**Participant Information Sheet/Consent Form**

**Interventional Study** -*Adult providing own consent*

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

**Short Title:** Pelvic floor muscle exercise during pregnancy

**Protocol number:** ACTRN12617001030369p

**Project Sponsor** Western Sydney University

**Coordinating Principle investigator/Principle investigator:** Dr Jenny King

**Associate Investigators:** Sahar S. Sobhgol, PhD Candidate, School of Nursing and Midwifery, Western Sydney University, Prof Hannah Dahlen, PhD, Principal Supervisor, School of Nursing and Midwifery, Western Sydney University, Prof Caroline Smith, PhD (Clinical research), Campbelltown campus of Western Sydney University, Dr Holly Priddis, PhD, School of Nursing and Midwifery, Western Sydney University

**Location:** Women’s health clinics ofWestmead Public Hospital

**1 Introduction**

We would like to invite you to participate in this research project, which is exploring the effect of pelvic floor muscle exercise during pregnancy on sexual function, childbirth outcomes and on urinary/faecal incontinence symptoms during pregnancy and at three months after birth. The pelvic floor muscles play an important role in supporting the organs contained in the pelvis and supporting the pregnancy itself. We want to know if performing regular pelvic floor muscle exercise during pregnancy will help to strengthen pelvic floor muscles and lead to a better sexual function, better childbirth experience, and less symptoms of urinary or faecal incontinence, which occur sometimes during pregnancy or after birth.

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 do not understand or want to know more about. Before deciding whether 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 do not 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.

**2 What is the purpose of this research?**

Pregnancy and childbirth can affect pelvic floor muscle strength. There is limited information available about the effect of pelvic floor exercise on sexual function during pregnancy and also on childbirth. Therefore, we are planning to investigate the effect of pelvic floor muscle exercise on sexual function during pregnancy and the first three months following birth. We are also interested in looking at whether pelvic floor exercise is associated with better birth experiences, such as reduced duration of labour, reduced episiotomy, and reduced symptoms of incontinence.

**3 What dose participation in this research involve?**

You will be participating in a randomised controlled research study. 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 exercise group and a non-exercise group. In this study, the non-exercise group will receive routine pregnancy care during pregnancy (which you would get anyway if not in the trial) and the exercise group will receive both routine pregnancy care and training on pelvic floor muscle exercise. The results are compared at the end of study 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). This research project has been designed to make sure the researchers interpret the results in a fair and appropriate way and avoids researchers or participants jumping to conclusions. There are some requirements to participate in this study. For example, eligible participant must be older than 18 years old, currently in a relationship, expecting their first baby, are pregnant with a singleton baby, have a low risk pregnancy, are able to read and understand English, and not having previous medical conditions such as previous urinary incontinence or diabetes before pregnancy. There are no additional costs associated with participating in this research project. All education about pelvic floor exercise and relevant counselling (if required) as part of the research project will be provided to you free of charge.

**4 What does the participant have to do?**

In this study, we will allocate you either to a non-exercise group where you will not need to do pelvic floor exercises during pregnancy (as taught by the researcher), or to an exercise group where we will ask you to perform pelvic floor exercises daily. If you are in the exercise group, you are expected to perform pelvic floor muscle exercises daily as you are instructed from 20 weeks’ pregnancy until birth. There is no dietary requirement or life style restriction because of participating in this study. You will be able to continue taking your medications as advised by your doctor or health care professionals. However, you are expected to inform the researcher if there is any change in your circumstances or if you use any other methods of pelvic floor exercises or perineal stretching.

If you are in a group where you do not perform daily pelvic floor exercises during pregnancy, you will continue with your routine pregnancy care. The first session will take approximately 30 to 45 minutes and it is the only actual visit you will have with researcher. After that, the researcher will only contact you via text messages or email to remind you of answering the questionnaires (6 questionnaires in total) at less than 20 weeks and at 36 weeks of pregnancy, and at three months after birth. Answering the questionnaires will take 20 to 30 minutes of your time.

If you are allocated to the exercise group, it means you will learn how to perform pelvic floor muscle exercises taught by the researcher at the first visit and you will keep performing these exercises daily from 20 weeks’ pregnancy until birth. The first visit will take about one hour and the researcher will gather some information about you and teach you how to perform pelvic floor muscle exercises, give you a diary to record the number of pelvic floor muscle exercises you will do daily, will discuss with you about follow up fortnightly messages and will explain to you about the questionnaires. There will not be any visits with the researcher after this. However, the researcher is available in the clinic if you have any questions or concerns during pregnancy. The researcher will stay in touch with you by sending you fortnightly text messages. The content of these messages is something like this **[**“Hi, I hope you are doing well with your daily pelvic floor exercises. Please keep performing your exercises. If you need a new diary, or if you have any question, please contact the researcher at the clinic or call her phone number. Wish you the best with exercises**”]**. We also will give you a monthly diary to record your exercises daily and you need to complete it and return it to the researcher either via email or in your next antenatal visit and the researcher will give you a new diary. We will also give you some red dots, which are reminders, so you can remember to perform your pelvic floor exercises daily. You can stick them on the shower, or on your toothbrush or toothpaste, or at the queues (on your mobile, book etc.). We also will give you questionnaires (7 short questionnaires in total) to answer at 20 weeks’ pregnancy, at 25 weeks’ pregnancy, 36 weeks’ pregnancy and also at three months after birth. We will remind you of the questionnaires via fortnightly text messages, **[**A message like this: “Hi! We sent you some questions to answer via your email or mobile phone. It would be great if you answer them. If any question is not clear for you, please contact the researcher at clinic or via her phone number. Thank you.”**]**. Answering the questionnaires may take 20-30 minutes of your time.

Whether you are in exercise group or the non-exercise group, the questionnaires will be sent to you either electronically or in paper. There are different sets of questions. Some questions are about your sexual function and relationship status, which are of a sensitive nature. We appreciate your answers and we reassure you that the information will be kept confidential. If you do not understand some questions and you need more clarification, you can always contact the researcher. However, if you choose not to answer the questions, then your choice will be respected.

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 using new treatments including any other method for strengthening pelvic floor muscles or perineal stretching in pregnancy.

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

The research setting is antenatal clinic of Westmead Hospital**.** We will also gather information about your general health at the time of booking into hospital and at your birth and after birth. All the information will be kept confidential and linked to a four-digit study code**.**

**6 Does the participant have to take part in this research project?**

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 staff caring for you.

**7 What are the alternatives to participation?**

You do not have to take part in this research to receive pelvic floor muscle exercise programs. Other options are participating in private programs outside of the hospital or continuing with routine pregnancy care.

**8 What are the 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; better childbirth experience such as reduced duration of labour, reduced need for episiotomy, and reduced symptoms of urinary or faecal incontinence symptoms during pregnancy and after birth.

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

There is a possibility that you might experience a level of distress due to:

* the sensitive nature of some of the questions in the questionnaires,
* or feeling that you need to do exercises on a daily basis.

In these cases, you are encouraged to discuss your worries with the researcher at the antenatal clinic during working hours and weekends in Westmead Hospital.

**10 What if new information arises during this research project?**

If new information becomes available during study, the researcher will tell you know about it and discuss with you whether you can continue in the research project. If the researcher decides that you can continue in the research project, you will be asked to sign an updated consent form.

**11 Can the participant have other treatments during this research project?**

Whilst you are participating in this research project, you may not be able to take other pelvic floor muscle exercises programs being taught by another institutions or health care professionals. It is important to tell the researcher if you are using acupuncture or other alternative treatments, general fitness, pelvic floor exercises and perineal stretching.

**12 What if I withdraw the participant from this research project?**

If the researcher withdraws you from study during the research project, the researcher will not collect additional personal information from you, although personal information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law.

**13 What if I withdraw from the research project?**

If you decide to withdraw from this research project, please notify the researcher before you withdraw. The researcher will inform you if there are any special requirements linked to withdrawing. If you do withdraw your consent during the research project, the researcher will not collect additional personal information from you, although personal information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law.

14. **Could this research project be stopped unexpectedly?**

This research project may be stopped unexpectedly for a variety of reasons. These may include:

* Unacceptable side effects
* The pelvic floor exercises being shown to work and not need further testing
* Or if the decision made by Western Sydney University or by Local Sydney health District

 **15        What happens when the research project ends?**

You can continue performing pelvic floor exercises on your own or/alternatively you can join fitness or exercises classes to perform pelvic floor muscle exercises. If you have any question about pelvic floor exercises after completion of this study, you can discuss it with your local doctor. The result of this study will be published in the form of thesis and paper publication within approximately 6 to 12 months after completion of study and you will be able to access them via internet or by contacting, the researcher.

**16 What will happen to information about me?**

By signing the consent form, you consent to the researcher collecting and using personal information about you for the research project. Any information obtained in connection with this research project will be linked to a study code and will remain confidential. Your information will not be identifiable, will be kept in a password-protected computer, and locked filing cabinet in Westmead Hospital. Only the researchers mentioned above will have access to this data. All the information will be destroyed five years after completion of research*.* Your information will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law.

Information about you may be obtained from your health records held at this health service for the purpose of this research. By signing the consent form you agree to the research team accessing health records if they are relevant to your participation in this research project

Your health records and any information obtained relevant to the study during the research project are subject to inspection for the purpose of verifying the procedures and the data.  This review may be done by the relevant authorities and authorised representatives of Western *Sydney University,* the institution relevant to this Participant Information Sheet, *Western Sydney Local Health district*, or as required by law. By signing the Consent Form, you authorise release of, or access to, this confidential information to the relevant research personnel and regulatory authorities as noted above.

The overall results of the study will be published as group data as publications or presentation in a variety of forums, which means that the results will be presented to other people in a way that will not individually identify you or any other participant. Information about your participation in this research project may be recorded in your health records.

In accordance with relevant *NSW* privacy laws, you have the right to request access to the information collected and stored by the research team about you. You also have the right to request that any information with which you disagree be corrected. Please contact the research team member named at the end of this document if you would like to access your information.

Any information obtained for the purpose of this research project *and for the future research described in Section 16* that can identify you will be treated as confidential and securely stored.  It will be disclosed only with your permission, or as required by law.

**17        Complaints and compensation**

If you suffer any complications as a result of this research project, you should contact the study team as soon as possible and you will be assisted with arranging appropriate medical treatment. If you are eligible for Medicare, you can receive any medical treatment required to treat the complication, free of charge, as a public patient in any Australian public hospital.

**18 Who is organising and funding the research?**

This research project is being conducted by the researchers named above and is sponsored and funded by *Higher degree education in Western Sydney University.*

No member of the research team will receive a personal financial benefit from your involvement in this research project (other than their ordinary wages).

You will not benefit financially from your involvement in this research project even if, for example, the knowledge acquired from analysis of your data prove to be of commercial value to *Western Sydney University*.

**19        Who has reviewed the research project?**

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC).  The ethical aspects of this research project have been approved by the HREC of *Western Sydney Local Health District.*

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2007)*. This statement has been developed to protect the interests of people who agree to participate in human research studies.

**20        Further information and who to contact?**

The person you may need to contact will depend on the nature of your query.

If you want any further information concerning this project or if you have any medical problems, which may be related to your involvement in the project (for example, any side effects), you can contact the researcher on *0452503035* or any of the following people:

|  |  |
| --- | --- |
| Name | *Hannah Dahlen* |
| Position | *Professor of midwifery,* Western Sydney University |
| Telephone | 02 96859118 |
| Email |  h.dahlen@westernsydney.edu.au |

 **What if I have a complaint?**

For matters relating to research at the hospital at which you are participating, the details of the local site complaints person are:

**17 Complaints contact person**

|  |  |
| --- | --- |
| Name | Patient advice and liaison service |
| Position | Patient Advice and Liaison Service |
| Telephone | (02) 88907014 |
| Email | wslhd-pals-mail@health.nsw.gov.au  |

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

**Reviewing HREC approving this research** **and HREC Executive Officer details**

|  |  |
| --- | --- |
| Reviewing HREC name | *WSLHD Human Research Ethics Committee* |
| HREC Executive Officer | *Kellie Hansen* |
| Telephone | *02 8890 8183* |
| Email | *Wslhd-researchoffice@health.nsw.gov.au* |

**Local HREC Office contact (Single Site -Research Governance Officer)**

|  |  |
| --- | --- |
| Name | Research Governance Officer  |
| Position | Research Governance Officer |
| Telephone | Tel 02 88909007 |
| Email  | wslhd-rgo@health.nsw.gov.au  |

**Consent Form -** *Adult providing own consent*

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

**Short Title:** Pelvic floor muscle exercise during pregnancy

**Protocol number:** ACTRN12617001030369p

**Project Sponsor** Western Sydney University

**Coordinating Principle investigator/Principle investigator:** Dr jenny King

**Associate Investigators:** Sahar S. Sobhgol, PhD candidate of School of Nursing and Midwifery of western Sydney University, 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.

**Location**: Women’s health clinics ofWestmead Public Hospital

**Declaration by Participant**

I have read the Participant Information Sheet or someone has read it to me in a language that I understand.

I understand the purposes, procedures and risks of the research described in the project.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the study without affecting my future health care.

I understand that I will be given a signed copy of this document to keep.

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| --- |
|  |
|  | Name of Participant (please print) |  |  |  |  |
|  |
|  | Signature |  |  Date |  |  |
|  |

|  |
| --- |
|  |
|  | Name of Witness\* to Participant’s Signature (please print) |  |  |
|  |
|  | Signature |  |  Date |  |  |
|  |

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

I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

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|  |
|  | Name of Study Doctor/Senior Researcher† (please print) |  |  |
|  |  |
|  | Signature |  |  Date |  |  |

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

**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**: ACTRN12617001030369p

**Project sponsor:** Western Sydney University

**Coordinating investigator** Dr Jenny King

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

 Caroline Smith, Sahar Sadat Sobhgol

**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.

|  |
| --- |
|  |
|  | Name of Participant (please print) |  |  |  |  |
|  |
|  | Signature |  |  Date |  |  |
|  |

*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 |  |  |
|  |

† A senior member of the research team must provide the explanation of and information concerning withdrawal from the research project.