Influence of assistive soft-robotic glove use on actual arm use in daily life

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The primary objective is to examine the influence of assistive soft-robotic glove use on actual use of the arm and hand in daily life. Secondary objectives are to examine retention of the effect on arm use in daily life after cessation of assistive...

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

Summary

ID

NL-OMON56312

Source
ToetsingOnline

Brief title
Arm use with soft-robotic glove

Condition

- Other condition

Synonym
neurologic disorders, trauma-related injuries

Health condition

patients with hand limitations due to trauma-related injuries or neurologic disorders

Research involving
Human

Sponsors and support

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

Intervention

Keyword: arm activity, assistive device, hand function, soft-robotics

Outcome measures

Primary outcome

The main study parameter is actual arm use as measured by two MotionWatch8 devices, containing an accelerometer, one around each wrist. In essence, the *raw* accelerometer signal will be transformed into an *activity count signal*. Actual amount of arm-hand use will then be calculated in several ways, focusing on the duration of use and the intensity of use of the affected arm-hand.

Secondary outcome

Maximal grip strength and survey questions about perceived hand function and overall wellbeing, in addition to glove use data, hand function, perceived amount and quality of hand use and pain, and quality of life questionnaires.

Study description

Background summary

Hand rehabilitation after neurologic or orthopaedic disorders/injuries can only achieve so much and chronic hand dysfunction with mild disability often persists. Tools such as adaptive clothing, shower accessories, one-handed can openers etc., can compensate for functional limitations, but these often avoid active involvement of the affected body parts. With rapid developments in the field of advanced soft-robotic devices, assistive robotic devices are becoming available to be applied in real life situations, in unsupervised setting such as peoples* homes. When an assist-as-needed approach is applied as the basis for control of the glove, optimal, hybrid, support becomes possible: assisting

ADL where needed, while stimulating active and highly functional movements within the user*s abilities. An example of a wearable soft-robotic glove, with an assist-as-needed approach via movement intention detection, is Carbonhand (Bioservo Technologies AG; Kista, Sweden), which supports grip by assisting finger flexion. In previous studies we found that use of the Carbonhand system as assistive device has a beneficial effect on hand function, by directly improving functional task performance. Moreover, unsupported hand function also increased after 4-6 weeks use of the glove. This therapeutic effect of assistive use is believed to be related to people being enabled by the glove*s assistance to use their affected hand more in daily life tasks than they did or could without the glove*s support. If confirmed, an assistive soft-robotic glove forms a powerful tool not only to provide direct support in ADL, but also to enable patients to use their affected hands more in ADL. This turns use of a smart assistive device into the highly intensive and functional training integrated in daily life at home.

Study objective

The primary objective is to examine the influence of assistive soft-robotic glove use on actual use of the arm and hand in daily life. Secondary objectives are to examine retention of the effect on arm use in daily life after cessation of assistive soft-robotic glove use; to examine changes in (perceived) hand function and well-being after using an assistive soft-robotic glove at home, and it*s retention after cessation of glove use; to examine the relation between glove use time, actual arm use in daily life and changes in (perceived) hand function and well-being; to assess user experience and satisfaction with regard to glove use (amount and activities), actual arm use in daily life, hand function and well-being

Study design

A partially concurrent multiple baseline single case experimental design (SCED) with three phases (baseline of 2-4 weeks, glove use at home during 6 weeks, retention phase without glove use of 4 weeks), and randomized baseline length. During this period, participants use the Carbon hand in daily life for 6 weeks to support the performance of daily activities in the home environment. Here, a diary is kept to record how much the Carbonhand is used and during which (type of) activities. Repeated assessments of arm activity in daily life, grip strength, perceived hand function and wellbeing are performed 1-2 times per week by the subjects at home (with supervision from a researcher via videocall), for a total of at least 15 times, throughout all three phases. Besides the initial screening visit, additional assessments are scheduled at the end of each phase (pre, post and follow-up assessments) with an extended battery of hand function tasks and patient-reported outcomes related to experiences during the study, (perceived) hand use, hand function and functional ability, quality of life.

Intervention

The SCED in this study will consist of three phases: a baseline phase (control condition) of varying length (randomized between min. 2 weeks and max. 4 weeks), followed by a 6-week intervention phase, consisting of home use of an assistive soft-robotic glove, and a subsequent follow-up phase of 4 weeks without glove use to assess retention. All participants will use the Carbonhand system during ADL at home for 6 weeks. The participants are free to choose for which activities, when and for how long they use the Carbonhand. However, it is recommended to use the Carbonhand at least 180 minutes a week during the most common ADL, such as household activities, dressing/undressing, eating/drinking/cooking, and/or leisure activities.

Study burden and risks

The risks for the subjects are limited to a minimum. The Carbonhand system is a device that facilitates handgrip as initiated by the user him/herself. It provides support only when necessary based on voluntary, active initiation by the person him/herself. Furthermore, the Carbonhand system is a so-called soft-robotics 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 hand movements that normally occur in ADL and are within the abilities of each individual. Additionally, all the evaluation measurements used in these studies are non-invasive and involve no risks for the participants. The burden for the participants is relatively high, with repeated assessments (self-administered or with remote supervision) of 1-2 per week for a duration of 12-14 weeks in total and 3 lab visits with 1-1,5h of additional hand function tests and questionnaires. On the other hand, participants are expected to experience a direct benefit in support during ADL when using the soft-robotic glove, as well as an improved unsupported hand function, which might persist up to 4 weeks at least. All participants will undergo the same conditions, with the only difference the length of the baseline phase (varying randomly between 2 and 4 weeks).

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

• Age between 16 and 90 years
• Experience difficulties in performing ADL due to hand function limitations as a result of trauma-related injury or neurologic disorder
• Being in a chronic/stable phase of disease as judged by their physician
• Able to activate the soft-robotic glove by generating pressure on finger/palm sensors when grasping an object
• Ability to relax an active grip
• Sufficient cognitive status to understand two-step instructions
• Having (corrected to) normal vision
• Able to provide written informed consent
• Living independently

Exclusion criteria

• 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 to the extent that the glove can*t be donned/activated comfortably
• Co-morbidities limiting functional use/performance of the arms and/or hands
• Severe spasticity of the hand (>=2 points on Ashworth Scale)

• Severe proximal weakness (MRC shoulder elevation<4)
• Used the Carbonhand system in the past 3 months
• Participation in other studies that can affect functional performance of the arm/hand
• Receiving arm-/hand function therapy during the course of the study
• Insufficient digital literacy to conduct video calls
• Insufficient knowledge of the Dutch or English language to understand the purpose or methods of the study

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	03-06-2024
Enrollment:	5
Type:	Actual

Medical products/devices used

Generic name:	Carbonhand
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	21-12-2023
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
ClinicalTrials.gov	NCT06033027
CCMO	NL85214.091.23