Participant Information Sheet/Consent Form

Interventional Study - *Adult providing own consent*

Flinders University

Title	The acute and chronic effects of hydrotherapy program on pelvic pain and cardiometabolic health in women with endometriosis: a randomised controlled trial
Short Title	Hydrotherapy and endometriosis-induced pelvic pain
Protocol Number	297.19
Coordinating Principal Investigator **Principal Investigator**	Dr Joyce Ramos
Associate Investigator(s)	Prof Lance Dalleck, Louise Gerschwitz, and A/Prof Claire Drummond
Location	Flinders University Room G119, G120, and G128 Exercise Science/Clinical Exercise Physiology Laboratory, Sturt Gym, Flinders University, Bedford park, SA, 5042 SA Aquatic and Leisure Centre 443 Morphett Rd, Oaklands Park SA, 5046

Part 1 What does my participation involve?

1 Introduction

You are invited to take part in this research project. The research project is testing the impact of 'hydrotherapy' compared to an identical land-based exercise program on pelvic pain, mental, and cardiometabolic health of women diagnosed with endometriosis.

This Participant Information Sheet/Consent Form 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 don't understand or want to know more about. Before deciding whether or not 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 don't wish to take part, you don't 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 and Consent Form to keep.

2 What is the purpose of this research?

The majority of women with endometriosis (up to 80%) experience long-term pain between the abdomen and the thighs (pelvic pain). As a consequence, those with this condition have reduced participation in various aspects of life including school, work and physical activity, imposing health and economic burden.

Exercise is now recognised as a first line of treatment for reducing pain and risk factors for cardiovascular disease (i.e. blood pressure, blood cholesterol, blood sugar level, etc). However, the specific impact of a water-based (hydrotherapy) versus land-based exercise program in managing pelvic pain and improving health in women with endometriosis has yet to be investigated.

Purpose of the study:

To compare the effects of hydrotherapy compared to an identical land-based exercise program in the management of pelvic pain and overall health in women with endometriosis

The study will be conducted in two phases:
Phase 1 – Acute exercise (to investigate the effect of one exercise session)

Phase 2 – Chronic exercise (to investigate the long-term effect of the different exercise interventions, conducted 3 x per week for 8 weeks)

This research has been initiated by Dr Joyce S. Ramos, Louise Gerschwitz, Prof Lance Dalleck, and A/Prof Claire Drummond.

This research is being conducted by Flinders University

3 What does participation in this research involve?

You will be participating in a randomised controlled experimental research project. We do not know which exercise intervention is best for improving endometriosis-induced pelvic pain. To find out we need to compare different types of exercise (hydrotherapy versus land-based

exercise program). We randomly assign people into groups and give each group a different exercise intervention. The results are compared to see if one is better.

This research project has been designed to make sure the researchers interpret the results in a fair and appropriate way and avoids researchers or participants jumping to conclusions.

Participation in this study will require:

- Completion of online questionnaires on pain (1) at rest, during, and immediately after your initial exercise session
- Completion of online questionnaires on pain (1), mental health (2), and health-related quality of life at each time point (baseline and after 8 weeks)
- Monitor the dosage of medications you use to manage pain
- Six (6) visits to the Exercise Science/Clinical Exercise Laboratories at Flinders University, Sturt Campus, for testing
- Phase 1: You will be required to attend one (1) supervised training session to determine the acute effect of the exercise intervention.
- Phase 2: You will continue the same exercise program from Phase 1, but conducted three (3) exercise sessions per week for eight (8) weeks.

All exercise sessions will be supervised by a qualified Exercise Physiologist

Testing Visits:

These will occur six (6) times: at baseline (2), after 1 exercise session (2), and after 8 weeks (2).

You will be asked to attend the Exercise Science/Clinical Exercise Physiology laboratories at Flinders University for 2 hours per testing session

- During your testing visits at Flinders University you will undertake the following tests and measures: A maximal treadmill test while the electrical activity of your heart is monitored with an ECG. Please refrain from strenuous exercise for 48 hours and caffeine and alcohol for 24 hours before arriving at the laboratory.
- Measures of the stiffness and function of your blood vessels by putting a small pen like device on the pulse in your neck, and blood pressure cuffs around your right arm and upper thigh. Please fast for 12 hours prior to this measurement. Also refrain from strenuous exercise for 48 hours and caffeine and alcohol for 24 hours before arriving at the laboratory.Waist circumference, hip circumference, weight, and height
- Blood pressure. Please fast for 12 hours prior to this measurement. Also refrain from strenuous exercise for 48 hours and caffeine and alcohol for 24 hours before arriving at the laboratory.
- A small sample of blood (24mL, approximate 6 tablespoons) will be collected to measure your fasted glucose level, cholesterol level, and other markers of health. Please fast for 12 hours prior to this measurement. Also refrain from strenuous exercise for 48 hours and caffeine and alcohol for 24 hours before arriving at the laboratory.
- A side-view posture analysis will be conducted using a movement screen application to calculate a number of angles specific to your posture

After the initial testing, you will be randomly assigned into one of three (3) groups:

1) Hydrotherapy – you will complete water-based exercise activities at the SA Aquatic and Leisure Centre for an hour each session, three times per week

2) Land-based intervention – you will complete exercise activities in the pool at the SA Aquatic and Leisure Centre for an hour each session, three times per week
3) Waitlist-control – you will continue with your usual daily activities and will be re-randomised to either the hydrotherapy or land-based exercise intervention after 8 weeks.

All exercise training sessions will be under the supervision of an experienced and qualified Exercise Physiologist.

There are no additional costs associated with participating in this research project, nor will you be paid. Parking and reasonable travel costs incurred during your participation in this trial will be covered by the investigators. All tests required as part of the research project will be provided to you free of charge.

There is no money available to pay you for your involvement in the study.

It is desirable that your local doctor be advised of your decision to participate in this research project. If you have a local doctor, we strongly recommend that you inform them of your participation in this research project.

4 Other relevant information about the research project

Forty-eight females (reproductive age; aged 18 to 45 years) diagnosed with mild to moderate endometriosis will be recruited and randomized to participate in either the i) water-based; ii) land-based exercise program; or iii) waitlist control. This trial will consist of two phases. The first phase will require the participants to attend one supervised training session to determine the acute effect of the exercise interventions. Participants will then enter the second phase of the trial and will continue with the same exercise program from Phase 1, but conducted 3 times per week until the 8-week follow-up. Following Phase 2, participants from the waitlist control group will be re-randomised into either of the exercise groups. The participants will be tested at baseline, after a single exercise session, and after 8 weeks follow-up. Written informed consent will be obtained from all participants before inclusion. All participants will receive verbal and written information about their exercise training intervention.

5 Do I have to take part in this research project?

Participation in any research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage.

If you do decide to take part, you will be given this Participant Information and Consent Form to sign and you will be given a copy to keep.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your relationship with Flinders University and SA Aquatic and Leisure Centre.

6 What are the alternatives to participation?

You do not have to take part in this research project to receive cardiometabolic health benefits from exercise. The current exercise guideline to induce cardiometabolic health (i.e. improve blood pressure, lipid profile, and blood glucose level) is 150-300 minutes / 2.5 - 5 hours per week of moderate-vigorous intensity continuous training (MICT, i.e. brisk walking at 60-70%

peak heart rate for 30 min, 5 times per week). Our proposed exercise programs are therefore considered to either have greater exercise intensity or volume relative to standard care (MICT).

7 What are the possible benefits of taking part?

We cannot guarantee or promise that you will receive any benefits from this research. However, you will be given a written results sheet at the end of each testing session and this will be explained to you face-to-face at the time. You will gain increased knowledge and awareness of your health and fitness through information that is not routinely assessed by your GP. These additional measures include levels of fitness, waist circumference, weight, blood cholesterol and glucose, and the health of your blood vessels. Additionally, possible benefits may include determination of the best type of exercise to better manage your pelvic pain. If this study is shown to improve the targeted outcomes, it may be strongly implemented as a management recommendation for this population, which currently does not exist.

8 What are the possible risks and disadvantages of taking part?

Risks involved with the study:

- Exercise intervention/tests used in the study may increase risk of musculoskeletal injury, or fatigue, and cardiovascular events such as heart attack. It is recognised that for many people, particularly those who are not very active, the risk of adverse effects during vigorous activity increases. While short-term increases in adverse effects have been shown, the longer-term benefits of regular PA outweigh these risks. The short-term increases in adverse effects may generally include muscle and joint soreness and tiredness. There is also a potential for more serious events such as dizziness, chest pain, or life-threatening events. Life-threatening events are extremely rare and estimated at approximately 1 in every 600,000 hours of vigorous exercise (ACSM 2007). To reduce the risk, pre-screening and exercise prescription will be conducted to identify and provide modifications to reduce risks of adverse events. Participants will also be instructed to warm-up prior to exercise, and complete cool-down and stretching following exercise. Participants have the right to withdraw from the study at any point if they feel the exercise is too uncomfortable. All research staff will be required to have a first-aid certificate to enable immediate attendance/care to a potential incident.
- The discomfort associated with the blood drawing procedures is minimal. There is a risk that bruising, nerve damage, fainting, excessive bleeding, allergies, and infection may occur and that the arm might become sore. Risk of bruising, fainting, nerve damage, excessive bleeding, allergies, discomfort, or infection from the blood sampling will be minimized because all samples will be performed by a trained phlebotomist following standard blood drawing procedures. The total amount of blood drawn during each testing session will not exceed 24 mL, which is equivalent to approximately 6 teaspoons. No syringes, lancets, needles or other devices capable of transmitting infection from one person to another shall be reused. All of these items, which are disposable, will be destroyed after each use. As an additional safeguard in preventing contamination, new disposable gloves will be worn for all blood samples. All contaminated items will be disposed of promptly in sharps containers.
- It is possible that you may find questions about your well-being uncomfortable. While we think it is unlikely, if you do experience any distress as a result of completing the surveys, the investigator and study staff will provide counselling to help you with your concern. Any counselling or support will be provided by qualified staff who are not members of the research project team. This counselling will be provided free of charge.

All suspected adverse results/incidental findings (i.e. if you are found to be depressed or have anxiety) will be reported to you without diagnosis. You will be encouraged to seek medical follow-up from your general practitioner or specialist for further investigation. With your permission, research staff will also contact your GP/specialist about the suspected adverse result/incidental finding.

9 What will happen to my test samples?

You will be asked to provide additional consent for the collection of your blood during the research project.

The remaining blood samples will be retained for another 5 years following the conclusion of the project for auditing purposes. The blood aliquots will be de-identified and stored at -80 degrees celsius. Arrangements will be made with our Work Health and Safety personnel (Barbra Kupke) for the storage and access to the blood samples, similar to our previously approved exercise study (Ethics no. 334.16). Only individuals who are part of the research team will have access to the stored samples.

10 What if new information arises during this research project?

Sometimes during the course of a research project, new information becomes available about the intervention that is being studied. If this happens, a member of the research team will tell you about it and discuss with you whether you want to continue in the research project. If you decide to withdraw, a member of the research team will make arrangements 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.

Also, on receiving new information, the research team 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.

11 Can I have other treatments during this research project?

It is important to tell the study staff about any treatments or medications you may be taking, including over-the-counter medications, vitamins or herbal remedies, acupuncture or other alternative treatments. You should also tell a research staff member about any changes to these during your participation in the research project.

12 What if I withdraw from this research project?

If you decide to withdraw from the project, please notify a member of the research team before you withdraw. This notice will allow that person or the research supervisor to discuss any health risks or special requirements linked to withdrawing.

If you do withdraw your consent during the research project, the relevant study staff will not collect additional personal information from you, although 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 be aware that data collected by the sponsor up to the time you withdraw will form part of the research project results. If you do not want them to do this, you must tell them before you join the research project.

13 Could this research project be stopped unexpectedly?

This research project may be stopped unexpectedly for a variety of reasons. These may include reasons such as:
• Unacceptable side effects
• The exercise program being shown not to be effective
• The exercise program being shown to work and not need further testing

14 What happens when the research project ends?

When the study has finished you will be provided with all of your results within approximately 3 months. You will also be given the opportunity to ask any questions regarding the results and anything else to do with the study in a de-briefing session.
The study data will be retained for 5 years.

Part 2 How is the research project being conducted?

16 What will happen to information about me?

By signing the consent form you consent to the relevant research staff collecting and using personal information about you for the research project. Any information obtained in connection with this research project that can identify you will remain confidential. Personal information gained from the study such fitness and cardiovascular measures will be recorded but not easily identified to any individual. To ensure longevity of the data, results will also be kept in a password locked computer with access granted only to the primary investigators. Your information will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law.

Information about you may be obtained from your health records held at this and other health services for the purpose of this research. By signing the consent form you agree to the study team accessing health records if they are relevant to your participation in this research project.

Your health records and any information obtained during the research project are subject to inspection (for the purpose of verifying the procedures and the data) by the relevant authorities the institution relevant to this Participant Information Sheet, Flinders University, or as required by law. By signing the Consent Form, you authorise release of, or access to, this confidential information to the relevant study personnel and regulatory authorities as noted above.

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. Hardcopy data (e.g. signed consent forms and case report forms [CRFs]) will be stored within locked filing cabinets located in the Exercise Science/Clinical Exercise Physiology Unit, College of Nursing and Health Sciences, Flinders University. Only the research team will have access to these filing cabinets. The CRFs and other source data will be kept in a separate folder to the consent forms to ensure the study data is not identifiable. On completion of the project, identifying data will be removed from the record.

In accordance with relevant Australian and South Australian privacy and other relevant laws, you have the right to request access to your information collected and stored by the research team. You also have the right to request that any information with which you disagree be corrected. Please contact the study team member named at the end of this document if you would like to access your information.

Any information obtained for the purpose of this research project that can identify you will be treated as confidential and securely stored. It will be disclosed only with your permission, or as required by law.

Your de-identified data may be used in future projects.

17 Complaints and compensation

If you suffer any injuries or complications as a result of this research project, you should contact the study team as soon as possible and you will be assisted with arranging appropriate medical treatment. If you are eligible for Medicare, you can receive any medical treatment required to treat the injury or complication, free of charge, as a public patient in any Australian public

hospital. Participation in this study does not impact on your basic legal right to seek compensation; however, if you do suffer harm, you may receive compensation without litigation.

18 Who is organising and funding the research?

This research project is being conducted by Dr Joyce S. Ramos, Louise Gerschwitz, Prof Lance Dalleck, and A/Prof Claire Drummond.

This research project is being conducted by Flinders University and supported by SA Aquatic and Leisure Centre.

SA Aquatic and Leisure Centre may benefit financially from this research project if, for example, the project assists this company to obtain evidence of analgesic, mental, cardiometabolic health benefits of hydrotherapy.

By taking part in this research project you agree that the data generated from analysis of samples or measurements collected from you (i.e. samples of your blood) may be provided to SA Aquatic and Leisure Centre.

SA Aquatic and Leisure Centre may directly or indirectly benefit financially from the data generated from analysis of samples or from knowledge acquired through analysis of your samples or measurements.

You will not benefit financially from your involvement in this research project even if, for example, your samples (or knowledge acquired from analysis of your samples or measurements) prove to be of commercial value to SA Aquatic and Leisure Centre.

In addition, if knowledge acquired through this research leads to discoveries that are of commercial value to SA Aquatic and Leisure Centre, there will be no financial benefit to you or your family from these discoveries.

No member of the research team will receive a personal financial benefit from your involvement in this research project (other than their ordinary wages).

19 Who has reviewed the research project?

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the HREC of Southern Adelaide Local Health Network.

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.

20 Further information and who to contact

The person you may need to contact will depend on the nature of your query.

If you want any further information concerning this project or if you have any medical problems which may be related to your involvement in the project (for example, any side effects), you can contact the principal investigator on +61882013272 or any of the following people:

Clinical contact person

Name	Joyce Ramos
Position	Principal Investigator
Telephone	+61882013272
Email	joyce.ramos@flinders.edu.au

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

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Complaints contact person

Position	Director, Office for Research
Telephone	8204 6453
Email	Health.SALHNofficeforresearch@sa.gov.au

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

Reviewing HREC approving this research and HREC Executive Officer details

Reviewing HREC name	Southern Adelaide Clinical
HREC Executive Officer	Executive Officer
Telephone	8204 6453
Email	Health.SALHNofficeforresearch@sa.gov.au

Consent Form - *Adult providing own consent*

Title	The acute and chronic effects of hydrotherapy program on pelvic pain and cardiometabolic health in women with endometriosis: a randomised controlled trial
Short Title	Hydrotherapy and endometriosis-induced pelvic pain
Protocol Number	
Coordinating Principal Investigator **Principal Investigator**	Dr Joyce S. Ramos
Associate Investigator(s)	Prof Lance Dalleck and A/Prof Claire Drummond
Location	Flinders University Room G119, G120, and G128 Exercise Science/Clinical Exercise Physiology Laboratory, Sturt Gym, Flinders University, Bedford park, SA, 5042 SA Aquatic and Leisure Centre 443 Morphett Rd, Oaklands Park SA, 5046

Declaration by Participant

I have read the Participant Information Sheet or someone has read it to me in a language that I understand.

I understand the purposes, procedures and risks of the research described in the project.

I give permission for my doctors, other health professionals, hospitals or laboratories outside this hospital to release information to Flinders University concerning my disease and treatment for the purposes of this project. I understand that such information will remain confidential.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the study without affecting my future relationship with Flinders University and SA Aquatic and Leisure Centre

I understand that I will be given a signed copy of this document to keep.

Name of Participant (please print) _____

Signature _____ Date _____

Name of Witness* to Participant's Signature (please print) _____

Signature _____ Date _____

* Witness is not to be the investigator, a member of the study team or their delegate. In the event that an interpreter is used, the interpreter may not act as a witness to the consent process. Witness must be 18 years or older.

Declaration by Senior Researcher†

I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

Name of
Senior Researcher† (please print) _____

Signature _____ Date _____

† A senior member of the research team must provide the explanation of, and information concerning, the research project.

Note: All parties signing the consent section must date their own signature.

I understand that, if I decide to discontinue the study treatment, I may be asked to attend follow-up visits to allow collection of information regarding my health status.

I consent to the storage and use of blood and tissue samples taken from me for use, as described in the relevant section of the Participant Information Sheet, for:

- This specific research project
- Other research that is closely related to this research project
- Any future research.

Form for Withdrawal of Participation - *Adult providing own consent*

Title	The acute and chronic effects of hydrotherapy program on pelvic pain and cardiometabolic health in women with endometriosis: a randomised controlled trial
Short Title	Hydrotherapy and endometriosis-induced pelvic pain
Protocol Number	
Project Sponsor	
Coordinating Principal Investigator/ Principal Investigator	Dr Joyce Ramos
Associate Investigator(s)	Prof Lance Dalleck and A/Prof Claire Drummond
Location	Flinders University Room G119, G120, and G128 Exercise Science/Clinical Exercise Physiology Laboratory, Sturt Gym, Flinders University, Bedford park, SA, 5042 SA Aquatic and Leisure Centre 443 Morphett Rd, Oaklands Park SA, 5046

Declaration by Participant

I wish to withdraw from participation in the above research project and understand that such withdrawal will not affect my routine treatment, my relationship with those treating me or my relationship with Flinders University.

Name of Participant (please print) _____

Signature _____ Date _____

In the event that the participant's decision to withdraw is communicated verbally, the Senior Researcher will need to provide a description of the circumstances below.

Declaration by Senior Researcher†

I have given a verbal explanation of the implications of withdrawal from the research project and I believe that the participant has understood that explanation.

Name of
Senior Researcher† (please print) _____

Signature _____ Date _____

† A senior member of the research team must provide the explanation of and information concerning withdrawal from the research project.

Note: All parties signing the consent section must date their own signature.