WESTERN SYDNEY
UNIVERSITY

Participant Information Sheet

Project Title: Acupuncture for the treatment of endometriosis related chronic pelvic pain: A feasibility study – Healthy Controls CPM and EEG

Project Summary:

You are invited to participate in a research study being conducted by Dr Mike Armour, Professor Caroline Smith, Associate Professor Jason Abbot, Dr Genevieve Steiner, Dr Siobhan Schabrun, Dr Jing Song, Dr Xiaoshu Zhu. The overall study is designed to explore if acupuncture is an acceptable and suitable intervention to treat pelvic pain in women with Endometriosis. This part of the study looks how the descending pain inhibition system and pain processing in the brain works in healthy people.

How is the study being paid for?

This study is internally funded by Western Sydney University.

Why is this study being done?

Women with pelvic pain caused by endometriosis often have pain that continues despite medical or surgical treatment. A variety of pain inhibiting mechanisms exist in several parts of the brain and spinal cord. In individuals with various chronic pain conditions several of these mechanisms have been shown to be dysfunctional. Evidence suggests that if one or more of these pain control mechanisms is not engaged it may increase the development of chronic pain states even when the initial cause of the pain has been resolved. Two possible areas where pain processing could be problematic are central pain processing in the brain and alterations in the body's pain pathways descending from the brain. Our clinical trial on women with endometriosis has been completed and we now need to compare the results from these women with healthy people of a similar age so that we know if their descending pain pathways are not working optimally. We also wish to examine how acupuncture, in healthy people, might change these pain pathways, and if this is different to that of women with pelvic pain.

This study will use a technique called conditioned pain modulation (CPM) to examine any alterations in body's pain pathway and another technique called an EEG, a non-invasive test that looks at brain activity.

What will I be asked to do?

You will be asked to

- Fill in a daily pelvic pain diary for four weeks prior to joining the study. This is to make sure you don't have any pelvic or menstrual symptoms that might suggest a pelvic pain disorder.
- Attend one clinic visit at Western Sydney University, Campbelltown, where you will have an EEG (a non-invasive test that looks at brain activity) a test which examines your sensitivity to pain, called CPM. The test which examines your sensitivity to pain uses a small probe on your forearm to apply pressure. The moment this turns into pain the test will stop. Participants will have pressure applied three times on one arm and then have their other hand placed in ice water for 2 minutes and then pressure applied again.
- You will have information about your age and other demographics recorded.

How much of my time will I need to give?

- The visit to Western Sydney University clinic will take about 2 hours in total.

- Filling in the daily pain diary will take about 1-2 minutes per day.

What benefits will I, and/or the broader community, receive for participating?

As you are one of our 'healthy' control participants, there will not be any direct benefits to you for participating. This study will investigate if other factors, related to changes in pain inhibitory mechanisms, are involved in the persistent nature of pain related symptoms in women with endometriosis. This will provide a platform for further research on the possible influence of these changes in the development of persistent pelvic pain.

Will the study involve any risk or discomfort for me? If so, what will be done to rectify it?

Pressure thresholds - CPM is a well-established, reliable and safe measure of pain processing. A test will be performed to identify the point at which a pressure sensation from a small device placed on your forearm changes from that of pressure to pain. You will be asked to indicate this point and the sensation will be relieved immediately. This is a threshold test and as such you are to indicate when the sensation first becomes painful. It is not a test of how much pressure or pain you can tolerate.

How do you intend to publish or disseminate the results?

It is anticipated that the results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that the participant cannot be identified such as tables showing overall information for the entire group of women.

Will the data and information that I have provided be disposed of?

In accordance with the relevant Australian privacy and other relevant laws, you have the right to request access to your information collected and stored by the research team. Please contact the study team member named at the end of this document if you would like to access your information.

All information collected for this study will be stored securely and destroyed 15 years after the results are published in accordance with university policy.

Can I withdraw from the study?

Participation is entirely voluntary and you are not obliged to be involved. If you do participate you can withdraw at any time without giving reason

If you do choose to withdraw, any information that you have supplied can be withdrawn on your request.

Can I tell other people about the study?

Yes, you can tell other people about the study by providing them the contact details of the chief investigator. They can then contact the chief investigator who can provide them with the appropriate information.

What if I require further information?

Please contact Dr Mike Armour via m.armour@westernsydney.edu.au or 0415363201 should you wish to discuss the research further before deciding whether or not to participate

What if I have a complaint?

If you have any complaints or reservations about the ethical conduct of this research, you may contact the Ethics Committee through Research Engagement, Development and Innovation (REDI) on Tel +61 2 4736 0229 or email humanethics@westernsydney.edu.au.

Any issues you raise will be treated in confidence and investigated fully, and you will be informed of the outcome.

If you agree to participate in this study, you may be asked to sign the Participant Consent Form. The information sheet is for you to keep and the consent form is retained by the researcher/s.

This study has been approved by the Western Sydney University Human Research Ethics Committee. The Approval number is H11984.