Participant Information Sheet and Consent Form

Royal Brisbane and Women's Hospital

Title	Hydrotherapy in the management of persistent pelvic pain: a pilot randomised controlled trial
Short Title	Hydrotherapy for Persistent Pelvic Pain
Protocol Number	HREC/2019/QRBW/54836
Coordinating Principal Investigator/ Principal Investigator	Cara Masterson, Advanced Physiotherapist, RBWH
Associate Investigator(s)	Janene Stephens, Advanced Physiotherapist, RBWH Lorelle Hawes, Senior Physiotherapist, RBWH Emily Edwards, Physiotherapist, RBWH Melissa Webber, Physiotherapist, RBWH Michelle Cottrell, Research Coordinator, RBWH Jennifer Paratz, Senior Research Fellow, RBWH

Introduction: You are invited to take part in this research project which aims to evaluate the effect of different types of management on the symptoms and quality of life for patients with Persistent Pelvic Pain due to endometriosis.

This Participant Information Sheet and Consent Form tells you about the research project. It explains the assessments 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 in the research project.

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.

What is the purpose of this research? Hydrotherapy has been proven to be a very effective treatment option for other persistent pain conditions, such those affecting the lower back, hips or knees. To date, there have not been any studies investigating the use of hydrotherapy in the persistent pelvic pain population. As such, the aim of this research is to investigate whether a course of hydrotherapy, in addition to usual care, improves symptoms and quality of life in patients with Persistent Pelvic Pain due to endometriosis, when compared to usual care alone. Positive outcomes may result in more women gaining relief from persistent pelvic pain and hydrotherapy becoming another treatment option for management of this condition. This study has been initiated by the principal investigator (Ms Cara Masterson), where the results of this research will be used to inform ongoing clinical care offered by the RBWH Physiotherapy Department.

What does participation in this research involve? You will be participating in a randomised controlled research project. Sometimes we do not know which treatment is best for treating a condition. To find out we need to compare different treatments. We allocate people into groups and give each group a different treatment. The results are compared to see if one is better. To try to make sure the groups are the same, each participant is put into a group by chance (random). You have a 50/50 chance of receiving either usual care or usual care plus hydrotherapy. If you choose to participate in this research project, you will be asked to sign the attached Consent Form prior to any study assessments being performed. Your choice to participate, or not participate, in this study will in no way affect your normal management throughout the RBWH Physiotherapy Department. There will be no additional costs associated with participating in this research project, nor will you be paid.

'Usual care' will involve attending fortnightly appointments with a pelvic floor trained physiotherapist over an 8-week period (4 sessions in total). Usual care can involve a variety of physiotherapy treatment techniques which will be determined based upon your symptoms and initial physiotherapy assessment. Treatment techniques considered beneficial for your presenting symptoms will be discussed with you throughout your physiotherapy management.

Patients allocated to the 'usual care plus hydrotherapy' group will receive usual care as detailed above in addition to attending a weekly group-based hydrotherapy class over an 8-week period. Classes will be supervised by a physiotherapist and will be held in the hydrotherapy pool located within the RBWH Physiotherapy Department.

Regardless of the group that you are assigned to, you will be asked to complete three questionnaires when you first enter the study, and then again 8 weeks later. These questionnaires are designed to measure pain severity, health-related quality of life and pelvic floor symptoms and will take no longer than 10 minutes to complete on each occasion. At the end of the 8-week study period you will also be asked to complete a 'Patient Experience and Satisfaction Survey', expected to take no longer than 5 minutes to complete.

Other relevant information about the research project: In addition to the information collected directly from yourself as described above, the research team will also be collecting information about your assessment and management as part of your usual care at the RBWH Physiotherapy Department. This information is on the Physiotherapy Assessment Form completed by your treating Physiotherapist and forms part of your medical record held at the RBWH. Attendance and discharge dates will also be noted. This information will help the research team determine if there are any differences between the two treatment groups which may affect the results of the study.

This is a single site investigation where the research will only be conducted at the Royal Brisbane and Women's Hospital. We expect to recruit at least 20 participants for this study, with a minimum of 10 in each group.

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 routine treatment, your relationship with those treating you, or your relationship with The Royal Brisbane and Women's Hospital.

What are the alternatives to participation? If you do not wish to participate in this research project you will continue to be offered standard treatment services (usual care) by the RBWH Physiotherapy Department. Your physiotherapist will discuss these options with you before you decide whether or not to take part in this research project. You can also discuss the 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 reduction in symptoms relating to your condition, and/or improvement in health-related quality of life. Positive results from this study will support the ongoing provision of hydrotherapy for women referred to the RBWH Physiotherapy Department with Persistent Pelvic Pain, as well as support the use of hydrotherapy into the wider health community, subsequently having a positive benefit for the future management of individuals with Persistent Pelvic Pain.

What are the possible risks and disadvantages of taking part? The study has been designed to investigate our research question with minimal degree of risk or inconvenience to you. There are no foreseen risks associated with taking part in this research project above what would be anticipated with participating in standard physiotherapy care (usual care). As part of screening your eligibility for inclusion in this research project, it is deemed that you have no obvious medical conditions that would prevent you from safely participating in hydrotherapy. Participation in this study will incur no financial cost to you, nor will it have any effect on your current relationship and management with any Queensland Health services. The research team envisage that participating in this study will carry no risk or disadvantages as your identity will remain completely anonymous throughout the entire research process (known only by the research team).

Can I have other treatments during this research project? You are allowed to continue all of your current treatments, including medications, throughout the duration of this study. If there is a change to your medications, or any other aspect of your treatment for your Persistent Pelvic Pain, please notify a member of the research team.

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. Upon request to withdraw from the study a 'Form for Withdrawal of Participation' will be provided for completion. As part of this form, it will be your decision as to whether any data collected prior to your withdrawal shall also be removed from the study. Withdrawal from this research project will in no way affect your current management and relationship with health services in Queensland.

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; or
- Any issues deeming the hydrotherapy pool inappropriate for use.

You will be notified as soon as it becomes apparent that the research project is to be stopped unexpectedly. In the event that the research project is stopped, you will still be offered standard physiotherapy (usual care) by your treating physiotherapist at the RBWH Physiotherapy Department.

What happens when the research project ends? Following your participation in this research project you will be continued to be offered standard physiotherapy treatment (usual care) by your treating physiotherapist at the RBWH Physiotherapy Department.

Upon completion of the research project results will be disseminated through various platforms including conference presentations, and a manuscript to be submitted to a peer-reviewed journal for publication. The dissemination of the project outcomes will be presented in a group format, such that an individual participant's identity will remain confidential at all times. If you are interested in the final outcome of this study, by contacting a member of the research team, you can be provided with a summary of the results.

What will happen to information about me? By signing the consent form you are providing consent for the research team to collect and use personal information about you for the research project. Any information obtained in connection with this research project that can identify you will remain confidential at all times. All identifiable information that is collected throughout the study will be replaced by a unique participant code. A secure file, that can only be accessed by the research team, will be created that matches the unique code to the participant's name to ensure data accuracy. All data collected specifically for this study will be stored securely by the research team, and for a total period of 15 years, as per the recommended National Health and Medical Research Council (NHMRC) guidelines. 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.

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.

Information about your participation in this research project may be recorded in your health records as part of the care provided to you by the RBWH Physiotherapy Department.

In accordance with relevant Australian and/or Queensland 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 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.

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.

Who is organising and funding the research? This research project is being conducted by the Physiotherapy Department, Royal Brisbane and Women's Hospital. No member of the research team will receive a personal financial benefit from your involvement in this research study (other than ordinary wages). There are no conflicts of interest from either the research team member or Queensland Health.

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 the Royal Brisbane and Women's Hospital.

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: 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:

Name	*Cara Masterson*
Position	*Team Leader, Women's & New Born Services, Physiotherapy Department, Royal Brisbane and Women's Hospital*
Telephone	*(07) 3646 4319*
Email	*cara.masterson@health.qld.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 name	*Royal Brisbane and Women's Hospital HREC*
HREC Executive Officer	*Co-ordinator*
Telephone	*(07) 3646 5490*
Email	*RBWH-HREC@health.qld.gov.au*

Queensland Government

Consent Form

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Declaration by Participant

1. I have read the Participant Information Sheet, or someone has read it to me in a language that I understand.
2. I understand the purposes, procedures and risks of the research described in the project.
3. I give permission for my healthcare professionals and/or hospital to release information to the research team concerning my condition and treatment for the purposes of this project. I understand that such information will remain confidential.
4. I have had an opportunity to ask questions and I am satisfied with the answers I have received.
5. 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 health care.
6. I understand that I will be given a signed copy of this document to keep.

Name of Participant (please print): _____

Signature: _____ Date: _____