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Multi-Modal behavioural program for management of Premenstrual Syndrome and functional health and well-being in university students

(Griffith University ethics ref no: 2018/705)

INFORMATION SHEET

Research Team

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Why is the research being conducted?

Research has revealed that certain lifestyle factors and health behaviours can have a positive impact upon quality of life, chronic disease risk factors and other health related areas for women with Premenstrual Syndrome. The purpose of this project is to investigate the effectiveness of a 12-week structured lifestyle program (Younger Women's Wellness Program) in improving health and wellness in women who have premenstrual syndrome. The Program focuses on physical activity, healthy eating, better sleep and lifestyle habits and improving quality of life. The program has been developed especially for young women with Premenstrual Syndrome and is based on latest research evidence.

You are invited to participate in this research because you are a female between the age group 18-35 years, studying at the University, have premenstrual symptoms and are able to speak and read English. You also need to be computer literate and have access to a smartphone and a reliable internet connection to partake in the online assessments and to access online information.

This is a wellness program and is not intended to replace any existing medical care or treatment for premenstrual symptoms that you may be receiving from your local GP or specialist.

What you will be asked to do

If you agree to participate in the study, you will be asked to complete an online questionnaire on enrolment in the study, and then at 12 weeks. You will be required to fill the consent form and the eligibility checklist first and if you are eligible, you will fill a questionnaire that asks about current lifestyle and a range of health information and symptoms and takes around 15-20 minutes to complete. You do not have to complete any questions you are uncomfortable answering.

You will then be randomly allocated to one of the 3 groups,

Group 1: Younger Women's Wellness Program + Smartphone Application – Participants will receive health education material, including a Program Journal Book PDF copy or a hardcopy book – the participant would be given a choice for their preferred mode of delivery. The journal/book will encourage you to bring together the various components of the health education provided and incorporate it into your life over a 12-week period. The journal includes a weekly planner, where you are encouraged to plan your exercise for the following week. The participants will receive access to self-directed resources and access to a period and PMS tracker smartphone application. The participants can enter their menstrual cycle dates and symptoms on the application.

All the participants will receive a phone call on week 6 by the researcher to make sure they don't have any difficulties accessing the program and if they are able to follow the instructions of the program. Once the study has concluded, they will be asked to participate in a brief interview to comment on the program, the most useful components, its strengths and weaknesses, and the aspects they liked or did not like.

Group 2: Smartphone Application- The participants will receive access to a period and PMS tracker smartphone application. The participants can enter their menstrual cycle dates and symptoms on the application.

All the participants will receive a phone call on week 6 by the researcher to make sure they don't have any difficulties accessing the program and if they are able to follow the instructions of the program. Once the study has concluded, the participants will be asked to participate in a brief interview to comment on the program, the most useful components, its strengths and weaknesses, and the aspects they liked or did not like.

Group 3: Younger Women's Wellness Program- Participants in Group 3 will receive the PDF copy of the book or the hardcopy hard copy book/Journal along with fact sheets and resources.

All the participants will receive a phone call on week 6 by the researcher to make sure they don't have any difficulties accessing the program and if they are able to follow the instructions of the program. Once the study is concluded, the participants will be asked to participate in a brief interview to comment on the program, the most useful components, its strengths and weaknesses, and the aspects they liked or did not like.

The participants who complete the 12-week study will go in a draw to win one of the four $50 Westfield gift cards. If the intervention is effective, the participants in Group 2 and 3 will be offered access to all the materials provided to group 1 participants after the study has finished.

The basis by which participants will be selected

If you are a female aged between 18-35 years, studying at the University and have some premenstrual symptoms, you are eligible to participate in the study. If you have any physical illness or injury that prevents you from exercising, or if you suffer from some mental health problem that will prevent you from completing the 12-week program, you will be excluded from the study.

The expected benefits of the research

It is anticipated that this project may directly benefit you by encouraging sustained and positive health behaviours such increased exercise and healthy eating.

Risks to you

There are minimum risks associated with your participation in this project. These include risk of injury related to physical activity such as muscle soreness or soft tissue strains. To minimise this risk, any recommended exercise will be built up gradually over time with regular stretching encouraged. Research staff will also be available for advise or support by telephone or email.

Your confidentiality

All comments and responses on questionnaires will be treated confidentially. Any data collected as part of this project will be stored securely. Research data will be retained in a password protected electronic file at Griffith University for a period of five years before being destroyed. Please note that non-identifiable data collected in this project may be used as comparative data in future projects. The research results will be reported in an academic thesis and may also be disseminated via journal articles and conference presentations.

Your participation is voluntary

Your participation in this project is entirely voluntary. If you do agree to participate you can withdraw from participation at any time during the project without comment or penalty. Your decision to participate will not impact upon your current or future relationship with Griffith University.

Questions / further information

If you have any questions or require further information or need to access a plain language summary of research results you can contact one of the research team members below,

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The ethical conduct of this research

Griffith University conducts research in accordance with the *National Statement on Ethical Conduct in Human Research* and is committed to research integrity and the ethical conduct of research projects. However, if you do have any concerns or complaints about the ethical conduct of the research project you may contact the Manager, Research Ethics on 3735 4375 or research-ethics@griffith.edu.au.

Privacy Statement- non-disclosure

The conduct of this research involves the collection, access and/or use of your identified personal information. The information collected is confidential and will not be disclosed to third parties without your consent, except to meet government, legal or other regulatory authority requirements. A de-identified copy of this data may be used for other research purposes. However, your anonymity will at all times be safeguarded. For further information consult the University's Privacy Plan at http://www.griffith.edu.au/about-griffith/plans-publications/griffith-university-privacy-plan or telephone (07) 3735 4375.

I agree to proceed to the eligibility checklist

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