INFORMATION STATEMENT

Research Project: HELLEN: A robot to assist patients to stand and exercise

Investigators:

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You are being invited to take part in a research project.

Before agreeing to participate in this research study it is important that you read the following explanation. It describes the purpose, procedures, benefits and risks of the project and what will be required from you. Ask as many questions as you like and take time to decide whether or not you wish to take part.

Purpose of the project:

More than one-third of people who survive a stroke or head injury need help in walking and some will never regain the ability to stand without assistance. This affects the patient's ability to participate in rehabilitation, their long term health, and the ability to do social, work and leisure activities.

You are being invited to participate because you have had a stroke or head injury over 3 months ago, and now have difficulty with standing and walking. We will be offering an exercise therapy program using a robotic exoskeleton (HELLEN) to try to find out if this type of exercise therapy can help people who have severe disability, to stand and exercise and improve their health.

About HELLEN:

HELLEN is a REX robotic exoskeleton. This is a device that fits around your lower body with joints that align with your own joints. There are a few different types of therapy robots but this one is unique in that it is free standing, is operated by a joystick control, and allows freedom of the arms whilst in use. The first barrier to accessing this technology is its expensive price, however the Hunter has been fortunate to be the first recipients in Australia of this robot, HELLEN (Hunter's Exoskeleton for Lower Limb Exercise and Rehabilitation).

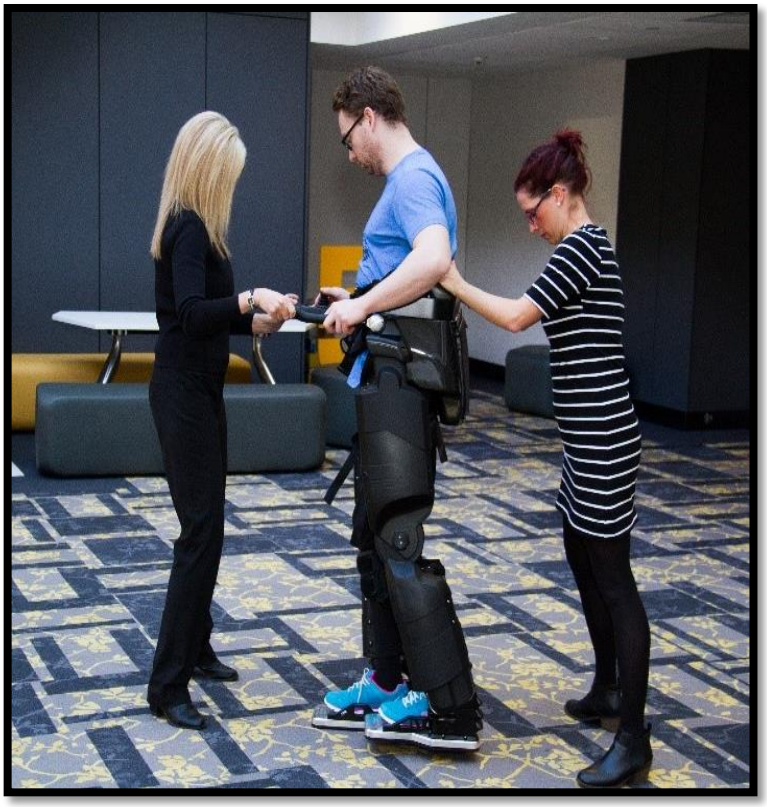
There is currently no available evidence examining the use of this therapy robot in patients with stroke. Therefore we need to determine its value as a stroke rehabilitation tool before it is made available to the wider Hunter community.

The manufacturers of this robotic device have several videos online that you may be interested in viewing. Here is a link to one of them:
https://www.youtube.com/watch?v=cQKZL2hazNs

Explanation of the procedures:

This study will be conducted in the Hunter Building at the University of Newcastle. You are encouraged to bring a family member/carer to accompany you if you wish.

If you agree to participate a researcher/physiotherapist, Nicola Postol, will ask you some medical questions and take some measurements of your legs to make sure exercising in HELLEN is suitable to support you and enable you to exercise. You will be placed on a waiting list for 12 weeks so that we know what your baseline level of function is, then you will be in the study for 12 weeks. Access to this type of therapy is only available while you are enrolled in the study.



Time required:

People who participate in this study will be required to travel to the University of Newcastle 2 times a week for 12 weeks. We have a car park designated for your use and on arrival our assistant will meet you at the car park with a wheelchair to assist you to the research room. Each session will last for one hour. The amount of time you are in the robotic device will vary but may be up to 30 minutes each session. You will also be given a home program of exercises to do in between the sessions which will be reviewed and updated each session. It will be necessary to take some measures to see if exercising with HELLEN is beneficial. This will be conducted at the start of the study, after the first 6 weeks of therapy, after the last session of therapy, and then again 3 months after the program has finished. These are standard physiotherapy assessments and will take approximately one hour of your time. If this study is suitable for you, you may also be asked to have two MRI scans, one before you start exercising with HELLEN and the other at the end of the study. This will be conducted at HMRI (Hunter Medical Research Institute) at the John Hunter Hospital campus. These scans will be done on separate days, but during the same weeks, as your initial assessment and last treatment session. You will also be asked if you wish to participate in measuring oxygen consumption. This will involve wearing a mask during a treatment session in HELLEN. The mask provides detailed information about your exercise tolerance. If you agree to this testing, you will complete these tests during your third or fourth session in HELLEN, and again on your

last treatment session. Part of this testing can include blood testing, but only if you are willing to have blood samples taken.

What is a MRI scan?

MRI is a brain scanning technique which allows us to measure changes in brain activity. Volunteers lie on a table which slides into the cylinder of the scanner. Inside the cylinder is a magnet which produces a magnetic field used to produce brain images. During the scanning procedure, pulses of loud beeps and knocking sounds are produced by the scanner. All volunteers will wear headphones to reduce these noises and to receive instructions from the radiographer. You can talk to the radiographer via an intercom and will be given a hand held buzzer, if activated the MRI staff will speak to you immediately and remove you from the scanner if necessary.

Before the MRI scan you will be asked to remove all metallic objects such as jewellery, jackets with zippers, bras with underwire and medication patches. Navel rings made purely of stainless steel do not need to be removed. We also advise women to remove any eye makeup as it may cause slight eye irritation when in the scanner. Lockers are available to store your personal items whilst you are in the scanner.

All the imaging will be carried out within established safety guidelines and there are no known harmful effects of MRI when operated at these field strengths. MRI uses the same radio waves as are used in radio and TV transmission which have much lower energy than x-rays.

Who should not have an MRI scan?

A few people find being in the confined space of the scanner claustrophobic (severe discomfort in enclosed spaces). Therefore you should not consent to an MRI if you believe you may become claustrophobic as the scanning itself is very expensive and it is only practical for us to carry out the scanning if you are relaxed and comfortable.

If you have any surgical implants, including aneurysm clips, cardiac pacemakers, cochlear and dental implants, then for your own safety you cannot be scanned. As an extra precaution women who may be pregnant are not eligible.

Before being allowed in the scanner you will complete a short questionnaire to make sure you meet all the safety precautions.

What is oxygen consumption?

Those who wish to complete oxygen consumption testing as part of the HELLEN trial will have the air they breathe in and out analysed with a machine called the Cosmed K5. Assessing oxygen consumption allows us to see how hard participants are exercising during a treatment session in HELLEN. We can then compare this to oxygen consumption during walking. This testing will only be carried out twice during the treatment phase of the trial.

Another way to see how hard someone is exercising is to take a small sample of blood from skin capillaries. This is called blood lactate testing. The earlobe is a convenient site for skin blood sampling as there is minimal risk for spreading blood to objects via hand contact. The

earlobe also allows for sampling at a site that does not readily contact other potentially hazardous items and a number of blood samples can be obtained from a single wound over a period of time. Blood may however be sampled from the finger if requested by the participant.

Participants may consent to the oxygen consumption testing, and not the blood lactate samples, and may also participate in the HELLEN trial without completing either of these tests.

Risks and Discomforts:
There should only be minimal risks and discomfort associated with this research. During the robotic therapy you will be strapped into HELLEN and there is a mild risk that you may experience skin reddening or areas of pressure under the straps. The researchers will check your skin regularly to make sure there is no skin irritation. We do not anticipate any blood pressure problems or anxiety about being in the device, but we will monitor your blood pressure to make sure it stays within normal limits, and an investigator will be in close attendance at all times and will aim to keep you as comfortable as possible throughout the session.

Costs:

There is no financial compensation for your participation in this research. Tea and coffee will be provided for you and your carers on the days of your involvement.

Benefits:

We cannot guarantee that you will receive any benefits from this study. However we anticipate that by assisting you to exercise in standing you will gain some health benefits that are known to be associated with this type of activity.

Withdrawal from the study:

Participation in this study is completely voluntary. If you decide not to participate there will be no prejudice. If you decide to participate you are free to withdraw your consent and to stop your participation at any time with no 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. The results of the study may be published for scientific purposes but your identity will not be revealed. Only the researchers will have access to the study data. All study information will be kept in a locked cabinet or password protected computer and then destroyed after 7 years.

Ethical Approval:

This project has been reviewed by, and received ethics clearance through the Hunter New England Human Research Ethics Committee (Ref: 16/08/17/4.06) it will be carried out according to the National Statement on Ethical Conduct in Research Involving Humans (2007)

produced by the National Health and Medical Research Council of Australia. This statement has been developed to protect the interests of people who agree to participate in human research studies.

If you have any comments or concerns about your rights as a participant in this study or a complaint about the manner in which the research is conducted, you may contact the Manager of research Ethics and Governance,

Dr Nicole Gerrand
Manager Research Ethics and Governance,
Hunter New England Health
Ph 4921 4950
Email: HNEHREC@hnehealth.nsw.gov.au

Questions:

If you have any questions about the research at any time, you can contact the principal investigator: Jodie Marquez: 49212041.