User acceptance of the ironHand: a wearable soft robotic glove supporting daily activities in elderly with impaired hand function

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON41797

Source
ToetsingOnline

Brief title
A soft robotic glove supporting daily activities in elderly

Condition

- Other condition
- Age related factors

Synonym
Ageing, Elderly

Health condition

Handfunctie problemen bij veroudering

Research involving
Human

Sponsors and support

Primary sponsor: Revalidatiecentrum Het Roessingh
Source(s) of monetary or material Support: Ambient Assistant Living Joint Program Call 6 (Europese Unie)

Intervention

Keyword: arm/hand function, elderly, robotics, wearable support

Outcome measures

Primary outcome

The main study parameters are outcomes related to user acceptance (System

Usability Scale) in phase 1 and functional task performance (Jebsen-Taylor Hand

Function test) in phase 2.

Secondary outcome

Secundary study parameters are outcomes related to user acceptance, perceived

use and changes in hand motor function.

Study description

Background summary

Elderly people frequently experience difficulties with 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. New technological innovations can support the functional performance of the arms and hands directly by a wearable soft robotic device assisting a person*s own function. If people can maintain or increase use of their hands/arms in daily life, this might ultimately even benefit their (unsupported) arm function in ADL.

Study objective

The primary objective of this study is to explore user acceptance of the ironHand (iH) system by elderly. Secondary objectives are to examine the direct effect on functional task performance, changes in hand strength and movement execution of such a wearable robotic device in elderly.

Study design

This observational, cross-sectional study will consist of two phases. Phase one will focus on user acceptance and phase two on functional task performance.

Study burden and risks

The iH system might have a beneficial effect on hand function, by directly improving functional task performance. However, the exact benefit cannot be predicted, because this is the topic of the current research.
The risks for the subjects are limited to a minimum. The iH system is a device that facilitates hand grip and opening 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 iH 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 arm/hand movements that normally occur in ADL and within the abilities of each individual. Additionally, all the evaluation measurements used in these studies are non-invasive and involve no risks for the subjects.

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

• Elderly adults over the age of 55 years
• Experience difficulties in performing ADL due to their decline in hand function as result of aging
• Absence of wounds on their hands that can give a problem when using the glove
• Absence of severe contractures limiting passive range of motion
• Absence of co-morbidities limiting functional use of the arms/hands
• People should have at least 10 degrees of active flexion and extension of the fingers
• Sufficient cognitive status to understand two-step instructions
• Having (corrected to) normal vision
• Living at home
• Provided written informed consent

Exclusion criteria

• People with severe sensory problems of the affected hand
• People with severe acute pain of the affected hand
• Participation in other studies that can affect functional performance of the arm and hand
• People having insufficient knowledge of the Dutch language to understand the purpose or methods of the study

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-06-2015
Enrollment:	40
Type:	Actual

Medical products/devices used

Generic name:	Robot assisted arm/hand function
Registration:	No

Ethics review

Approved WMO

Date:	02-06-2015
Application type:	First submission
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 NTR
CCMO	NL52324.044.15