Project Title: Acupuncture for the treatment of endometriosis related chronic pelvic pain: A feasibility study

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 and Associate Professor Kenny Lawson. This study is designed to explore if acupuncture is an acceptable and suitable intervention to treat pelvic pain in women with Endometriosis.

How is the study being paid for?

This study is being paid for by Western Sydney University as part of an early career fellowship development grant.

Why is this study being done?

Endometriosis is the presence of endometrial tissue outside the uterus. Worldwide endometriosis is about as common as lower back pain and in Australia at least 15% of women show some symptoms suggestive of endometriosis. One of the major symptoms of endometriosis is chronic pelvic pain, as well as pain during the period, pain on intercourse, pain on urination and pain on bowel motions. Current medications to treat these symptoms, such as the oral contraceptive pill can help many women but often the side effects can be bothersome. Surgery is effective for many women but is invasive and can be costly.

Acupuncture has recently shown some promise in treating the pain related to endometriosis, with two small studies suggesting that acupuncture can significantly reduce the severity of the pain. However current research isn’t conclusive on whether acupuncture can reduce chronic pelvic pain and we know very little information about the mechanisms by which acupuncture might treat endometriosis. In this study we will determine if our planned treatment methods will work (or are ‘feasible’) and to determine if women find this kind of treatment and measurements acceptable. This study aims to investigate this and will allow us to determine if we should do a much larger trial.

What will I be asked to do?

You will be asked to

- You will need to fill in a diary each day rating any pelvic pain you have out of ten and also listing any other symptoms like pain on urination. You will also need to fill in this diary during your menstrual period. You will need to fill this diary in for 4 weeks prior to starting the study so we can get an accurate idea of your pain and other symptoms and to make sure you are eligible for the trial. Once the study has started you will need to fill in this diary every day for the 8 weeks that the trial is running.
- Attend two clinic visits at Western Sydney University, Campbelltown, before and after the study treatment where you will have a blood test taken, have an EEG (a non-invasive test that looks at brain activity) and a test which examines your sensitivity to pain. The test which examines your sensitivity to pain uses a small probe on your forearm to apply pressure, heat or cold. The moment this turns into pain the test will stop. You will also need to complete some questions about your endometriosis symptoms and overall health before and at the end of the study.
• Before you are allocated to a particular group you will need to complete a brief survey about your expectations about how acupuncture might help and a longer survey on your medical history, hospital visits, medication usage and any impact that endometriosis has had on your academic and work performance.
• If you are in the acupuncture group, you will need to visit a local participating practitioner located conveniently for you twice per week for 8 weeks (a total of 16 acupuncture treatments), with at least two days between each treatment session.
• If you are in the usual care group, you will continue to take your medication(s) or other treatment for your endometriosis as per normal.
• At the end of the study, you will fill in a questionnaire about your experience in the study.
• No matter which group you are in, you will still be able to take pain relief if you require it, but you will just need to note that in your diary.

How much of my time will I need to give?

• The visit to Western Sydney University clinic and acupuncture visits will last about 45 minutes each.
• The survey on acupuncture expectations will take less than 5 minutes to complete.
• The survey on your medical history and impact of endometriosis should take 30-60 minutes to complete.
• The daily diary should take less than 2 minutes to complete each day.
• The questionnaire on your endometriosis symptoms and other health related quality of life should take around 20 minutes to complete.
• In total if you are in the acupuncture group you will need to spend around 16 hours over 8 weeks participating in the study. If you are in the usual care group, you will need to spend around 4 hours in total participating in the study.

What is acupuncture?

Acupuncture has been practised by the Chinese for over two thousand years and is now a well-accepted medical practice in Australia. A trained experienced acupuncturist will insert very fine stainless steel needles into specific treatment points on the body called “acupoints”. Up to 14 points are needled at each session. The needles penetrate an average of about 0.5-2cm. After the needles are inserted, you will need to lie quietly on the treatment table until the needles are removed 25 minutes later. Acupuncture should not be painful, though most people say they feel some kind of sensation, often described as a pressure or heavy sensation, but it does not feel like an injection or a blood test due to the fact the needles are very thin.

Who will provide the acupuncture treatments?

We have selected experienced acupuncturists who have had a minimum of five years clinical experience and who are registered with the Chinese Medicine Board of the Australian Health Practitioner Regulation Agency. These acupuncturists have received additional training from Dr Armour on providing acupuncture for the trial. You may choose your acupuncturist from our list of selected and trained practitioners who have been engaged to provide treatments from this study.

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

If you are currently suffering from endometriosis related chronic pelvic pain you may get a reduction in either your daily or your menstrual related pain from having acupuncture treatment, although there is no guarantee this will happen. You will also get a blood test which will show your levels of an inflammatory marker that could be useful to your doctor when determining how your endometriosis is changing. The immediate benefits for the community will not be realised until a full scale trial is undertaken.
To cover the costs of travel out to Western Sydney University each participant will receive a $50 petrol voucher at the conclusion of the study.

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

Acupuncture is generally a very safe procedure. Serious side effects (eg damage to nerves) are very rare – less than one per 10,000 treatments – and most of these side-effects are not likely to occur in this study due to our careful choice of needles, participants, and acupoint location.

All needles used are sterile, single-use and disposable, hence the risk of skin infection is minimal and no more than having a usual injection.

“Minor” side effects occur at the rate of 1-3% of patients, and include drowsiness, minor bleeding or bruising, pain during treatment, worsening of symptoms, tiredness or fainting. Serious side effects such as punctured lungs have been reported in medical literature but are considered very uncommon, and are avoidable in this trial as we will not use acupuncture points that are located near the lungs.

Pressure and thermal pain thresholds - A test will be performed to identify the point at which a pressure sensation and a hot sensation from a small device placed on your forearm changes from that of pressure or heat to pain. You will be asked to indicate this point and the sensation will be relieved immediately. Instead of heat we may use a cold sensation from an ice bath but the procedure remains the same. 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, heat or cold you can tolerate. This procedure will be repeated 3 times. Central Pain Mechanisms - Thermal and pressure stimuli (as described above) will be applied repeatedly just above your threshold to pain. The number of stimuli will be kept to a minimum and you can request to stop any time.

Blood samples – These will be taken by a trained professional who is experienced in drawing blood samples for research. All sterile precautions will be observed. There is the possible risk of a bruise on the forearm after the sample is taken, however pressure will be applied immediately after needle removal which will minimise this risk.

**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. We can also forward your results to your general practitioner if you wish. Please speak to our research team if you wish this to happen.

All information collected for this study will be stored securely and destroyed 5 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.