Changes in movement profile related to use of a soft-robotic glove during high-demand tasks

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON51416

Source
ToetsingOnline

Brief title
Soft-robotic glove support of high-demand tasks

Condition

- Other condition
- Neuromuscular disorders

Synonym
muscle weakness, Neuromuscular disorders, sarcopenia

Health condition

spierkrachtvermindering door veroudering

Research involving
Human

Sponsors and support

Primary sponsor: Revalidatiecentrum Het Roessingh
Source(s) of monetary or material Support: Europese Unie

Intervention

Keyword: Hand function, Movement analysis, Soft-robotic glove, Wearable device

Outcome measures

Primary outcome

The main study parameters are the kinematic movement profile during a high-demand ADL task (reaching/grasping/transporting a heavy object), as measured by 3D motion capture (amongst others: movement duration, hand opening; joint excursions; endpoint error).

Secondary outcome

Experienced pain/discomfort, handgrip strength and endurance, number of repetitions of ADL task, muscle oxygen saturation and EMG parameters.

Study description

Background summary

The hand is important to perform activities of daily living (ADL). However, many people experience a loss of hand function as result of a traumatic brain injury, spinal cord injury, stroke or orthopedic problems, or due to ageing. To improve hand function, or reduce its decline, one can benefit from exercise therapy or use of assistive aids to improve ADL independence. A promising innovative approach combining both is a wearable soft-robotic glove that supports hand grip. With this glove, performance of functional activities can be supported directly, while also facilitating repeated use of the affected arm and hand during functional daily activities. One of our previous studies showed that besides a direct support effect, a therapeutic effect on performance was found after several weeks of using the soft-robotic CarbonHand glove as support during ADL. However, several participants reported complaints of increased pain and/or overload, mainly at the beginning of the trial. Clinicians suspect that

a (too) high intensity of hand use compared to normal is contributing to this observation. This might be related to more fatigue experienced when using the glove in high-demand tasks, due to a larger movement capacity (faster, further, more repetitions) and can be associated with decreased blood perfusion/lower saturation levels at muscular level and altered muscle activation and movement coordination.

Study objective

The primary objective is to examine the effect of use of the assistive Carbonhand system during strenuous ADL tasks on the kinematic movement profile, compared to not using Carbonhand. Secondary objectives are to examine whether pain or discomfort is experienced in strenuous activities with the Carbonhand system as well as the characteristics and locations of such pain/discomfort, and to examine whether use of Carbonhand is associated with increased handgrip strength, larger number of ADL task repetitions, diminished blood perfusion / reduced tissue saturation at the muscle and/or changes in muscle activity, compared to not using Carbonhand.

Study design

The study is a cross-sectional intervention study with one measurement session, where participants will perform maximum handgrip strength tests and high-demand ADL-tasks with and without the Carbonhand system.

Intervention

All participants will perform each movement task with and without the Carbonhand system. The Carbonhand system is a CE-marked medical device and it consists of a glove that supports finger flexion via sewn-in tendons and a control unit housing the actuators that pull on the tendons and the batteries. The grip support is activated by applying very light pressure on sensors in the fingertips of the glove, and de-activated by releasing the pressure on the sensors.

Study burden and risks

The study is non-therapeutic, so no direct benefits for the participants are involved. On the other hand, the study set-up involves non-invasive measurements of movements that are at all times within a subjects ability. Also, the device under study is a CE-marked device, minimizing risks associated with its use. Therefore, subjects suffer no negative effects or disadvantages, except for the invested time and effort and potentially some mild and transient muscle aches due to the exertion during the movement tasks. As the mechanisms underlying experienced fatigue and/or overload in the previous study in association with Carbonhand use are bound to the study population involved in

the previous study, this study should also be conducted with a similar study population.

Contacts

Public
Revalidatiecentrum Het Roessingh

Roessinghsbleekweg 33b
Enschede 7522AH
NL
Scientific
Revalidatiecentrum Het Roessingh

Roessinghsbleekweg 33b
Enschede 7522AH
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Frail elderly with reduced hand function:
• Age between 65 and 90 years
• Experience difficulties in performing ADL due to a decline in hand function
• Able to make a pinch grip between thumb and middle or ring finger
• Sufficient cognitive status to understand two-step instructions
• Having (corrected to) normal vision
• Able to provide written informed consent
Neuromuscular patients:

• Age between 18 and 80 years
• Experience difficulties in performing ADL due to a decline in hand function that can be attributed to a diagnosed neuromuscular disease
• Being in a chronic and stable phase of disease
• Able to make a pinch grip between thumb and middle or ring finger
• Sufficient cognitive status to understand two-step instructions
• Having (corrected to) normal vision
• Able to provide written informed consent

Exclusion criteria

Frail elderly with reduced hand function:
• Currently receiving treatment for a disease affecting arm/hand function
• Used the CarbonHand system in the past 3 months
• Severe sensory problems of the most-affected hand
• Severe acute pain of the most-affected hand
• Wounds on the hands that can provide a problem when using the glove
• Severe contractures limiting passive range of motion
• Severe spasticity of the hand (>=2 points on Ashworth Scale)
• Severe proximal weakness (MRC shoulder elevation<4)
• Insufficient knowledge of the Dutch language to understand the purpose or methods of the study
Neuromuscular patients:
• Severe sensory problems of the most-affected hand
• Severe acute pain of the most-affected hand
• Used the CarbonHand system in the past 3 months
• Wounds on the hands that can provide a problem when using the glove
• Severe contractures limiting passive range of motion
• Co-morbidities limiting functional use/performance of the arms/hands
• Severe spasticity of the hand (>=2 points on Ashworth Scale)
• Severe proximal weakness (MRC shoulder elevation<4)
• Insufficient knowledge of the Dutch language to understand the purpose or methods of the study

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	17-10-2022
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	28-04-2022
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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 ClinicalTrials.gov
CCMO	NL80144.091.21