WESTERN SYDNEY
UNIVERSITY

Participant Information Sheet – Endometriosis and Acupuncture

Project Title: The efficacy of acupuncture for endometriosis pain and related symptoms: a randomized controlled trial

Project Summary:

You are invited to participate in a clinical trial being conducted by Nora Giese, PhD candidate at NICM Health Research Institute under the supervision of Associate Prof Mike Armour, NICM Health Research Institute, Dr Amelia Mardon, NICM Health Research Institute, and Emeritus Prof Caroline Smith, NICM Health Research Institute.

This research aims to evaluate the efficacy and safety of three months of two different types of acupuncture for endometriosis pain and other symptoms.

If you are aged between 18 and 45 years, live in metropolitan Sydney, have a confirmed diagnosis of endometriosis with pelvic pain, and do not intend to become pregnant in the next six months, you may be eligible to participate in the study. To confirm your eligibility, we will need to ask you more questions before you start.

Why is this study being done?

Endometriosis is a condition where endometrial-like tissue grows outside the uterus. The direct consequences of endometriosis usually include different chronic pain symptoms, but also other symptoms beyond pain, such as fatigue, bloating, and gastrointestinal disturbances. The typically complex range of symptoms affects the quality of life of women with endometriosis. Endometriosis has also been consistently associated with mental health issues such as anxiety and depression. Unfortunately, many of the pharmaceutical medications for endometriosis have bothersome side effects or should only be used for a short period of time due to concerns related to dependence and addiction. Therefore, it is important to define other treatment options that are safe, effective, and associated with minor side effects.

Acupuncture has shown promising results in previous research for the management of endometriosis. In addition, it is also considered a safe treatment. Acupuncture is the insertion of fine needles into specific body points. It is part of Traditional Chinese medicine (TCM) and aims to restore the balance, which is believed to be impaired in pathological conditions such as endometriosis. Each needle addresses the entire network, reflecting TCM's holistic approach.

We will test whether two types of acupuncture can improve endometriosis symptoms. We will also examine the safety of the treatment by monitoring any adverse events you might experience.

What will I be asked to do?

1) Initially, we will ask you to consent to screen you for eligibility. We will then screen you for eligibility either by an online questionnaire or by phone call with the PhD candidate Nora Giese. Afterwards, you will be asked to provide confirmation of your endometriosis diagnosis either by laparoscopy, laparotomy with or without histological confirmation,

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specialized transvaginal ultrasound scans (TVUSS), or ovarian endometrioma detected by imaging (MRI, ultrasound) in the past five years. Following the assessment for eligibility, you will be asked to provide informed consent to participate in this trial.

2) Following informed consent to participate in the study, you will be asked to answer some questions about yourself (demographics, e.g., age), your medical history, and your health (including pain severity, quality of life, and mental wellbeing. You will also be asked to complete a weekly endometriosis diary, provided as online questionnaires over a 1-month screening period. This will allow us to capture the severity of your menstrual and/or non-menstrual pelvic pain as well as your current medication use before you enter the treatment period.

3) After completion of the 1-month screening period, you will be randomly allocated to one of two groups receiving two different types of acupuncture. The randomization to the group is vital to ensure a high quality-design of this study. It means that the research team does not have any control over which group you will be allocated to, and you cannot choose the group.

The treatment period will be 3 months, followed by a further 3-month follow-up period. In both the treatment period and the follow-up period, you will be asked to continue your weekly endometriosis diary. Filling in the weekly diary is estimated to take ~2 minutes each time, or 1 hour in total, spread across 7 months.

In summary, the overall study period will be 7 months (28 weeks):

- 1 month (4 weeks) of baseline screening
- 3 months (12 weeks) of treatment
- 3 months (12 weeks) of follow-up.

Acupuncture groups

The acupuncture treatments will take place approximately once a week over a course of 3 months at NICM Health Research Institute, 158 Hawkesbury Rd, Westmead, NSW 2145.

Each treatment will take ~45 minutes of your time. It will not include any other TCM treatment component such as moxibustion, Chinese herbal medicine, or recommendations regarding lifestyle or diet, since we aim to assess the efficacy of acupuncture as a standalone intervention.

The acupuncture treatments will be given by the PhD candidate Nora Giese. Nora Giese is trained in acupuncture and holds a Master's Degree in Advanced Oriental Medicine. She has >10 years of experience in treating people with endometriosis, with at least 15 patients with endometriosis per week.

4) In both acupuncture groups, you are allowed to continue with your current medication as prescribed. This includes hormonal treatment and any rescue analgesic medication for All women will be asked to fill in three types of online questionnaires.

Trial entry form

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You will be asked to fill in a trial entry form before commencement of screening period, which includes questions about your demographics, such as age, educational level, and your medical history.

Weekly endometriosis diary

You will further be asked to fill in your endometriosis diary once a week over the course of 7 months. The questions concern your menstrual pain (in case you have been menstruating), non-menstrual pelvic pain, and other pain symptoms, the number of days and type of analgesic medication you took for pain relief, as well as any adverse events during the 3-month intervention period in case you are in one of the acupuncture groups.

In-depth questionnaires

You will furthermore be asked to complete in-depth questionnaires at three time points: at baseline, at the end of treatment, and after you have completed the 3-month follow-up period.

In these questionnaires, you will be asked in more detail about your symptoms, such as your most impactful endometriosis symptoms, the impact of your pain symptoms on different aspects of your life such as mood, sleep, and impact on level of intimacy or sexual relationships, as well as severity/impact of fatigue. You will furthermore be asked for details of your health-related quality of life and any impact of endometriosis on your ability to work. Finally, we will ask you about your satisfaction with the treatment.

These questionnaires allow a deeper understanding of your symptoms, including but not limited to pelvic pain, and its impact on your life. These insights will help us to understand if acupuncture may cause improvements in symptoms beyond pain and in your overall quality of life and mental health. Lastly, understanding your level of satisfaction with the treatment allows us to understand whether acupuncture meets your needs. This is especially relevant in light of low satisfaction rates, which have been reported for hormonal treatments.

pain relief.

5) You may be invited to participate in a follow-up interview of 30-60 minutes after completion of the three months of treatment, examining your experience of receiving acupuncture in this clinical trial. Women will be invited depending on various factors such as changes/lack of changes in their endometriosis symptoms. The final decision can therefore only be made after the completion of the treatment period. These interviews will be conducted by a researcher who has not been part of the research team until this point in time.

In these interviews, you will be asked on your experience of participating in this trial, e.g., if you found anything that you thought was beneficial, or if there has been anything that you did not enjoy.

Reimbursement

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You will be offered a reimbursement (e.g., for travel expenses or inconvenience) of $60 in total. 50% ($30) will be paid after six treatments and the remaining 50% ($30) after the conclusion of the in-person visits. Reimbursements will be given by Mastercard gift cards.

Parking

Parking will be provided free of charge at NICM Health Research Institute.

How is the study being paid for?

Nora Giese is a National Endometriosis Clinical and Scientific Trials (NECST) Network Fellow and is supported by a NECST Network scholarship for conducting this research project for her PhD at NICM Health Research Institute, Western Sydney University.

How much of my time will I need to give?

Receiving acupuncture treatments over 3 months approximately once per week, including the initial consultation to determine your TCM diagnosis based on your individual signs and symptoms, will take **~9 hours and 15-30 minutes in total** and requires your presence at NICM Health Research Institute, 158 Hawkesbury Rd, Westmead, NSW 2145.

You can fill in all questionnaires online at any time which is convenient - however, on certain days.

- Filling in the trial entry form is estimated to take 20 minutes.
- Filling in the weekly endometriosis diary is estimated to take ~2 minutes each time.
- Filling in the in-depth questionnaires at three points in time (before commencement, at the end of treatment, and at 3-month follow-up) is estimated to take ~30-55 min at each time point.

In summary, filling in questionnaires is estimated to take **~4 hours of your time in total,** spread across 7 months.

Follow-up interview: In case you have been chosen for a follow-up interview, this will take 30-60 minutes of your time.

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

This trial is designed to meet the requirements of cutting-edge research by overcoming the shortcomings of previous research on acupuncture for endometriosis. By meeting this ambitious goal, this research has the potential to result in recommendations for acupuncture in endometriosis in clinical guidelines, and therefore aims to make a difference in clinical decision-making.

We cannot guarantee or promise that you will receive any benefits from this research; however, possible benefits may include an improvement in your overall health through the study intervention.

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

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Medical treatments often cause side effects. You may have none, some, or all of the effects listed below, and they may be mild, moderate, or severe. If you have any of these side effects or are worried about them, talk with your treating practitioner, the PhD candidate Nora Giese.

There may be side effects that the researchers do not expect or do not know about, and that may be serious. Tell your treating practitioner immediately about any new or unusual symptoms that you get. Many side effects go away shortly after treatment ends. However, sometimes side effects can be serious, long-lasting, or permanent. If a severe side effect or reaction occurs, your treating practitioner may need to stop your treatment. Your treating practitioner will discuss the best way of managing any side effects with you.

The known risks of acupuncture are rare and minor adverse events. These may include minor bleeding or hematoma (6.1%) and pain (1.7%), with 2.2% requiring treatment. If you have any of these study effects, tell your treating practitioner. In case of adverse events requiring medical attention, you will be accompanied to a medical doctor for a check-up.

What should I do if I experience any side effects?

If you notice any adverse event such as bruising, mild pain or other unexpected symptoms:

- Keep the area clean and avoid pressing or rubbing it.
- Minor bruising usually resolves on its own within a few days.
- If you are concerned, please contact the study team using the contact details provided below.
- If you experience severe or unusual symptoms, seek medical advice promptly and inform the study team as soon as possible.

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 you cannot be identified, except with your permission. Confidentiality will be maintained by using anonymized data only.

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

Please be assured that only the researchers will have access to the raw data you provide. However, your data may be used in other related projects for an extended period of time.

In accordance with the Australian privacy and other relevant laws, you have the right to request access to your information that we have collected and stored by the research team. Please contact the PhD candidate Nora Giese, N.Giese@westernsydney.edu.au, if you would like access to your information.

We will store all information collected for this study securely and destroy it 15 years after the results are published in accordance with university policy and the Australian Code for the Responsible Conduct of Research.

Can I withdraw from the study?

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Participation is entirely voluntary, and you are not obliged to be involved. If you do participate, you can withdraw at any time without giving a reason by sending a short message to the PhD candidate.

If you do choose to withdraw before commencement of treatment period, any information that you have provided will be deleted.

If you do choose to withdraw after commencement of treatment period, any information that you have provided cannot be deleted because it needs to be included in the data analysis to maintain the reliability of results.

Can I access acupuncture after the completion of trial?

If you wish to use acupuncture after the completion of the study, it is available with one of ~5,000 acupuncturists in Australia. AHPRA registered practitioners can be found on the AHPRA website https://www.ahpra.gov.au/.
The cost of acupuncture treatments are likely to range from $30 to $200 per acupuncture session, depending on the provider and their location.

Can I tell other people about the study?
Yes, you can tell other people about the study by providing them with the PhD candidate's contact details.

What if I require further information?

Please contact the PhD candidate Nora Giese should you wish to discuss the research further before deciding whether to participate.

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Privacy Notice

Western Sydney University staff and students conduct research that may require the collection of personal and/or health information from research participants.

The University's Privacy Policy and Privacy Management Plan set out how the University collects, holds, uses and discloses personal or health information. Further details about the use and disclosure of this information can be found on the Privacy at Western Sydney webpage.

What if I have a complaint?

If you have any complaints or reservations about the ethical conduct of this research, you may email the Ethics Committee through Research Services: 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.

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The information sheet is for you to keep, and the consent form is retained by the researchers.

This study has been approved by the Western Sydney University Human Research Ethics Committee. The Approval number is H16706.

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What will happen to my information if I agree to it being used in other projects?

Thank you for considering being a participant in a university research project. The researchers are asking that you agree to supply your information (data) for use in this project and to also agree to allow the data to potentially be used in future research projects.

This request is in line with current University and government policy that encourages the re-use of data once it has been collected. Collecting information for research can be an inconvenience or burden for participants and has significant costs associated with it. Sharing your data with other researchers gives potential for others to reflect on the data and its findings, to re-use it with new insight, and increase understanding in this research area.

You have been asked to agree to Extended consent.

Extended consent

When you agree to extended consent, it means that you agree that your data, as part of a larger dataset (the information collected for this project), can be reused in projects that are

- an extension of this project
- closely related to this project
- in the same general area of this research.

The researchers will allow this data to be used by members of the research team only.

To enable this re-use, your data will be held at the University in its data repository and managed under a Data Management Plan. The stored data available for re-use will not have information in it that makes you identifiable. The re-use of the data will only be allowed after an ethics committee has agreed that the new use of the data meets the requirements of ethics review.

The researchers want to keep the data for 15 years for possible reuse. After this time, the data will be securely destroyed.

You are welcome to discuss these issues further with the researchers before deciding if you agree. You can also find more information about the re-use of data in research in the National Statement on Ethical Conduct in Human Research – see Sections 2.2.14 - 2.2.18.

https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018

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