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PARTICIPANT INFORMATION STATEMENT

Research Project: A new intervention in upper limb rehabilitation (Outpatient trial)

You are being invited to take part in a research project. This project has been funded by the Hunter Medical Research Institute (HMRI) and the AusIndustry entrepreneurs program. This project is being led by Dr Marquez and Dr Wakely from the College of Health Medicine and Wellbeing at the University of Newcastle. Assisted by Caitlyn Potts, Daniel Steemson, Dimithi Kasthurirathne and Tanishq Khandelwal from the medical program, and Alex Batho from Neuromoves.

Before agreeing to participate in this study it is important that you understand why we are doing the research, risks, and benefits and what you will need to do. Ask as many questions as you like. Discuss it with any family or friends that you like, and take time to decide whether you wish to take part.

Purpose of the project:

This study is for people who have had a stroke or traumatic brain injury and do not have full use of their arm. We want to know if a device that provides stimulation and feedback when you move will help to improve recovery. To be able to use the device you need to have some movement in your arm and not experience motion sickness.

About the device:

The device consists of a glove and a virtual reality headset. The glove will be worn on your affected arm and the headset will be worn on your head covering your eyes. These are connected to a computer and sensors which provide you with feedback. You will do activities such as cleaning your teeth and picking up objects in a virtual world you can see through the headset. The glove will give electrical stimulation and sensory feedback to help you to complete the tasks.

Explanation of the procedures:

A research assistant will ask you some medical questions and assess your arm to make sure the device is suitable for you. You will then be randomly allocated (like tossing a coin) to one of two groups. If you are in the first group (the control group,) you will receive routine therapy three times a week for 5 weeks. If you are in the second group (the device group) you will receive the routine therapy with 15 minutes of each session spent using the device. If you are assigned the first group, you will have the option to try the device at the end of the study.

Time required:

Measurements will be taken at the beginning and end of the study for both groups to allow us to test the effects of the therapy. These are standard therapy assessments and will take about one hour of your time. Some of these assessments will be surveys about how you feel, how tried you get and your general health as well as some physical tests such as strength and movement. These assessment sessions will be in addition to the 15 therapy sessions.

Risks and Discomforts:

There is minimal risk associated with this research. During therapy your arm will be inside a glove and you will wear goggles, and there is a mild risk of skin reddening or pressure areas. The therapist will check your skin regularly to make sure there is no irritation. The electrical stimulation will be set by the therapist at a level that is comfortable for you. If this changes at any time throughout the session, please notify the therapist who will change the level or stop at your request. As you cannot see the real world while using the virtual reality headset, there is a risk of falling. For this reason, you will be seated. The therapist will always be close by to give you rest breaks and make sure you are comfortable. If you experience any other symptoms such as motion sickness, nausea, dizziness or anxiety please tell the therapist.

Costs:

There is no financial reward for your participation in this research. We may be able to assist with your transport costs if required.

Benefits:

We cannot guarantee you will receive any benefits from this study.

Withdrawal from the study:

Participation in this study is completely voluntary. If you decide not to participate there will be no prejudice and this will not affect your relationship with the centre or your therapy. If you do decide to participate you are free to withdraw your consent and to stop your participation at any time without penalty. You do not have to give a reason. If you choose to withdraw from the study you may also ask that any information relating to you also be withdrawn.

Confidentiality:

All the information gathered from this study will remain strictly confidential. All information we collect about you will be de-identified. This means that a code will be used instead of your name to store your data, and your name and contact information will be stored separately from this data. This information will only be accessed by researchers, except as required by law. Your data will be kept for 5 years in a locked filing cabinet and password protected files at the University of Newcastle. Your de-identified data may be made available for other analyses in the future, but if this occurs the data provided to them will not contain any identifying information about you. The results of the study may be published for scientific purposes, but your identity will not be revealed.

Complaints about this research

This research has been approved by the Hunter New England Human Research Ethics Committee of Hunter New England Local Health District, Reference 2019/ETH01251

Should you have concerns about your rights as a participant in this research, or you have a complaint about the manner in which the research is conducted, it may be given to the researcher, or, if an independent person is preferred, to Dr Nicole Gerrand, Manager Research Ethics, Research Office, Hunter New England Human Research Ethics Committee, Hunter New England Local Health District, Level 3, POD, HMRI, Lot 1 Kookaburra Circuit, New Lambton Heights NSW 2305, telephone (02) 49214950. HNELHD-HREC@health.nsw.gov.au

What to do if you wish to participate:

If you are interested in participating in this research please contact Dr Jodie Marquez from the research team to discuss the project further and arrange an appointment. Similarly, if you have any questions about the research at any time, you can contact Dr Marquez: Jodie.Marquez@newcastle.edu.au or 49212041