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Non-invasive analysis of uterine structure and contractions in healthy function and endometriosis

Participant Information Sheet

Lead Researchers:

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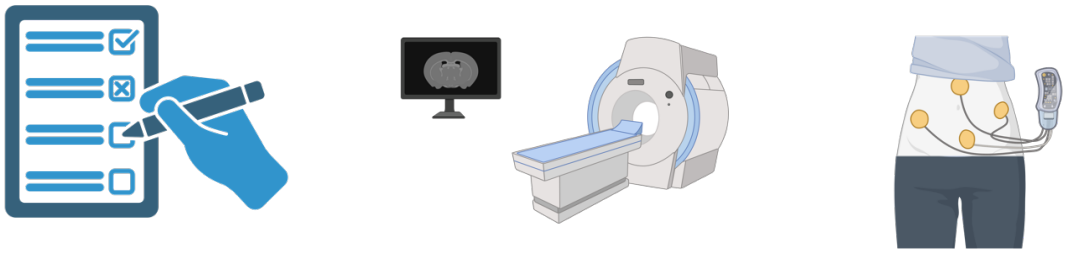
1 Introduction

You are invited to take part in a study which aims to improve understanding of the structure and contractions of the uterus as part of the normal menstrual cycle, in both healthy people and people with endometriosis or other uterine dysfunctions (such as heavy menstrual bleeding). The study will use a combination of medical imaging (MRI) and external electrode data collection to both help understand contractions and to explore ways to measure them in a way that minimises risk and discomfort to participants. The study will involve the following activities:

1. Filling out a questionnaire
2. MRI scan
3. External electrode recording



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Your participation is completely voluntary (your choice). If you don't want to take part, you don't have to give a reason. If you do want to take part now, but change your mind later, you can pull out of the study at any point during the procedure, or up to two weeks after your session.

This Participant Information Sheet will help you decide if you would like to take part in the study. It sets out why we are doing the study, what your participation would involve, what the benefits and risks to you might be, and what would happen after the study ends. We will go through this information with you and answer any questions you may have. You do not have to decide today whether or not you will participate in this study. Feel free to talk about the study with other people, such as family, whānau, friends, or healthcare providers before you decide.

It is important to note that no researchers in the project are medically qualified, and no diagnostic assessment will be made of any data collected in this study. Therefore, the researchers are not able to provide any medical advice on endometriosis or any other health issues and you will not be assessed for endometriosis or any other condition in this study.

If you agree to take part in this study, you will be asked to sign a Consent Form. You will be given a copy of both the Participant Information Sheet and the Consent Form to keep. This document is 7 pages long, please make sure you have read and understood all the pages.

1.1 Voluntary participation and withdrawal from this study

Your participation in this study is completely voluntary. You have the right to not participate, or to request withdrawal of your data up to two weeks after your MRI without giving a reason, by getting in touch with any of the research team listed above.

For students of the Researchers: neither grades nor academic relationships will be affected by participation or non-participation in this study, and you are free to contact the HoD should you feel this assurance is not met (contact details at end of this document).

2 Study Details

2.1 What is the purpose of this study?

The focus of our study is to investigate the structure and function, namely contractions, of the uterus. When the uterus contracts, it means that the muscles around the edge of the uterus are tightening and loosening in a wave. Contractions of the uterus are often spoken about in relation to pregnancy, but it is less well known that the uterus will also undergo a cycle of contractions throughout the month when there is no pregnancy. We know very little about these contractions, and particularly how the shape of the uterus might change how these contractions look.

We are particularly interested in a condition known as endometriosis. Endometriosis is a chronic (long-term, recurring) condition that occurs when cells from the uterus are found growing in other parts of the body. For those with this condition, this can result in significant pain and other symptoms. As of yet, we don't have a good understanding of why endometriosis occurs in some people and not others, and although invasive (surgical) or hormonal treatments are sometimes available, there is no cure.

The aim of our study is to use MRI imaging and electrode measurements of the abdomen to investigate uterine structure and activity. Our research hopes to expand our understanding of endometriosis, and the uterus more generally, but investigating if there is any difference in the shape and function of the uterus for healthy people and people with endometriosis or other uterine dysfunctions, and record contractions of the uterus and see if we can find a link between the uterus shape, contractions, and time of menstrual cycle.

The benefits of this study extend beyond the academic community. By enhancing our understanding and potential treatment of endometriosis, we can better serve individuals affected by this disorder. This research could lead to new diagnostic tools or treatment options for those affected and their communities.

2.2 Who can take part in the study?

You have been chosen to participate because you have a uterus and either have no history of endometriosis OR have been diagnosed (including self-diagnosed) as suffering from endometriosis or another uterine condition.

Key inclusion and exclusion criteria for potential participants include:

- You must be between 20 and 40 years of age,
- You must not currently, or have previously, be going through menopause,
- You must be currently menstruating and not on a contraceptive which prevents your period,
- You must have no current or no previous pregnancies for any length of time,
- You must have no metallic, magnetic, or electric implants in your body,
- If you have previously had a gynaecological procedure or surgery (procedures related to the uterus, ovaries, or cervix), please contact the research team to confirm your eligibility,
- You must be able to provide informed consent.

These criteria can be used as a 'self-screening' tool. They are important for the study aims and in some cases your safety.

2.3 What will my participation in the study involve?

If you agree to participate you will be asked to come to either a) the CAMRI unit at faculty of Medical and health science, University of Auckland, or B) at an Auckland Radiology Group Clinic, such as the Henderson or Remuera clinics, for 1 session. The session is expected to take up to 3 hours.

Your involvement will include several steps, these are summarised below (further detail on each step can be found in the table on the next page). If you would prefer, you can request a female-only research team for any or all of these activities. However, we are unable to guarantee a female technician for the MRI scan itself. At any point during your session you are welcome to ask questions or provide further information or feedback to the research team.

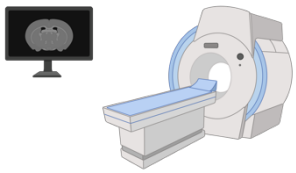
- Please fast for at least 2 hours prior to your session, if possible up to 4 hours, with no fluids for the final 2 hours.
- We welcome the presence of a support person or a whānau/family member during the session, should you desire.
- Upon arrival, you will be given a plain summary of the study requirements. We will discuss the study with you and you can ask any questions or provide any information or feedback you wish to share with us. When you are ready to do so, you will be asked to sign a consent form after having any questions answered to your satisfaction.
- A questionnaire will be used to collect around your menstrual health (for example, when was your last period, how long is your menstrual cycle, etc.). This can be completed in the 24 hours prior to your session or during the session. The questionnaire should take between 10 and 30 minutes to complete. You are welcome to ask any questions or provide any feedback or further information about menstrual health. We may also ask questions during your session to clarify information about your menstrual

cycle, and to record time last eaten and pain medication taken on the day of the session, as relevant to the study. If you do not wish to answer these questions there is no obligation to do so.

- Undergo an MRI scan(s), for which you will need to change into a gown. You will be lying flat on your back for the duration of the scan. The time you spend in the MRI machine will not exceed 1 hour.
- Undergo non-invasive electrode measurements. You can be in your own clothing for these measurements, and you will be lying down with your abdomen exposed. Sections of skin on your abdomen will be cleaned and prepared for electrode placement by a member of the research team. Once electrodes are placed the measurement will take approximately 45 minutes.

Please be aware that the study involves questions which may be sensitive or potentially cause embarrassment, specifically details around your menstruation and menstrual health, and contraception. If you do not wish to answer a particular question you have no obligation to do so, however in the case of your menstrual health and contraception this may make you ineligible as a participant in the study.

To help understand what will happen during your session, please refer to the table below which provides detail on each of the activities. Note, the order of the MRI and Electrode measurements activities may be switched depending on logistics on the day:

Activity	**Description**
Arrival and Consent	Explanation of study, answering questions, signing consent.
Questionnaire 	If not completed in the 24 hours prior to your session, fill in questionnaire with ability to ask researchers about any questions or concerns. This questionnaire will take between 10 and 30 minutes. It is useful for the questionnaire to know when your last period occurred prior to your session.
MRI 	You will be asked to complete a short safety checklist for the MRI scanner and to change into a gown and remove all items of jewellery. You will undergo a series of MRI scans of your torso and pelvis in a supine position (on your back). The total time in the machine will not exceed one hour. There will be a button to alert technicians/researchers if you are uncomfortable or need to speak with the research team at any time.
Electrode measurements 	You will be in your own clothes for the electrode recordings. For the recordings, it will be required that you will have the skin of your abdomen exposed and cleaned (using an alcohol wipe or alternative). There will also be a light wiping of mildly abrasive tape or gel across the areas of skin the electrodes will attach to. Electrodes will be attached to the skin and measurements taken over a period no longer than an hour.

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Your participation in this study is completely voluntary and you may withdraw from the study at any point during your session, or in the two weeks following, and we will delete any collected data.

You may optionally consent to future contact from the research team if follow-up studies are planned.

2.4 What are the possible benefits of this study?

It is unlikely there will be direct benefit to you or your whānau / family. However, by allowing us to perform this study you will have helped to develop tools that enable personalised healthcare models which may benefit you or your whānau / family in the future. You will not receive payment for any new products, tests or discoveries that might come from this research.

2.5 Who pays for the study?

There is no cost to taking part in this study. You will receive a $50 supermarket voucher as an acknowledgement of the time and effort you have contributed towards the study. This study is funded by the Aotearoa Foundation through the Aotearoa Fellowship (held by Dr Claire Miller), and by the Wellcome Institute through a Wellcome Leap Grant (P.I. Prof. Leo Cheng).

3 Can anything go wrong?

3.1 What are the possible risks of this study?

MRI and external electrode measurement procedures are regarded as safe and painless. MRI machines do not expose participants to potentially harmful radiation. There are minimal risks of claustrophobia or discomfort due to noise in the MRI machine, and of minor discomfort associated with the skin preparation steps required for the attachment of the electrode for the electrode measurements. We will manage these risks by: 1) you will provided a button to alert technicians and researchers if you begin to feel uncomfortable or wish to speak to anyone at any point in time during the MRI; 2) earplugs will be supplied to reduce noise during the scan; and 3) exercising care and gentleness when preparing the skin and regularly checking in with you about any discomfort during the process.

The investigator of this study takes responsibility to ensure that appropriate care is provided to participants during the study. If any new information becomes available during the study that may affect your health or influence your decision to continue, you will be informed promptly.

3.2 What if something does go wrong?

If you were injured in this study, you would be eligible to apply for compensation from ACC just as you would be if you were injured in an accident at work or at home. This does not mean that your claim will automatically be accepted. You will have to lodge a claim with ACC, which may take some time to assess. If your claim is accepted, you will receive funding to assist in your recovery.

If you have private health or life insurance, you may wish to check with your insurer that taking part in this study won't affect your cover.

3.3 Will my data be assessed for any medical issues?

We are not using a clinical protocol for the imaging and no researchers in the project are medically qualified, and therefore no diagnostic assessment will be made of any data collected in this study. In the unlikely event that the imaging studies lead to the identification of incidental findings (conditions discovered unintentionally with clinically significant implications), you will be informed using the contact details you provide on the consent form. In this instance, we may then ask you to nominate a health provider that we can convey the relevant information to or you will be advised to contact your health provider.

4 What will my data be used for?

4.1 What will happen to my information?

During this study the research team will record information about you and your study participation. All identifiable information collected is confidential. Identifiable information is any data that could identify you (e.g. your name, date of birth) and will be removed from your data before being used for any research. The data will not be linked back to you.

De-identified (Coded) Information

To make sure your data cannot be linked back to you, identifiable information will not be included in any report generated by the research group. Instead, you will be identified by a code (i.e. de-identified). The study investigators will keep a list that links your code to your name, ensuring your identification through your coded data if necessary, for instance, in case of your withdrawal from the study. The results of the study may be published or presented, but not in a form that would reasonably be expected to identify you.

Security and Storage of Your Information

Your identifiable information will be stored electronically on secure servers managed/approved by The University of Auckland during the study. After the study it will be transferred to a secure archiving site and stored for at least 6 years. The consent form will be kept for a maximum of 10 years before being permanently destroyed. The de-identified data from this study will remain on University of Auckland approved servers and data repositories for a minimum of 6 years after the publication of study results and their retention period will be extended in accordance with prevailing health data storage regulations.

Māori Data Sovereignty

Māori data sovereignty is about protecting information or knowledge that is about (or comes from) Māori people. We recognise the taonga of the data collected for this study and we are in consultation with Iwi United Engaged around collection, ownership, and use of study data.

4.2 What will happen to the results of this research?

During or upon completion of the study, research findings will be submitted for publication in international journals that report medical and scientific research. Individual results will not be made available to participants, since the data collected is being used to make inferences on the population as a whole. A summary of results will be available for interested participants at the end of the study as a report and links to published articles. The identity of the participants will remain completely confidential when the results are published or discussed publicly.

There is the potential that research from this and/or future studies could contribute to the development of a commercial product in the future (e.g. a tool to provide diagnosis of endometriosis). Your data will not make up any part of any product (identifiable or de-identified data), but your de-identified data may be used for research to develop the product. You will not receive payment for any new products, tests or discoveries that might come from this or future research.

4.3 Will my taking part in this study be kept confidential?

All identity information (e.g. name, date of birth) that is collected about you during the course of this research will be kept strictly confidential. This information will remain strictly confidential and no material that could personally identify you will be released to anyone outside this study, or used in any reports on this study.

5 Contact details

5.1 Who do I contact for more information or if I have concerns?

If you have any questions, concerns or complaints about the study at any stage, you can contact:

Auckland Bioengineering Institute, University of Auckland, 70 Symonds Street, Auckland

Dr Claire Miller
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A/Prof Alys Clark
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Tel: 09 373 7599, ext.85119

Chair, Auckland Health Research Ethics Committee (AHREC)
ahrec@auckland.ac.nz
Tel: 373 7599, ext. 83711
The University of Auckland, Private Bag 92019, Auckland 1142

5.2 Who has approved this study?

Approved by the Auckland Health Research Ethics Committee on 04/03/2024 for three years. Amendments approved by the Auckland Health Research Ethics Committee on 16/09/2025. Reference number AH26914.

For concerns of an ethical nature, you can contact the Chair of the Auckland Health Research Ethics Committee at ahrec@auckland.ac.nz or at 373 7599 ext. 83711, or at Auckland Health Research Ethics Committee, The University of Auckland, Private Bag 92019, Auckland 1142