



## Participant Information Sheet

**Interventional Study - Adult providing own consent**

### Camden & Campbelltown Hospitals

<b>Title</b>	Acupuncture for Antenatal Depression
<b>Short Title</b>	AcuAnteDep
<b>Protocol Number</b>	1.0
<b>Project Sponsor</b>	University of Western Sydney
<b>Coordinating Principal Investigator/ Principal Investigator</b>	Simone Ormsby
<b>Associate Investigator(s)</b>	Professors' Smith, Dahlen & Hay & Dr Lind
<b>Location</b>	Camden & Campbelltown Hospitals

### Part 1 What does my participation involve?

#### Introduction

You are invited to take part in this study involving a new treatment, acupuncture for antenatal depression. This Participant Information Sheet tells you about the research project. It explains the tests and treatments involved. Knowing what is involved will help you decide if you want to take part in the research.

Please read this information carefully. Ask questions about anything that you do not understand or want to know more about. Before deciding whether to take part, you might want to talk about it with a relative, friend or your local doctor. Participation in this research is voluntary. If you do not wish to take part, you do not have to. You will receive the best possible care whether or not you take part.

If you decide you want to take part in the research project, you will be asked to sign the consent section. By signing it, you are telling us that you:

- Understand what you have read
- Consent to take part in the research project
- Consent to have the tests and treatments that are described
- Consent to the use of your personal and health information as described.

You will be given a copy of this Participant Information Sheet to keep.

#### What is the purpose of this research?

The purposes of this research are to investigate whether acupuncture can reduce the severity of depressive symptoms in pregnancy and improve overall quality of life and, in addition, whether this effect continues into the post-birth period. Recent research has suggested that acupuncture may be helpful in the treatment of antenatal depression however there are still

questions to be answered and a need for a well-designed study to see whether acupuncture really does help with reducing the severity of depression in pregnancy.

The results of this research will be used by the study investigator Simone Ormsby, to obtain a Higher Degree by Research, Doctorate of Philosophy. This study is under the principal supervision of Professor Caroline Smith as well as the co-supervisory team, Professor's Hannah Dahlen and Phillipa Hay and Dr Joanne Lind, from the Western Sydney University.

### **What does participation in this research involve?**

This study is open to pregnant women aged 18 years or older identified as mild to moderately depressed by the Edinburgh Postnatal Depression Scale (EPDS) at their first antenatal hospital visit. In this study, we are unable to recruit women who: have been suffering from a major depressive episode of greater than 2 years duration; have phobias to acupuncture needles or have major obstetric complications such as bleeding, pre-eclampsia, gestational diabetes or premature rupture of membranes.

This is a 'randomized controlled trial': This means that study participants will be randomly placed into groups and given different treatments in order for the results from each to be compared, to see if one is better than another. You will be randomly allocated to one of three study groups. Neither the clinician Ms Ormsby, nor you will be able to decide which treatment you receive. Regardless of the group to which you are assigned, you will continue to receive normal antenatal hospital care as well as your regular depression treatment.

In this study, the 3 groups are acupuncture plus usual care for the treatment of depression, progressive muscle relaxation (PMR) plus treatment for depression and usual care only for the treatment of depression.

The treatments will commence during the 24<sup>th</sup> week of pregnancy and will be completed at the end of the 31<sup>st</sup> week of pregnancy. Data will be collected at the commencement of the study, midway through and at the end but also at birth, and at a 6-week post-birth follow up. The specific details of what will occur at each stage of the study are provided below in a table.

The requirements of all the participants in this study will be:

1. 3 questionnaires will need to be filled out 4 times assessing levels of depression, stress and anxiety as well as quality of life at the commencement of the study, 4 and 8 weeks later, and 6 weeks following delivery. Another questionnaire assessing your early mothering experiences also needs to be completed 6 weeks following delivery.
2. All participants will be required to answer some questions about their sleep at 4 weeks and at the end of the study at 8 weeks. Those participants receiving either treatment will also be required to answer questions about the treatments at these same 2 times.
3. 3 saliva samples are to be collected to assess the level of the hormone oxytocin, as this hormone has been shown to be altered in depression and may affect your ability to bond with your baby. These will be collected at commencement of the study and at 4 and 8 weeks later.
4. 2 blood samples will also be collected, one at commencement of the study and the other at the end, 8 weeks later. These will be used to measure oxytocin receptor levels, as these are also altered in depression.
5. Those participants randomised to receive a treatment will need to attend the clinic at either Campbelltown or Camden Hospitals or the National Institute of Complementary Medicine (NICM), to receive weekly treatments for 8 weeks.
6. Every week from commencement to the end of the study a form assessing depression levels will also need to be completed.

The questions and questionnaires will either be provided to you directly by Ms Ormsby or her assistant Ms Patterson or via mail or the internet.

If you are assigned to the acupuncture group, Ms Ormsby or an additional acupuncturist will also take your pulse and insert acupuncture needles into points located on your lower legs, arms, back and head. Needles will stay in for approximately 10-15 minutes. At the end of the session, 1-2 very small stainless steel balls will be taped to the outer aspects of your ears, to remain in place as long as possible until the next session.

If you are assigned to the progressive muscle relaxation group, each week you will be required to lie in a comfortable position while you are guided through a specific muscle relaxation technique. In the first session, the overall technique will be taught and in the following sessions, a different area of the body will be focused on. The aim each time will be to achieve overall body relaxation.

If you are assigned to the usual care only group, you will not receive any treatments during the study period however you will be offered 4 acupuncture treatments after the study is completed.

### **How will the research be monitored?**

Every week the principle researcher's supervisory panel at scheduled meetings will monitor the conduct of the research. In addition, staff involved in facilitating the smooth running of the project in the obstetric departments of Campbelltown or Camden Hospitals will be in regular communication with the principle researcher regarding the conduct and progress of the research.

### **Will taking part in this study cost me anything, and will I be paid?**

There are no additional costs associated with participating in this research project, nor will you be paid.

### **What do I have to do?**

If you decide to participate, you will be required to continue with your normal depression treatments as well as regular pregnancy care provided by your obstetric antenatal team.

### **Do I have to take part in this research project?**

If you do not wish to take part, you do not have to. Your relationship with those assisting you will not be affected in any way whatsoever if you decide not to take part. If you do decide to take part, you will be given a Consent Form to sign and you will be given a copy of this sheet to keep.

### **What are the alternatives to participation?**

Other options are available if you are not already receiving help such as antidepressant medications and psychotherapy. Your obstetric antenatal care team will discuss these and possibly other options with you before you decide whether to take part in this study. You can also discuss your options with your local doctor.

### **What are the possible benefits of taking part?**

We cannot guarantee or promise that you will receive any benefits from this research; however, possible benefits may include a reduction in the severity and duration of depressive symptoms both in pregnancy and after your baby is born. You may also experience an overall improvement to the quality of your life.

This is an important study because acupuncture is unlikely to be offered to women until we have a better understanding of the advantages or any problems that may arise when acupuncture is used for antenatal depression. The study aims to further knowledge however; it may not directly benefit you.

### **What are the possible risks and or disadvantages of taking part?**

All medical procedures involve some risk of injury. In addition, there may be risks that are currently unknown or unforeseeable. In spite of all reasonable precautions, you might develop medical complications from participating in this study.

When receiving acupuncture, sometimes people report discomfort when a needle is inserted such as a sharp sensation, which may last for a second or two. Some people do not feel anything while the needles are in. Possible side effects may include nausea, dizziness, fainting, increased pain or bruising. The risk of minor side effects is small (a rate of 1.3 per 1000 treatments).

Acupuncture needles are sterile prior to insertion, and are used only once. All needles are disposed of into a sharps-container. The area of needle insertion is also sterilised with an alcohol swab prior to insertion.

There are minimal possible risks of receiving progressive muscle relaxation, which may include slight discomfort whilst lying in the same position for lengthy periods of time and dizziness when getting up too quickly after lying down for long periods.

It is not expected that any of the possible mild and or infrequent side effects will require treatment but in the unlikely event that they do, they will be treated directly by the clinician or you will be referred to your obstetric antenatal care team.

In this study, 2 blood samples are required and having blood taken may cause some discomfort, bruising, minor infection or bleeding. If this happens, it can be easily treated.

If you become upset or distressed because of your participation in the research, or independently of the study, the clinician will arrange a prompt referral to your antenatal care team for appropriate support, which may involve medication and or counselling. Any counselling or support will be provided by your antenatal care team free of charge.

### **What will happen to my samples?**

You will be asked to provide additional consent for the collection of your blood and saliva for this study. Blood samples will be collected by Douglass Hanly Moir Pathology Service at either Campbelltown or Camden before being transported directly to the Western Sydney University either by the principal investigator Ms Simone Ormsby or by her assistant Ms Tiffany Patterson. Saliva samples will be collected at the Western Sydney University or at either Campbelltown or Camden Hospitals by either Ms Ormsby or Ms Patterson before being directly transported to the Western Sydney University. All samples collected will be coded but re-identifiable if required. Privacy/confidentiality of stored tissue samples will be maintained. Any sample remaining after completion of the study will be securely stored in a freezer; however, as these samples may also be useful in future research, we would like to ask you for unspecified consent, which would allow for the possibility of these samples being used again. If this is to occur, separate ethics approval will be sort for the new study. After a certain time, samples will begin to degrade and need to be destroyed and appropriately disposed of.

### **Confidentiality / Privacy**

Under Australian privacy law, all information collected about you must be kept confidential, unless you agree to it being released. If you consent to take part in this study, your medical records and the data collected for the study will be looked at by the research team. They may also be looked at by authorised people from the Western Sydney University to check that the study is being carried out correctly. All of these people will have a duty of confidentiality to you as a research participant and no information that could identify you will be given to anyone else. The only exception that may apply is if a serious worsening of your depression occurs and the clinician deems it necessary to share information with either your obstetric antenatal health care team or the acute mental health service team CoMHET at Campbelltown or Camden Hospitals or both.

**Table 1: Study events, times and requirements**

Study Stages	Location	What you need to do / what will happen	Time needed
Visit 1: Sign up <b>Pregnancy Week 20 – 21.</b>	Campbelltown or Camden Obstetrics Department	If after reading the study details & considering your options you decide to sign up, the following will be required: - Filling out of the consent form - Filling out the Trial Entry Form	2 min 5 -10 min
Visit 2: Sample & Questionnaire Collection: <b>Pregnancy Week 24.</b>	Douglass Hanly Moir Pathology Service	Collection of 1st blood & saliva sample Collection of your 3 questionnaires. Ms Ormsby or Ms Patterson will check that these have been fully completed.	20 – 25 min 10 - 15 min
Randomisation <b>Pregnancy Week 24.</b>	By phone	You will be told which group you are in. If you are in either treatment group, you will be given your treatment schedule. 1 <sup>st</sup> treatment is this week.	5 – 10 min
Visit 3: 1st treatment: <b>Pregnancy week 24.</b> <u>Acupuncture &amp; PMR.</u>	Camden Hospital or NICM, WSU.	Attend your first acupuncture or PMR session at pregnancy week 24. This first treatment session includes a case history assessment.	75 min
Visit 4 - 6: <b>Pregnancy week 25 - 26.</b> <u>Acupuncture &amp; PMR</u>	Camden Hospital or NICM, WSU.	The first fifteen minutes will be spent discussing how you are & your signs and symptoms prior to you receiving either acupuncture or PMR.	60 min
Visit 7a: <b>Pregnancy week 27.</b> <u>Acupuncture &amp; PMR.</u>	Camden Hospital or NICM, WSU.	The first fifteen minutes will be spent discussing how you are & your signs and symptoms prior to you receiving either acupuncture or PMR. Collection of 2 <sup>nd</sup> saliva sample. Collection of 3 questionnaires, sleep & study questions.	60 min 10 min 15 - 20 min
Visit 7b: <b>Pregnancy week 27. Usual Care only.</b>	Camden Hospital or NICM, WSU.	Collection of 2 <sup>nd</sup> usual care saliva sample, 3 questionnaires & sleep question.	05 - 10 min
Visit 8 - 10 : <b>Pregnancy Week 28 - 30.</b> <u>Acupuncture &amp; PMR .</u>	Camden Hospital or NICM, WSU.	The first fifteen minutes will be spent discussing how you are & your signs and symptoms prior to you receiving either acupuncture or PMR.	60 min

Visit 11a: <b>Pregnancy week 31</b> <u>Acupuncture &amp; PMR.</u>	Camden Hospital or NICM, WSU.	The first fifteen minutes will be spent discussing how you are & your signs and symptoms prior to you receiving either acupuncture or PMR. Collection of the final saliva sample. Collection of 3 questionnaires & sleep & study questions.	60 min  05 – 10 min 15 – 20 min
Visit 11b: <b>Pregnancy week 31</b> Usual Care only.	Douglass Hanly Moir Pathology	Final blood & saliva sample collection. Collection of 3 questionnaires & sleep question.	20 – 25 min 10 – 15 min
Post Birth Follow Up <b>Pregnancy weeks 38 - 43.</b>	Service By phone or sms	Once your baby is born, please let the Ms Ormsby know and she will arrange the 6-week post-birth follow up.	05 – 10 min
<b>6 weeks post-birth</b>	By phone and email	4 questionnaires will be either posted or emailed to you. Ms Ormsby will contact you to facilitate the return of the filled out questionnaires.	20 – 25 min

### **Confidentiality / Privacy Continued.**

The results of this study will be published, for example in scientific journals, you will not be identified by name and a summary of findings will be provided to you by letter.

Any information regarding genetic disease predisposition will not be obtained nor will any samples be used to create tissue banks or for any commercial purposes. In addition, any genetic material and information, where potentially identifiable, will not be released for other uses without the participant's prior consent, unless required by law.

### **What if new information arises during this research project?**

Sometimes during the course of a research project, new information becomes available about the treatment that is being studied. If this happens, your clinician will tell you about it and discuss with you whether you want to continue in the study. If you decide to withdraw, your clinician will arrange for your regular health care to continue. If you decide to continue in the research project, you will be asked to sign an updated consent form.

In addition, on receiving new information, your clinician might consider it to be in your best interests to withdraw you from the research project. If this happens, he/ she will explain the reasons and arrange for your regular health care to continue.

### **Can I have other treatments during this research project?**

During the entire duration of the study, that is from signing up to participate at pregnancy week 20 – 21 right up until 6 weeks past the birth of your baby, you will not be able to receive either acupuncture or progressive muscle relaxation during the study other than that provided by the clinician.

### **What if I withdraw from this research project?**

If you wish to withdraw from the study after it has started, you can do so at any time without having to give a reason. There will be no consequences to you for withdrawing from the study and it will not affect the type of care you receive from either the clinician or any of the obstetric antenatal care team, now or at any time into the future. 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 also be aware that data collected up to the time you withdraw will form part of the research project results and it may not be possible to return to you your samples and or withdraw your data from the study results if these have already had your identifying details removed.

If you do decide to withdraw from the project, please notify the clinician before you withdraw. This notice will allow the clinician or research supervisors' time to discuss any special requirements linked to withdrawing.

### **Complaints and compensation**

If you suffer any injuries or complications because of this study, you should contact the Ms Ormsby as soon as possible, who will then assist you in arranging appropriate medical treatment. You may have a right to take legal action to obtain compensation for any injuries or complications resulting from the study. Compensation may be available if your injury or complication is sufficiently serious and is caused by unsafe equipment, or by the negligence of one of the parties involved in the study (for example, the phlebotomist, the hospital, or 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.

### **Who is organising and funding the research?**

This research is being conducted as part of a Higher Degree by Research at the Western Sydney University. No external sponsorship is involved and no member of the research team will receive any personal financial benefit from your involvement in this research project.

### **Who has reviewed the research project?**

All research in Australia involving humans is reviewed by an independent Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the HREC of the South Western Sydney Local Health District (SWSLHD).

If you have any concerns about the conduct of the study, or your rights as a study participant, you may contact the HREC of the South Western Sydney Local Health District (SWSLHD) directly. Any issues you raise will be treated in confidence and investigated fully, and you will be informed of the outcome

This project will be carried out according to the National Statement on Ethical Conduct in Human Research (2007). This statement has been developed to protect the interests of people who agree to participate in human research studies.

### **Further information and who to contact**

When you have read this information, the researcher will discuss with you any queries you may have. If you would like to know more at any stage, please do not hesitate to contact the clinician Simone Ormsby at NICM, WSU. If you have any problems during the study, please contact Simone Ormsby on +61 2 4620 3290 or 0414 476 711 or by email on [simone.ormsby@westernsydney.edu.au](mailto:simone.ormsby@westernsydney.edu.au) or Professor Caroline Smith on + 61 2 4620 3777 or by email on [caroline.smith@westernsydney.edu.au](mailto:caroline.smith@westernsydney.edu.au).

If you feel you require urgent medical attention, please either call an ambulance or attend the emergency department of your local hospital. The contact phone number for Campbelltown and Camden Hospital is 02 4634 3000.

For matters relating to research at the site at which you are participating, the details of the local site complaints person are:

**Reviewing HREC approving this research and HREC Executive Officer details**

This study has been approved by the South Western Sydney Local Health District Human Research Ethics Committee. Any person with concerns or complaints about the conduct of this study should contact the Ethics and Research Governance Office, Locked Bag 7279, LIVERPOOL BC, NSW, 1871 on 02 8738 8304, fax 02 8738 8310, email [research.support@sswahs.nsw.gov.au](mailto:research.support@sswahs.nsw.gov.au), website: <http://www.sswahs.nsw.gov.au/swslhd/ethics/default.html> and quote HREC/14/LPOOL/400, SSA -14/228.

**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.**