Reade, center for rehabilitation and rheumatology
Source(s) of monetary or material Support: initiator= sponsor

Intervention

Outcome measures

Primary outcome

In this pilot study, we defined outcomes, no primary outcomes. For all outcomes: see section 'secondary outcomes'.

Secondary outcome

For the patient:

1. Mobility, measured by the Rivermead mobility index (RMI);

2. Independence in performing basic activities of daily living, measured by the Barthel index (BI);

3. Walking ability, assessed with the ten metre walking test and timed up and go test (TUG);

4. Extended Activities of daily living, measured by the Nottingham extended ADL (NEADL);

5. Functional outcome, measured by Modified Rankin Scale (MRS) dichotomised to good outcome (0-2) or poor outcome (3-6);

6. Selectivity lower extremity, assessed with the Fugl Meyer (FM) lower extremity;

7. Strength of the lower limb, assessed with the Motricity Index (MI);

8. Balance, assessed with the Berg Balance Scale (BBS);

9. Length of stay in the rehabilitation center, defined as moment of admittance – moment of possible discharge;

10. Daily (ambulatory) activity in a subgroup of patients, measured by an activity monitor (Activ8, 2M engineering Ltd, Veldhoven) for a week.

For the caregiver:

The experienced strain of the caregiver measured by the Expanded Caregiver strain index. (CSI +).

For both:

1. Amount of (additional) practice done by the couples in the intervention and controlgroup, this will be measured with a diary;

2. Satisfaction with the intervention, measured by purpose-made questionnaires;

3. Registration of participation rates and choice of app/booklet;

4. Emotional functioning, measured with the Hospital Anxiety and Depression Scale (HADS);

5. Fatigue, measured by the fatigue severity scale;

6. Self-efficacy, measured by the general self-efficacy scale;

7. Quality of life, for the patient measured with the Stroke Impact Scale 3.0. (SIS 3.0); For the caregiver measured by the CarerQOL;

8. Problems and side events like falls will be recorded in the diary.

Study description

Background summary

Rationale:

Several systematic reviews have indicated that additional exercise therapy and repetitive task training have a significant effect on functional outcome after stroke. 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 and adherence of the patient and caregiver. For that innovative ICT techniques could be used.

Objective:

The primary aim of this pilot study is to evaluate the feasibility of a caregiver mediated exercises programme combined with ICT support (CARE4STROKE) in patients with stroke. The other aims are to establish the primary measurement for outcome for a future RCT and to investigate the impact of CARE4STROKE on outcome.

Study design:

The present study has a randomized controlled trial design.

Study population:

20 stroke patients admitted in Reade, center for rehabilitation and rheumatology, and their caregivers will participate in this study.

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.

Main study parameters/endpoints:

The study outcomes are for the patient: mobility (Rivermead mobility index); (Extended) Activities of daily life (Barthel index and Nottingham extended ADL); Walking ability (ten meter walk test and timed up and go test); Functional outcome (Modified Rankin Scale); Selective movement lower extremity (Fugl Meyer); Strength lower extremity (Motricity index); Balance (Berg Balance scale); Length of stay in the rehabilitation center and daily (ambulatory) activity in a subgroup of patients (activity monitor). For the caregiver: Experienced strain of the caregiver (expanded caregiver strain index). For both: Amount of (additional) practice (recorded with a diary); Satisfaction (custom-made questionnaires); Registration of participation rates and choice app/ booklet; Emotional functioning (Hospital anxiety and depression scale); Fatigue (fatigue severity scale); Self-efficacy (general self-efficacy scale); Quality of life (patient: stroke impact scale, caregiver: CarerQOL); and report of problems and adverse events (diary).

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

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. There is a slight risk of adverse events like falls, but care is taken to assure safe performance of the exercises. This will be accomplished by safety instructions and close guidance 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.

Study objective

Caregiver mediated exercises next to usual therapy will improve functional outcome for adults with stroke in gait, gait related abilities and ADL
with a reduced length of stay (LOS) when compared to usual care alone. In addition we

hypothesize that this programme leads to increased levels of self-efficacy for patient and caregiver and a reduced caregiver burden.

Study design

Outcome measures will be measured at baseline prior randomization, after the eight week intervention period and at 12 weeks (follow up) by an independent assessor who is not involved in training. Length of stay in the rehabilitation center will be reported at discharge of the patient. Self reports in the diary will take place during the intervention. Satisfaction will be measured at the end of the period and only in the intervention group.

Intervention

The CARE4STROKE programme consists of eight weeks of complementary exercise therapy done with a caregiver, next to the usual therapy. 31 standardized exercises are available, that can be customized per patient and caregiver to the individual situation. These exercises were devised in collaboration with movement scientists and physical therapists and were shown to be feasible and safe in preliminary informal exploratory patient-caregiver try-outs. The exercises can be presented in a book version with photo's and text or in an smartphone/ tablet app with video's and voiceover. Regular reminders to exercise can be given by the app. (see appendix for examples) The exercises are aimed at improving skills related to walking ability like sitting, standing and making transfers, or are supporting exercises to improve mobility, strength and balance. The patient and their caregiver are asked to do the exercises minimally 5 times a week for 30 minutes on at least both weekend days or the equivalent dosage with an adopted schedule. When the intervention is correctly performed patients will have a surplus of 150 minutes of caregiver mediated therapy a week.

Patients and their caregiver will have a weekly session with a trained therapist. In this session, the participating couple will be instructed as to which exercises should be performed safely during the next week and evaluate the exercises done last week. All patients and caregivers will be supported by a handbook with instructions.

The programme starts when the patient is admitted in Reade. When the discharge date of the patient is earlier than the finishing of the programme, the programme continues at home with monitoring from the treating therapist.

The participants in the control group will receive usual care according to the Dutch guidelines for patients with stroke and the Royal Dutch Guidelines of Physical Therapy.

Contacts

Public

Reade
Overtoom 283
J.D.M. Vloothuis
Amsterdam 1054 HW
The Netherlands
+31 (0)20 6071747
Scientific
Reade
Overtoom 283
J.D.M. Vloothuis
Amsterdam 1054 HW
The Netherlands
+31 (0)20 6071747

Eligibility criteria

Inclusion criteria

Inclusion criteria for the 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. Being in the early rehabilitation phase (24 hours- 3 months);

6. Being able to follow instructions (a MMSE score > 23 points);

7. Functional Ambulation Score (FAC) < 5;

8. A score of <11 on the Hospital Anxiety and Depression Scale (HADS).

Inclusion criteria for the 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;

5. A score of <11 on the Hospital Anxiety and Depression Scale (HADS);

6. Medically stable and physically able to perform the exercises together with the patient.

Exclusion criteria

Exclusion criteria for both patient and caregiver will be serious comorbidity which interferes with participation.

To determine suitability of both patient and partner, an intake exercise session together with a trained therapist will be scheduled prior to inclusion. The therapist will check the inclusion/exclusion criteria and judge if the exercises can be done adequately and safely.

Study design

Design

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

Recruitment

NL

Recruitment status:	Suspended
Start date (anticipated):	15-01-2013
Enrollment:	20
Type:	Anticipated

Ethics review

Positive opinion

Date:	28-11-2012
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 41664
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL3581
NTR-old	NTR3739
CCMO	NL34618.048.12
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON41664

Study results

Summary results
N/A