This study is about overweight women with PCOS who are trying to regulate their menstrual cycle and improve their fertility. The purpose is to investigate the role of naturopathy (herbal medicine + a consultation with a naturopath), in addition to diet and exercise, to find out whether or not naturopathy can improve physical characteristics, menstrual regularity and fertility.

**What does the study involve?**

The study involves your participation in a 12 week exercise and healthy eating program, with the possibility of also taking herbal medicine tablets and meeting with a naturopath once a month.

You will be randomly assigned to one of two groups: diet and exercise or diet and exercise plus naturopathy. You cannot choose which group you would like to be in.

The diet and exercise program will be supervised by a qualified exercise physiologist and designed according to the latest evidence based guideline for women with PCOS. It recommends a healthy diet and exercising for 150-180 minutes per week.

This study involves 2 face to face exercise sessions, at week 1 and week 12, and home based exercises with weekly contact by email or telephone with an exercise physiologist or researcher. A specific exercise program will be prescribed which includes 150 minutes of exercise per week. You will be required to monitor your exercise using a pedometer to record your weekly physical activity and monitor your progress as well as a diary to keep record.

The diary will also contain space for you to record your menstrual cycle details like the first day of your period. Ovulation tests will also be given to you and may be used to confirm when you are fertile or the first and second part of your cycle.

The diary will be explained in detail at the beginning of the trial. You will be interviewed to confirm your suitability and asked questions about your menstrual cycle and lifestyle habits. The same questions will be asked at the end of the trial. There are 2 questionnaires at the beginning and end of the trial. These address PCOS and how you are feeling.

You may be allocated to a group which also receives naturopathy. Naturopathy involves taking 3 herbal medicine tablets each day, plus another 2 tablets daily before ovulation.

The use of herbal medicine is common practice for women with PCOS, women trying to improve their menstrual regulation and well-being and get pregnant. The naturopathic consultation will take place at a consultation room at the university or by telephone for half an hour to provide individualised information and support.
How much time will the study take?

Overall the study will take 12 weeks. The questionnaires should take about 20 minutes. The trial entry interview will take about 40 minutes. Each week will involve at least 150 minutes of home based exercises plus email contact. If you are allocated to the naturopathy group, 30 minutes every 4 weeks at Complied or by telephone.

If you have an irregular menstrual cycle you may be invited to do a blood test at Douglas Hanly Moir at the conclusion of the trial which will take about half an hour depending on where you live and the location of the blood collection rooms for blood tests.

Will the study benefit me?

Being on the study may help you lose weight and improve symptoms associated with PCOS including your menstrual regularity.

Will the study involve any discomfort for me?

The exercise will be supervised by a qualified exercise physiologist and tailored to individual characteristics however some people may find exercise uncomfortable.

You will be supported and monitored throughout the 12 week exercise program. Warm up and cool down stretching may reduce muscular pain from exercise as can drinking water, however with any improvement of body composition, there may be some muscular discomfort. If this occurs please immediately inform the exercise physiologist and exercises will be adjusted accordingly.

Some people experience side effects from herbal medicine such as nausea or headaches. These symptoms are usually temporary and subside if the dose of the herbal medicine is reduced, however if side effects are overwhelming or you cannot manage to take the herbal medicine, please contact the researcher Susan Arentz on the number or email below.

If you find that you are feeling upset or distressed because of, or during the trial, please contact the researcher Susan Arentz. Alternatively if you feel more comfortable the free telephone counselling service Lifeline on 13 11 14 or contact your GP.

Susan Arentz 0403 044 247 or email s.arentz@uws.edu.

How is this study being paid for?

The study is being supported by funds for Susan Arentz to complete her PhD. The herbal medicine tablets are being provided by Mediherb Australia.

Will anyone else know the results?

All aspects of the study, including results, will be confidential and only the researchers will have access to information on participants. Results will be presented as part of a manuscript for publication. Participants in the trial will receive a copy of the manuscript by e-mail or mail.

Can I withdraw from the study? Participation is entirely voluntary: you are not obliged to be involved and, if you do participate, you can withdraw at any time without giving any reason and without any consequences.

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.

What if I require further information?

When you have read this information, Susan Arentz will discuss it with you further and answer any questions you may have. If you would like to know more at any stage, please feel free to contact Susan Arentz PhD candidate.

What if I have a complaint?

This study has been approved by the University of Western Sydney Human Research Ethics Committee. The Approval number is H9407.

If you have any complaints or reservations about the ethical conduct of this research, you may contact the Ethics Committee through the Office of Research Services on Tel +61 2 4736 0229 Fax +61 2 4736 0013 or email humanethics@uws.edu.au.