



Participant Information Sheet – Medical (Specific)

Project Title: Acupuncture for weight loss in Polycystic Ovary Syndrome: a feasibility study

Project Summary: This is a preliminary study which will provide information on whether it is possible to conduct a larger clinical trial on acupuncture or ear acupuncture for weight loss in Polycystic Ovary Syndrome (PCOS).

You are invited to participate in a research study being conducted by Dr Carolyn Ee, Research Fellow at NICM Health Research Institute.

How is the study being paid for?

The study is funded by an NHMRC in CRE in PCOS Project Grant and by a Western Sydney University Partnership Grant in partnership with the company Neural Ear Stimulation International

Why is this study being done?

Polycystic Ovary Syndrome(PCOS) is a very common women's health condition affecting at least 10% of Australian girls and women. It often results in irregular periods, infertility, acne, excess facial and body hair, and an increased risk of developing serious and chronic health conditions like diabetes and heart disease.

Women with PCOS are more prone to having excess weight, and excess weight makes the symptoms of PCOS worse. Weight loss will improve the symptoms and complications of PCOS. A healthy diet, reducing calories, and increasing exercise can help women with PCOS lose weight, however many women find it difficult to lose weight even with changing their lifestyle habits, and there is a need for additional weight loss treatments. Metformin is a medicine that can help women with PCOS lose weight but currently it is not indicated on the Pharmaceutical Benefits Scheme for treatment of PCOS. Also, the combination of lifestyle and Metformin may still not be enough to help women achieve their desired weight loss.

There has been interest in the role of acupuncture as an additional treatment for weight loss. Acupuncture (including ear acupuncture, which involves applying acupuncture needles to points around the ear) has been shown to be more effective for weight loss than sham or "fake" acupuncture in adults without PCOS, and also shows promising results in women with PCOS. However, the current research on acupuncture for weight loss in PCOS is insufficient in telling us whether or not it is an effective weight loss treatment. We are interested in the possible role of acupuncture as an additional treatment for weight loss in women with PCOS. To answer this question, we will need to conduct a large clinical trial. **Prior to embarking on such a large and expensive study, we want to do a small, preliminary study to see if acupuncture may be effective, whether it is possible (feasible) to conduct a larger study, and whether our proposed treatment is acceptable to women in the community with PCOS.** We have completed focus groups with women with PCOS which have informed the design of this study.

What will I be asked to do?

If you decide to participate, you will be asked to:

- **Have your diagnosis of PCOS** confirmed by Dr Ee, who is the Chief Investigator in this trial and a practising GP. Dr Ee will contact you via telephone and ask you questions about your menstrual cycle and whether you have signs of high testosterone such as excessive hair growth or male pattern balding, and about your previous blood test and ultrasound reports. You may be requested to provide Dr Ee with copies of your reports. If this is the case, please remove all identifying details before faxing or emailing your reports. Alternatively, you can request your pathology or radiology provider to send the reports securely to Dr Ee's clinic rooms, in the same way as they send reports to your regular GP.
- **Attend two clinic visits** at Western Sydney University, Campbelltown, before and after three months of treatment, during which you will be asked to complete a number of surveys about your health, and a research assistant will measure your weight, height, waist measurement, blood pressure and heart rate using an electrocardiograph (ECG) machine. You will be reimbursed up to \$40 in total for travel costs.
- **Have blood tests taken before and after three months of treatment**, including a two hour Oral Glucose Tolerance Test. If you are diagnosed with diabetes or impaired glucose tolerance after this test, you will be referred back to your GP for management, as you will not be eligible to join the study.
- All women are asked to register for and take part in the **GetHealthy program** (the lifestyle intervention), which is a telephone coaching service provided by the NSW Government.
- **Women will be randomised to one of three groups:** GetHealthy program only, acupuncture, or ear acupuncture. You will have a 1 in 3 chance of being allocated to one of these groups.
- If you are randomly allocated to receive **body acupuncture**, you will be asked to attend 11 acupuncture treatments over twelve weeks. Treatments are given twice a week in the first 2 weeks, weekly for 4 weeks, and then fortnightly for 6 weeks. For quality assurance purposes, a de-identified photograph may be taken of the acupuncture point location to be verified by the investigators of the study. No identifying features will be included in the photograph.
- If you are randomly allocated to receive **ear acupuncture**, you will be asked to attend 6 acupuncture treatments over twelve weeks, and wear a small ear acupuncture stimulation device for up to 96 hours after each acupuncture treatment. For quality assurance purposes, a de-identified photograph may be taken of your ear after insertion of the device to be verified by the investigators of the study. No identifying features will be included in the photograph. Treatments are given weekly for 2 weeks, then fortnightly for 4 treatments.
- After the first treatment, **complete a brief survey** about your expectations from acupuncture and which treatment you thought you had just received
- **Wear an accelerometer** for 5-7 days before you start the study, and in the final week (Week 11). An accelerometer is a pedometer worn as a waistband.
- **Record the first day of each menstrual period** for 12 weeks, in a menstrual calendar
- Provide some basic details about your medical history and demographic details before you start the study
- At the end of the study, complete a survey about your experience in the study
- At 3 and 6 months after the completion of the study, a research assistant will contact you by telephone to ask if you have fallen pregnant

How much of my time will I need to give?

- The clinic visits will last up to one and a half hours each.
- Body acupuncture visits will last about 45 minutes each.
- The ear acupuncture visits will last about 30 minutes each
- The blood tests will take at least two hours each
- The survey on acupuncture expectations will take less than 5 minutes to complete
- The GetHealthy program involves up to 13 telephone calls of up to 15 minutes each, plus time taken to meet your diet and exercise goals

- The survey completed at the end will take around half an hour to complete.

Your total estimated time commitment for the entire study (3 months), if you are in the acupuncture group, is approximately 15-16 hours, not including travel and exercise time.

What is acupuncture?

If you agree to take part in the study, you will have a 1 in 3 chance of being randomly allocated to receive acupuncture as well as the lifestyle intervention.

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 12 points are needled at each session. The needles penetrate an average of about 0.5-2cm. The acupuncturist will connect four of the needles to an electro-acupuncture machine. This delivers a vibration to the needles for additional stimulation of the acupuncture points, which is thought to increase the effect of acupuncture. After the needles are inserted, you will need to lie quietly on an examination couch until the needles are removed 20-30 minutes later. During this time you will be provided with a buzzer in case you are uncomfortable or need attention during treatment.

What is ear acupuncture?

All women have a 1 in 3 chance of being randomly allocated to receive ear acupuncture stimulation as well as the lifestyle intervention.

Ear acupuncture is a form of acupuncture that involves inserting very small needles into acupuncture points around the ear. We are trialling a small medical device, the "Neurova", that has received approval by the Federal Drug Administration in the USA for treatment of chronic pain. This device delivers micro-currents to the ear acupuncture points to increase the acupuncture effect, and is worn just behind the ear for up to 96 hours after each acupuncture treatment. After 96 hours you can easily remove the device and discard it in the medical sharps container that will be provided to you. Please bring this container in when you attend for your final clinic visit, so that we can dispose of it according to health regulations. You will not receive any acupuncture needles on the body if you are allocated to this group.

Is acupuncture painful?

No, acupuncture is not painful, although a lot of patients do report feeling some sensation, but this is usually not particularly uncomfortable. The needles are much finer and a different shape to the needles used during injections or blood tests, which accounts for their greater comfort.

If you decide to participate in the study, you can discuss any concerns about acupuncture with Dr Carolyn Ee who is a medical doctor as well as an acupuncturist.

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 Ee 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.

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 with body acupuncture 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.

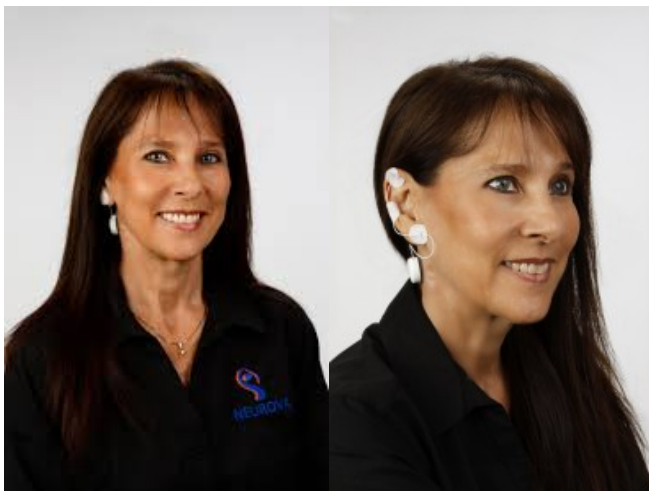
What are the risks of receiving ear acupuncture stimulation with the Neurova device?

The Neurova ear acupuncture stimulation device has been clinically trialled and is generally well tolerated. Pain and dizziness has been reported with ear acupuncture stimulation.

Infection of the cartilage of the ear is a very rare complication of receiving ear acupuncture. There have been no reports of this in the past 27 years. However, should you notice any redness, swelling, pus, or pain around needle insertion, please consult a medical doctor immediately, as this type of infection can lead to disfigurement if not treated with antibiotics.

While it is unlikely that there will be a serious side effect during pregnancy, there is no safety data for use of this device in pregnancy. Therefore, if you are allocated to the ear acupuncture group, you will be asked to use adequate contraception for three months while you are receiving ear acupuncture. Please cease using the device immediately if you discover that you are pregnant.

While the Neurova device is small, it will most likely be visible, especially if you have short hair. Please see below for photos of the Neurova when attached.



What should I do before and after having acupuncture?

Try not to attend for treatment when hungry or dehydrated. It increases your chance of fainting.

Be aware of the risk of drowsiness. If you do get drowsy, you will need to stay in the clinic until this passes, which is usually within an hour.

There are no special instructions for you to follow after having acupuncture, apart from taking it easy for the next 24 hours.

If you are receiving ear acupuncture, please disconnect the device before any contact with water, such as having a shower or bath, or going swimming.

What is the Get Healthy program?

The GetHealthy program is provided for free by the NSW government. It is a telephone coaching service aimed at helping people have healthy lifestyles. All women will be asked to register for GetHealthy (We can assist you with this process). You will have up to 13 10-15 minute phone calls over 3 months with a trained health coach. During these calls you and your coach will set health goals that are important to you, and talk about the sorts of things you can do to achieve them. Your coach will plan calls so you can talk about how you are going, give you more ideas about other actions you could try to help meet your goals and keep you on track. You will be asked to set at least one of your health goals to match the goals of the study to lose weight.

You can register for the GetHealthy program even if you have done it previously, and you may continue it after study completion, as the coaches continue to call you until 6 months after registration.

Can I use other treatments while I am having acupuncture?

Although we encourage you to avoid starting new treatments such as complementary therapies (vitamins, supplements) while you are having acupuncture, there is no requirement for you to use only acupuncture while you are in the study. We will ask you about any new treatments you might have started during the study at your 12 week visit.

Where will I get the blood tests taken, and what are the risks?

Blood tests are taken by qualified collection staff at Laverty Pathology. You will be asked to fast overnight (8-14 hours) for a Two Hour Oral Glucose Tolerance Test. During a fast, you must not have anything to eat or drink.

Water is acceptable, but NO soft drinks, tea, milk, coffee or fruit juices may be taken during the fast. Smoking is not permitted on the day of the test and until the test is completed.

On arrival at your chosen Collection Centre, a blood sample will be taken from you by one of Laverty's trained collecting staff. You will then be asked to drink a sweet glucose drink and blood will be collected one and two hours later.

Please note that you will be required to remain in the Collection Centre for the duration of the test. We suggest you bring a book to read to help pass the time.

Blood tests are usually well tolerated, however some people may experience minor pain or discomfort, and bleeding or bruising. Some people may feel dizzy during the fast.

What is involved in measurement of my heart rate?

We are interested in the effect of acupuncture and ear acupuncture on heart rate variability, or the degree to which your heart rate varies. This is an indicator of the "fight or flight" response, which can have an impact on weight control.

To measure your heart rate accurately, we will use an electrocardiograph machine at our laboratories. You will be asked to remove your shirt or blouse in order for a trained female research assistant to apply three adhesive electrodes onto your chest area. Following this you are asked to lie quietly for a few minutes while your heart rate is recorded. This procedure involves no discomfort apart from the

need to partially disrobe. You will have this procedure done before and after the three months of treatment.

Please do not consume any caffeine or smoke for 2 hours before your clinic visit.

What is involved in the clinic visits?

During the two clinic visits (before and after the study) you will be asked to complete surveys about your quality of life and about any anxiety or depressive symptoms, and have your weight, height, and blood pressure checked as well as heart rate monitoring as described above. Our research assistant, who is female, will also be obtaining a score of how much excessive hair you might have. This will involve asking you to disrobe so that she can visualise your chest, back, legs, lower abdomen, and top of buttocks. You will not need to remove your bra or underwear and the examination will take place in a private consultation room. This examination might take a few minutes and is done by observation only. It is a reliable indicator of how much excessive testosterone you may have and is commonly performed in clinical consultations of women with PCOS.

What will happen to information about me?

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.

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

You may benefit from participating in this study in several ways. First, acupuncture may help you lose weight, although there is no guarantee that it will, and also no guarantee that you will receive real acupuncture. Second, you will have your health monitored throughout this study. This includes having your weight and blood pressure monitored, and measuring your quality-of-life. This information will be very useful for your doctor in treating your PCOS symptoms, and we can forward your results to your doctor on your request. Third, you will receive health and lifestyle coaching from a trained health coach, although it is important to understand that this service is already provided for free for any NSW resident.

We will reimburse you up to \$40 in total for travel costs associated with taking part in this study. You will be able to claim this after you attend for your second (and final) clinic visit.

The benefits to the broader community will not be realised for some time yet, but if acupuncture is shown to be effective for weight loss, it could be a valuable additional treatment because it is readily available in the community and is a generally low-risk treatment.

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 including in medical journals and at conferences. In any publication and/or presentation, information will be provided in such a way that the participant cannot be identified.

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 and that your data will not be used in any other projects. Please note that minimum retention period for data collection is five years post publication. The data and information you have provided will be securely disposed of.

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 a reason. Your decision to participate, or to decline participation, will not in any way affect your current treatment from your medical doctor.

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

Can I tell other people about the study?

Yes, you can tell other people about the study by providing them with the chief investigator's contact details. They can contact the chief investigator to discuss their participation in the research project and obtain an information sheet.

Data storage

There are a number of government initiatives in place to centrally store research data and to make it available for further research. For more information, see <http://www.and.s.org.au/> and <http://www.rdsi.uq.edu.au/about>. Regardless of whether the information you supply or about you is stored centrally or not, it will be stored securely and it will be de-identified before it is made available to any other researcher.

What if I require further information?

Please contact Dr Carolyn Ee or the Research Officer Adele Cave should you wish to discuss the research further before deciding whether or not to participate.

Dr Carolyn Ee c.ee@westernsydney.edu.au or 0490435100

Adele Cave a.cave@westernsydney.edu.au or 0487 472 273

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 H11973.