Comfort during prolonged exposure to repetitive forces mimicking exoskeleton use

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

Summary

ID

NL-OMON51390

Source
ToetsingOnline

Brief title
Comfort thresholds for repetitive forces

Condition

- Other condition

Synonym
n/a (healthy)

Health condition

not applicable (healthy)

Research involving
Human

Sponsors and support

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

Intervention

Keyword: comfort, exoskeleton, physical human-robot interaction, safety

Outcome measures

Primary outcome

The main study parameter is the level of discomfort as indicated continuously by the participants through a slider with a visual analogue scale. The scale reaches from no discomfort at all to maximum imaginable discomfort. A separate switch which releases all forces if activated by the participant is used to detect onset of pain.

Secondary outcome

The secondary study parameters are the number of completed test sessions/dropouts, subject characteristics (height, weight, age, gender), records of observations of skin changes or other negative signs (directly after force application and several days after the session), and surface EMG recordings of the rectus femoris muscle.

Study description

Background summary

Exoskeletons can be used for rehabilitation, as assistive device for patients, or to support workers during strenuous tasks. To fulfil their purpose, they need to apply forces to the user*s musculoskeletal system. The forces are transmitted at skin level through an interface, often in the form of cuffs. Adverse events causing discomfort and injuries to the skin and underlying

tissue can be attributed to those interaction forces. While there is some information about safe limit values for impact forces or pressure and shear applied for short durations, little is known regarding comfort and safety thresholds for repetitive forces applied over long durations as is the case in exoskeleton use. This study therefore aims at gaining new knowledge on safe and comfortable limit values for continuous repetitive shear and normal forces applied through a cuff.

Study objective

The primary objective is to determine comfort thresholds for prolonged exposure to repetitive normal and shear stress exerted to the human thigh via a cuff with straps, using different force patterns comparable to those exerted during exoskeleton use. The secondary objectives are to determine the feasibility of the experiment, the influence of subject characteristics on comfort thresholds, the occurrence of skin injuries or other negative signs, and whether characteristics of muscle activity can be related to discomfort.

Study design

The study is a cross-sectional intervention study with one measurement session, where participants will provide a continuous comfort rating during exposure to repetitive normal and shear forces.

Intervention

A pre-defined set of prolonged repetitive force patterns will be applied to each participant*s thigh though a contact force which is similar to cuffs commonly used in gait exoskeletons. The forces will be applied by a custom made actuated test device and are based on normal use of exoskeletons.

Study burden and risks

The study is non-therapeutic, so no direct benefits for the participants are involved. The procedures are non-invasive and safety measures are taken to avoid excessive force exertion to the participants or other unsafe situations. Therefore, subjects suffer no negative effects or disadvantages, except for the invested time and the discomfort experienced during the force execution. Pain will be avoided as participants can trigger a release of the forces at any time. Any changes to the participants* skin or other negative signs will be monitored and followed up on until they have resolved.

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

• Between 18 and 35 or between 55 and 85 years of age
• Able to provide informed consent

Exclusion criteria

• Unable to follow simple instructions
• Insufficient knowledge of the Dutch or English language to understand the purpose and methods of the study
• Skin lesions at the thigh
• Sensory impairments
• Severe blood pressure fluctuations

• Inability to sit in required posture in experiment chair for 60 minutes
• Taking blood thinners or showing signs for increased bleeding tendency

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	25-04-2022
Enrollment:	20
Type:	Anticipated

Ethics review

Approved WMO

Date:	02-05-2022
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	glinicaltrials.gov (tbd)
CCMO	NL80800.091.22