SingHealth

PARTICIPANT INFORMATION SHEET AND CONSENT FORM

You are being invited to participate in a research study. Your participation in this study is entirely voluntary. Before you take part in this research study, the study must be explained to you and you must be given the chance to ask questions. Your questions will be answered clearly and to your satisfaction. Please read the information provided here carefully. If you agree to participate, please sign the consent form. You will be given a copy of this document.

STUDY INFORMATION

Study Title:

Transperineal ultrasound as a biofeedback tool for pelvic floor muscle therapy in postpartum patients.

This research study is recruiting at the following SingHealth institution(s). Please note that the word "SingHealth" refers to the institution where you are recruited into the study.

SINGAPORE GENERAL HOSPITAL

Principal Investigator:
Dr Asad Abdul Rahim MRCOG
Obstetrics and Gynaecology
Tel: 6321 4530
Institution Mainline: 6222 3322

PURPOSE OF THE RESEARCH STUDY

The purpose of this research study is to find out if using ultrasound as a biofeedback tool while being taught pelvic floor exercises improves the strength, technique and adherence to pelvic floor muscle therapy after childbirth.

You were selected as a possible participant in this research study because you have recently had a vaginal delivery of a baby and are attending our clinic for a pelvic floor assessment.

What is "biofeedback"? Biofeedback is the process by which patients are able to control, train and modify voluntary body functions with the aid of tools for the purpose of improving health and wellbeing.

This research study targets to recruit 94 participants from Singapore General Hospital.

STUDY PROCEDURES & YOUR RESPONSIBILITIES IN THIS STUDY

The study involves the following:

- Completion of a pre-study questionnaire asking you about your current exposure to, and awareness of pelvic floor muscle therapy.
- A review by one of our study team to assess any pelvic floor symptoms you may have had since the birth of your child.
- A visual inspection and clinical examination by a qualified clinician of your pelvic floor muscles, any tears you have sustained and your current pelvic floor muscle strength.
- Ultrasound scan of your pelvic floor muscles with/without biofeedback.
- Follow up review with repeat ultrasound scan and post-study questionnaire.

All those that choose to participate will be taught pelvic floor exercises and have their pelvic floor scanned. However, you will be randomised according to whether or not you will be able to view the images of the scan while being taught. Randomisation means assigning you to one of two groups by chance. You will have 50/50 chance of being allocated to either group. We will not allocate you based on any of your personal details, clinical examination or answers you give in your questionnaire. You will know which group you are in but the teaching given to you and all the other participants will be same.

Medical history:
We will collect information (data) from your medical records. The information will include demographic data (such as your age, weight, number of deliveries and obstetric history), delivery data (such as how you delivered your baby, what tear you sustained, how it was repaired) and symptom data (such as if you have any pelvic floor symptoms since your delivery).

Questionnaire:
We will ask you to complete two questionnaires, each taking less than 5 minutes to complete. One will be completed at the initial assessment – the “pre-study questionnaire”. The second will be during the follow up visit in 3 months time- called the “post-study questionnaire”.

Ultrasound:
We will obtain ultrasound images of your pelvic floor at rest and during a pelvic floor muscle contraction. We will measure the strength of your contraction. A set of images will be obtained during your first visit and a repeat set will be taken during your follow up visit (usually 3 months later).

Your participation in the study will last 3 months. You will need to visit the doctor’s office two times in the course of the study (first time is today and the second will be 3 months from now).

If you agree to participate in this study, you should follow the advice and directions given to you by the study team.

WHAT IS NOT STANDARD CARE OR IS EXPERIMENTAL IN THIS STUDY

The study is being conducted because transperineal ultrasound has not yet proven to be an effective tool to teach pelvic floor exercises in women who have recently given birth. We hope that your participation will help us to determine whether using transperineal ultrasound as a biofeedback tool will improve the effectiveness and adherence to pelvic floor exercises.

POSSIBLE RISKS, DISCOMFORTS OR INCONVENIENCES

Questionnaires:
Some of the questions might make you feel uncomfortable or upset. You may refuse to answer any of the questions and/or take a break at any time during the study. Rest assured, the answers you give will be held confidentially and will not be used to plan, modify or discriminate your clinical care nor your participation in the study.

Personal privacy and confidentiality:
This study uses information that may affect your privacy. To protect your confidentiality, only a unique code will be used to identify information that we collected from you.

As there will be a link between the code and your identifiable information, there is still a possibility of data breach. A data breach is when someone sees or uses data without permission. If there is a data breach, someone could see or use the data we have about you. Even without your name, there is a chance someone could figure out who you are. They could misuse your data. We believe the chance of this is very small, but it is not zero.

Ultrasound:
Ultrasound scans are very safe in the postpartum period. These types of scans involve using high frequency sound waves (that humans cannot hear) to create a visual representation of the structures of the body. Unlike CT or x-ray scans, they do not involve the use of ionizing radiation which has the potential to damage cells of the body with prolonged and repeated exposure. High energy ultrasound has been known to cause a heat reaction to body organs. However, for the purposes of this study, we will be using only low-dose ultrasound energy. We will aim to use it for the shortest period possible to minimize any effects to you.

The ultrasound probe will be placed on your external genitalia (transperineal). It will be wrapped with a single-use, disposable probe cover and we will use a sterile gel to act as a conductive agent for a better ultrasound image. The study team will ensure that all equipment will be sterilized before use and all hand hygiene protocols will be followed before the examination begins. Transperineal ultrasound is relatively non-invasive (i.e it does not enter the body in any way). However, we understand that examination of the genital area can be a intrusive test and we will make every effort to ensure that you are comfortable for the entire process. We will give you time to undress and redress privately and all examinations will be performed in the presence of a female chaperone. If you feel uncomfortable in any way, please report it to the principal investigator.

POTENTIAL BENEFITS
If you participate in this study, you may reasonably expect to benefit from the study in the following way:

<u>Direct benefits</u>
You may improve the strength and effectiveness of your pelvic floor exercises.
You may gain an insight into the function of your pelvic floor muscles.

<u>Indirect benefits</u>
You will be part of the first group in the world to formally test if visual assessment of the pelvic floor using ultrasound has an impact on how well pelvic exercises can be learnt.

Participation in the study may reveal new insights into how the pelvic floor structures interact with each other.

ALTERNATIVE IF YOU DO NOT PARTICIPATE IN THE STUDY

If you choose not to take part in this study, the alternative is to have what is considered standard care for your condition. In our institution, this would be an assessment of symptoms followed by a clinical examination. The physiotherapist will still perform an assessment of your pelvic floor strength and train you to use your pelvic floor muscles. The physiotherapist will also offer you transperineal ultrasound to help guide you with this. As this will not be under the controlled conditions of the study it will therefore not be used as part of the our research.

You may discuss the possible risks and benefits of the alternatives with your doctor or the Principal Investigator to make an informed decision whether to take part in this study.

COSTS & PAYMENTS IF PARTICIPATING IN THIS STUDY

Transperineal ultrasound of the pelvic floor forms part of your usual medical care. There is no additional cost to you for participating in this research study. The cost of your usual medical care (procedures, medications and doctor visits) will continue to be billed to you.

You will not receive any payments or reimbursements for taking part in this study.

INCIDENTAL FINDINGS

During the course of the study, there is a possibility that we might unintentionally come to know of new information about your health condition from the ultrasound scan that is conducted as part of the study. These are called “incidental findings”.

“Incidental findings” are findings that have potential health or reproductive importance to a participant like you and are discovered in the course of conducting the study, but are unrelated to the purposes, objectives or variables of the study. These findings may cause you to feel anxious and may affect your current or future life and/or health insurance coverage. Examples of potential incidental findings that may be discovered during the course of this study may include but are not limited to uterovaginal prolapse, defects in muscles of the pelvic floor, vaginal/labial cysts and urethral diverticulae, You will be asked to indicate whether you wish to be re-identified and notified in the event of an important incidental finding that is related to you.

If you agree to be re-identified and notified, your study doctor/ a qualified healthcare professional will explain the incidental finding to you and discuss and advise you on the next steps to follow. You may wish to do more tests and seek advice to confirm this incidental finding. The costs for any care that will be needed to diagnose or treat an incidental finding would not be paid for by this research study. These costs would be your responsibility.

If you do not wish to be re-identified and notified, your decision will be respected. However, in exceptional situations such as discovery of life-threatening incidental findings with available treatment options, you will be contacted to confirm your decision whether to learn more about the incidental findings. In rare situations where the incidental findings have public health

implications and as required by the law (e.g. under the Infectious Diseases Act), you will be contacted and informed of the incidental findings.

PARTICIPANT'S RIGHTS

Your participation in this study is entirely voluntary. You have a right to ask questions, which the study team will do their best to answer clearly and to your satisfaction.

In the event of any new information becoming available that may be relevant to your willingness to continue in this study, you (or your legal representative, if relevant) will be informed in a timely manner by the Principal Investigator or his/her representative and will be contacted for further consent if required.

WITHDRAWAL FROM STUDY

You are free to withdraw your consent and discontinue your participation in the study at any time, without giving any reasons and without your medical care being affected. If you decide to stop taking part in this study, you should tell the Principal Investigator.

If you withdraw from the study:

- Your ongoing clinical care will continue as usual.
- You will not be asked/persuaded to return to the study.

However, any research information or data obtained before your withdrawal of consent will be retained and may continue to be used. This is to allow a complete and comprehensive evaluation of the research study.

Your study doctor, the Principal Investigator of this study may stop your participation in the study at any time for one or more of the following reasons:

- Failure to follow the instructions of the Principal Investigator and/or study staff.
- The Principal Investigator decides that continuing your participation could be harmful to your health or safety.
- Pregnancy
- The study is cancelled.

RESEARCH RELATED INJURY AND COMPENSATION

If you follow the directions of the Principal Investigator of this research study and you are injured due to the ultrasound scan done under the plan for the research study, our institution will provide you with the appropriate medical treatment.

Payment for management of the normally expected consequences of your treatment (i.e. consequences of your treatment which are not caused by your participation in the research study) will not be provided.

You still have all your legal rights. Nothing said here about treatment or compensation in any way alters your right to recover damages where you can prove negligence.

CONFIDENTIALITY OF STUDY AND MEDICAL RECORDS

Your participation in this study will involve the collection of Personal Data. “Personal Data” means data about you which makes you identifiable (i) from such data or (ii) from that data and other information which an organisation has or likely to have access. Examples of personal data include name, national registration identity card (NRIC), nationality, passport information, date of birth, and telephone number.

Personal Data collected for this study will be kept confidential and stored in Singapore. Your study records and medical records (if applicable), to the extent required by the applicable laws and regulations, will not be made publicly available. To protect your identity, your Personal Data will be labelled with a unique code. The code will be used in place of your name and other information that directly and easily identifies you. The study team will keep a separate file that links your code to your Personal Data. This will be kept in a safe place with restricted access. In the event of any data sharing with third parties (e.g. funding agencies, research collaborators) whether locally or overseas and publication regarding this study, your identity will remain confidential.

However, the monitor(s), the auditor(s), the Institutional Review Board, and the regulatory authority(ies) will be granted direct access to your original medical records (if applicable) and study records to verify study procedures and data, without making any of your information public.

By signing the Consent Form, you consent to (i) the collection, access to, use and storage of your Personal Data by SingHealth, and (ii) the disclosure of such Personal Data to our authorised service providers and relevant third parties as mentioned above. To the fullest extent permitted by applicable law, under no circumstances will SingHealth and/or its affiliates be liable for any direct, indirect, incidental, special or consequential loss or damages arising out of any data breach event.

All data collected in this study are the property of SingHealth. The data will be used for the purpose of this research study only, unless you give permission for your data to be made available for future use in other research studies. For this purpose, consent for future research will be sought from you.

By participating in this research study, you are confirming that you have read, understood and consent to the SingHealth Data Protection Policy, the full version of which is available at www.singhealth.com.sg/pdpa.

WHO HAS REVIEWED THE STUDY

This study has been reviewed by the SingHealth Centralised Institutional Review Board for ethics approval.

If you have questions about your rights as a participant, you can call the SingHealth Centralised Institutional Review Board at 8126 3660 during office hours (8:30 am to 5:30pm).

WHO TO CONTACT IF YOU HAVE QUESTIONS REGARDING THE STUDY

If you have questions about this research study or in the case of any injuries during the course of this study, you may contact your study doctor, the Principal Investigator listed under STUDY INFORMATION section, at the beginning of this document.

If you have any feedback about this research study, you may contact the Principal Investigator or the SingHealth Centralised Institutional Review Board.

CONSENT FORM FOR RESEARCH STUDY

Study Title:
Transperineal ultrasound as a biofeedback tool for pelvic floor muscle therapy in postpartum patients.

Declaration by Research Participant

- I agree to participate in the research study as described and on the terms set out in the Participant Information Sheet. The nature, risks and benefits of the study have been explained clearly to me and I fully understand them.

- I understand the purpose and procedures of this study. I have been given the Participant Information Sheet and the opportunity to discuss and ask questions about this study and am satisfied with the information provided to me.

- I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reasons.

- By participating in this research study, I confirm that I have read, understood and consent to the SingHealth Data Protection Policy.

Consent to be Re-identified and Notified in the case of an Incidental Finding

There may be potential incidental findings arising from this research. Please indicate whether you consent to re-identification and notification about the incidental finding:

☐ Yes, I wish to be re-identified and notified in the case of an incidental finding from this research. I can be reached by:

Phone/ Email:

☐ In the event that I cannot be reached, please contact the following person nominated by me: [Optional]

Name/ Phone/ Email:

☐ No, I do not wish to be re-identified and notified in the case of an incidental finding from this research. However, I understand that in exceptional or rare situations, I will be contacted as described in the Participant Information Sheet:

- In exceptional situations such as discovery of life-threatening incidental findings with available treatment options, I will be contacted to confirm my decision whether to learn more about the incidental findings.
- In rare situations where the incidental findings have public health implications and as required by the law (e.g. under the Infectious Diseases Act), I will be contacted and informed of the incidental findings.

Name of participant	Signature/Thumbprint (Right / Left)	Date of signing

To be completed by translator, if required

The study has been explained to the participant/ legal representative in

_____ by _____.
Language Name of translator

To be completed by witness, where applicable

I, the undersigned, certify that:

- I am 21 years of age or older.
- To the best of my knowledge, the participant or the participant's legal representative signing this informed consent form had the study fully explained to him/her in a language understood by him/ her and clearly understands the nature, risks and benefits of the participant's participation in the study.
- I have taken reasonable steps to ascertain the identity of the participant or the participant's legal representative giving the consent.
- I have taken reasonable steps to ascertain that the consent has been given voluntarily without any coercion or intimidation.

Witnessed by: _____ _____
Name of witness Date of signing

_____
Signature of witness

1. An impartial witness (who is 21 years of age or older, has mental capacity, who is independent of the research study, and cannot be unfairly influenced by people involved with the research study) should be present during the entire informed consent discussion if a participant or the participant's legal representative is unable to read, and/or sign and date on the consent form (i.e. using the participant's or legal representative's thumbprint). After the written consent form and any written information to be provided to participant is read and explained to the participant or the participant's legal representative, and after the participant or the participant's legal representative has orally consented to the participant's participation in the study and, if capable of doing so, has signed and personally dated the consent form, the witness should sign and personally date the consent form. This is applicable for Clinical Trials regulated by HSA and Human Biomedical Research under the HBRA.

2. For HBRA studies, the witness may be a member of the team carrying out the research only if a participant or the participant's legal representative is able to read, sign and date on the consent form.

Investigator's Statement

I, the undersigned, certify to the best of my knowledge that the participant/ participant's legal representative signing this consent form had the study fully explained to him/her and clearly understands the nature, risks and benefits of the participant's participation in the study.

_____	_____	_____
Name of Investigator/ Person obtaining consent	Signature	Date

INFORMATION & CONSENT FORM FOR FUTURE RESEARCH

This is an optional component that is separate from the research study. You may still participate in the research study if you say "No" to this. Please ask questions if you do not understand why we are asking for your permission.

In this Consent Form for Future Research, we seek your permission to keep all information collected about you (Personal Data and research data) for Future Research. Except if you withdraw your consent or there are limits imposed by law, there is no limit on the length of time we will store the data. Researchers will use the data for research long into the future.

This is what will be done with the data:

- We may use the data to answer additional research questions in other research studies which are outside the scope of the research study ("Future Research"). We may also share the data with other researchers within and/or outside of Singapore, for use in Future Research.
- You should not expect to get personal test results from Future Research. However, it may be possible that incidental findings will be detected in the course of conducting Future Research. If this happens, we may contact you to find out if you would like to learn more. Only medically actionable incidental findings (where medical treatment is available) will be disclosed. You will be asked to indicate whether you wish to be re-identified and notified in the event of an important incidental finding that is related to you.
- We may also use the data for purposes other than research such as teaching, or training future researchers and development of health policy.

This is what will be done to protect confidentiality of the data:

- Any information that could identify you will be removed (de-identified) before this de-identified data is used and/or shared with other researchers and/or deposited into research data repository.
- The open-access and controlled-access research data repositories have robust procedures in place to protect confidentiality of the stored data. Although these repositories do not have your identifying information, it may be possible to identify you based on information in the databases when combined with information from other public sources (including information you tell people or post about yourself). We believe the chance of this happening is currently very low.
- If you decide at a later time that you do not want the data to be used for Future Research, you can contact the Principal Investigator or study team at any time. All the data that has not been used or shared with other researchers will be removed and discontinued from further use, unless this information has already been deposited into the research data repository or included in analyses or used in publications.

The use of your data in Future Research may result in intellectual property rights and commercial profits. If this should occur, you will not be compensated and will not receive any financial benefits or proprietary interest.

CONSENT FORM FOR FUTURE RESEARCH

This component is optional. You do not have to agree to it in order to participate in the research study.

Please indicate your choice using the relevant checkbox.

☐ I do not agree to have my data stored for future use in other research studies.

☐ I agree to have my data stored for future use in other research studies, as described above. I understand that I will not be contacted again personally, for approvals to use and share my data for such Future Research. Research arising in the future, will be subject to review by the relevant institutional review board, where applicable.

Disclosure of incidental findings arising from Future Research

☐ I wish to be re-identified and notified of any incidental findings that are medically actionable (with available treatment options).

☐ I do not wish to be re-identified and notified of any incidental finding that are medically actionable (with available treatment options). However, I understand that in exceptional or rare situations such as discovery of life-threatening findings), I may be contacted to confirm my decision whether to learn more about the incidental findings.

I understand the purpose and nature of this optional component (storage of data for future use). I have been given the Information & Consent Form for Future Research and the opportunity to discuss and ask questions about this optional component and am satisfied with the information provided to me.

I confirm that I have read, understood and consent to the SingHealth Data Protection Policy.

_____	_____	_____
Name of participant	Signature/Thumbprint (Right / Left)	Date of signing

To be completed by translator, if required

The optional component (storage of data for future use) has been explained to the participant/ participant's legal representative in

_____ by _____.
Language Name of translator

To be completed by witness, where applicable

I, the undersigned, certify that:

- I am 21 years of age or older.
- To the best of my knowledge, the participant or the participant's legal representative signing this Information & Consent Form for Future Research had the optional

component fully explained to him/her in a language understood by him/ her and clearly understands the purpose and the nature of this optional component.

- I have taken reasonable steps to ascertain the identity of the participant or the participant's legal representative signing this Information & Consent Form for Future Research.
- I have taken reasonable steps to ascertain that the participant or the participant's legal representative has not been coerced into giving consent.

Witnessed by: _____ _____

Name of witness Date of signing

_____

Signature of witness

1. An impartial witness (who is 21 years of age or older, has mental capacity, who is independent of the research study, and cannot be unfairly influenced by people involved with the research study) should be present during the entire informed consent discussion if a participant or the participant's legal representative is unable to read, and/or sign and date on the consent form (i.e. using the participant's or legal representative's thumbprint). After the written consent form and any written information to be provided to participant, is read and explained to the participant or the participant's legal representative, and after the participant or the participant's legal representative has orally consented to the participant's participation in the study and, if capable of doing so, has signed and personally dated the consent form, the witness should sign and personally date the consent form. This is applicable for Clinical Trials regulated by HSA and Human Biomedical Research under the HBRA.

2. For HBRA studies, the witness may be a member of the team carrying out the research only if a participant or the participant's legal representative is able to read, sign and date on the consent form.

Investigator's Statement

I, the undersigned, certify to the best of my knowledge that the participant/ participant's legal representative signing this Information & Consent Form for Future Research had the optional component (storage of data for future use) fully explained to him/her and clearly understands the purpose and the nature of this optional component.

_____	_____	_____
Name of Investigator/ Person obtaining consent	Signature	Date