Armed4Stroke: Allied Rehabilitation using caregiver MEDiated Exercises for Stroke

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We hypothesize that the Armed4stroke program will: 1) Increase patients self-reported level of mobility, measured with the Stroke Impact Scale. 2) Smoothen the transition to patients own home situation, which will shorten the length of stay for...

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22043

Bron
NTR

Verkorte titel
Armed4Stroke

Aandoening

stroke, telerehabilitation, caregiver mediated exercises

Ondersteuning

Primaire sponsor: Amsterdam UMC
Overige ondersteuning: Wetenschappelijk College Fysiotherapie, WCF call 2017

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Mobility domain of the Stroke Impact Scale (SIS version 3.0), which measures self-reported health status.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: Several systematic reviews have indicated that additional exercise therapy and repetitive task-oriented training have a significant effect on functional outcome after stroke. Exercise therapy typically focuses on restoring and/or improving motor function, especially recovery of walking ability is an important goal for patients post stroke. Stroke rehabilitation and exercise therapy is typically front loaded, with resources mainly focused on inpatient care. Consequently, stroke survivors and their caregivers experience the transition from inpatient care to the community as a significant hurdle. Support tapers off and the majority of stroke survivors become physically inactive. The Armed4Stroke program is directed at training caregivers as co-therapist to increase the level of exercises at home and to smoothen the transition from inpatient rehabilitation to the community.

Objective: The primary objective of the present study is to assess the added values of using tele-rehabilitation services, combined with caregiver mediated exercises to improve the level of self-reported mobility at home. Secondary objectives are to assess the added value of Armed4Stroke on length of inpatient stay, activities of daily living and psychosocial measures.

Study design: Single-blind randomized controlled trial.
Study population: Stroke patients who follow in- or outpatient rehabilitation.

Intervention: The Armed4Stroke program consists of eight weeks of complementary exercise therapy done with a caregiver, supported by tele-rehabilitation, next to the usual therapy. The couple has regular face-to-face sessions with the physical therapist. The web based tele-rehabilitation system is complementary to the face-to-face support. Through this system, the patient can communicate a-synchronically with the physical therapists. This communication takes place in a messaging environment, which means that communication takes place through the exchange of text messages.

Main study parameters/endpoints: Mobility domain of the self-reported health status following the Stroke Impact Scale (SIS version 3.0).

Doel van het onderzoek

We hypothesize that the Armed4stroke program will:

1) Increase patients self-reported level of mobility, measured with the Stroke Impact Scale.

2) Smoothen the transition to patients own home situation, which will shorten the length of stay for patients who start armed4stroke during clinical rehabilitation.

3) Have a positive influence on the psychosocial measures in terms of anxiety and depression, health-related quality of life and self-efficacy.

Onderzoeksopzet

Outcome measures will be measured at baseline prior to randomization, after the eight week intervention period and again 6 months after randomisation (follow-up) by a blinded assessor who is not involved in training. The BBS, MI and CSI are part of regular clinical practice and results of these tests will be used whenever possible.

Onderzoeksproduct en/of interventie

The Armed4Stroke program consists of eight weeks of complementary exercise therapy done with a caregiver, supported by tele-rehabilitation, next to the usual therapy.

Complementary exercise therapy:

When starting the intervention, the couple will receive a tailor-made exercise program, containing task-specific exercises focusing on gait and gait related activities. The exercise program is progressive in nature and is developed to achieve important milestones for community ambulation, where goals will be based on. The program is supported by videos of the exercise, which are built into a web-based tele-rehabilitation system. The patient and their caregiver are asked to do exercises minimally 5 times a week for 30 minutes. The tele-rehabilitation system also includes exercises that the patient can perform independently. Towards the end of the intervention period, one of the goals should also be to reduce the involvement of the caregiver and increase independency of the patient. The couple has regular face-to-face sessions with the physical therapist. There will be at least 4 face-to-face sessions during the whole intervention period. In these sessions, the exercise program will be adapted according to the progress of the patient and to (adjusted) goals. The face-to-face support will also aim to assist study participants in maintaining motivation to continue the program and to identify and address any barriers to exercise together or alone.

Tele-rehabilitation:

The web based tele-rehabilitation system is complementary to the face-to-face support. Through this system, the patient can communicate a-synchronically with the physical therapists. This communication takes place in a messaging environment, which means that communication takes place through the exchange of text messages. The therapist can use the web-based tele-rehabilitation system to monitor the adherence to the CME. In addition,

the therapist can communicate with the patient and is able to monitor the patient's progress by regularly to asking questions to the patient regarding the exercises that have been done and by giving feedback about the progress. Messages can be sent in which the goals and exercises are repeated to keep the couple motivated.

The participants in the control group will receive usual care according the Royal Dutch Guidelines of Physical Therapy.

Contactpersonen

Publiek

Postbus 58271
Rinske Nijland
Amsterdam 1040 HG
The Netherlands
020-6071931

Wetenschappelijk

Postbus 58271
Rinske Nijland
Amsterdam 1040 HG
The Netherlands
020-6071931

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Inclusion criteria for the patient will be:

1) < 3 months after stroke

2) 18 years or older

3) Written informed consent

4) Able to understand the Dutch language (on sufficient level to understand instructions and complete the questionnaires)

5) Knowing and able to appoint a caregiver who he/she wants to participate in the programme (with a maximum of two caregivers)

6) Living independently before the stroke

7) Living at home or planned to be discharged home

8) Being able to follow instructions (a MoCA score > 20 points)

9) Sufficiently motivated for CME

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 for CME

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Exclusion criteria for both patient and caregiver will be a serious comorbidity that interferes with participation. To determine suitability of patient and partner, one exercise session with a trained therapist will be scheduled prior randomisation. The therapist will check the inclusion/exclusion criteria and judge if the exercises can be done adequately and safely.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel

Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	02-09-2019
Aantal proefpersonen:	72
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	11-12-2018
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7422
NTR-old	NTR7664

Register	ID
Ander register	NL67357.029.18 METC : 858001102 WCF

Resultaten

Samenvatting resultaten
N/A