Phantom Motor Execution via Myoelectric Pattern Recognition, Augmented Reality, and Serious Gaming as a treatment of Phantom Limb Pain

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Primary objective: Assess the efficacy of Phantom Motor Execution (PME) aided by Myoelectric Pattern Recognition (MPR), Augmented and Virtual Reality (AR-VR), and Serious Gaming (SG) to reduce Phantom Limb Pain (PLP). Secondary objective: Assess the...

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

Summary

ID

NL-OMON48734

Source
ToetsingOnline

Brief title
Phantom motor execution

Condition

- Other condition

Synonym
Phantom Limb Pain

Health condition

Fantoompijn na een amputatie

Research involving

Human

Sponsors and support

Primary sponsor: Chalmers Technical University
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Amputation, Augmented reality, Phantom Limb Pain, Treatment

Outcome measures

Primary outcome

Primary: Changes in PLP will be measured in terms of differences between the Pain Rating Index registered at the beginning (1st session) and at the end of the treatment (15th session).

Secondary outcome

Secondary: The effects of the treatment will be measured as changes in the PDI measures at the beginning (1st session) and at the end of the treatment (15th session).

Study description

Background summary

Phantom Motor Execution restores brain changes related to the loss of a limb and by doing so alleviates Phantom Limb Pain, which is believed to be maintained by such changes.

Study objective

Primary objective: Assess the efficacy of Phantom Motor Execution (PME) aided by Myoelectric Pattern Recognition (MPR), Augmented and Virtual Reality (AR-VR), and Serious Gaming (SG) to reduce Phantom Limb Pain (PLP).
Secondary objective: Assess the effects of the proposed treatment in terms of disability associated with pain as evaluated by the Pain Disability Index

(PDI).

Study design

International, multicentre, double-blind, randomized, controlled, clinical trial.

Intervention

Experimental treatment: Phantom Motor Execution (PME) aided via MPR/AR-VR/SG (Myoelectric Pattern Recognition/Augmented Reality-Virtual Reality/Serious Gaming). Referred in the text as PME only.
Control treatment: Phantom Motor Imagery (PMI) aided via MPR/AR-VR/SG. Referred in the text as PMI only.

Study burden and risks

Patients will have 15 treatment sessions of maximally 2 hours. Treatment is executed using the Neuromotus system. This system has been used in regular patient care for more than two years already. A risk analysis has been carried out and it was concluded that this is a low-risk treatment. The benefit of the system is higher than all the risks in using the system.
There will be 3 follow-up sessions after the last treatment session. During the follow-up sessions questions and questionnaires have to be answered.

Contacts

Public
Chalmers Technical University

Maskingränd 2 50
Gothenburg SE-412 96
SE
Scientific
Chalmers Technical University

Maskingränd 2 50
Gothenburg SE-412 96
SE

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Subject must be older than 18 years, must have an acquired amputation of upper or lower limb.
• If the subjects are under pharmacological treatments, there must be no variations on the medicament dosages for at least one month (steady consumption).
• The last session of previous treatments must be at least 3 months old.
• Any pain reduction potentially attributed to previous PLP treatments must be at least 3 months old.
• Subjects must have control over at least a portion of biceps and triceps muscles for upper limb amputations, and quadriceps and hamstrings for the lower limb amputations.
• The subject has signed a written informed consent.
• The subject must be in a stable prosthetic situation (i.e. satisfied with the fitting of the prosthesis) or being a nonuser.
• At least six months should be passed since the amputation: acute PLP cases should not be included in the study.
• The patient subject should not have a significant cognitive impairment that prevents the patient from following instructions.
• Subjects with abundant soft tissue on their stump will not be automatically excluded, however, an evaluation in the system is required to analyze if sufficient electromyography signals can be recorded.

Exclusion criteria

• The subject should not have any condition associated with risk of poor protocol compliance.
• The subject should not have any other condition or symptoms preventing the patient from entering the study, according to the investigator*s judgment.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-11-2017
Enrollment:	25
Type:	Actual

Medical products/devices used

Generic name:	Neuromotus: a system using augmented reality and serious gaming;controlled by pattern recognition (m
Registration:	No

Ethics review

Approved WMO Date:	08-06-2017
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	15-05-2019
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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
CCMO	NL61001.042.17