Participant information sheet and consent form

Electroacupuncture for improving erectile dysfunction after robotic assisted radical prostatectomy. A randomised controlled trial and feasibility study.

Invitation

You are invited to take part in a research study on the effect of electroacupuncture (EA) and acupuncture on recovery of erectile function in men who have undergone robotic assisted radical prostatectomy with bilateral or unilateral nerve spare. The objective is to investigate whether the intervention, in addition to standard recovery care post-surgery, can improve potency recovery.

The study is being conducted by:

- Emma Wong, registered health practitioner (CMBA) and PhD research candidate Western Sydney University
- Dr Suzanne Grant (PhD), Senior research fellow, Western Sydney University, Senior Acupuncturist, Living Room, Chris O'Brien Lifehouse
- Professor Henry Woo, Urologist SAH and Chris O'Brien Lifehouse
- Associate Professor Ruban Thanigasalam, Urologist, Chris O'Brien Lifehouse
- Dr Sean Walsh (PhD), Senior Lecturer, Faculty of Science, University of Technology Sydney

Before you decide whether you wish to participate in this study, it is important for you to understand why the research is being done and what it will involve. Please take the time to read the following information carefully and discuss it with others if you wish.

1.'What is the purpose of this study?'
The purpose of the study is to investigate whether a combination of electroacupuncture and acupuncture is a feasible model of rehabilitation for erectile dysfunction after robotic assisted radical prostatectomy.

2. 'Why have I been invited to participate in this study?'
You may be eligible to participate in this study because you are > 18yrs and have had a robotic radical prostatectomy with unilateral or bilateral nerve spare and have erectile dysfunction as a result of surgery.

You may not be eligible if you have

- Demand type pacemaker
- Implantable metal plates or pins in the pelvic area
- Needle phobia
- Penile prosthesis
- morbid obesity (BMI index >40)

3. 'What if I don't want to take part in this study, or if I want to withdraw later?'
Participation in this study is entirely voluntary. It is completely up to you whether you participate. If you decide not to participate, it will not affect the treatment you receive now or in the future. Whatever your decision, it will not affect your relationship with the staff caring for you. If you wish to withdraw from the study once it has started, you can do so at any time without having to give a reason. If you do withdraw your consent during the research project, the study doctor and relevant study staff will not collect additional personal information from you, although personal information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law. You should be aware that data collected by the sponsor up to the time you withdraw will form part of the

research project results. If you do not want them to do this, you must tell them before you join the research project.

4. 'What does this study involve?'
If you agree to participate in this study, you will be asked to sign the Participant Consent Form. You will be given a copy of the consent form for your records. The information collected at the enrolment session includes your contact information, cancer treatment history, and three questionnaires that help understand your quality of life and erectile function. These provide a baseline score for potency function prior to the treatments commencing. You will also be invited to participate in a short survey about your experience at completion of the study.

If you agree to participate in the study, you will be randomly placed in Group A or Group B.
Group A will receive the electroacupuncture. You will be asked to attend 10 acupuncture treatment sessions over an eight-week period. Two sessions in the first two weeks, then weekly after this. Each acupuncture session will last around 50 minutes. During each treatment session, you will

- 5-10 minutes of discussion with the investigator prior to the treatment.
- You will then need to disrobe, keeping your underwear on.
- You will be asked to lay on the treatment table in a face down (prone) position. The table has special breathing holes so you will be able to comfortably breathe and hear.
- Pillows and bolstering will be provided under the face, pelvis and ankles to support your position and to reduce discomfort and towels will be used for discretion.
- The locations for needle insertion will be swabbed
- The needles are next inserted: you will feel a tap as the needles insert
- Once the needles are correctly placed, the EA device will be connected to the needles
- The investigator will turn on the device and increase the amplitude of the stimulus to your tolerance level.
- There will be two further adjustments to the device, 7 minutes apart.
- You will then lay in on the table for 20 mins.
- In total, you will spend 41 minutes receiving treatment.

At the end of the treatment time, you will be informed of the device being switched off and removed. All needles are removed

Group B: will continue with usual care and be asked to complete the questionnaires at specific time points. If you are randomized into this group, you will be offered the electroacupuncture treatment at the end of the study with no cost to you if it has shown benefit.

5. 'How is this study being paid for?'
The study is being undertaken as part of a PhD project for a student from Western Sydney University.

6. 'Are there risks to me in taking part in this study?'
All medical procedures - whether for diagnosis or treatment, routine or experimental – involve some risk of injury. In addition, there may be risks associated with this study that are presently unknown and unforeseeable. In spite of all precautions, you might develop medical complications from participating in this study. The risks of participating in this study and receiving treatment include:

- There is a risk of bruising and discomfort from the acupuncture procedure.
- There is risk of uncomfortable sensation from the electrical stimulus
- Although uncommon, some people can feel nauseous or dizzy after treatment

Uncommon risks include There is a risk of cross infection. Risks will be minimized by ensuring that All standard skin penetration precautions are used with all the procedures to limit the potential risk of cross infection. All needles are single-use and sterilised, disposed into the Sharps upon withdrawal.

- Single use gloves will be used for barrier protection.
- PPE will be used where required

7. 'What happens if I suffer injury or complications as a result of the study?'
If you suffer any injuries or complications as a result of this research project, you should contact the study team as soon as possible and you will be assisted with arranging appropriate medical treatment. If you are eligible for Medicare, you can receive any medical treatment required to treat the injury or complication, free of charge, as a public patient in any Australian public hospital.

In the event of loss or injury, you may have a right to take legal action to obtain compensation if your injury or complication is sufficiently serious and is caused by unsafe equipment, of by the negligence of one of the parties involved in the study (for example, the clinician). If you receive compensation that includes an amount for medical expenses, you will be required to pay for your medical treatment from those compensation monies. You do not give up any legal rights to compensation by participating in this study.

If you are not eligible for compensation for your injury or complication under the law, but are eligible for Medicare, then you can receive any medical treatment required for your injury or complication free of charge as a public patient in any Australian public hospital.

8. 'Will I benefit from the study?'
While we intend that this research study furthers medical knowledge and may improve treatment of post prostatectomy erectile dysfunction in the future, there is possibility that it may not be of direct benefit to you.

9. 'Will taking part in this study cost me anything, and will I be paid?
Participation in this study will not cost you anything, nor will you be reimbursed for participating in the study.

10. 'How will my confidentiality be protected?'
All the information collected from you for the study will be treated confidentially, and only the researchers named above will have access to it. Any personal identifiable information, such as name, address, and phone number will not be included in the study. The research database will be compiled without the use of personal identifiers. The database will be held securely at on the Western Sydney University subscription.
Your urologist will be informed of your participation in the trial.

11. 'What happens with the results?'
By signing the consent form you consent to the study doctor and relevant research staff collecting and using personal information about you for the research project. Any information obtained in connection with this research project that can identify you will remain confidential. Your information will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law.

Data will be stored for 15 years and kept securely at the Western Sydney University Westmead campus. Information about you may be obtained from your health records held at this and other health services for the purpose of this research. By signing the consent form you agree to the study team accessing health records if they are relevant to your participation in this research project.

It is anticipated that the results of this research project will be published and/or presented in a variety of forums, including scientific journals or meetings. In any publication and/or presentation, information will be provided in such a way that you cannot be identified.

Information about your participation in this research project may be recorded in your health records.
In accordance with relevant Australian and New South Wales privacy and other relevant laws, you have the right to request access to your information collected and stored by the research team. You also have the right to request that any information with which you disagree be corrected. Please contact the study team member named at the end of this document if you would like to access your information.

Any information obtained for the purpose of this research project that can identify you will be treated as confidential and securely stored. It will be disclosed only with your permission, or as required by law.

12. 'What happens to my treatment when the study is finished?'
This study has no bearing at all on the direction of your treatment.

13. 'What should I do if I want to discuss this study further before I decide?'
When you have read this information, Emma Wong will discuss it with you and any queries you may have. If you would like to know more at any stage, please do not hesitate to contact Emma Wong

14. 'Who should I contact if I wish to withdraw from the study?'

If you want any further information concerning this project, if you would like to withdraw your consent to take part in this study or if you have any medical problems which may be related to your involvement in the project (for example, any side effects), you can contact the principal study researcher on **Emma Wong on 0402 021 124 or e.wong2@westernsydney.edu.au**

This study has been approved by the Western Sydney University Human Research Ethics Committee. The Approval number is H14239

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

Reviewing HREC approving this research:

Reviewing HREC name	Sydney Adventist HealthCare Limited Ethics Committee
Telephone	02 9487 9604
Email	research@sah.org.au
AHCL project ID	2020-040

Thank you for taking the time to consider this study.

If you wish to take part in it, please sign the attached consent form.

This information sheet is for you to keep.

Consent Form

Title:	Electroacupuncture for improving erectile dysfunction after robotic assisted radical prostatectomy. A randomised controlled trial and feasibility study.
HREC Number:	
Coordinating Principal Investigator:	**Emma Wong**
Student Researcher:	Emma Wong
Location:	SAH, Chris O'Brien Lifehouse, NICM Westmead

Declaration by Participant

- I have read the Participant Information Sheet, or someone has read it to me in a language that I understand.
- I understand the purposes, procedures and risks of the research described in the project.
- I have had an opportunity to ask questions and I am satisfied with the answers I have received.
- I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the project without affecting my future health care.
- I understand that I will be given a signed copy of this document to keep.
- I give consent for the research team to obtain the necessary information from my Urologist (please tick) ☐

Name of Participant (please print) _____

Signature _____ Date _____

Witness _____ Date _____

Declaration by PhD Researcher†

I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

Name of PhD Researcher† (please print) _____

Signature _____ Date _____

† A senior member of the research team must provide the explanation of, and information concerning, the research project.

Note: All parties signing the consent section must date their own signature.