SingHealth

PARTICIPANT INFORMATION SHEET AND CONSENT FORM

STUDY INFORMATION

Protocol Title:

Physical Activity Tracking and Exercise In Postpartum Women: A Pilot Study

Principal Investigator:

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Sponsor:

National Medical Research Council (NMRC) Centre Grant

PURPOSE OF THE RESEARCH STUDY

You are being invited to participate in a research study. 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. Please read carefully the information provided here. If you agree to participate, please sign the consent form. You will be given a copy of this document to take home with you.

The purpose of this study is to examine the effects of walking exercise in postpartum women. Postpartum is an important phase in the reproductive years of women. Weight retention after childbirth can lead to chronic diseases, including obesity, cardiovascular disease and other metabolic related diseases such as diabetes or high blood pressure. Steps trackers have been shown to be useful in encouraging women to increase their physical activity. We hope to evaluate the effects of walking and also the effects of a physical activity intervention based on a wearable steps tracker. We also hope to learn what the optimal weight loss is for postpartum women and how weight loss can lower the risk factors of chronic diseases.

This study will recruit 200 participants from KK Women's & Children's Hospital; of which will commence four to eight weeks after delivery and terminate 12 to 16 weeks after commencement.

STUDY PROCEDURES AND VISIT SCHEDULE

If you agree to take part in this study, you will be randomised to be in one of the two groups; the group with intervention (interventional group) and the group without intervention (control group). Randomisation means assigning you to one of the two groups by chance, like tossing a coin or rolling dice.

If you agree to take part in this study, you will be asked to come back to KKH within four to eight weeks after delivery. Your participation in the study will last approximately 12 to 16 weeks after commencement.

You will be recommended to increase your steps by 500 per week till you reach a minimum of 10,000 steps in the end of 12th week. Your daily steps will be recorded via the steps tracker. You will also receive motivational text messages weekly. If you are randomized into the control group, you will receive routine postpartum medical care. But if you are randomized into the interventional group, you will be given the steps tracker to wear at all times except during bathing and swimming.

During the study follow-ups, you will be asked to complete a physical activity questionnaire. Anthropometric measurements (height, weight, blood pressure, BMI, waist circumference, hip circumference and waist-to-hip ratio) will be done for all visits. Breastfeeding questionnaire will be asked in Visits 2 and 3. As we are also doing a chronic disease risk assessment, lipid profile and blood biomarkers will be done on Visits 1 and 3.

Schedule of visits and procedures (for both control group and interventional group):
Recruitment - at wards after delivery:

- Take consent
- Anthropometric measurements
- Collect delivery outcomes

Visit 1 - 6 weeks after delivery (±2 weeks):

- Anthropometric measurements
- Watch is given (For Intervention group)
- International physical activity questionnaire
- 8mls (2 teaspoons) of blood sample

Visit 2 – 10 weeks after delivery (±2 weeks):

- Anthropometric measurements
- Breastfeeding questionnaire
- Download the report from Actigraph tracker. (For Intervention group)

Final Visit – 14 weeks after delivery (±2 weeks):

- Anthropometric measurements
- Download the report from Actigraph tracker (For Intervention group)
- Breastfeeding questionnaire
- International physical activity questionnaire
- 8mls (2 teaspoons) of blood sample

Any individually-identifiable data obtained during the course of this study will be stored and used only for the purposes of this study. These data will not be used for future research.

Any human biological material obtained during the course of this study will be stored and analysed only for the purposes of this study for a period not exceeding 6 years, and will be destroyed after completion of the study.

The human biological material collected will not be used in restricted human biomedical research involving human-animal combinations in accordance to the Human Biomedical Research Act 2015 of Singapore (HBRA). The human biological material will be stored in Singapore.

YOUR RESPONSIBILITIES IN THIS STUDY

If you agree to participate in this study, you should:

- Keep your study appointments. If it is necessary to miss an appointment, please contact the study staff to reschedule as soon as you know you will miss the appointment.
- Inform the Principal Investigator as soon as possible about any side effects that you may have encountered.
- Be prepared to visit the hospital (three visits) and undergo all the procedures that are outlined above.

WHAT IS NOT STANDARD CARE OR EXPERIMENTAL IN THIS STUDY

In this study, the procedure(s) that are being performed for the purposes of the research are not routine assessments.

The blood tests done in this project and the information derived from the questionnaire will not be released to you or your doctor as they are not meant for diagnostic nor screening purposes. However, there will be no interference to your care by your own doctor.

There will be no identifying information on these specimens except for a unique identifying number assigned to you at study participation and that no personal identifying information will be released to relevant third parties.

POSSIBLE RISKS, DISCOMFORTS AND INCONVENIENCES

- Completion of the questionnaires will take about 10 – 15 mins of your time;
- Collection of blood (8mls – 2 teaspoons) may cause some discomfort; and occasionally some bruising and swelling at the needle insertion site. Fainting and excessive bleeding rarely occurs.

POTENTIAL BENEFITS

There is no assurance you will benefit from this study. However, your participation may contribute to the medical knowledge about the development of effective screening tests that would allow the early identification of a small group of women at high risk for complications.

ALTERNATIVES

The alternative is not to participate in this study. There will be no change in the original course of the postnatal care provided by your doctor. If you choose not to take part in this study, the additional procedures such as the anthropometric and blood pressure measurements, questionnaires and blood test will not be performed.

COSTS OF PARTICIPATION

If you take part in this study, the following will be performed at no charge to you:

- Anthropometric measurements
- 8mls (2 teaspoons) of blood collection for chronic disease assessment
- Blood pressure measurement

These costs will be borne by KK Women's and Children's Hospital.

You will be reimbursed for your time, inconvenience and transportation costs as follows:

- If you complete visit 1, you will be paid $50 and if you complete visit 2 and visit 3, you will be paid $100 for each.

INCIDENTAL FINDINGS

In the case of an "incidental finding" (i.e. any abnormality that we did not expect to see in this study or unrelated to the purpose of this study), we will not re-identify and give you any results from the research.

PARTICIPANT'S RIGHTS

Your participation in this study is entirely voluntary. Your questions will be answered 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.

The human biological material collected for the study will be deemed to be given to KK Women's and Children's Hospital. You give up your rights to the human biological material and any intellectual property rights that may be derived from the use of the human biological material.

By signing and participating in the study, you do not waive any of your legal rights to revoke your consent and withdraw from the study at any time.

WITHDRAWAL FROM STUDY

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

If you withdraw from the study, all study procedures will be discontinued. However, the data that have been collected until the time of your withdrawal will be kept and analysed. The reason is to enable a complete and comprehensive evaluation of the study.

The human biological material collected for the study will be deemed to be given to KK Women's and Children's Hospital and will not be returned to you. However, you retain your right to ask the Principal Investigator to discard or destroy any remaining samples if they have not been anonymised/ the human biological sample(s) is individually-identifiable and has not been used for the research or it has been used for research but it is practicable to discontinue further use of the human biological sample(s) for the research.

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.
- 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 trial substance or research procedure given 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 will not be provided by the KK Women's and Children's Hospital.

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 collected for this study will be kept confidential. Your records, to the extent of the applicable laws and regulations, will not be made publicly available. Only your Investigator(s) will have access to the confidential information being collected.

However, Regulatory Agencies, Institutional Review Board and Ministry of Health will be granted direct access to your original medical records to check 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 KK Women's and Children's Hospital, and (ii) the disclosure of such Personal Data to our authorised service providers and relevant third parties.

"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 medical conditions, medications, investigations and treatment history.

Research arising in the future, based on this "Personal Data", will be subject to review by the relevant institutional review board.

Data collected and entered into the Case Report Form(s) or Data Collection Form(s) are the property of KK Women's and Children's Hospital. In the event of any publication regarding this study, your identity will remain confidential.

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 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 the Principal Investigator A/Prof Chern Su Min Bernard at 6394 1770.

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 6323 7515 during office hours (8:30 am to 5:30pm).

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

CONSENT FORM

Details of Research Study

Protocol Title:

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Principal Investigator:

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I agree to participate in the research study as described and on the terms set out in the Participant Information Sheet.

I have fully discussed and understood the purpose and procedures of this study. I have been given the Participant Information Sheet and the opportunity to ask questions about this study and have received satisfactory answers and information.

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

By participating in this research study, 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 parent / legal guardian / legal representative, where applicable

I hereby give consent for the above participant to participate in the proposed research study. The nature, risks and benefits of the study have been explained clearly to me and I fully understand them.

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

Name of participant's parent/ legal guardian/ legal representative	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 in a language understood by him/ her and clearly understands the nature, risks and benefits of his/ her 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 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 or legal representative 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 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 and clearly understands the nature, risks and benefits of his/ her/ his ward's/ her ward's participation in the study.

_____ _____ _____

Name of Investigator/ Person obtaining consent | Signature | Date