

CycleTrack: Understanding Menstrual Health

Participant Information Sheet V1.2

Thank you for your interest in this study

This second part of CycleTrack aims to collect detailed data on menstruation (periods) and health and wellbeing throughout the menstrual cycle.

Before you decide whether to take part, it is important that you understand why the research is being done and what taking part will involve. Please take time to read the following information carefully.

What is this study about?

Women's health, particularly menstrual health, has historically been under-researched. We want to change this by collecting high-quality information about the full range of menstrual experiences – from those who have no difficult symptoms to those who experience challenges like pain and heavy bleeding.

We want to understand:

- What factors influence symptoms across the menstrual cycle
- Why some people experience more difficult periods than others
- How healthcare professionals might better support women and people who menstruate

To do this, we will collect information on things including:

- Menstrual symptoms
- Mood and mental health
- Diet, exercise, alcohol use and smoking
- Sleep quality

This information will be collected using daily questionnaires, a fitness tracker worn on the wrist, and menstrual fluid samples collected during periods. From these menstrual samples, we will generate biological data (such as information about genes and proteins) to help us better understand the biological processes in menstrual health.

Who can take part?

BiB participants who have completed the BiB CycleTrack questionnaire and:

- are currently menstruating (have had a period in the past two months, and are expecting to have a period in the next three months),
- are not pregnant or breastfeeding
- have not gone through menopause
- currently live in the UK
- have use of a smartphone or tablet

You can take part whether you have a natural cycle or are using hormonal contraception.

What will happen when taking part?

If you are eligible and decide to take part, you will complete a consent form and then receive a pack either by post or in person.

Containing:

- Instructions for taking part
- A Garmin smartwatch and charger
- A finger-prick ferritin (iron) test kit
- 30 ovulation test strips and a urine cup
- Three menstrual fluid collection and return kits
- A pair of reusable period pants
- Prepaid packaging for returning the smartwatch (or you may keep the device if you wish)
- Menstrual information and resources booklet

The study will last for up to 16 weeks, or until you have experienced three menstrual periods, whichever is sooner.

What will I be asked to do?

If you take part, you will be asked to:

1. Download smartphone apps

You will install two apps on your smartphone, which will be used to deliver daily questionnaires, collect data from the smartwatch, and record menstrual sample information. You will receive full instructions on how to use these apps.

2. Complete daily questionnaires

Each day, you will be asked to answer a few short questions, taking around 2-5 minutes. You will receive reminders on your phone.

3. Complete a ferritin test

At the start of the study, you will take a finger-prick test to measure iron levels and record the result in the app.

4. Wear the smartwatch

You will be asked to wear the smartwatch during the day and overnight throughout the study. It will collect information about your heart rate, physical activity and sleep.

5. Use ovulation tests

Around the middle of your cycle, you will use ovulation test strips as instructed and record the results in the app. This helps us understand which stage of the menstrual cycle you are in.

6. Collect menstrual fluid samples

On the first flow day of each period, you will wear a special menstrual pad called a Q-pad for a few hours until the collection strip is full. You will be asked to repeat this with a second pad. The filter strips will be posted back to the laboratory using prepaid packaging. We will include a pair of reusable period pants, which you may choose to wear alongside the pads for extra protection.

If you need help in setting everything up, our experienced Community Research Assistants can help you with that either over the phone or in person.

What are the possible benefits and risks of taking part?

Benefits

There may be no direct health benefits to you from taking part in this study. However, your participation will help improve understanding of menstrual health and may benefit women and people who menstruate in the future.

As a thank you for your time, you will receive:

- Up to £120 in shopping vouchers (£30 in month/cycle one, £40 in month/cycle two, and £50 in month/cycle three)
- A Garmin smartwatch which you may keep
- A personalised summary of your study data, showing changes across your menstrual cycle

Risks and inconveniences

We do not expect any serious risks from taking part in this study.

Some parts of the study may cause mild discomfort or inconvenience. For example:

- The finger-prick for ferritin may cause brief discomfort
- Completing daily questionnaires and collecting menstrual samples may take time

If at any point you feel uncomfortable or wish to stop taking part, you are free to do so.

Do I have to take part?

No, taking part is completely voluntary. If you decide to take part, but change your mind later, you can stop being part of the study at any time, without giving a reason. We will only use research data that we have collected about you up to that point. If your data have already been used in analyses or included in reports or scientific publications, it may not be possible to remove them. We will explain your options to you if you decide to withdraw. Whatever you decide, your rights will not be affected in any way.

If you have questions that would help you decide, please contact the study team.

Who is organising and funding this research?

BiB (Born in Bradford) at Bradford Teaching Hospitals and University of Bristol are the two sites where data and samples are collected. University of Exeter is the sponsor for this study with Prof Gemma Sharp overseeing the research.

The study has been funded by Wellcome Leap. It has been reviewed by an independent Research Ethics Committee to make sure it is conducted safely and respectfully. This study has been reviewed and given favourable opinion by Yorkshire & The Humber – Bradford Leeds Research Ethics Committee (IRAS ID 363885; REC reference 26/YH/0078).

How will we use information about you?

We will need to use information from you for this research project. This information will include your name and contact details. People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

The University of Exeter is the sponsor of this research.

The University of Exeter is responsible for looking after your information. We will share your information related to this research project with the following types of organisations:

- Researcher organisations (such as Universities, Commercial or Pharmaceutical companies) who analyse the data for scientific and research purposes
- Data centres who will store or back-up your data

We will keep all information about you safe and secure by:

- Holding data on secure servers
- Following strict rules on how to use and protect research data
- Only sharing data that is needed and making sure you cannot be identified from the data that is shared.

International transfers

We may share or provide access to data about you outside the UK for research related purposes to:

- support academic and non-academic (commercial/pharmaceutical) researchers who apply to access your data to answer a research question
- support international initiatives or archives

If this happens, we will only share the data that is needed. We will also make sure you can't be identified from the data that is shared where possible. This may not be possible under certain circumstances – for instance, if you have a rare illness, it may still be possible to identify you. If your data is shared outside the UK, it will be with the following sorts of organisations:

- Researcher organisations (such as Universities, Commercial or Pharmaceutical companies) who analyse the data for scientific and research purposes
- Data centres who will store or back-up your data

We will make sure your data is protected. Anyone who accesses your data outside the UK must do what we tell them so that your data has a similar level of protection as it does under UK law. We will make sure your data is safe outside the UK by doing the following:

- some of the countries your data will be shared with have an adequacy decision in place. This means that we know their laws offer a similar level of protection to data protection laws in the UK
- we use specific contracts approved for use in the UK which give personal data the same level of protection it has in the UK. For further details visit the Information Commissioner's Office (ICO) website: <https://ico.org.uk/for-organisations/uk-gdpr-guidance-and-resources/international-transfers/>
- we do not allow those who access your data outside the UK to use it for anything other than what our written contract with them says
- we need other organisations to have appropriate security measures to protect your data which are consistent with the data security and confidentiality obligations we have. This includes having appropriate measures to protect your data against accidental loss and unauthorised access, use, changes or sharing
- we have procedures in place to deal with any suspected personal data breach. We will tell you and applicable regulators when there has been a breach of your personal data when this is legally required. For further details about UK breach reporting rules visit the Information Commissioner's Office (ICO) website: <https://ico.org.uk/for-organisations/report-a-breach>

How will we use information about you after the study ends?

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study. We will keep your study data for a maximum of 30 years. The study data will then be fully anonymised and securely archived or destroyed.

What are your choices about how your information is used?

- you can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have

- you have the right to ask us to access, remove, change or delete data we hold about you for the purposes of the study. You can also object to our processing of your data. We might not always be able to do this if it means we cannot use your data to do the research. If so, we will tell you why we cannot do this
- If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study

Where can you find out more about how your information is used?

You can find out more about how we use your information, including the specific mechanism used by us when transferring your personal data out of the UK:

- our leaflet <http://www.hra.nhs.uk/patientdataandresearch>
- by asking one of the research team
- In our Privacy Policy on our website: <https://borninbradford.nhs.uk/privacy-policy/>
- By contacting the BiB study team via email: borninbradford@bthft.nhs.uk or tel. 01274 274474
- You can read how the University of Exeter uses and protects research data here: <https://www.exeter.ac.uk/about/oursite/privacy/research/#a6>

Some information for this study will be collected using secure third-party services (apps), such as online questionnaires or mobile or wearable device platforms. Specifically, the study will collect data using two apps, one called Labfront and one called Qvin. You can view Labfront's data policy here: <https://help.labfront.com/labfront-privacy-policy>, and Qvin's here: <https://q-vin.com/privacy-policy>. The wearable device is made by Garmin, but Garmin will not collect any data themselves. These services are used to help collect data efficiently and securely. When you set up these apps, you may be asked to agree to their terms and privacy policy. These companies will only collect the information needed for this study and are required to keep it secure and confidential. Data collected through these services is non identifiable data and will be securely transferred to the University of Exeter and stored on secure University systems. The research team will not store study data on personal devices or unencrypted media.

What happens to my biological samples?

With your permission we store biological samples (menstrual blood) you provide to help answer the research questions in this study and to support future health-related research like how hormone levels change over time.

Your samples will be anonymised with a unique study ID number. Your name and other personal details will not be attached to the samples.

Samples collected for this study will be analysed, and any remainder will be stored securely in laboratories at the University of Exeter for up to 10 years, in line with the Human Tissue Act and relevant biobanking regulations.

We may also use samples for genetic research, which helps us understand how genes affect health and disease. We do not plan to carry out studies that would produce results that are important for your individual clinical care or that of your family.

Any future use of samples must be approved through Born in Bradford governance processes. If samples are no longer required, they will be securely destroyed.

Who do I contact if I have any questions?

If you have any questions about the study or any problems during this study, please contact our BiB CycleTrack team. They will be happy to answer any questions you may have:

 Call us: 01274 274444 (Monday to Friday 8am to 4pm)  Email us at borninbradford@bthft.nhs.uk

Or write: Born in Bradford, Bradford Royal Infirmary, Duckworth Lane, Bradford, BD9 6RJ

To speak to someone independent of the research team about issues concerning this research, please email the Trust Data Protection Officer (DPO) on dataprotectionofficer@bthft.nhs.uk at Bradford Teaching Hospitals NHS Foundation Trust, or the University of Exeter's Research Ethics and Governance Team: cgr-reg@exeter.ac.uk

Thank you very much for your continued support