Therapeutic effect of prolonged use of a wearable soft-robotic glove during ADL on reduced hand function

Published: 04-03-2019
Last updated: 15-05-2024

The primary objective of the present study is to examine the therapeutic effect of the Carbon Hand system on handgrip strength in patients with hand function problems, after using the glove for six weeks at home. Secondary objectives are related to...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21637

Source
NTR

Brief title
iHand clinical trial

Synonym
upper extremity; hand function; hand strength; robotics; rehabilitation; assistive technology; activities of daily living; wearable devices; soft-robotic glove; wearable; hand; robot; assist; protocol; therapy; support; intervention; function

Health condition

orthopedic disorders, spinal cord injury, traumatic brain injury, stroke

Research involving
Human

Sponsors and support

Primary sponsor: Roessingh Research and Development
Source(s) of monetary or material Support: SME Instrument H2020

Intervention

- Medical device

Explanation

Outcome measures

Primary outcome

Handgrip strength

Secondary outcome

Maximal pinch strength, Handgrip endurance, Action Research Arm Test, Jebson-Taylor Hand Function Test, glove use data, Numeric Pain Rating Scale, Michigan Hand Outcomes Questionnaire- Dutch Language Version, Motor Activity Log, EuroQol-5D, Short-Form 36, Semi-instructed interview

Study description

Background summary

Different patient populations, such as orthopedic patients, spinal cord injured patients, traumatic brain injured patients and stroke patients frequently experience difficulties in performing activities of daily living (ADL) due to a decline in hand function. They often need personal and/or assistive devices to carry out ADL. However, personal assistance will not result in more independence in performing ADL, while assistive devices have the potential to provide the assistance that is necessary to perform ADL independently. A wearable soft robotic glove was developed that can support the functional performance of the hand directly by assisting a person’s own function. In this way, people will probably use their affected hand more often during daily life, which can potentially result in an improved hand function after prolonged use of the robotic glove.

Study objective

The primary objective of the present study is to examine the therapeutic effect of the Carbon Hand system on handgrip strength in patients with hand function problems, after using the glove for six weeks at home. Secondary objectives are related to arm-/ hand function, amount of glove use and quality of life.

Study design

A multicenter uncontrolled intervention study will be conducted with three pre-assessments (T0, T1 and T2), a post-assessment (T3) and a follow-up assessment (T4).

Intervention

wearable soft-robotic glove (Carbonhand system)

Study burden and risks

The Carbon Hand may have a beneficial effect on hand function, by directly improving functional task performance. It may be possible that the functional use of the hand improves, allowing people to be more active in ADL and to maintain or improve their health status. The exact therapeutic benefit will be studied in the current research.

The risks for the participants are limited to a minimum. The Carbon Hand is a device that only facilitates handgrip based on voluntary, active initiation by the person him/herself. Furthermore, the Carbon Hand system is a so-called soft-robotic device, constructed from soft materials that are comfortable to wear and compliant with human movement. This prevents potential occurrence of pressure points for example. All movements conducted during the study will consist of arm-/hand movements that normally occur in ADL and within the abilities of each individual. Additionally, all the evaluation measurements used in this study are non-invasive and involve no risks for the participants."

Contacts

Public
Roessingh Research and Development
Anke Kottink

0880875733
Scientific
Roessingh Research and Development
Anke Kottink

0880875733

Eligibility criteria

Age
Adults (18-64 years)

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

Inclusion criteria

1. Age between 18-80 years 2. People should be in a chronic and stable phase of disease 3. Receiving/having received treatment for limitations in performing ADL due to a decline in hand function (regardless of underlying disorder) at a rehabilitation center/department 4. People should have at least 10° of active extension of the wrist and fingers and 10 degrees of active flexion of the fingers 5. People should be able to make a pinch grip between thumb and middle or ring finger 6. People should be able to put on the Carbon Hand glove 7. Sufficient cognitive status to understand two-step instructions 8. Living at home 9. Provided written informed consent

Exclusion criteria

1. Severe sensory problems of the most-affected hand 2. Severe acute pain of the most-affected hand 3. Wounds on their hands that can give a problem when using the glove 4. Severe contractures limiting passive range of motion 5. Co-morbidities limiting functional use/performance of the arms/hands 6. Severe spasticity of the hand (≤2 points on Ashworth Scale) 7. Participation in other studies that can affect functional performance of the arm/hand 8. Receiving arm-/hand function therapy during the course of the study 9. Insufficient knowledge of the Dutch language to understand the purpose or methods of the study

Study design

Design

Study phase:	N/A
Study type:	Interventional
Intervention model:	Single
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	25-06-2019
Enrollment:	63
Type:	Actual

Medical products/devices used

Product type:	Medical device
Brand name:	Carbonhand

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Approved WMO

Date:	13-03-2019
Application type:	First submission
Review commission:	Medical Research Ethics Committees United (MEC-U) Postbus 2500 3430 EM Nieuwegein 088 320 8784 info@mec-u.nl

Study registrations

Followed up by the following (possibly more current) registration

ID: 55770
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL7561
CCMO	NL68135.044.19
OMON	NL-OMON55770

Study results