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Appraisal

Trial Protocol

The PACT trial: PAtient Centered Telerehabilitation

Effectiveness of software-supported and traditional mirror therapy in patients with phantom limb pain following lower limb amputation: protocol of a multicentre randomised controlled trial

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Abstract

Introduction: Non-pharmacological interventions such as mirror therapy are gaining increased recognition in the treatment of phantom limb pain; however, the evidence in people with phantom limb pain is still weak. In addition, compliance to self-delivered exercises is generally low. The aim of this randomised controlled study is to investigate the effectiveness of mirror therapy supported by telerehabilitation on the intensity, duration and frequency of phantom limb pain and limitations in daily activities compared to traditional mirror therapy and care as usual in people following lower limb amputation. **Method**: A three-arm multi-centre randomised controlled trial will be performed. Participants will be randomly assigned to care as usual, traditional mirror therapy or mirror therapy supported by telerehabilitation. During the first 4 weeks, at least 10 individual sessions will take place in every group. After the first 4 weeks, participants will be encouraged to perform self-delivered exercises over a period of 6 weeks. Outcomes will be assessed at 4 and 10 weeks after baseline and at 6 months follow-up. The primary outcome measure is the average intensity of phantom limb pain during the last week. Secondary outcome measures include the different dimensions of phantom limb pain, pain-related limitations in daily activities, global perceived effect, pain-specific self-efficacy, and quality of life. **Discussion**: Several questions concerning the study design that emerged during the preparation of this trial will be discussed. This will include how these questions were addressed and arguments for the choices that were made.

Trial registration: U.S. National Institutes of Health Clinical Trials Registry. **Registration number**: NCT02076490. **Was this trial prospectively registered**: Yes. Date: 28.02.2014. **Funded by**: Ministry of Health, State of North Rhine-Westphalia, Germany and the European Union through the NRW Ziel2 Program as a part of the European Fund for Regional Development. **Funder approval number**: 005-GW02-035. **Anticipated completion**: July 2015. **Correspondence:** Andreas Rothgangel, Department of Rehabilitation Medicine, Research School for Public Health and Primary Care CAPHRI, Maastricht University, Maastricht, The Netherlands. Email: andreas.rothgangel@zuyd.nl

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Commentary

Phantom pain is common following limb amputation. Although data are limited prognosis is regarded to be poor and there are few effective treatment options.[1] Mirror therapy has been investigated in 2 small trials and its effects on reducing pain intensity are promising. A significant concern with mirror therapy and related interventions such as graded motor imagery for complex regional pain syndrome (CRPS) is that they often require considerable therapist and patient time to achieve therapeutic benefits.

This three-arm randomised controlled study will investigate the effectiveness of telerehabilitation-supported mirror therapy for phantom limb pain. The effectiveness of mirror therapy will be determined by comparing telerehabilitation supported mirror therapy to mirror therapy and care as usual. The primary outcome is pain intensity. Secondary outcomes include duration and frequency of phantom limb pain and activities of daily living. These patient-centered outcomes are appropriate for this patient group and reflect the patient's main concerns.

The study is powered to detect a two-point difference on an 11-point numerical rating scale of pain intensity. This is an ambitious between-group difference as pain interventions rarely achieve effects of this magnitude. If successful this would represent a major advance in the management of this complex and difficult-to-manage condition. The researchers also plan to conduct a cost-effectiveness and cost-utility analysis of the intervention. This will provide high quality information to guide policy makers and health care providers/consumers.

This is a well-designed and high quality trial. Although neither the patients nor the therapist delivering the intervention will be blinded to allocation, efforts have been taken to minimise most other known sources of bias. This will lead to a high confidence in the findings.

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