PHYANTOM MOTOR EXECUTION AS A TREATMENT FOR PHANTOM LIMB PAIN: An international, double blind, randomised, controlled clinical trial

Eva Lendaro¹, Liselotte Hermanson², Helena Burger³, Corry van der Sluis⁴, Brian McGuire⁵, Monika Pilch⁵, Lina Bunketorp⁶, Katarzyna Kulbacka-Ortiz⁶, Anita Stockselius⁷, Christina Ragno⁷, Wendy Hill⁸, Geers Sybille⁹, and Max Ortiz-Catalan¹,¹⁰,*

¹ Biomechatronics and Neurorehabilitation Laboratory, Department of Electrical Engineering, Chalmers University of Technology, Gothenburg, Sweden, ² Örebro University Hospital, Örebro, Sweden, ³ University Rehabilitation Institute, Ljubljana, Slovenia, ⁴ University Medical Centre Groningen, Groningen, Netherlands, ⁵ Centre for Pain Research, National University of Ireland, Ireland, ⁶ Sahlgrenska University Hospital, Gothenburg, Sweden, ⁷ Rehabcenter Sfären, Bräcke Diakoni, Stockholm, Sweden, ⁸ Atlantic Clinic for Upper Limb Prosthetics, Institute of Biomedical Engineering, University of New Brunswick, New Brunswick, Canada, ⁹ Fysische Geneeskunde en Revalidatie, University Hospital Gent, Gent, Belgium, ¹⁰Integrum AB, Gothenburg, Sweden.

* Corresponding author

Background: Phantom limb pain (PLP) is a deteriorating condition that can greatly diminish quality of life. Control over the phantom limb and the exercise of such control have been hypothesized to reverse maladaptive brain changes correlated to PLP. Preliminary investigations have shown that decoding motor volition using myoelectric pattern recognition (MPR), while providing real-time feedback via virtual and augmented reality (VR-AR), facilitate phantom motor execution (PME) and reduced PLP.

Objectives: Here we present the outline of an international, multicentre, double blind, randomized, controlled clinical trial to assess the effectiveness of PME in alleviating PLP. The clinical trial is expected to be completed by April 2020.

Methods: Sixty-six subjects suffering from PLP in upper or lower limbs will be randomly assigned to PME and Phantom Motor Imagery (PMI) interventions. Subjects will receive 15 interventions of 1.5 hours exposed to the same VR-AR environments and using the same device. The only difference between interventions is that in PMI, subjects will imagine rather than execute phantom movements: this will make it possible to isolate the effect of the motor exercise. Changes in PLP measured using the Pain Rating Index between the first and last session will be the primary variable of evaluation. Follow-up interviews will be conducted up to six months after the last intervention.

This investigation has been designed in such a way that participants of the two treatment groups will use the same device under the same circumstances. The only difference between the two groups is the type of interaction with the virtual environments. In the PME intervention, motor volition is decoded interpreting the signals from the stump’s muscles via myoelectric pattern. The predicted outcome is then used by the software to send appropriate commands to the virtual environments. In this way the user can control the virtual environments by moving the phantom limb as prior to amputation.

In the control treatment (PMI) patients are not allowed to produce phantom movements. Rather, they must just imagine to perform them while observing the VR/AR limbs autonomously moving. The myoelectric signals will be recorded as in the PME treatment, however here they will be used to monitor that the patient does not produce muscular contractions rather than decoding of motor volition.