WESTERN SYDNEY
UNIVERSITY

Participant Information Sheet

Period screening intervention study – Extended consent

Project Title:

Beyond the score: evaluation of a web-based period impact screening intervention in young people.

Project Summary:

We are inviting young people aged 14-25 who have had their menstrual periods for more than 12 months, to participate in a research study to measure the impact of a period symptom checklist and website. The checklist and website are aimed at helping young people recognise if their periods are 'normal' and how to manage them. Our team is looking to see how this web-based checklist and information is best delivered to meet the needs of young people.

The study is being led by Melissa Parker from Western Sydney University and Canberra Health Services, A/Prof Mike Armour from Western Sydney University, Dr Amelia Mardon from Adelaide University, Dr Beck O'Hara from Flinders University and Dr Abdel-Latif Mohamed from the Australian National University and Canberra Health Services.

How is the study being paid for?

This research is being funded under a doctoral research program through Western Sydney University and Fellowship funding from the ACT Government Health Directorate Research and Innovation Fund.

What will I be asked to do?

If you wish to take part in the study, you can complete the online screening survey to make sure you are able to participate and are happy to be contacted about the study. The researcher will contact you by phone to discuss the study and answer any questions you may have. After giving consent to take part, participants will be invited to complete the first set of questionnaires. Following completion of the first set of questionnaires, participants will be randomly put into one of three groups for the duration of the study.

Doing the study involves answering online questionnaires. Each participant is randomly assigned to a group, with each group having variation in their participation. At the end of the study all participants will be treated the same, having equal access to everything.

Western Sydney University
ABN 53 014 069 881 CRICOS Provider No: 00917K
Locked Bag 1797 Penrith NSW 2751 Australia
westernsydney.edu.au

How much of my time will I need to give?

You will need to complete a set of questionnaires 3 times during the study which we expect will take around 20-30 minutes each time. The whole study will be done over a 6-month period of time. The questions will be answered at the beginning of the study, at 3 months and then at 6 months.

What benefits will I, and/or the broader community, receive for participating?

There may not be any direct benefit to you from participating in this study. You may learn more about your periods and periods in general. At the end of the study all young people will have the benefit of being able to assess the normality of their periods and access information about what to do. A long-term aim of this study is to provide appropriate information, delivered in the best way to suit young people. All participants who complete the study (the final questionnaires at 6 months) will go into a draw and five participants will receive a $100 gift card.

Will the study involve any risk or discomfort for me? If so, what will be done to rectify it?

We do not expect any risks due to the fact we are looking at your experience of using web-based self-screening and health information. Some people may experience discomfort when reading or learning about periods and period problems. If you have any distress you can reach out to Lifeline or a similar free service: https://www.lifeline.org.au/ or Kids Helpline (https://kidshelpline.com.au); Reach Out (https://au.reachout.com/); Head to Health (https://www.headtohealth.gov.au/).

How do you intend to publish or disseminate the results?

Initial study findings will be used to change and improve a period health website for all users and inform future research on period websites. The results of this research will be presented in many ways including scientific publications and conference presentations. In any publication and/or presentation, information will be provided in such a way that you cannot be identified. Improvements to the website will be available to any people with internet access.

What will happen with my information if I agree to it being used in projects other than this one?

The researchers are asking that you agree to supply your information (data) for use in this project and to also agree to allow the data to potentially be used in future research projects.

Western Sydney University
ABN 53 014 069 881 CRICOS Provider No: 00917K
Locked Bag 1797 Penrith NSW 2751 Australia
westernsydney.edu.au

This request is in line with current university and government policy that encourages the re-use of data once it has been collected. Collecting information for research can be an inconvenience or burden for participants and has significant costs associated with it. Sharing your data with other researchers gives potential for others to reflect on the data and its findings, to re-use it with new insight, and increase understanding in this research area.

You have been asked to agree to Extended consent.

Extended consent

When you agree to extended consent it means that you agree that your data, as part of a larger dataset (the information collected for this project) can be re-used in projects that are

- an extension of this project
- closely related to this project
- in the same general area of this research.

The researchers will allow this data to be used by researchers in other related projects for an extended period of time. To enable this re-use, your data will be held at the University in its data repository and managed under a Data Management Plan. The stored data available for re-use will not have information in it that makes you identifiable. The re-use of the data will only be allowed after an ethics committee has agreed that the new use of the data meets the requirements of ethics review.

Please note that minimum retention period for data collection is five years post publication. The data and information you provide will be retained indefinitely.

You are welcome to discuss these issues further with the researchers before deciding if you agree. You can also find more information about the re-use of data in research in the National Statement on Ethical Conduct in Human Research – see Sections 2.2.14 - 2.2.18.

https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018

Can I withdraw from the study?

Participation is entirely voluntary, and you are not obliged to be involved. If you do participate you can withdraw at any time. Your filled out questionnaires can be deleted from the study before analysis of questionnaire data. Once all the questionnaire

Western Sydney University
ABN 53 014 069 881 CRICOS Provider No: 00917K
Locked Bag 1797 Penrith NSW 2751 Australia
westernsydney.edu.au

responses have been combined together and analysed it will not be possible to remove individual responses. Although your contribution still remains anonymous.

Can I tell other people about the study?

Yes, you can tell other people about the study by sending the invitation link to other people or providing them with the details of the Lead Investigator, Melissa Parker, PhD Candidate.

What if I require further information?

Please contact Melissa Parker should you wish to discuss the research further before deciding whether to participate.

Melissa Parker email: 22121078@student.westernsydney.edu.au

Privacy Notice

Western Sydney University staff and students conduct research that may require the collection of personal and/or health information from research participants.

The University's Privacy Policy and Privacy Management Plan set out how the University collects, holds, uses and discloses personal or health information. Further details about the use and disclosure of this information can be found on the Privacy at Western Sydney webpage.

What if I have a complaint?

If you have any complaints or reservations about the ethical conduct of this research, you may email the Ethics Committee through Research Engagement, Development and Innovation (REDI) on Tel +61 2 4736 0229 or email: humanethics@westernsydney.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 Participant Consent Form. The information sheet is for you to keep, and the consent form is retained by the researcher/s.

This study has been approved by the Western Sydney University Human Research Ethics Committee. The Approval number is H16644.

Western Sydney University
ABN 53 014 069 881 CRICOS Provider No: 00917K
Locked Bag 1797 Penrith NSW 2751 Australia
westernsydney.edu.au