Participant Information Sheet

Non-Interventional Study - Adult providing own consent

Flinders Medical Centre

Title	Health-related quality of life Australian parous women without rectus diastasis (abdominal separation) [21-100].
Coordinating Principal Investigator/ Principal Investigator	A/Prof. Nicola Dean, Dr Siobhan Fitzpatrick
Associate Investigator(s)	Prof. David Watson, A/Prof. Rosalie Grivell, Dr Tamara Crittenden
Location	Online, GP Plus Marion and other healthcare settings

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Part 1 What does my participation involve?

1 Introduction

You are invited to take part in this research project, 'Health-related quality of life Australian parous women without rectus diastasis (abdominal separation).' This is because you are a woman in Australia who has had at least one child. During pregnancy, most women have separation of the abdominal muscles. After birth, this separation usually returns to normal. Unfortunately, in some women, the separation persists. This is called rectus diastasis. The research project is aiming to find out the impact that this condition has on the quality of life and symptoms of women. You have been invited to participate, because you have abdominal muscles that have returned to near normal after childbirth.

This Participant Information Sheet 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 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 provide verbal consent on a videocall with a researcher. By providing verbal consent you are telling us that you:
- Understand what you have read
- Consent to take part in the research project
- Consent to the use of your personal and health information as described.

You can download a copy of this Participant Information Sheet to keep.

2 What is the purpose of this research?

The aim of this project is to investigate the impact of rectus diastasis (abdominal separation) after pregnancy on the quality of life, back pain, and urinary incontinence of women, compared to women without the condition. In this project, we are interested in women without the condition.

Rectus diastasis is a poorly understood medical condition. In Australia, there are no specific guidelines for its diagnosis, management, and very limited options for surgical treatment. This study aims to examine the health-related quality of life, back pain, and urinary incontinence symptoms of women with

normal abdominal muscles, so we can compare them with women with rectus diastasis. If we can demonstrate a difference, we can:

- Better define the condition and its associated symptoms.
- Help to create protocols to diagnose and treat it.
- Advocate for greater resources to be put towards its diagnosis and treatment, (such as physiotherapy and surgery).

This project has not received any funding or sponsorship. The results of this research will be used by Dr Siobhan Fitzpatrick towards obtaining a Doctor of Philosophy degree. We also plan to publish the results in a medical journal to help other doctors understand this condition and how best to treat it.

3 What does participation in this research involve?

After reading this Participant Information Sheet, you will have time to consider taking part in this research project. If you consent to participate you can select the "Get Involved" option and complete the expression of interest form online. Selecting this option indicates that you are happy to be contacted by one of our researchers. If you are happy to proceed, a female researcher will invite you to attend a one-on-one Zoom meeting where she will answer any questions you may have about the study and record your verbal consent to participate.

After providing the researcher with some basic contact details, you will be sent a link to some online questionnaires to complete in your own time. You will be required to fill in the Short-Form (SF-36), Oswestry Disability Index (ODI) and the International Consultation on Incontinence Questionnaire-Urinary Incontinence Short Form (ICIQ-UI-SF). These are commonly used, validated questionnaires for measuring different aspects of your health and wellbeing. A questionnaire about your medical and obstetric history is also included so that you can let us know a little more about your health. You will just need to commit about 10-15 minutes of your time to fill out the questionnaires online.

After completing the questionnaires, you will be invited to attend a face-to-face appointment with the female researcher at a time a place convenient to you. If you are based in Adelaide, this will take place at GP Plus Marion. If you are based elsewhere in Australia, the researcher will coordinate an appropriate GP practice or private clinic setting with you. During this appointment the researcher will measure your height, weight, and abdominal circumference, as well as measure the distance between your abdominal muscles using a bedside ultrasound scanner.

If you are based in Adelaide, the researcher will ask if you are happy to consent to an additional ultrasound measurement with a female sonographer to check if the two abdominal muscle measurements are similar. After a 15-minute break, there will be a second lot of measurements (4 in total). The whole session will take less than half an hour.

This research project has been designed to make sure the researchers interpret the results in a fair and appropriate way and avoids study doctors or participants jumping to conclusions.

There are no costs associated with participating in this research project, nor will you be paid.

4 What do I have to do?

You will need to complete the online questionnaires and attend a face-to-face appointment to have an ultrasound scan.

5 Other relevant information about the research project

This project aims to recruit approximately 150 women with normal abdominal muscles. In another study we will compare these results to 150 women with rectus diastasis. To fully understand the health and quality of life impact of rectus diastasis, we need to compare these outcomes in a large population of Australian women with and without rectus diastasis.

6 Do I 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. Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your routine treatment.

7 What are the possible benefits of taking part?

There will be no clear benefit to you from your participation in this research. However, possible benefits may include that the study highlights a reduced quality of life associated with rectus diastasis, identifying it as an important medical condition potentially affecting millions of Australian women.

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

The researchers realise that if your experience of rectus diastasis is difficult, or circumstances in your life became difficult after your diagnosis, some of the online questions may raise stressful or upsetting thoughts for you. If you become upset or distressed from your participation in the research, the researchers will be able to arrange for counselling or other appropriate support. Any counselling or support will be provided by qualified staff who are not members of the research project team. This counselling will be provided free of charge. Alternately, you can call Lifeline to talk to someone: 13 11 14. Their helplines are open 24/7.

9 What if I withdraw from this research project?

Even if you consent to participate, and later change your mind, you may withdraw at any time without negative consequences. You will just need to notify a member of the research team. If you decide to leave the research project, the researchers will not collect additional personal information from you, although personal information which has already been collected and de-identified will be retained to ensure that the results of the research project can be measured properly and to comply with law. You should be aware that data collected up to the time you withdraw will form part of the research project results, although it will be de-identified so your personal information will remain anonymous.

10 What happens when the research project ends?

At the end of your online questionnaire, you will be asked if you would like a summary of key findings once the project is complete. Otherwise, there will be no other attempts to contact you about the research or any follow-up once the project is completed.

Part 2 How is the research project being conducted?

11 What will happen to information about me?

Any information obtained in connection with this research project that can identify you will remain confidential. Your information will be given a code number, so no one will be able to trace information you have provided back to you. Data will be kept in a password-protected file in a secure file directory on the SA Health server. 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. All data collected, including only partially completed questionnaires, will be kept for a minimum of 15 years in this protected format.

It is anticipated that the results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that you cannot be identified, except with your permission. Information about your participation in this research project may be recorded in your health records.

12 Who is organising and funding the research?

This research project is being conducted by Dr Siobhan Fitzpatrick. No member of the research team will receive a personal financial benefit from your involvement in this research project.

13 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 Royal Australian College of General Practitioners (RACGP) National Research and Evaluation Ethics Committee (NREEC).

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.

14 Further information and who to contact

Clinical contact person

Name	Dr Siobhan Fitzpatrick
Position	Research Registrar, Department of Plastic & Reconstructive Surgery
Telephone	08 8204 5213
Email	siobhan.fitzpatrick@sa.gov.au

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

Complaints contact person

Institution	RACGP NREEC
Position	RACGP Research and Ethics Officer
Telephone	03 8699 0385
Email	ethics@racgp.org.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	RACGP NREEC
HREC Executive Officer	NREEC Chairperson
Telephone	03 8699 0385
Email	ethics@racgp.org.au

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

Name	
Position	
Telephone	
Email	