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| Human Research Ethics Committee |
| Office of research Services |

**Project Title: The effect of pelvic floor muscle exercise on female sexual function during pregnancy and the first three months postpartum: A randomised controlled trial**

**Project Sponsor:** Sponsored by Western Sydney University

**Coordinating Principal Investigator:** Sahar Sadat Sobhgol, PhD candidate of Midwifery, School of Nursing and Midwifery of Western Sydney University.

**Who is carrying out the study?** Sahar Sadat Sobhgol, PhD candidate of Midwifery, School of Nursing and Midwifery of Western Sydney University.

**Associate Investigator(s):** Prof Hannah Dahlen, Principal Supervisor at school of Nursing and Midwifery of Western Sydney University, Prof Caroline Smith (Clinical research, Campbelltown campus of Western Sydney University, Dr Holly Priddis, school of Nursing and Midwifery of Western Sydney University. Dr Jenny King, Onsite Supervisor

**What does my participation involve?**

You are invited to take part in this research project testing the effect of a method of pelvic floor muscle exercise on improving sexual function and childbirth outcomes. This Participant Information Sheet/Consent form tells you about the research project. 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. 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 participate in the exercises 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?**

There are limited studies about the effects of pelvic floor exercise on sexual function particularly during pregnancy and after birth. Pregnancy and particularly childbirth can affect pelvic floor muscle strength which can impact on sexual health and other outcomes such as incontinence. Pelvic floor muscle exercise is considered a free and safe practice to strengthen pelvic floor muscle strength. Therefore, we are planning to investigate the effect of antenatal pelvic floor muscle exercise on sexual function during pregnancy and following the birth. We are also interested in looking at whether they may improve some birth outcomes, and incontinence.

**What dose 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 put people into two groups called an intervention and control group. The control group will receive routine standard care during pregnancy (which you would get anyway if not in the trial) and the intervention group will receive both standard routine antenatal care and also training on pelvic floor muscle exercise. The results are compared to see if one leads to better outcomes. To try to make sure the groups are the same, each participant is put into a group by chance (random).

**What is randomisation?**

Randomisation is like a tossing a coin, you will not be able to choose which group you will be allocated to.You will be randomly allocated to either control or intervention group.

**What is the program being studied?**

We will provide you with education on how to perform pelvic floor muscle exercises. You will be followed up fortnightly via text messages as a reminder. There is no cost to participate in this study. You will be given self-report questionnaires to complete electronically when you enter the study, at around 36 weeks of pregnancy and three months after birth, so the researcher will not be able to identify you when they analyse the data. You will also be provided with a diary to record your daily exercises.

**How much time will the study take?**

The program will start from when you are 20 weeks pregnant until you have given birth. In addition, contact will also be made with you three months after birth asking you to complete a questionnaire. If you are allocated in study group, you will be followed up fortnightly via text messages during pregnancy. You will be encouraged to continue pelvic floor exercise after birth. These fortnightly messages will cease once your baby has been born. If you are allocated in control group, there will not be follow up contacts during pregnancy. However, you will be asked to complete the questionnaires at the time of booking, at 36 weeks pregnancy and at three months following birth.

**Other relevant information about the research project?**

We will also need to gather information about your general health at the time of booking into hospital and receiving antenatal care, as well as your birth history in order to be able to interpret the findings of this research. Your information will be kept confidential.

**What do I have to do?**

We will send you questionnaires and a diary to complete which can be done electronically, so the researchers will not know who is answering and so can’t identify you. However, you have the option of answering the questions in paper form and return them to researcher if you choose this option. You can send your completed diary and questionnaires to the researcher via email. There is no specific requirement (such as dietary, life style or medication change) from you while participating in this study. However, you can let your researcher knows if you are having or experiencing any changes or new treatments including any other method for strengthening pelvic floor muscles or perineal stretching methods in pregnancy.

**Do I have to take part in this research project? Can I withdraw from the study after participation?**

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 and it will not affect your relationship with hospital or staff caring for you.

**What are alternative to participation?**

You don’t have to take part in this research to receive pelvic floor muscle exercise programs. Other options are participating in private programs outside of hospital or continuing with standard routine antenatal care.

**What are possible benefits of taking part?**

We cannot guarantee or promise that you will receive any benefits from this research; however, possible benefits may include some improved aspects of sexual health; childbirth outcomes and reduced symptoms of urinary or faecal incontinence.

**What are the possible risks and disadvantages of taking part?**

There is no harm reported so far as a result of pelvic floor exercise according to the information available. However, it might neither cause any harm nor any benefit.

**How is the study being paid for?**

The study is funded by Western Sydney University. There is no cost to participate in this study.

**Will anyone else know the results? How the results will be disseminated?**

Any information acquired from you will be strictly confidential and only the researchers named above will have access to it. Your name will be removed from any data collected from you and your data will be linked to a participant number. The information will be destroyed 5 years following the completion of the study. The overall results of the study will be published as group data, which means that the results will be presented to other people in a way that will not individually identify you or any other participant.

**Can I tell other people about this research?**

Yes, you can tell other people about the study by providing them with the investigators contact details. They can contact the chief investigator and participate in the study.

**What if I require further information?**

When you have read this information, Sahar Sobhgol will discuss it further with you and answer your questions. If you would like to know more at any stage, please feel free to contact her direct supervisor: Prof Hannah Dahlen at School of Nursing and Midwifery at UWS on 02 96859118.

**What if I have a complaint?**

This study has been approved by the University of Western Sydney, Human Research Committee and NSW Department of Health Area Health Service.

If you have any complaints or reservations about the ethical conduct of this research, you may contact the Ethics Committee through the Office of Research Services on Tel +61 2 47360229 Fax: +61 2 47360013 or email humanethics@uws.edu.au

Any issues you raise will be treated in confidence and investigated fully, and you will be informed of the outcome. If you agree to participate in this study, you may be asked to sign the Participants Consent form.

The information sheet is for the participant to keep and the consent form is retained by the researcher.

**Form for Withdrawal of Participation -** *Adult providing own consent*

*It is recommended that this form NOT be included as part of the PICF itself, but that it be developed at the same time and made available to researchers for later use, if necessary. Note that a participant’s decision to withdraw their separate consent to the use and storage of tissue will need to be documented separately and linked to the PICF used for that purpose.*

**Title**: The effect of pelvic floor muscle exercise on female sexual function in pregnancy and three month following birth: a randomised controlled trial

**Short title:** Pelvic floor muscle exercise in pregnancy

**Protocol number**:

**Project sponsor:** Western Sydney University

**Coordinating investigator/** Dr Jenny King

**Principal investigator:** Sahar Sadat Sobhgol

**Associate Investigator (s)** Prof Hannah Dahlen, Dr Holly Priddis, Prof

 Caroline Smith

**Location:** Antenatal clinics of Westmead Public Hospital

**Declaration by Participant**

I wish to withdraw from participation in the above research project and understand that such withdrawal will not affect my routine treatment, my relationship with those treating me or my relationship with Westmead Public Hospital.

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|  | Name of Participant (please print) |  |  |  |  |
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|  | Signature |  |  Date |  |  |
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*In the event that the participant’s decision to withdraw is communicated verbally, the Study Doctor/Senior Researcher will need to provide a description of the circumstances below.*

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**Declaration by Study Doctor/Senior Researcher†**

I have given a verbal explanation of the implications of withdrawal from the research project and I believe that the participant has understood that explanation.

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|  | Name of Study Doctor/Senior Researcher† (please print) |  |  |
|  |  |
|  | Signature |  |  Date |  |  |
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† A senior member of the research team must provide the explanation of and information concerning withdrawal from the research project.