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**Participant Information Sheet V2.0 22/03/2023**

**REC ref: 23/IEC08/0008, date of approval 30/03/2023**

Exploring strategies to support the health and well-being of people living with HIV

* You are invited to a group discussion that will help us understand more about what additional support people living with HIV might need to improve their health and well-being.
* Before you decide whether to take part, it is important that you understand what is involved.
* Please take your time to read this sheet, discuss with others if you want to, and ask questions.
* You are free to decide whether to take part in this study. If you choose not to, this will not affect the care you receive in future.
* Thank you for reading this information.

**Brief Summary**

* In this study we will talk to you about your experiences in a group discussion.
* We will only use the information that you provide for the research study
* All researchers working on this study will keep your **data secure** and follow all **privacy** rules (as outlined in the UCL privacy notice detailed below).
* At the end of the study, we will **save** some of the data you provide in case we need to check it.
* We will make sure no-one can work out who you are from the reports we write.

The following information tells you more about this.

**What does taking part involve?**

1. A group discussion (focus group) led by two researchers with extensive experience of research about sexual health and HIV.
2. The focus group will be in person **or** online.
3. We will provide you with details of a group and ask you to take part.
4. We will provide you with £40 as a thank you for participating.
5. The focus group will last around two hours - however, you can stop whenever you want to.
6. We will ask you questions about the types of health and well-being needs people living with HIV have and explore some options for what types of support might work.
7. We will not ask you specific information about your own experiences but you are free to volunteer them.
8. The focus group audio (sound) will be recorded.
9. Audio recordings will be transcribed by a UCL approved professional transcription company operating under a signed confidentiality agreement.
10. Your name and other identifying information will be removed from the focus group transcript. You will be given a unique study number that cannot be linked back to you. This will include a small amount of information, such as your age, gender and (approximately) how long ago you found out that you were living with HIV: e.g., ‘Participant 10, 40-year-old female, diagnosed 12 years ago’.
11. After the focus group, we will not need to contact you again unless you would like us to send you a summary of the study results or if you would like to withdraw.

**Why is the study needed?**

HIV is now considered a chronic manageable health condition with excellent treatment outcomes. However, many people living with HIV face issues with their mental and physical health and need extra support to live well. The best ways to provide that support are not always clear and it is important to understand what people living with HIV want from services. This study will help researchers design a support service which can then be tested to see how well it works.

**Why have I been invited?**

You are being asked to take part because you are a person living with HIV. You are eligible for this study if you:

* Are aged 18 or over
* Have confirmed HIV
* Are able to give consent to this study

**Do I have to take part?**

No. Taking part in this study is completely voluntary and saying ‘no’ will not affect any future care that you receive. If you wish to take part, we will ask you to sign a consent form to record this. You are free to withdraw at any time, without giving a reason.

**What are the possible benefits of taking part?**

You may benefit from learning more about HIV and by talking about the subject matter with others who have experiences. The NHS may benefit from more effective ways of supporting people with HIV to live well.

**What are the possible disadvantages and risks of taking part?**

* We are asking you to take time out of your day to take part in the focus group.
* We will ask general questions about health and well-being. We may discuss mental health, drug or alcohol use and stigma or discrimination. Some of these questions are quite sensitive and you could find them upsetting.
* You may take a break from the focus group discussion at any time. If the focus group raises concerns for you about your health, or causes you any form of emotional distress, you should discuss this with the facilitators, your care team, or with your GP, whichever you feel most comfortable.
* Details of available support and contact numbers are provided at the end of this information sheet.
* If you tell us something serious (such as thoughts about harming yourself), we will need to tell your healthcare provider to ensure that you get the support you need.
* The information below outlines the steps we have taken to ensure that your confidential data is protected.

**How will information about me be kept confidential?**

We will protect your privacy at all times. These steps are taken to ensure confidentiality:

* Your consent to take part in the study will be recorded on a paper form alongside your name. These forms will be stored securely in a locked cabinet in a restricted access office at an NHS hospital, and separately from the focus group recording. If your focus group is by video call, your consent will be electronically recorded. These files will also be kept securely on the University secure server, accessible only by password protected computers.
* The text from your focus group recording will not include any personal identifying details but will use your unique study number, as above.
* All study data will be stored in a protected, restricted access location and will be accessible only to the named researchers working on this study, and authorised individuals of the University who check that the study is being carried out properly. We may have to breach your confidentiality if you tell us something relating to serious harm, abuse or any information that gives rise to risks of injury to yourself or others. If the researcher observes or receives evidence of incidents likely to cause serious harm, the researcher has a duty to report the risk to the necessary people, which may include your GP.
* Although we will keep your data confidential and we will ask all other participants in your group to do the same, we cannot control what people from the group might say afterwards. For that reason you may not want to share sensitive details about yourself in the group.

### **How will we use information about you?**

We will analyse the recording from your focus group using special software. The data from this will be used to develop a new model of care that we will test in a trial to see if it improves mental health and wellbeing in people living with HIV. More details of this study and the trial can be found at [www.niche.ac](http://www.niche.ac)

We will write reports and academic articles using this data. We will take care not to identify you using this data and will write our reports in a way that no-one can work out that you took part in the study. Once we have finished the study, we will keep the data so we can check the results. Data will be stored for 20 years on a secure University server, with all access controlled by the University Research Data Service. Anonymised focus group transcripts may be used in other work within the NICHE research programme, or considered for use with other research projects working on related topics that meet specific criteria and have received ethical approval. Anonymised transcripts will only be used in future research with the approval of the Principal Investigator, Professor Alison Rodger.

### **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.
* We need to manage your records in specific ways for the research to be reliable. This means that we won’t be able to let you see or change the data we hold about you.

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

Please see the UCL privacy notice: <https://www.ucl.ac.uk/legal-services/privacy/ucl-general-privacy-notice-participants-and-researchers-health-and-care-research-studies>

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

* at [www.hra.nhs.uk/information-about-patients/](https://www.hra.nhs.uk/information-about-patients/)
* by asking the researcher named on this sheet
* by emailing the UCL Data Protection & Freedom of Information Officer:

[data-protection@ucl.ac.uk](mailto:data-protection@ucl.ac.uk)

**Who is organising and funding the study?**

This study has been set up by the Institute for Global Health, University College London (UCL) and the London School of Hygiene and Tropical Medicine. The sponsor is the UCL Joint Research Office. The study is funded by the National Institute for Health Research.

**Who has approved the study?**

All research in the NHS is reviewed by an independent group of people, called a Research Ethics Committee, which is there to protect your safety, rights, wellbeing and dignity.

This study has been reviewed and received a favourable outcome by HRA and Health and Care Research Wales (HCRW) Research Ethics Committee on 30/03/2023.

**What will happen to the results of this study?**

The results of the study will be written up and presented in a way that no-one can work out that you took part in the study. We will share the results of this study with those who took part at feedback seminars and other events. We will write up the research for publication in a medical journal and present at conferences to share the results with other researchers and patients.

Once we have finished the study, the research team will keep the research data for several years in case we need to check it. This is stored confidentially, as above.

**What if something goes wrong for me?**

If you have any concerns about the way you have been approached or treated during the study, please contact the lead researcher, [Dr Lucy Cullen] to discuss this (contact details below). You can also contact the Patient Advice and Liaison Service (PALS) at the Royal Free Hospital by calling 020 7472 6446 or 020 7472 6447, or email [rf.pals@nhs.net](mailto:rf.pals@nhs.net).

If you are harmed by taking part in the study, or if you are harmed because of someone’s negligence, then you may be able to take legal action.

**How have patients and the public been involved in this study**?

It is important that researchers show that their research takes account of the views of patients and ordinary members of the public. This study, the focus group topic guide and this information sheet have all been designed in collaboration with patients and the public.

**How to contact us**

If you have questions about this study, please talk to the lead researcher: Name: Dr Lucy Cullen

Position: Research Fellow

Address: IGH – UCL, Royal Free hospital, London, NW3 2QG

Email: Lucy.Cullen2@lshtm.ac.uk

Thank you for taking the time to consider taking part in this study.

**Information, advice and support is available from:**

**Terrence Higgins Trust Direct**

THT direct is a helpline open from 10am to 6pm Monday to Friday. Call THT Direct on 0808 802 1221 for support, advice and information or email at info@tht.org.uk.

**Samaritans**

Freephone Number: 116 123

A charitable organisation that runs a 24-hour helpline. Volunteers are trained to listen, rather than give advice or information.   
Website: [www.samaritans.org](http://www.samaritans.org)

# **Find a** **local NHS urgent mental health helpline** (calls are free):

# <https://www.nhs.uk/service-search/mental-health/find-an-urgent-mental-health-helpline>

# You can call for:

# 24-hour advice and support - for you, or someone you care for

# help to speak to a mental health professional

# an assessment to help decide on the best course of care