

PARTICIPANT INFORMATION SHEET

1. Introduction

Title of Project: Virtual Reality as a Treatment for Phantom Limb Pain – A Randomised Controlled Trial

2 Invitation

You are being invited to take part in a research study investigating the effect of two different forms of virtual motor training as a treatment for phantom pain. Before you decide, it is important for you to understand why the research is being done and what it will involve. This *Participant Information Sheet* will tell you about the purpose, risks and benefits of this research study. If you agree to take part, we will ask you to sign a Consent Form. If there is anything that you are not clear about, we will be happy to explain it to you. Please take as much time as you need to read it. You should only consent to participate in this research study when you feel that you understand what is being asked of you, and you have had enough time to think about your decision. Thank you for reading this.

3 Purpose of the Study

Phantom pain occurs in about 70-80% of all amputees and many continue to feel the lost body part which is called phantom arm or phantom leg. Some individuals feel that they can move their phantom arms or legs while others feel that the phantom limb is immobile and very painful. Although there are many different ways to treat phantom limb pain, there is still no satisfactory treatment to help all patients. During the last decade, TENS and mirror therapy have started to be used to treat phantom limb pain. A further development has taken place with the help of modern computer technology which enables the training of the amputated body part in a virtual reality. The method involves performing virtual motor training exercises i.e. patients learn to move an image of their phantom arm or leg and this is believed to stimulate repair mechanisms in the brain. We aim to investigate whether two different variants of this new technology effectively reduce phantom pain in amputees.

4 Study Design

The study is a randomized, controlled clinical trial. This means that the you have been randomly assigned to one of two groups that will receive different treatments for phantom limb. Both treatment methods are believed to be effective but we will examine if there is something in one of the two methods more effective than the other. If the current treatment does not give you any improvement, you'll be able to undergo the second form of treatment, if you wish, after completion of the first programme.

5 Taking part – what it involves

What will happen to me if I take part?

In the treatment, adhesive electrodes will be used: these will be attached to the skin on your stump. With these electrodes, signals from the stump muscles can be recorded. When the virtual arm or leg on the screen moves, you should either imagine or perform the same movements with your own phantom arm or leg. Activity in the stump muscles is recorded via the adhesive pads. The training also includes various computer games that are controlled by the system.

There are several possible explanatory mechanisms for the analgesic effect that can be achieved with virtual motor training. It is believed that the areas of the brain required for movements in the amputated arm are partially reactivated. The patient receives visual feedback that tricks the brain into thinking that there is an arm that receives the brain's movement commands. After each treatment, you will be asked to answer questions about how you experience phantom pain. At the first and last treatment session, you will also answer questions about how you experience your health overall. Individual interviews will be conducted on a sample of the study participants after treatment. The objective of the qualitative part is to explore how individuals experienced the treatment, and if and how this is perceived to have affected their health in general. To investigate whether the treatment has a lasting effect, you will be called for examination 1, 3 and 6 months after treatment.

Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form, a copy of which you can also keep. If you decide to take part, you are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect your rights in any way.

How long will my part in the study last?

There will be a total of 15 treatment sessions that last about 2 hours each. You can choose to receive the treatment one, two or five times a week.

What are the possible benefits in taking part?

If the treatment has the effect we expect, your phantom pain is likely to decrease. In the unlikely event that the treatment does not produce results, you will get the opportunity to try the other treatment option after the completion of the long-term follow-up.

What are the possible disadvantages and risks of taking part?

All elements of the study are done under safe conditions by trained and skilled staff and you will not be exposed to any risks associated with either treatment or evaluation. If you come into the treatment group that uses the stump muscles during exercise, you may experience tiredness in your muscles at the beginning of treatment. This, however, is transient.

What happens at the end of the study?

When the long-term follow-up is completed, you will have the opportunity to have a copy of your own results. On request, you can also get information about the overall results of the study. The study and its results will be announced by publication in international scientific journals.

What happens if I change my mind during the study?

You are entitled to change your mind about participating in this at any time without disadvantage or penalty. If you decide to withdraw, all your data will be destroyed and will not be used in the study.

6 Confidentiality

All information that is collected about you during the course of the research will be kept strictly confidential and will not be shared with anyone else. The information collected in this research study will be stored in a way that protects your identity.

Information obtained during this study will be compiled with the help of a computer to analyze the results. The information is treated as confidential and will be stored for 10 years. All data processing

will be done with coded identity (individuals cannot be recognized from their data) and the results will be presented in a way in which no individual can be identified. Your personal information is securely protected and cannot be accessed by unauthorized persons. The identity code concerning research participants will be kept securely at the project leader's site.

7 Responsible for the investigations

Coordinating Investigator:

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Thank you for taking the time to read this information sheet.