

## **Menstrual cycle status and risk of Iron deficiency**

### **Information Sheet**

We would like to invite you to participate in this research project. This project assesses menstrual cycle health and iron deficiency in females.

Please read the information sheet before deciding if you would like to participate.

For more information, please contact the lead researcher

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### **Why are we doing this research?**

Iron deficiency is common in females younger than 40 years. In New Zealand, Māori, Asian and Pasifika females are at even greater risk for iron deficiency. Females with iron deficiency may feel fatigued, irritated, depressed, and have poor attention and concentration. They are also more likely to get sick, experience negative health issues while pregnant, and feel like they are not performing well at work. Every month females experience menstrual bleeding. Heavy, or large volumes of menstrual bleeding each month increase your risk of iron deficiency. This is because you may be losing large volumes of iron. The goal of this project is to determine how many females experience heavy menstrual bleeding, and what may be causing this. Understanding differences in menstrual bleeding will help us understand your risk of becoming iron deficient.

### **Who are we looking for?**

- Healthy females aged 18-40 years and pre-menopause
- Have access to a smartphone
- Not currently pregnant or breastfeeding or have been in the last 12 months
- Not taking iron tablets or have been for the last 3 months
- Maximum of 10 hours of exercise per week
- Not currently using hormonal contraceptives (Marina IUD, hormonal implant, hormonal injection, Oral contraceptive i.e., pill) or have in the last 6 months
- Non-smoker
- Not previously diagnosed with an illness that affects iron status
- Not previously diagnosed with a gynaecological disorder that may affect reproductive hormones (e.g., PCOS, Polycystic Ovarian Syndrome).

### **What is going to happen?**

Once you have read the information sheet and if you are happy to participate, the research team will ask you to complete an online screening questionnaire before you complete a consent form. The research team will then schedule your first appointment at Massey University, Auckland Campus.

In the first session, we will ask you to complete an online survey. This survey will collect general health information. We will ask about your age, ethnicity, diet, medical history, physical activity levels, and reproductive health. We will also ask that you complete a food frequency questionnaire to provide us with an understanding of your dietary intake. The researchers will then complete a body composition assessment, and we will measure your height, weight, muscle, and fat mass. This assessment will be done using a Bioelectrical Impedance Analyser (BIA). After this assessment, we will ask that you are seated for 5 minutes before collecting a blood sample (~5 mls) to check your iron status. To finish, the research team member will set up the WILD AI app on your smartphone. They will show you how the app works and what information you will need to enter into the app. The research team member will give you your urinary ovulation tests, which will be completed at home each month and will check for ovulation. The researcher will explain to you how to complete these tests and how you will upload the results to your WILD AI app.

On the first day of menstrual bleeding after the first testing session, we ask that you start entering information into the WILD AI app. During menstrual bleeding, you will note down what days you have visible menstrual bleeding. We will also get you to estimate (e.g., heavy, moderate, light) the volume of menstrual blood loss each day. On the days you have menstrual bleeding or any time during the month when you have a menstrual symptom (e.g., fatigue, breast tenderness, headaches, nausea, bloating, food cravings), we ask that you note down what the symptom was and how much it impacted you. A member of the research team will contact you (e.g., via text or email) and remind you when you should do your urinary ovulation test. You will complete these tests at home on days 11-14 of your menstrual cycle (i.e., 5-7 days after bleeding stops) and will upload the results to your WILD AI app. We will repeat this process for 2 months or 2 menstrual cycles. During this time (i.e., the first 2 months of data collection) no visits to Massey University are needed.

At the start of the 3<sup>rd</sup> month, or at the start of the 3<sup>rd</sup> menstrual cycle bleed, you will enter the data collection phase of the study. This part of the study will last for 3 menstrual cycles (e.g., ~3 months). In each of the months, we will collect data in a unique phase of your menstrual cycle (e.g., times each month when there are different hormone concentrations in the body) and you will only have one data collection session per month. The three phases and days include the beginning of your menstrual cycle while you are bleeding (days 3-5), the middle of your cycle (~days 11-13), and towards the end of your cycle (days ~20-24). The research team will remind you via text, phone call, or email when the data collection date will occur for you.

During the data collection months, we will organise a time for you to come to Massey University, Auckland. During this visit, we will collect a blood sample (~ 10mls) to check your iron status, inflammation, and reproductive hormone levels. We will then ask you to complete an online survey with questions about your diet, mood, and stress levels. In the months where you collect your food and exercise record at the beginning and middle of your cycle, we will ask that you also attend a single session at the lab around ~days 20-24 cycle (i.e., 15-19 days after menstrual bleeding has stopped). During these visits, we will collect a resting blood sample to check your reproductive hormone levels. All onsite (at Massey University) testing days will be organized at a time and on a day during that

specified data collection period that best suits you. During the 3 months we will ask that you maintain the online menstrual tracking via the WILD AI app as you have in the previous two months.

The final session of the study will be 6 months after the first session and will be completed at Massey University. During this session, we will repeat the body composition assessment and take a final blood sample to check your iron levels. We will then unlink your WILD AI app from the research project.

Total face-to-face time for data collection at Massey University over the 6 months includes:

- First visit: 45-60 minutes
- 3 x in-person sessions: 15-30 minutes each
- 2 x in-person end-of-cycle blood tests: 5-10 minutes each
- Final session: 15-30 minutes

**Total: 200 minutes (3-3.5 hours) over 6 months**

Total online time for data collection over 6 months:

- ~4x urinary ovulation tests per month for 6 months and data upload: 5-10 minutes/per day when completing this test
- Data onto the app when bleeding, or presenting with a menstrual symptom: 3-5 minutes/day

**Total: ~10-15 hours in 6 months**

### **Data Management**

The data collected for this project is confidential and will be anonymous, so no individual or personal data will be identified. In the first session, you will be given a study identification number. All your data will then be stored under this identification number, this is to maintain the confidentiality of the data and secure storage. Data from WILD AI will be stored with the researchers. All data will be transferred under the unique study identification codes for participant privacy protection. The results of this project will be presented as group averages. No individual will be identified from the presented results. The overall summary of the results may be published or presented at conferences or seminars/workshops to academic and general population audiences.

Any raw data from this project will be retained in secure storage for 10 years, after which it will be destroyed. Raw anonymous data may be shared with external researchers for collaborations in research that focus on female health and wellbeing.

A summary of the project findings will be available to all participants. All participants will be sent this information via email.

### **Participants Rights:**

You are under no obligation to accept this invitation. Should you choose to participate, you have the right to:

- Withdraw from the study at any time, even after signing a consent form (if you choose to withdraw you cannot withdraw your data from the analysis after the data collection has been completed)
- Ask any questions about the study at any time during participation

- Provide information on the understanding that your name will not be used unless you permit the researcher to do so
- Be given access to a summary of the project findings after project completion
- Be given access to any personal data (body composition, and blood tests results) after the project completion

### **Māori Participant Rights:**

Bodily fluid is recognized by the research team as taonga. In our research project, bodily fluid is a 'gift/prized' possession. Any sample that is provided to us will remain the property or taonga of the participant. Before giving consent, we will provide you with details on how we will collect blood samples. We will also tell you how we will store the samples, and how we will be disposed of them. You will have the right to an act of Tikanga before any sample collection. This can be in any form that allows you to acknowledge the tapu nature of bodily fluids you have provided us e.g., karakia (blessing), whakatau (introduction), and tautoko (support). When giving consent you can select to have a Karakia with the disposal of remaining blood cells. This will be performed by Apirana Pewhairangi, the Senior Advisor - Tikanga Maori and Maori Engagement at Massey University, Albany Campus.

### **What are the benefits and risks of taking part in this study?**

There will be no cost for any of the procedures or assessments that are taken as part of this study. You will have access to your information including body composition and blood records. You may request this information after the study is completed. You will receive a report that summarises the main findings of the project.

To acknowledge the travel cost you will have when commuting to Massey for the face-to-face sessions, you will receive a \$20 petrol voucher for each visit to Massey. This is a total of \$140

We do recognise that there are some potential psychological risks associated with participation.

- These include discomfort with body composition measurements, recording of food intake, and menstrual cycle data (bleeding, symptoms, and ovulation tests). To reduce any discomfort, we will:
  - Complete the body composition assessment in a private room with a single researcher present. You will only need to remove your shoes and socks for this assessment.
  - Collect food records without any changes to your food intake. Your food record will be stored under your study identification number for your privacy. Food records will not be judged as good or bad by the research team.
  - You will report your menstrual cycle data on your personal device and at a time/place that suits you (e.g., at home). This gives you the privacy to complete this data entry in a space that you feel comfortable in.
- We understand that some people may have a fear of having a blood sample taken, or experience discomfort when blood samples are taken. Occasionally slight bruising can occur. The bruising usually disappears within a day or two. For this study:
  - All resting blood samples will be collected by trained phlebotomists. The risk of injury will be very low.
  - You may also be accompanied by a support person.
  - All blood samples will be collected in a private room.

- There are no personal risks to your health. The blood tests could potentially identify the need for follow-up with your doctor/GP.

### **Support process**

If we find that your blood results are outside normal ranges, we will advise you to talk to your doctor/GP. If you then require additional blood tests you may be liable for any of these costs. You will be able to book into the nutrition clinic after completing the study to get dietary advice from a registered dietitian. However, usual clinic fees will apply. After the study you will be able to use the WILD AI app. However, it will no longer be in the research project settings and no additional data will be collected by the researchers.

### **Project Contacts:**

If you have any questions regarding this study, please do not hesitate to contact either of the following people for assistance:

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### **Ethics Committee Approval Statement**

*This project has been reviewed and approved by the Massey University Human Ethics Committee: Southern A, Application 22/56. If you have any concerns about the conduct of this research, please contact Dr Negar Partow, Chair, Massey University Human Ethics Committee: Southern A, telephone 04 801 5799 x 63363, email [humanethicsoutha@massey.ac.nz](mailto:humanethicsoutha@massey.ac.nz).*