

BiB CycleTrack Questionnaire

Participant Information Sheet V1.2

We are very excited to invite you to take part in this new study collecting data on menstruation (periods) and health and wellbeing throughout the menstrual cycle. Before you decide whether to complete the questionnaire, it is important that you understand why the research is being conducted and what it will involve. Please read the following carefully.

Why are we doing CycleTrack?

CycleTrack is focusing on women's health, especially in relation to menstruation. There has been very little research on women's health and menstruation, and we want to change this by collecting high-quality information about the full range of menstrual experiences – from those who have no difficulties with their periods to those who experience things 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, and
- how doctors 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 and smoking, and
- sleep quality.

We will be collecting this information by asking you to complete a questionnaire.

Who can take part?

Any BiB participant, 18 years or over who has periods or who previously had periods is eligible to take part by completing the CycleTrack questionnaire.

If you have not received your personal link, please contact us or get in touch via email borninbradford@bthft.nhs.uk or phone **01274 274474**.

Why should you complete this questionnaire?

Menstrual Health has been overlooked for a long time but now Born in Bradford is part of a new wave of research into this area. By sharing your experiences, you'll be helping researchers to improve future health care and support and treatment in this area.

Do I have to complete the questionnaire?

Taking part is entirely voluntary. You may withdraw at any time. If you need help to complete this questionnaire, please contact us via email

borninbradford@bthft.nhs.uk or phone **01274 274474**. Our Community Research Assistants are very experienced and can help you either face to face or over the phone.

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 phone **01274 274474**,
- you can read how the University of Exeter uses and protects research data: <https://www.exeter.ac.uk/about/oursite/privacy/research/#a6>.

What are the benefits of completing the questionnaire?

By taking part, you are contributing to research that may improve understanding of menstrual health. You'll also receive a £10 shopping voucher as a thank you. A voucher code should reach you within two weeks after completion of the questionnaire and is usually sent to your email address.

What are the possible disadvantages or risks of taking part?

Some people may find some questions about periods or health sensitive or upsetting. If you feel affected by anything raised in this questionnaire, we have compiled a list of organisations who may be able to help:

<https://borninbradford.nhs.uk/what-we-do/studies/cycle-track/>

How is the questionnaire data collection managed and funded?

The study is funded by Wellcome Leap. University of Exeter is the sponsor with Prof Gemma Sharp overseeing the study. Data is collected by two sites, Born in Bradford at Bradford Teaching Hospitals and University of Bristol (Children of the 90s). All research in the NHS is reviewed and approved by an Ethics Committee. Favourable opinion for this study has been given by Yorkshire & The Humber – Bradford Leeds Research Ethics Committee (IRAS ID 363885; REC reference 26/YH/0078).

For any issues, questions or comments after reading this information or if you have problems accessing the questionnaire or voucher, please contact the Born in Bradford study team:

Email: borninbradford@bthft.nhs.uk Phone: **01274 274474**

Website: <https://borninbradford.nhs.uk/what-we-do/studies/cycle-track/>

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