Participant Information Sheet

Non-Interventional Study - Adult providing own consent

Flinders Medical Centre

Title	Experiences of Women with Rectus Diastasis (Abdominal Separation)
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	Flinders Medical Centre and Online

Part 1 What does my participation involve?

1 Introduction

You are invited to take part in this research project, 'Experiences of Women with Rectus Diastasis (Abdominal Separation)'. This is because you have been diagnosed by a health professional with having separation of the abdominal muscles, or Rectus Diastasis. The research project is aiming to understand the experiences of women living with this condition and how it affects their quality of life.

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 simple have to answer the questionnaire via the link below. By completing the questionnaire, 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 and save 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 experiences of women living with Rectus Diastasis (abdominal separation).

Separation of the abdominal muscles often occurs in women after pregnancy and 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 understand the personal perspectives of women living with this condition, any associated symptoms, and its effect on their quality of life.

This will:

- Enable us to appropriately guide further research into this condition.
- Provide an invaluable insight to health-care professionals currently treating this condition.
- Validate the experiences of other women living with this condition.

This project has not received any funding or sponsorship. The results of this research will be used by Dr Siobhan Fitzpatrick to contribute towards obtaining a Doctor of Philosophy degree.

3 What does participation in this research involve?

After completion of the online questionnaire, you may be invited to attend a one-on-one Zoom interview with a female researcher who will ask you a few questions about your experience of Rectus Diastasis, associated symptoms, your quality of life and any engagement with medical care. Participation is entirely voluntary and consent will be confirmed verbally before starting the interview. The interview will take about 60 minutes and can be held at time convenient to you. The interview will be recorded to help with looking at the results. We do not need to keep your name and you will be anonymous. Once the interview has been typed-up and saved as a file, the video file will then be destroyed. Any identifying information will be removed and the typed-up file stored on a password protected computer that only the research team will have access to. Your comments will not be linked directly to you.

If you complete the online questionnaire, it is assumed that you also consent to be contacted about the Zoom interview, but the researchers will confirm on the day that you are happy to proceed before asking any interview questions. If you are not invited to complete an interview, or do not fulfil the inclusion criteria, any questions you answered in the online questionnaire will still contribute to our research. You will also be given information about other related research projects once they have ethical approval.

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 just need to complete the online questionnaire and participate in the online Zoom interview. In answering all questions, just be as open and honest as you can.

5 Other relevant information about the research project

In this project, the research team is hoping to talk to 30 women about their experiences. Some women may have only recently been diagnosed, and some will be very familiar with the condition. Some may have already engaged with physiotherapists and surgeons about treatment options. We think that by talking to women at various treatment stages, we will get a range of different perspectives and experiences.

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, your relationship with those treating you or your relationship with Flinders Medical Centre.

7 What are the possible benefits of taking part?

There will be no clear benefit to you from your participation in this research. However, the sharing of your experiences will assist in our understanding of this condition and its impact on women's health related quality of life. We are very keen to fully understand this condition so we can diagnose and treat women like yourselves, more effectively.

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, it might make you upset to talk about it.

During the interview, if any questions raise stressful or upsetting thoughts for you, you may decline to answer that question, or you may ask for the interview to be stopped altogether.

If you become upset or distressed as a result of your participation in the research project, the research team will be able to arrange for counselling or other appropriate support. This counselling will be provided free of charge and in a timely manner.

9 What if I withdraw from this research project?

Even if you provide your consent about participating, 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 the one-on-one interview you will be asked if you would like a summary of key findings once the project is complete. You will also be asked if you would like to be notified about other related projects pending ethical approval. 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?

By completing the online questionnaire, we are taking this as you consenting to the research staff accessing your questionnaire responses. Any information obtained in connection with this research project that can identify you will remain confidential. Your story or information will be given an alias, 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 hospital's computer 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. The investigators cannot guarantee the security of the Zoom platform however all recorded content will be appropriately destroyed once transcribed. All data collected, including only partially completed questionnaires, will be kept for a minimum of 5 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 will not be recorded in your health records.

If there are any details about your information or story that you think might make you identifiable to others even without your name, you are encouraged to discuss this with the researcher at the beginning of your interview. If you would like to receive a summary of the key findings of the research project, please also discuss this with the researcher at the time of your interview.

12 Complaints and compensation

If you suffer any distress or psychological injury as a result of this research project, you should contact the research team as soon as possible. You will be assisted with arranging appropriate treatment and support.

You can also call Lifeline to talk to someone if you are feeling upset or overwhelmed after the research: 13 11 14. Their helplines are open 24/7.

13 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.

14 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 Flinders Medical Centre.

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

Clinical contact person

Name	Dr Siobhan Fitzpatrick
Position	Research Registrar, Department of Plastic & Reconstructive Surgery
Telephone	08 8204 5213 or 8204 5511 (switchboard)
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	Southern Adelaide Local Health Network
Position	Manager, Research Governance and Ethics
Telephone	8204 6453
Email	Health.SALHNOfficeforResearch@sa.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	Southern Adelaide Clinical
HREC Executive Officer	Executive Officer
Telephone	8204 6453
Email	Health.SALHNOfficeforResearch@sa.gov.au

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

Name	Southern Adelaide Local Health Network
Position	Research Governance Officer
Telephone	8204 6453
Email	Health.SALHNOfficeforResearch@sa.gov.au