VICTORIA UNIVERSITY

INFORMATION TO PARTICIPANTS INVOLVED IN RESEARCH

You are invited to participate.

You are invited to participate in a research project entitled "Comparative analysis of Home-based vs. Laboratory-based High-Intensity Interval training in females with Polycystic Ovary syndrome who are overweight and obese". This project is being conducted at Victoria University. The investigators involved are Prof. Andrew McAinch, Dr Rhiannon Patten, Ms Naina Tyagi, and A/Prof Andrew Garnham from the Institute of Health and Sport at Victoria University, Prof. Raymond Rodgers from the University of Adelaide, and Dr Anju Joham from Monas University.

Project explanation

Polycystic Ovary Syndrome (PCOS) affects over 10% of reproductive-age females in Australia, impacting both metabolic and reproductive health and increasing the risks of inflammation, anxiety, and depression. Exercise and diet are key treatments, but many females with PCOS struggle to stay active due to time constraints, low self-esteem, and body image concerns. High-intensity interval training (HIIT) is effective but is often expensive and limited to supervised facilities. Therefore, the potential solution to overcome these barriers is a home-based HIIT program. This study compares the effects of 12 weeks of home-based HIIT to lab-based HIIT on various health outcomes in women with PCOS and examines the long-term benefits at 3- and 6-month post-intervention. Focus groups will provide insights into participants' experiences and help improve future programs.

You are eligible to participate in this study if you:

- Are a female aged between 18-45 years (and pre-menopausal)
- Have been diagnosed with PCOS.
- Have a BMI greater than 25 kg/$m^{2.}$

Exclusion criteria: Pregnancy or breastfeeding, smoking, diabetes, uncontrolled hypertension (>160/100 mmHg), established CVD, renal impairment, and malignancy or taking medications that interfere with endpoints (e.g., insulin sensitisers, anti-obesity drugs).

What will I be asked to do?

First, you need to complete the following screening questionnaires: peripheral venous catheterisation questionnaire, risk factor assessment questionnaire and physical activity readiness questionnaire (PAR-Q). These questionnaires will confirm if you are eligible for the study and if required you may be asked to see your GP for approval to exercise before participating in the study. This screening session will also allow you to ask any questions about the study. If you are eligible and would like to participate in the study, you will be required to sign a consent form.

This research study will require you to undertake a:

- A 12-week exercise training program

And to complete the following procedures at baseline, post-intervention, and follow-up:

- Graded exercise test (GXT).
- Body composition assessment (weight, height, hip waist measurements and DXA scans).
- Blood sampling
- Physical activity monitoring using an accelerometer.
- Oral glucose tolerance test (OGTT).
- Continuous glucose monitoring (CGM).
- Exercise testing- graded exercise test.
- 7-day food diary.
- Menstrual diary throughout the intervention.
- Complete questionnaires regarding mental health and physical health.
- Focus group discussions conducted at post-intervention and 6 months follow-up.

What will I gain from participating?

We cannot guarantee that you will gain a direct benefit from this study. However, you may experience the benefits of increased physical activity including increased energy and improved metabolic and reproductive health. By joining this study, you will have the opportunity to access a structured exercise program designed by our team of researchers and fitness professionals. You will receive free exercise and body composition testing which carry a commercial value of $200-$300. Additionally, you will have access to motivation and support from our team, as well as educational resources on exercise guidelines, proper technique, and injury prevention.

How will the information I give be used?

All information obtained in this research project that can identify you will remain confidential and will only be used for research purposes. It will only be disclosed with your permission or in the very unlikely scenario that it is required by law, which would be for a criminal case and not to establish any health risk profile. Your samples will be stored without your name or personal details and identifiable only by the researchers involved in this study. With your additional consent, samples remaining will be stored for up to 15 years to potentially be used for future related analyses to further our understanding of PCOS and the benefit of exercise. De-identified data collected during the study will be used in student theses, conference presentations and published peer-reviewed papers. No personal details will be revealed.

What are the potential risks of participating in this project?

Before you volunteer for this study, make sure you carefully read the items below:

- It is important that you have not experienced one or more of the following:
  - Exercise testing that resulted in chest pain, or chest pain at any other time in the past 6 months related to exertion.
  - Current muscle and joint pain (e.g., arthritis) and/or nerve pain that will prevent comfortable participation in exercise.
- You are free to withdraw from this study at any time without any consequences or need for explanation.
- For any medical emergencies, a call to 000 will be made whether you are in the lab or at home. The researchers will also commence appropriate resuscitation methods while waiting for an emergency team to arrive.
- To assess your body composition (fat and lean mass), we will use a device called a DXA. This assessment exposes you to a small amount of radiation, however this is much less than the natural background radiation you receive yearly. No harmful effects have been demonstrated with this small exposure.
- Additionally, continuous glucose monitoring (CGM) will be used, which involves placing a small sensor under the skin to measure glucose levels in real-time. While CGM is generally well-tolerated, it can occasionally cause skin irritation or discomfort at the insertion site.
- There is a small risk of bruising or infection (e.g., tenderness and/or redness) from the blood sampling procedures. This risk will be minimised with blood sampling undertaken by trained personnel under sterile conditions.
- There is a risk of muscle soreness due to the exercise protocol (HIIT training). This is a normal response to this type of exercise, and while uncomfortable, it poses no significant health risk to you and passes after several days. This can be minimised by employing an adequate warm-up and performing each exercise with the correct technique.
- Participating in a research study with different exercise training and testing sessions can increase some people's psychological stress, while rare, this can occur. Should you experience any adverse or unusual psychological changes, you will be referred to a psychologist associated with this study, Prof. Alex Parker (Victoria University Psychologist). Prof. Alex Parker can be contacted at +61 (03) 9919 4000.

How will this project be conducted?

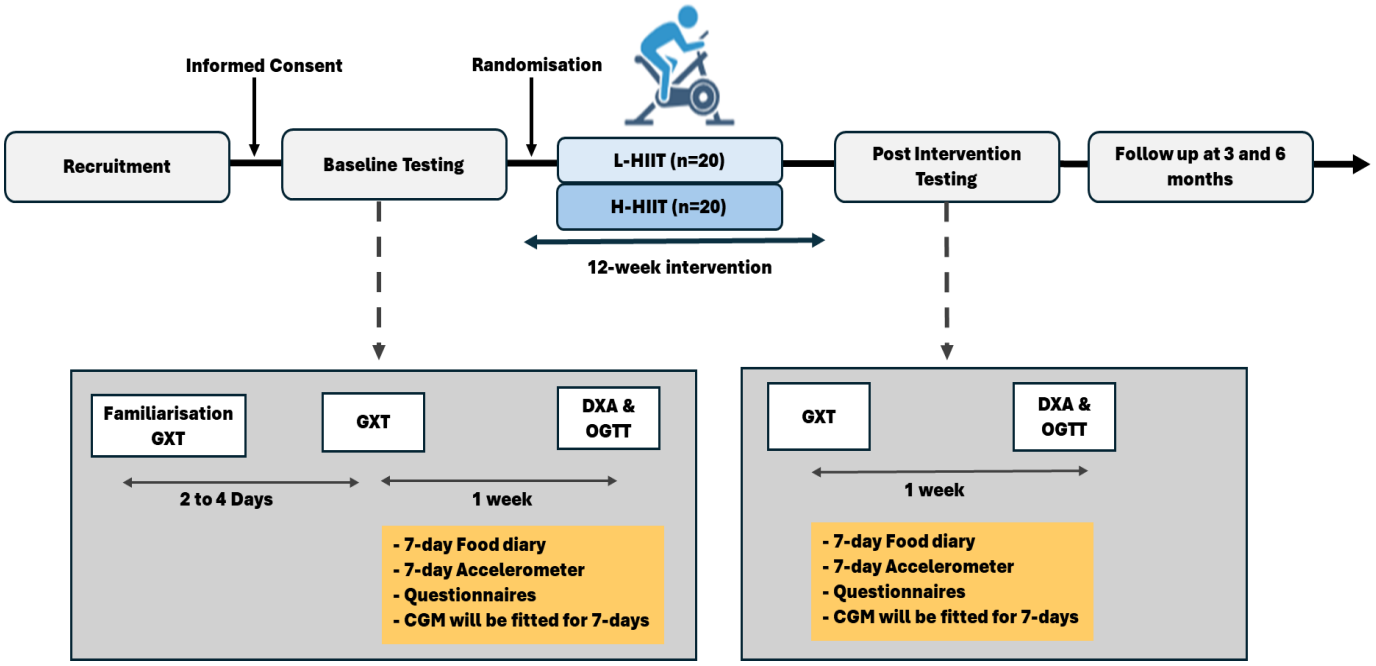

Figure 1. Trial flow diagram. DXA: dual x-ray absorptiometry, GXT: graded exercise test; OGTT: oral glucose tolerance test, CGM: continuous glucose monitor, L-HIIT: laboratory-based HIIT, H-HIIT: HIIT at home. Questionnaires: mental health (DASS-21, PCOSQ, SF-36) and physical health (IPAQ and PACES at post-intervention).

1. Recruitment via phone or in person Victoria University - Footscray Park (VU-FP) - approximately 30 min)

Before enrolling, you will discuss the study details and eligibility criteria with a research team member, either by phone or in person. You will then be asked to complete the following screening questionnaires: peripheral venous catheterisation questionnaire, risk factor assessment questionnaire and physical activity readiness questionnaire (PAR-Q). If multiple risk factors are identified, you will need medical approval from your GP. Your PCOS diagnosis will be confirmed using copies of your medical records, which will remain confidential. Also, the screening will include providing details regarding your height and weight to calculate the BMI score. A BMI score of above 25 will mean a place on the study may be offered to you. If you meet the eligibility criteria, you will be invited to provide informed consent to participate in the study.

2. Baseline Testing

- Familiarisation (1.5-2 hours)
  Written informed consent to participate will be confirmed. You will then perform an incremental exercise test on a cycle ergometer to assess your fitness, lasting between 6-20 minutes depending on your fitness level. Initially, the exercise will feel easy, but the effort will increase each minute. Try to exercise for as long as possible, but you may stop anytime. You will wear a mask for oxygen consumption analysis and a smartwatch to track your maximum heart rate (HR max). The highest heart rate achieved will be recorded as the maximum heart rate. If at any point you experience discomfort, dizziness, or any other unusual symptoms, please feel empowered to stop the exercise immediately.

- Graded Exercise Test (1 hour)
  You will undergo a maximal exercise test in the exercise physiology lab at VU-FP (Building P). Before the test, a research staff member will fit you with a continuous glucose monitor (CGM), which you will wear for 7 days. Following the exercise session, we will ask you to record a 7-day food diary, wear an accelerometer for 7 days for monitoring physical activity, and complete mental health, and HRQoL questionnaires. You will be given a menstrual cycle diary and will be required to map your cycles throughout the trial.

- DXA Scan & OGTT (3 hours)
  One week after the second session, you will have a DXA scan and an Oral Glucose Tolerance Test (OGTT) while wearing the CGM. You must fast overnight before the scan. A DXA scan will be performed to estimate your body composition (lean and fat mass). This involves lying still on the DXA scanner for approximately 7-14 minutes while the scanner passes over you. After the DXA scan, you will undergo an OGTT where a cannula will be inserted into your arm to collect blood samples. Your continuous glucose levels will be monitored using a CGM, which will be removed by a professional after the session.

  What is an oral glucose tolerance test?
  The OGTT is a routine test that is used to test blood sugar tolerance. You will be asked to drink a sugary drink (75g of sugar) and venous blood samples (10ml) will be taken every 30 minutes for 2 hours. During these two hours, you will be resting.

  What is a Continuous glucose monitor?
  Continuous glucose monitoring (CGM) is a reliable and valid monitor used for measuring 24-hour blood glucose responses throughout the day. The CGM sensor is gently inserted under your skin. The sensor stays in place for the duration of the monitoring period and is removed when the monitoring is complete. In case you have trouble with the monitor, you can contact a research team member and we can guide you through the process.

- At the end of these sessions, we will collect all data, including diaries and questionnaires.

3. 12-week intervention

After baseline testing, you will be randomized into either a lab-based or home-based HIIT group for 12 weeks, with sessions conducted in small groups of 3 to 6 people. Both groups will have three supervised sessions per week on a stationary cycle ergometer, either in person (lab-based) or via Zoom (home-based). You will rate your experience before, during, and after each session. HIIT session will consist of:

- Low-Volume HIIT: 2 sessions/week of 12 x 1 min at 90-100% peak heart rate (HRpeak) with 1 min active recovery.
- Aerobic HIIT: 1 session/week of 8 x 4 min at 90-95% HRpeak with 2 min active recovery.

HIIT at home: If you are randomised to the home-based HIIT group, you will get a magnetic bike trainer to turn your regular bicycle into a stationary exercise bike. You will also receive a smartwatch to monitor your heart rate during the program. The sessions will take place over Zoom. We will show you how to adjust your exercise intensity and speed to control your heart rate. The smartwatch will record your data, which will be shared with the researchers through an app.

The below table describes the training that will be conducted either in your home or in the laboratory.

Weeks	Session 1	Session 2	Session 3
1-2	5 min warm-up 8-12 x 1 min intervals at 90- 95% HR_{max}, 1min active recovery 5 min cooldown	3 min warm-up 4 x 8 min intervals at 85-95% HR_{max}, 2 min active recovery 5 min cooldown	5 min warm-up 4-6 x 4 min intervals at 90-95% HR_{max}, 1min active recovery 5 min cooldown
3-4	5 min warm-up 10-12 x 1 min intervals at 90- 95% HR_{max}, 1 min active recovery 5 min cooldown	3 min warm-up 6 x 8 min intervals at 85-95% HR_{max}, 2 min active recovery 5 min cooldown	5 min warm-up 6-8 x 4 min intervals at 90-95% HR_{max}, 1 min active recovery 5 min cooldown
4-6	5 min warm-up 12 x 1 min intervals at 90-95% HR_{max}, 1 min active recovery 5 min cooldown	3 min warm-up 8 x 4 min intervals at 85-95% HR_{max}, 2 min active recovery 5 min cooldown	5 min warm-up 12 x 1 min intervals at 90-95% HR_{max}, 1 min active recovery 5 min cooldown
7	VO_{2max} test	3 min warm-up 8 x 4 min intervals at 85-95% HR_{max}, 2 min active recovery 5 min cooldown	5 min warm-up 12 x 1 min intervals at 90-95% HR_{max}, 1 min active recovery 5 min cooldown
8-12	5 min warm-up 12 x 1 min intervals at 90-95% HR_{max}, 1 min active recovery 5 min cooldown	3 min warm-up 8 x 4 min intervals at 85-95% HR_{max}, 2 min active recovery 5 min cooldown	5 min warm-up 12 x 1 min intervals at 90-95% HR_{max}, 1 min active recovery 5 min cooldown

Table 1: The schedule for HIIT sessions planned for weeks for both lab and home-based groups.

4. Post-Intervention Testing

- Graded Exercise Test (2-3 hours):
  You will visit the exercise physiology lab at VU Footscray Park (Building P) for the GXT. A CGM will be fitted and worn for 7 days, followed by the graded exercise test. You will also wear an accelerometer, record a 7-day food diary, and complete various questionnaires (DASS-21, SF-36, PCOSQ, IPAQ). Post-intervention, you will rate your enjoyment using the PACES scale. Also, on the same day, we will conduct a focus group discussion to deeply understand the psychological and physiological changes experienced by you during the 12-week intervention. The discussion will be conducted in a quiet, private setting or remotely via Zoom based on your preference. Each session will last 45 to 60 minutes, allowing flexibility for discussion. Topics will include barriers and facilitators to exercise, motivations, benefits, challenges, and suggestions for improvement. Digital recordings and notes will be taken by a second research team member to ensure data accuracy. After the discussion, recordings will be transcribed to create a written record of the discussion.

- DXA Scan & OGTT (3 hours):
  During this visit, you will have a second DXA scan and undergo an OGTT while wearing the CGM, like the baseline test. All data, including diaries and questionnaires, will be collected at the end.

- Follow-up at 3- and 6 months post-intervention:
  Three months after the intervention, you will visit Victoria University Footscray Park to be fitted with a CGM for one week, complete a 7-day food diary, wear an accelerometer, and fill out physical and mental health questionnaires. The same procedure will be repeated at the 6-month follow-up, including a DXA scan and graded exercise test. You will also participate in another focus group, either online or in person.

All results will remain confidential throughout and after the completion of the study.

Who is conducting the study?

Institute of Health and Sport, Victoria University.

Chief investigator
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Student Researcher:
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Any queries about your participation in this project may be directed to the Chief Investigator listed above. If you have any queries or complaints about the way, you have been treated, you may contact the Ethics Secretary, Victoria University Human Research Ethics Committee, Office for Research, Victoria University, PO Box 14428, Melbourne, VIC, 8001, email researchethics@vu.edu.au or phone (03) 99194781 or 4461.