

PARTICIPANT INFORMATION LEAFLET For Service Users/Potential Service Users



Understanding the Impact of Remote Consultations in Sexual and Reproductive Health Services on Health Inequalities

Help Us to Improve Contraception & Sexual Health Services!

At the University of Birmingham, we are carrying out research to find out what people think of contraception and sexual health services.

If you can take part, your response will be treated confidentially.

Please take the time to read this information leaflet carefully.

CONTENTS

PART ONE of this information leaflet tells you the reasons for doing this study, what will happen to you if you take part, and what the benefits are.

PART TWO gives you more detailed information about how the study is being run and how your data will be used.

PART ONE

What is the CONNECT Study?

The COVID-19 pandemic led to a rapid move from in-person (face-to-face) consultations for contraceptive and sexual health services to remote consultations (telephone, video, online or text).

This research study will ask what patients and staff think about these changes, see whether these changes have introduced any health inequalities, and look at how best we can deliver these services going forward.

The health inequalities we will explore during this research will include investigating whether there are differences in health and healthcare between groups of people in terms of access to contraception and sexual services, how quickly treatment is received and whether effective treatment is given.

Why are my views important?

We want to know about your experiences of having an appointment, or trying to make an appointment, with contraception and sexual health services. For example, we will ask what you think about different ways you can have a consultation - e.g. face-to-face, over the telephone or online. Your answers will help us to check that we are providing the right kinds of care and support.

Who is taking part in the study?

We are asking all patients if they would be interested in taking part in a one-to-one interview. We plan to carry out around 60 interviews in total. If you decide not to participate in the study, it will not affect your care in any way.

How do I get involved?

- You can 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.
- Alternatively, fill in the '*I'm interested in taking part in the CONNECT Study!*' Expression of Interest Form and put it in the CONNECT 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.
- You can also visit our website for links to get involved.
- Or contact our researchers directly (information at the end of this leaflet).

What will happen if I 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 provide your informed consent – the form can be completed online, on paper or over the telephone.

We will then ask you to complete a *Screening Questionnaire* so that we can collect some background information.. This may also 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 as broad a range of characteristics and experiences as possible. 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 are able to invite you to take part in an interview we will arrange a suitable date and time to meet. If you would like to speak with someone about your sexual health or contraception, 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 in the centre, on University premises, online, or over the telephone - whatever works best for you. We will not ask you to talk about your own health. We will only ask for your views about having an appointment with contraception and sexual health services and your preferences on how these should be carried out. 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 £20 gift voucher to thank you for your time.

What are the possible disadvantages/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 having an appointment and will not ask you about your health. In the screening questionnaire, you will be asked some personal information, including your gender, ethnic group, and a few questions about your health to ensure a wide range of people take part in the research.

All questionnaire and interview answers are optional and you do not need to answer any questions you are uncomfortable with.

The researchers will stop the interview if necessary and can put you in touch with support if required.

What are the 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.

Will my taking part 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. More information about how your data is used and stored can be found in PART TWO of this leaflet.

If this research interests you, please continue to read [PART TWO](#) of this information leaflet for more information about the study

PART TWO

Who is organising and funding the study?

The study is organised and sponsored by the University of Birmingham and is funded by the National Institute for Health and Care Research (NIHR). The following NHS organisations have given support for the study:

- Central and North West London NHS Foundation Trust
- Hywel Dda University Health Board
- University Hospitals Birmingham NHS Foundation Trust

Who has reviewed this study?

All research in the NHS has been reviewed and given a favourable opinion by an independent Research Ethics Committee to protect your safety, rights, wellbeing and dignity. This study has received a favourable opinion from the North of Scotland Research Ethics Committee 2.

How are patients and the public involved in this study?

Public members sit on the panel that reviewed and agreed to fund the trial. We have consulted a group of service users during the design of this study. Our involvement of patients and the public (PPI) will continue throughout the study.

What if I have questions?

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 (PALS) for independent advice about taking part – see Contact Details at the end of this leaflet.

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).

More information about how my data will be used

Who is responsible for my data?

As Sponsor of the study, the University of Birmingham (UoB) is the data controller and has a legal obligation to hold your data in accordance with General Data Protection Regulation (GDPR) for public interest. Regulatory authorities will be given access to your data to check the study is carried out correctly.

How will my information be used?

Information includes your name, contact details, age, gender, ethnic group, sexual orientation, education and details about your health collected on the screening questionnaire. We will use this information to ensure we are including a wide range of people in the research. At interview we will collect your views on consultations in contraception and sexual health services and will use this information only for research. After the interview, data collected about you will not be linked to your name and you will be given a unique study ID number.

How will my information be transferred?

With your consent, your contact details will be sent to researchers at UoB by your local hospital via secure NHS email. Interview data collected by University College London (UCL) and UoB researchers will be transferred using secure servers (SharePoint and Data Safe Haven). No third parties will receive this information.

How will my information be stored?

We will keep all information about you safe and secure. All study data collected on paper will be held securely, in a locked room and within a locked cabinet that is accessible only to the research team at UoB and UCL where the researchers live. Computer files will be stored in password protected folders on encrypted computers that only the research teams at UoB and UCL can access. These include consent forms and screening questionnaires completed electronically on UoB secure servers, and typed up recordings (transcriptions) of your interview. Once interview recordings have been typed up (anonymously), the original audio recording will be deleted.

What will happen to my information when the study completes?

Once we have finished the study, your contact details will be deleted but we will keep your anonymised data so that it can be used to support future research. A

copy of your consent form will be retained for at least 10 years. We will write our reports in a way that no-one can work out that you took part in the study.

What are my choices about how my information is used?

We need to manage your records in specific ways for the research to be reliable. This means we won't be able to let you see or change the data we hold about you. If you change your mind within 7 days of having the interview, you can contact our researcher and your data will not be used and will be deleted.

Who can I contact for more information?

- The researcher - see Contact Details at the end of this leaflet.
- Sponsor's Data Protection Officer dataprotection@contacts.bham.ac.uk.
- Visit www.hra.nhs.uk/information-about-patients/ (printed copy available on request).

What if I have a complaint?

If you wish to complain about any aspects of the research, you can do so through the Patient Advice and Liaison Service (PALS) (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.

CONTACT DETAILS

Researcher Contact Details:

Tel: 0121 414 6486

Email: CONNECT-Study@contacts.bham.ac.uk

Study website: www.birmingham.ac.uk/connect-study

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

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

If you have concerns about contraception or sexually transmitted infections (STIs) or testing you can find more information at your local hospital's website or by telephoning your local clinic.