UNIVERSITY OF BIRMINGHAM

PARTICIPANT INFORMATION SHEET
For service users and potential service users

Enhancing access to sexual and reproductive health services for people with mental health conditions in the West Midlands: assessing knowledge, barriers, and facilitators

At the University of Birmingham, we are carrying out research to find out what people with mental health conditions think of contraception and sexual health services. If you take part, your responses will be treated confidentially. Please take the time to read this information leaflet carefully.

Study Summary

We are inviting people aged 16+ living in the West Midlands who identify as having a mental health condition (diagnosed or self-diagnosed) to take part in the EASE-MH Study. This research looks at the challenges people with mental health conditions face when trying to access sexual health or contraception services, and how these services can be improved.

If you choose to take part, you may be invited to a one-to-one interview with a researcher, lasting up to 45 minutes, at a time and place that suits you (in person, online or by phone). You will not be asked to share personal health details. Participants will receive a £15 gift voucher as a thank you.

In this research study we will use information from you. We will only use information that we need for the research study. We will let very few people know your name or contact details, and only if they really need it for this study. We will make sure no-one can work out who you are from the reports we write.

Everyone involved in this study will keep your data safe and secure. We will also follow all privacy rules. At the end of the study, we will save some of the data in case we need to check it AND for future research.

The information pack tells you more about this.

How to get involved:

- Complete the Expression of Interest Form (available via QR code or on paper).
- Contact the research team directly.
- Speak to your care team, who can pass your details on (with your permission).

Contact us:
For more information, visit our website or email the research team (details provided in the full at the end of this leaflet)

What is the purpose of the study?

This study looks at the difficulties people with mental health conditions have when trying to get tested for sexually transmitted infections (STIs) and/or access contraception in the West Midlands. It aims to find out what makes it hard, suggest ways to make it easier, and ensure the services work well for all. By talking to both patients and healthcare workers, the study will give advice on how to improve contraception and sexual health services for people with mental health conditions.

Why have I been invited?

We want to learn about the experiences of people with mental health conditions and how they know about, access, and experience using contraception and sexual health services in the West Midlands. This will help us make sure these services are easy to use and provide the right care and support.

We are inviting people with mental health conditions, whether they have used these services or not, to take part in a one-to-one interview. We plan to carry out 20 interviews in total.

We are looking for individuals that meet the following criteria:

- Aged 16 years or older
- Live in the West Midlands
- Identify as having a mental health condition (either diagnosed by a healthcare professional or self-diagnosed).

Do I have to take part?

Taking part in the study is your choice, and you do not have to take part. If you decide not to participate in the study, it will not affect your healthcare in any way. If you change your mind, you can stop at any time without giving a reason.

What will happen to me if I decide to take part?

One of our researchers will contact you to remind you about the study's aims and answer any questions you may have. If you think you would like to take part, you will be asked to complete a short Screening Questionnaire so that we can collect some background information. This may be completed online, on paper or over the telephone. All questions are optional, and you can choose which questions to answer and which you would rather not answer. You do not need to give a reason for skipping any questions.

We are aiming to interview people with a range of characteristics and experiences. This means that we may not be able to interview everyone that expresses an interest in taking part. Once we have your completed questionnaire, the researcher will be in touch to let you know

whether or not we are able to interview you on this occasion. If we do not invite you to interview, your screening questionnaire data will be deleted within 14 days.

If we are able to invite you to take part in an interview, we will ask you to provide your informed consent – the form can be completed online, on paper or over the telephone. Once this has been completed, we will arrange a suitable date and time to meet. If you would like to speak with someone about your sexual health/contraception or mental health, we can share details of local services that can support you.

There will be a one-to-one interview with a researcher. The interview can be held within Umbrella services, such as Whittall Street clinic, on university premises, online, or over the telephone - whatever works best for you. We will not ask you to talk about your own health. So that we can capture all your views, the interview will take up to 45 minutes. You will not be paid to take part, but if you come to the interview, you will be given a £15 gift voucher to thank you for your time. The interview will be audio recorded. The interview audio recordings will be deleted once they have been anonymously written up (transcribed).

After taking part in the interview, you will also be invited to join a workshop where the findings will be discussed with others, including healthcare professionals, service users, and patient groups to develop meaningful recommendations and shape the future of services and research related to mental and sexual health. Your involvement in the interviews will remain anonymous, no one will be able to identify you from the findings shared during the workshop.

What are the possible benefits of taking part?

The information that we get from this study will be used to make sure that people have a say in what services are provided locally. We will also share our findings with the people who manage and design NHS services so that they can make sure that the right kinds of care and support are available for people with mental health conditions.

What are the possible risks of taking part?

The risks in this study are low, however some people may feel uncomfortable with answering some of the questionnaire or interview questions.

In the interview we will only ask for your experiences and views of contraception and sexual health services. In the screening questionnaire, you will be asked some personal information, including your gender, ethnic group, and a few questions about your mental health to ensure a wide range of people take part in the research.

All questions are optional, and you do not have to answer anything you are uncomfortable with. The researchers will stop the interview if necessary and can put you in touch with support if required.

If you share anything during the interview that suggests you or someone else may be at risk of harm, the researcher may need to share this information with relevant services, in line with safeguarding procedures. Wherever possible, this will be discussed with you first. This is to help ensure your safety and the safety of others.

The University has in force a Public Liability Policy and/or Clinical Trials policy which provides cover for claims for "negligent harm" and the activities here are included within that coverage.

Will my taking part in the study be kept confidential?

Yes. We will only use information that we need for the research study. Your name and contact details will only be shared with those who need to know (the researchers carrying out the study).

Everyone involved in this study will keep your data safe and secure. We will also follow privacy rules. At the end of the study, we will save some of the data and it may be used for future research. We will make sure no-one can work out who you are from the reports we write.

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
- contact details
- age
- gender
- mental health conditions
- ethnic group
- sexual orientation
- education

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

- Research staff at the university or NHS who are working on the study
- Organisations that manage data storage or analysis in a secure way (e.g., trusted survey platforms or data services)
- A trusted transcription company to type up audio recordings

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

- Storing all information in password-protected systems
- Only allowing the research team to see your personal details
- Removing your name and any identifying details from the data wherever possible
- Keeping your screening answers separate from your name and contact details
- Using secure websites to collect any online information
- Not sharing anything that could identify you in reports or publications
- Following data protection rules and checking regularly that your information is safe
  Your data will not be shared outside the UK.

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 the minimum period of time required by the sponsor with a minimum of 10 years as the standard. 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

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

You can find out more about how we use your information:

- our leaflet: http://www.hra.nhs.uk/patientdataandresearch
- by asking one of the research team
- by sending an email to c.m.spurway@bham.ac.uk, or dataprotection@contacts.bham.ac.uk

What if I change my mind?

Your decision to take part in this research is entirely voluntary and you can change your mind at any stage without offering a reason and without it affecting your care. If you have already given the interview and no longer wish for your data to be used, please contact the researcher within 7 days to withdraw your consent to using your data. If we have not heard

from you within this time period, the interview data will still be used in the study analysis. This helps to ensure trust and confidence in the methods used and the research findings (research integrity).

How do I get involved?

- Scan the QR code (at the bottom of this leaflet) and fill in out digital expression of interest form. The researchers will contact you after you provide consent to be contacted.
- You can also visit our website for links to get involved or contact our researchers directly (information at the end of this leaflet).
- Speak to your direct care team for more information and to express an interest in taking part. They will ask for your verbal consent for your contact details to be passed on to the study researcher.
- You can fill in the *'I'm interested in taking part in the EASE-MH Study!' Expression of Interest Form* and put it in the secure locked box in the centre. The form asks for your name and contact details and records your consent to be contacted by the researchers.

What happens at the end of the study?

At the end of the study, we will analyse the information collected and share the findings in reports and academic articles. All data will be anonymised, meaning your name and personal details will not be used. We may include quotes from interviews, but these will not contain any information that could identify you. The findings will be published on the study website and if you agree, we can contact you via email to share with you the findings from the study.

What if I have a question?

If you have any questions about this study, you can access the study website or contact our researcher - details are at the end of the leaflet. You can also contact your hospital Patient Advice and Liaison Service for independent advice about taking part – see Contact Details at the end of this leaflet.

Who is organising and funding the study?

The study is organised and sponsored by the University of Birmingham and is funded by the Sexually Transmitted Infection Research Foundation (STIRF). University Hospitals Birmingham NHS FT has given its support to the study.

What if there is a problem?

If you wish to complain about any aspects of the research, you can do so through the Patient Advise and Liaison Service (see Contact Details). If you wish to complain about how researchers have handled your information, you should contact the research team. If you are not happy after that, the researcher will give you the contact details for the Data Protection Officer.

Thank you for taking the time to read this Participant Information Leaflet.

Further information and contact details

Further information and contact details

Tel: 0121 464 6486

Email: c.m.spurway@bham.ac.uk

Study website: https://www.birmingham.ac.uk/research/applied-health/research/ease-mh-study

(We will publish our findings on this website when the study is completed)

Health Economics Unit, University of Birmingham, Edgbaston, B15 2TT

Patient Advise and Liaison Service (PALS):

Tel: 0121 424 0808

Email: pals@uhb.nhs.uk

To express your interest in joining the study, please scan the QR code and fill out the form with your contact details. A researcher will follow up with you shortly.