Arm support treatment in the early phase after stroke.

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

Samenvatting

ID

NL-OMON26063

Bron
Nationaal Trial Register

Verkorte titel
EarlyArmSupport

Aandoening

stroke, cerebrovascular accident
beroerte, cerebrovasculair accident

Ondersteuning

Primaire sponsor: Roessingh Research and Development
Overige ondersteuning: Innovatiegelden van Revalidatie Nederland

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Before and after training changes in overall arm function (Fugl-Meyer assessment, Stroke

Upper Limb Capacity Scale) and work area are quantified.

Toelichting onderzoek

Achtergrond van het onderzoek

After a stroke, many patients suffer from an impaired motor task performance of the upper extremity. Optimal restoration of arm and hand function is important for stroke patients to independently perform activities of daily living. To stimulate restoration of arm function after stroke, intensive and task-specific training is essential. To implement this, the application of robotic devices in rehabilitation is promising. Especially, active movements may be facilitated by the application of arm support. One of the biggest advantages of arm support using a robotic device is currently the possibility to 'automate' treatment (a therapist can treat multiple patients simultaneously) so that the productivity of health care can be increased and the costs can be reduced. Contemporary research on this has focused on patients in the chronic phase after stroke. However, it is likely that especially patients in the sub-acute phase after stroke benefit from this application, since recovery processes can be stimulated directly.The purpose of this study is to compare the effect of arm support therapy with conventional therapy, directed at arm function in stroke patients in the sub-acute phase, with regard to both motor aspects and user experiences.Multicenter, randomized intervention study with evaluation measurements before and after 6 weeks of reach training. 70 stroke patients in the sub-acute phase (between 1 and 12 weeks post-stroke) from 7 Dutch rehabilitation centers (10 patients per center): Revalidatiecentrum Het Roessingh (Enschede), Sint Maartenskliniek (Nijmegen), De Hoogstraat (Utrecht), Beatrixoord (Haren), Groot Klimmendaal (Arnhem), Rijndam (Rotterdam) en Revalidatie Centrum Amsterdam. Participants are able to lift the arm (partially) and to perform reach-like movements.The participants receive reach training for the affected arm during 6 weeks, 3 times 30 minutes per week. The intervention group (35 persons) will train using the ArmeoBoom system for arm support and the control group (35 persons) will perform standardized reaching exercises, with similar training intensity.Before and after training changes in overall arm function (Fugl-Meyer assessment, Stroke Upper Limb Capacity Scale) and work area are quantified.Also, user experience of therapist and patient (semi-structured interviews) are identified after training. Both before and after training a Visual Analog Scale for pain is filled in by patients.

Doel van het onderzoek

Patients who are treated with the ArmeoBoom will have similar or improved arm function in comparison with the patients who receive conventional arm therapy. In case the improvement is similar, the therapy must be more efficient for a therapist (possibility to train two patients on the same time) to make the study succesfull.

Onderzoeksopzet

At baseline and within a week after the training period of 6 weeks.

Onderzoeksproduct en/of interventie

The participants receive reach training for the affected arm during 6 weeks, 3 times 30 minutes per week. The intervention group (35 persons) will train using the ArmeoBoom system for arm support and the control group (35 persons) will perform standardized reaching exercises, with similar training intensity.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Start of participation between 1 and 12 weeks post first-ever stroke;

2. Hemiparetic arm, with ability of some elbow extension (MRC score 2 or 3 out of 5);

3. Ability to understand and follow instructions;

4. Ability to endure training and evaluation sessions.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Co-morbidity of other diseases (incl. pain) that limit use of the arm.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-12-2010
Aantal proefpersonen:	70
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	29-09-2010
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 34496
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2430
NTR-old	NTR2539
CCMO	NL33365.044.10
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON34496

Resultaten

Samenvatting resultaten
Prange, GB. Rehabilitation Robotics - Stimulating restoration of arm function after stroke (dissertation). Enschede, University of Twente, 2009. ISBN 978-90-365-2901-3.