PARTICIPANT INFORMATION SHEET AND INFORMED CONSENT FORM

(for adult subjects and interventional studies)

1. **Title of study:** ***The effectiveness of a Urinary Incontinence App (UI-App) on Pelvic Floor Muscle Exercises in improving its adherence and continence status among pregnant women.***

2. **Name of investigator and institution:** Dr Aida Jaffar

3. **Name of sponsor**: Universiti Putra Malaysia

4. Introduction:

Urinary incontinence (UI) means loss of bladder control, affecting about 423 million or 21.6% women globally especially among Asian women. Urinary incontinence is common during pregnancy and pelvic floor muscle exercise or Kegel's exercise has been shown to be helpful in the management of this condition.

UI-Apps is a newly developed mobile application that aim to assist pregnant women with their urinary incontinence. This app will assist the user in assessing the presence of urinary incontinence and guide on pelvic floor muscle exercise.

You are invited to join this research as you are pregnant with urinary incontinence. This is a research looking at the effectiveness of the mobile application in detecting and managing urinary incontinence. This is a randomized control study in which all participants will be randomized systematically into intervention or wait-list control group. Both groups will have similar treatment but at different time. The intervention group will receive treatment during the antenatal period while the wait-list control group will have usual care. Subsequently, the wait-list control group will receive similar treatment during post-partum period.

This study has been approved by the Medical Research and Ethics Committee, Ministry of Health Malaysia.

5. What is the purpose of the study?

The purpose of this study is to assess the effectiveness of pelvic floor muscle exercise via mobile apps for the treatment of urinary incontinence. This research is necessary because urinary incontinence is very common during pregnancy and it can be prevented by doing the correct exercise
A total of 340 pregnant women will be recruited in Hulu Langat, Selangor. The whole study will last about 20 weeks from 28 weeks pregnancy till 8 weeks post-partum.

6. What kind of study products will I receive?

This study will only involve mobile application and all the assessments of your UI and pelvic floor muscle exercise will be done using the UI-App. You will not have any extra clinic

appointment, invasive procedure like blood taking or imaging procedure like ultrasound or urinary test to confirm your urinary incontinence. Please do not hesitate to contact person shall you have any inquiries or worries. Your involvement in this study is voluntary, you can withdraw from this study at any time with or without reason and this shall not affect your usual antenatal care.

This UI-app study needs you to answer sets of questionnaires, follow simple instruction to assess UI and pelvic floor muscle exercise using the mobile UI-App. The exercise used is proven safe, has no known major risks or complications and there is no other alternative procedure. There is no time limit for UI-app, it is there for you to use even after completing this study.

Apart from using the UI-App, all participants of this study will have their usual antenatal care and follow-up at the health clinics. They can always seek their medical doctor for any medical or obstetric issues. As stated above, there is very minimal risk from the investigational product (UI-app) and this study procedure. On the other hand, the findings of this study will be potentially useful for health professionals to improve the overall management of UI among pregnant women.

By agreeing to participate in this study, you allow the main researcher to get access to your medical record. The researcher has the right to withdraw any participants from the study shall there be any urgent medical or obstetric issues/reasons that occur during the study period. Examples of obstetric emergencies are premature labour, severe high blood pressure, pre-eclampsia or bleeding due to abruptio placenta while medical emergencies include sepsis, heart attack, epilepsy and stroke. In assuring your confidentiality, no other researchers can access your medical records.

The data of this study will be analysed in aggregate. The findings of this study will be discussed and published as per report to the funding body, ethics committee(s), articles in peer-reviewed journals, presentation at conferences or other professional forums. In any report, publication and/or presentation, information will be provided in such a way that you cannot be identified, except with your express permission. You will be informed if any new information relevant to consent becomes available via the apps. You will be informed automatically the study findings as it will in the “monitoring the progress”

7. What will happen if I decide to take part?

Thank you for agreeing to join this study. We would like to emphasize that this study will only involve mobile application and all the assessments of your UI and pelvic floor muscle exercise will be done using the UI-App.

This short note will explain how this UI-App and your responsibilities upon participating this study.

1. You will receive an email / short message system (SMS) / Whats-App with a link to download this app after signing the consent.
2. Once you have downloaded this app, you will need to log in the app using your username and password.
3. There will be a step-by-step instruction after you logged in. Please follow the instruction given.
4. There will be questions on your experience with Urinary Incontinence and pelvic floor muscle exercise (PFME). Kindly read carefully, please do not rush and enjoy the app.
5. Please report to us if you experience any discomfort (either feeling stress, anxious or any reason) while using the UI-App. The pelvic floor muscle exercise that is included in the UI-App has been proven safe and is used in managing pregnant women with urinary incontinence
6. It is very important for you to give your truthful answer to the questions and faithfully practice the exercise prescribed. As the result of this study will be used to help other pregnant women with UI in the future.
7. If you face any difficulty, you can ask at the (Frequently Asked Questions) FAQ section or do not hesitate to call the contact person given.

8. When will I receive the trial product and how should it be kept?

This UI-app will be available for you after completion of the study. There will be no added treatment except for the usual antenatal care as usual along with the UI-app.

9. What are my responsibilities when taking part in this study?

Your responsibilities upon participating this study:

1. To download the UI-Apps via the link provided after signing the consent form.
2. To follow the instruction given via the apps.
3. To report if you experience any discomfort (either feeling stress, anxious or any reason) due to this UI-Apps. This app is about urinary incontinence and pelvic floor muscle exercise and has been recommended in the guideline for the management in pregnant women with urinary incontinence. You should not be worry as it has been proven its effectiveness locally and internationally.
4. To do the assessments with your truly response. This is very important to help other pregnant women in future UI-App development.
5. Do not hesitate if you feel you would like to withdraw from this study as your involvement in this study is voluntarily and will not affect your future healthcare appointment or follow-up.

10. What kind of treatment will I receive after my participation in the trial?

No study product will be given to you at the end of your participation in the study. Whether you complete the study or withdraw early, your doctor will discuss the best alternatives for your future treatment with you.

11. What are the potential risks and side effects of being in this study?

There is also a risk that participants may feel pressured to provide information they believe is desirable by the data collector during the study phase. To ensure that participants answer honestly, the research assistant will explain and ensure them that their answers will be kept completely confidential, with no identifying information will ever be attached to the information given. There will be no other alternative procedures in this study.

12. What are the benefits of being in this study?

The benefit for this study, will be as the results will be used to develop new recommendations on ways to improve the antenatal care by our Ministry of Health under Maternal Child Health programme. The outcome of this study with the use of mHealth technology will be precious to the policy makers and local stakeholders. If this UI-application is shown to be effective, the efforts to share this intervention will benefit not just pregnant women but also elderly populations or anyone who has urinary incontinence. By downloading this UI-app, it will educate and improve the people awareness towards UI and PFME. Eventually, results of this study may contribute the quality improvement of our antenatal care and care of the elderly population.

13. What if I am injured during this study?

This study carries little risk to the participants as you may feel anxious answering the questions, or using the app. However, the UI-app will be designed in such a way that it will be user friendly and stress-free. There will be a trained research assistant to assist you during the recruitment, obtaining consent and downloading the mobile app. As participant, you can answer or use the app at your own time and convenience, thus we expect the psychological distress or anxiety that you may have is very minimal. This study is non-invasive, does not involve any biological product or blood, hence no added physical or biological risks to the participants. If any injuries do occur as a direct result of participating in the study, you need to visit your antenatal doctor or any doctor in primary care clinic immediately.

14. What are my alternatives if I do not participate in this study?

You do not have to participate in this study to get treatment for your disease or condition.

15. Who is funding the research?

This study is fully sponsored by Universiti Putra Malaysia which will pay for all research related products.

16. Can the research or my participation be terminated early?

Research doctors or sponsors may terminate this research or terminate your participation in this research at any time, if necessary.

17. Will my medical information be kept private?

Yes. The research assistant is a trained professional and we will ensure participants' (your) information are kept confidential and protected all the time. Your information will be then de-identified by the research assistant by removing all your personal identified information and replace with unique code prior to entry into the study database. This is very important as an essential step to create and preserve anonymity of the participants.

If you give us your permission by signing the consent document, we plan to discuss/publish the results in a variety of forums, including: reports to the funding body for monitoring purposes; annual reports to ethics committee(s) for monitoring purposes; peer-reviewed journals; presentation at conferences or other professional forums. In any report, publication and/or presentation, information will be provided in such a way that you cannot be identified, except with your express permission. Any publications resulting from this study will not identify your place of work.

18. Who should I call if I have questions?

If you have any questions about the study or if you think you have a study related injury and you want information about treatment, please contact the study doctor, Dr Aida Jaffar at telephone number 0176776768.

If you have any questions about your rights as a participant in this study, please contact:
JAWATANKUASA ETIKA & PENYELIDIKAN PERUBATAN
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INFORMED CONSENT FORM

Title of Study: ***The effectiveness of a mHealth App on Pelvic Floor Muscle Exercises in improving compliance and continence status amongst pregnant women.***

By signing below I confirm the following:

- I have been given oral and written information for the above study and have read and understood the information given.
- I have had sufficient time to consider participation in the study and have had the opportunity to ask questions and all my questions have been answered satisfactorily.
- I understand that my participation is voluntary and I can at anytime free withdraw from the study without giving a reason and this will in no way affect my future treatment. I am not taking part in any other research study at this time. I understand the risks and benefits, and I freely give my informed consent to participate under the conditions stated. I understand that I must follow the researcher's assistant instructions related to my participation in the study.
- I understand that study staff, qualified monitors and auditors, the sponsor or its affiliates, and governmental or regulatory authorities, have direct access to my medical record in order to make sure that the study is conducted correctly and the data are recorded correctly. All personal details will be treated as STRICTLY CONFIDENTIAL
- I will receive a softcopy of this subject information/informed consent form signed and dated.

Subject:

Signature: I/C number:

Name: Date:

Investigator conducting informed consent:

Signature: I/C number:

Name: Date:

Impartial witness: *(Required if subject is illiterate and contents of participant information sheet is orally communicated to subject)*

Signature: I/C number:

Name: Date: