Feasibility of a functional hand orthosis (MyHand) to support hand function in stroke

Published: 17-06-2016
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To explore whether wearing the orthosis improves the performance of functional activities, additionally to obtain insight in the usability of the orthosis.

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

Summary

ID

NL-OMON46169

Source
ToetsingOnline

Brief title
Feasibility MyHand orthosis

Condition

- Central nervous system vascular disorders

Synonym
cerebrovascular accident, Stroke

Research involving
Human

Sponsors and support

Primary sponsor: Revalidatiecentrum Het Roessingh
Source(s) of monetary or material Support: Fonds NutsOhra

Intervention

Keyword: assistive device, hand function, stroke

Outcome measures

Primary outcome

Main outcome measure is the Wolf Motor Function Test (WMFT).

Secondary outcome

Action Research Arm Test (ARAT), System Usability Scale (SUS), Motor Activity

Log (MAL), an interview (including *Patiënt Specifieke Klachten (PSK) lijst*)

and a diary in which the use duration per activity will be noted.

Study description

Background summary

After a stroke, restoration of hand function often lags behind and the hand is being used less and less. The MyHand orthosis was developed to support stroke patients in predominantly hand opening, in order to support and increase the hand function during daily functional activities. When using such an orthosis, ultimately support of activities of daily living (ADL) can be integrated with the ultimate intensive training of task-specific actions: active involvement of the arm and hand in daily activities.

Study objective

To explore whether wearing the orthosis improves the performance of functional activities, additionally to obtain insight in the usability of the orthosis.

Study design

Cross-sectional study, consisting of a direct comparison of functional task performance with and without orthosis on 2 occasions: at first use and after 3 practice sessions within 1 week.

Intervention

All subjects will receive the same intervention: use of a dynamic functional hand orthosis to support hand function during functional tasks.

Study burden and risks

There is a possibility that the grasping functionality of the hand will improve during wearing of the orthosis, however this can*t be guaranteed since this is the objective of the current study. Potential risks for the subjects (e.g., discomfort when wearing the orthosis and overexertion) are limited as much as possible by only applying supervised use of the orthosis and asking only movements that are within the abilities of the patient, in both the practice sessions and the evaluation tests.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Time post-stroke at least 4 weeks
- Hemiparesis of arm and hand (Brunnstrom stage 3-4)
- Age between 18 and 80
- Able to complete sessions (at least 3,5h)
- Free from co-morbidity that affects movement of the arm
- Free from fixed contractures in arm and hand
- Mentally competent and able to follow instructrions

Exclusion criteria

- Potential other diseases that affect the wellbeing of the subject and the measurements (such as fever, flu, etc.)

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	19-05-2017
Enrollment:	5
Type:	Actual

Medical products/devices used

Generic name:	functional hand orthosis
Registration:	No

Ethics review

Approved WMO Date:	17-06-2016
Application type:	First submission
Review commission:	METC Twente (Enschede)
Approved WMO Date:	02-03-2017
Application type:	Amendment
Review commission:	METC Twente (Enschede)

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
Other	in aanvraag bij Nederlands Trial Register
CCMO	NL57353.044.16