



Menstrual Cycle Tracking Study

Principal Investigator: Associate Professor Bryndl Hohmann-Marriott

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PARTICIPANT INFORMATION SHEET

Introduction

We are a research team who believes that menstrual cycles are a key part of health, wellbeing and hauora. We appreciate your interest in this project. This information sheet will tell you more about the project, and we are happy to answer any questions you have.

Please read this information sheet carefully. Take time to consider and, if you wish, talk with relatives or friends, before deciding whether or not to participate. If you decide to participate we thank you. If you decide not to take part there will be no disadvantage to you and we thank you for considering our request.

What is the aim of this research project?

Health, wellbeing, and hauora are supported through knowledge and experience of one's own menstrual cycles. A current approach to understanding menstrual cycles is by self-tracking using technologies including hormone self-testing and period tracking apps.

Our overall goal is to understand how self-testing and self-tracking apps play a role in individuals' knowledge and perceptions of their own menstrual cycles and ovulation. This research project is a first step, where we will try to find the most effective way to collect data from participants using both a menstrual tracking app and a hormone self-test.

Who is funding this project?

This study is funded by a MedTech grant “Menstrual Apps for Diagnosis and Health Literacy.”

<https://www.cmdt.org.nz/research-acceleration-programme>

Who are we seeking to participate in the project?

We are looking for participants who are:

- Age 18 - 40
- With menstrual cycles
- Not using hormonal contraception (such as the Pill, Jadelle, Depo, Mirena)
- Currently tracking cycles using Flo and/or Clue app on a mobile phone
- Residing in Aotearoa New Zealand

If you participate, what will you be asked to do?

If you participate, you will need to:

Take part in two interviews with the researchers (in-person or Zoom); we will schedule interviews at the beginning and end of the study. The interviews will take about 20-40 minutes.

Have the Flo and/or Clue apps installed on your mobile phone, and install the Mira app on your mobile phone.

For one cycle, track **each day of a complete menstrual cycle**. We anticipate that this may take half an hour per day at the beginning of the cycle, but may take less time with practice.

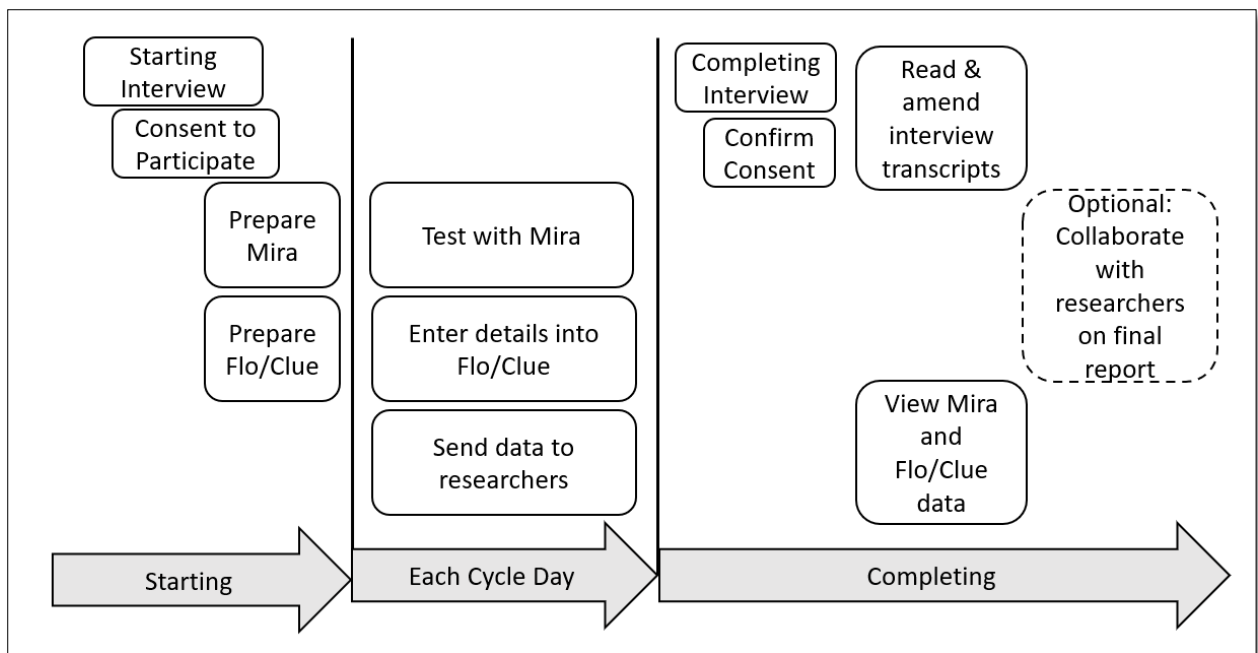
Tracking includes:

- Receiving a reminder by text or email for each day of one cycle,
- Entering details into Flo/Clue for each day of one cycle,
- Testing your hormones for each day of one cycle using the Mira self-testing system, and
- Sending data to the researchers (by e-mail and a brief online survey)

All participants will be provided with a Mira self-testing kit. The Mira self-testing kit requires you to test the hormone levels in your urine at home. (More information here:

https://help.miracare.com/en_us/categories/how-do-i-use-mira-S1AH56fHs). At the end of the study, you will have the option of keeping the Mira device or returning it to the researchers.

All participants will be sent a summary of the study results.



Is there any risk of discomfort or harm from participation?

Tracking your cycle every day means that you will have a daily reminder of your menstrual cycle. If this would be stressful to you, we recommend not taking part in this study or ensuring that you have good support available. If you find that daily tracking raises concerns about your menstrual cycle, we advise that you contact your healthcare provider and remind you that you may stop participating in the study.

What information will be collected, and how will it be used?

We will ask you for your mobile phone number and your email address.

Interviews will be recorded and transcribed. Transcription will be by the researchers and/or research assistants. Research assistants will sign a confidentiality pledge.

We will be collecting data from the apps about your period (bleeding), hormone levels, and estimated ovulation date.

You will provide the app data in one or more ways:

- Sending a screenshot to the research e-mail

- Taking a brief online survey

- Giving the researchers permission to view data on your Mira dashboard

You will decide which way you would prefer to provide the data, and can change your preferences at any time by e-mailing the researchers (or the Mira team for the Mira dashboard).

During the study, if you miss two days we will follow up by text or e-mail, and if you have not responded within two days we will call you to check if you are ok.

Data from the apps will be analysed by the researchers and/or research assistant. Research assistants will receive a dataset with all identifying information removed.

Interviews will be transcribed by a researcher, a professional transcription service, or automated transcription program. If an automated transcription program is used, your data uploaded to a third party based overseas and thus out of control of the research team. If you do not want an automated service to be used, please let the researchers know.

After the second interview, we will send you transcripts of the interviews and an overview of your data for the complete cycle. You will have the opportunity to amend the transcripts.

We will store all your data in a secure folder.

What about anonymity and confidentiality?

We plan to use this study to develop a larger study, and we also plan to publish a report about this study. You will have the choice of whether you prefer to be named or anonymous. In either case, we would welcome your input on the published report.

If you prefer to remain anonymous, all identifying information will be removed or changed from your transcripts and a pseudonym will be used in all published reports. You will have the opportunity to select a pseudonym and to amend the transcripts.

If you agree to participate, can you withdraw later?

You may withdraw from the study at any time before December 2024, when we will produce the final report. You may withdraw for any reason, and with no disadvantage to yourself.

Any questions?

If you have any questions now or in the future, please feel free to contact either:

Bryndl Hohmann-Marriott Associate Professor School of Social Sciences	Bryndl.hohmann-marriott@otago.ac.nz
Michael Pankhurst Senior Lecturer Department of Anatomy	Michael.pankhurst@otago.ac.nz

This study has been approved on 1 July 2024 by the University of Otago Human Ethics Committee (Health), H23/016. If you have any concerns about the ethical conduct of the research you may contact the Committee through the Human Ethics Committee Administrator (phone +64 3 479 8256

or email gary.witte@otago.ac.nz). Any issues you raise will be treated in confidence and investigated and you will be informed of the outcome.



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CONSENT FORM FOR PARTICIPANTS

Following signature and return to the research team this form will be stored in a secure place for ten years.

Name of participant: _____

1. I have read the Information Sheet concerning this study and understand the aims of this research project.
2. I have had time to talk with other people of my choice about participating in the study.
3. I confirm that I meet the criteria for participation which are explained in the Information Sheet.
4. All my questions about the project have been answered to my satisfaction, and I understand that I am free to request further information at any stage.
5. I know that my participation in the project is entirely voluntary, and that I am free to withdraw from the project before its completion in December 2024.
6. I know that as a participant I will take part in two interviews with the researchers, will monitor daily a complete menstrual cycle using a menstrual app as well as a hormone self-test kit, and will send data daily to the researchers.
7. I know that the interviews will explore my experiences with my menstrual cycle and with the daily data collection and that if the line of questioning develops in such a way that I feel hesitant or uncomfortable I may decline to answer any particular question(s) , and /or may withdraw from the project without disadvantage of any kind.
8. I understand the nature and size of the risks of discomfort or harm which are explained in the Information Sheet.
9. I know that when the project is completed all paper records and electronic files which represent the data from the project will be placed in secure storage and kept for at least ten years.

10. I understand that my interview data may be transcribed by an automated service, but that I can ask the researchers not to use any automated transcription programs.

11. I know that I will be sent my transcript and an overview of my data for the complete cycle, as well as a summary of the study results.

12. I understand that the results of the project may be published and be available in the University of Otago Library, but that either:

I agree that any personal identifying information will remain confidential between myself and the researchers during the study, and will not appear in any spoken or written report of the study; or

I agree to be named or identified in the study and will sign a waiver form.

13. I know that there is no payment offered for this study, and that no commercial use will be made of the data.

Signature of participant:

Date:

Name of person taking consent:

Date:



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WAIVER OF CONFIDENTIALITY FORM FOR PARTICIPANTS

Following signature and return to the research team this form will be stored in a secure place for ten years.

Name of participant: _____

1. I have consented to participate in this study and have signed a consent form.
2. I agree to be named or identified in the study.
3. I understand that I will be able to view my transcripts and amend details that will appear in published work.
4. I understand that I can withdraw my waiver of confidentiality at any time up to December 2024.

Signature of participant:

Date:

Name of person taking consent:

Date: