UCL School of Pharmacy
BMA House
Tavistock Square, London WC1H 9JP
T +44 (0) 20 7753 5800

Participant Information Sheet and Consent Form for the SUPA Study (Stage 1):

People's views about treatment with antiretrovirals over time

Version: 1.1

Date: 29.08.2013

ISRCTN#: 35514212
REC#: 13/EE/0235

SCHOOL OF PHARMACY

UCL School of Pharmacy
BMA House
Tavistock Square, London WC1H 9JP
T +44 (0) 20 7753 5800

PARTICIPANT INFORMATION SHEET 1

1. Invitation

We would like to invite you to take part in a research study. Before you decide whether or not to take part we would like you to understand why the research is being done and what it would involve for you.

Please take time to read the following information carefully. You can take it away to discuss it with others if you wish. A researcher from our research team will go through the information sheet with you and answer any questions you have. We would suggest this should take about 10 minutes.

Please ask us if there is anything that is not clear, or if you would like more information. Take time to decide whether or not you wish to take part. Thank you for reading this.

2. What is the purpose of the study?

The purpose of this study is to find out what people think about HIV treatment and how that changes over time. The results from this study will be used to help us understand people's experiences with HIV treatment before they start it and after they have started it. This will enable us to develop better ways to support people facing treatment decisions and people taking treatment with HIV medicines (called antiretrovirals). We hope this study will help us improve the quality of care for people with HIV.

3. Why have I been chosen?

You have been selected to participate in this study because you are receiving HIV care and support at the Homerton Hospital, King's College Hospital, Queen Elizabeth Hospital or North Middlesex Hospital. It is also because you have been offered treatment with HIV medicines. We would like as many people as possible to participate, and so your contribution is important.

4. Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and refer to in the future. You will also be

UCL School of Pharmacy
BMA House
Tavistock Square, London WC1H 9JP
T +44 (0) 20 7753 5800

asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason; you can still discuss your options with your healthcare team. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive or your access to health services you currently receive.

5. What will I have to do?

If you agree to take part, you will be asked to fill out a questionnaire about your views on treatment (what you think and how you feel about HIV treatment). Filling out the questionnaire each time should take 5-10 minutes. You will be asked to fill out this questionnaire 4 times over 12 months. This means filling out the questionnaire when you agree to take part in the study, and 3, 6, and 12 months later. You will be informed of the dates to fill the questionnaire in advance. Filling out the questionnaires can be done with the researcher before or after your regular appointments to see the doctor or nurse. If you need to reschedule your regular clinic appointment, we will also reschedule a time to fill out the questionnaire that works for you.

An alternative to filling out the questionnaire around your usual clinic appointments is to fill it out over the phone with our researcher. You should only do this if you feel comfortable and if you have a private space in which you can speak on the phone. At your first visit, you will select a password which our researcher will ask you for to ensure that we are speaking with the right person on the phone. This will prevent people who have access to your phone from being able to speak to us on your behalf.

The first time you fill out the questionnaire, we will also ask you to complete another short written questionnaire about you and your medical history. The questionnaire will record things including your latest CD4 count, viral load, date of HIV diagnosis, and ethnicity. This will allow us to compare views and experiences of people at different HIV stages and with different ethnic backgrounds.

UCL School of Pharmacy
BMA House
Tavistock Square, London WC1H 9JP
T +44 (0) 20 7753 5800

If you don't know these details we will ask for permission from you to get them from your medical notes. We would only look for information relevant to this study. Please see box number 4 on the Consent Form, page 8.

6. When will I complete the questionnaire?

We would like you to complete the questionnaire today, while you are here in the clinic, either before or after seeing the doctor. There is a private space available for you to complete your questionnaire, if you would prefer this. The researcher will make sure you don't miss your appointment with the nurse or doctor. The researcher is not part of your hospital care team. If you would like to take part in the study but are unable to complete the questionnaire here in the clinic, you may take it away to complete, and you can fill it out over the phone with the researcher. This would involve telling your responses to the different questionnaire questions over the phone to the researcher. If you do decide to take the questionnaire away, the researcher will ask if you agree to give a contact number (text or phone) or email which we would use to send a single reminder to you about completing the questionnaire. This reminder would not mention HIV and would not carry information on the clinic.

You will be asked to fill out the same questionnaire about your views on treatment again as you come in for routine appointments to see the nurse or the doctor over the next 12 months. This means filling out the questionnaire 3 more times. If you do not have the time to fill out the questionnaire, you will have the option of doing it over the phone with the researcher.

Please note: If you consent to take part in this study, you may also be given a participant information sheet about another study which is looking at a support programme for patients who may be offered to start treatment for HIV soon or who

UCL School of Pharmacy
BMA House
Tavistock Square, London WC1H 9JP
T +44 (0) 20 7753 5800

may be getting ready to start treatment. Receiving this information sheet does not mean that you have automatically agreed to take part in a second study. You will only be given information about this support programme study to see if you may be potentially interested.

7. Will my questionnaire responses be confidential?

Yes, completely. Your name, NHS or clinic number will NOT be written on the questionnaire. Your answers will NOT be seen by the doctors and nurses in the clinic, and your answers will NEVER be recorded in your clinic notes. This is because the researchers are from a different institution and not part of your hospital clinic. Your completed questionnaire can be placed in a sealed envelope which will not be opened by the clinic staff. The information you provide during the study will NOT be shared with other statutory authorities (for example, immigration bureau).

Everything that you say in your research visits will be kept strictly confidential. None of the things you say will be discussed with your healthcare team. Only in the unlikely event that you or others are at risk of death or serious harm would we discuss this with your regular HIV doctor. This is consistent with disclosure policies in your regular clinic.

If you are registered with a GP, we would like to keep him or her up to date, by sending a letter if you agree to join the study. If you do not want us to contact your GP please tell a member of the research team. Please also leave section 6 of the consent form blank (page 8).

All information that you provide will be stored securely with a randomly generated number instead of your name or hospital number. It will not be possible to match the information you provide to you or your medical records.

All identifying data will be destroyed after 15 years, to follow good clinical practice (GCP).

UCL School of Pharmacy
BMA House
Tavistock Square, London WC1H 9JP
T +44 (0) 20 7753 5800

A completely anonymised version of the data (this means that the data cannot be linked to you or your medical records) may be used in future research under the direction of Professor Rob Horne. All future studies will have to pass ethical approval. We would not contact you again for this, as it will not be possible to identify you.

8. Will any other information about me be gathered?

You will be asked if you agree to us adding your routine HIV clinical information (from this clinic only) to the questionnaire information. This is so we can see how peoples' questionnaire responses relate to their current and future situation. The HIV clinical information would be:

- Your laboratory test results (e.g. viral load and CD4 count)
- Your HIV treatment details
- Other routine information on your HIV care (e.g. any illnesses or hospital admissions)

This is a standard procedure for studies of this nature. The clinical information is added in such a way that your questionnaire responses remain completely anonymous and confidential, and are NEVER put together with your name, NHS or clinic number. You do not have to agree to this, and you can still participate in the study if you do not agree.

9. What happens when the study stops?

Your anonymised responses will be added to everyone else's responses, and analysed by computer. We do this by looking at the information from the questionnaires you filled out and clinical data. The data will only be analysed for groups and not for individuals. This helps us understand how people's beliefs about ART change over time. The findings will be submitted to medical journals and presented at national or international health conferences. You will NOT be identified in any way in study reports, presentations or publications. Details of publications from this study will be made available on the SUPA study website (www.supaprogramme.co.uk).

10. What will happen to the information?

UCL School of Pharmacy
BMA House
Tavistock Square, London WC1H 9JP
T +44 (0) 20 7753 5800

Your anonymised responses will be added to everyone else's responses, and analysed using a computer programme. The data will only be analysed for groups and not for individuals. The findings will be submitted to medical journals and presented during national and international health conferences. You will NOT be identified in any way in study reports or publications. Details of publications from this study will be made available on the SUPA study website (www.supaprogramme.co.uk).

11. Are there any risks in taking part?

There is no risk to you in taking part in the study. If you find the questionnaire raises issues that concern you, or that you would like to discuss further, please ask the researcher to arrange for you to speak to a local health professional.

12. What are the possible benefits of taking part?

The study is not designed to benefit you directly. However, we hope the study findings will improve the HIV care that other HIV positive people receive in the future.

13. Who is leading this research?

A team of HIV specialists and researchers from the UK is leading this study. The study is being organised by the UCL School of Pharmacy, and is overseen by Brighton and Sussex University Hospitals NHS Trust. It is funded by the National Institute for Health Research (NIHR).

14. Who has reviewed this study?

The study has been reviewed by the National Institute for Health Research. The study has been given a favourable ethical opinion for conduct by the NRES East of England – Essex Research Ethics Committee.

15. What will happen if I don't want to continue on with the study?

UCL School of Pharmacy
BMA House
Tavistock Square, London WC1H 9JP
T +44 (0) 20 7753 5800

You can change your mind about taking part at any time, without having to give a reason. Your care will not be affected in any way. We would, however, like to use any information already collected, but would ask your permission first.

16. What if I have a problem?

If you have a complaint, or have any concerns about any aspect of the way you have been approached or treated during the course of this study, please talk to [RESEARCHER'S NAME] on [NUMBER].

Alternatively you can contact the Patient Advice and Liaison Service (PALS) between 09:30 and 17:00 hours, Monday to Friday at:

(INCLUDE HOSPITAL DETAILS)

PALS offers help, support and advice to patients and their relatives and friends, and can advise on the procedure for making a complaint.

17. Contact for further information

If you have any further questions concerning the study or if any problems arise during the study please contact [RESEARCHER'S NAME] on [NUMBER].

Direct line

Mobile

<u>Who else can I talk to?</u>

If you or your relatives have any questions about this study you may wish to contact the following organisation that is independent of the hospital at which you are being treated:

UCL School of Pharmacy
BMA House
Tavistock Square, London WC1H 9JP
T +44 (0) 20 7753 5800

HIV-i-Base is a treatment activist group which is HIV positive led and committed to providing timely HIV treatment information both to positive people and to health care professionals. You may contact them on 0808 800 6013 on Mondays, Tuesdays, and Wednesdays between 12:00 and 4:00 pm. You can also access their web site at http://i-base.info

18. What to do next

If you are at all unsure whether to take part in this study, you can have more time to think it over.

Thank you for taking the time to read this information and for considering taking part in this study.

SCHOOL OF PHARMACY

UCL School of Pharmacy
BMA House
Tavistock Square, London WC1H 9JP
T +44 (0) 20 7753 5800

CONSENT FORM

SUPA: People's views about treatment with antiretrovirals over time

Contact Researcher [NAME] on [LANDLINE] or [MOBILE]

		Please initial box
1.	I confirm that I have read and understand the information sheet dated 18.6.2013 (Version 1.0) for the above study. I confirm that have had the opportunity to contact the research team to ask questions, which have been answered to my satisfaction.	
2.	I understand that my participation is voluntary and that I am free to withdraw at any time. I understand that I do not have to give a reason if I withdraw. I also understand that my medical care or legal rights will not be affected if I withdraw.	
3.	I consent to the storage of personal information for the purposes of this study. This may include paper or electronic information. I understand that any information that could identify me will be kept strictly confidential and that no personal information will be included in the study report or other publications. I understand that all information will be stored confidentially and securely as explained in section 7 of the Participant Information Sheet.	
4.	I understand that everything that I say during research visits will be kept strictly confidential. I also understand that in the unlikely event that I or others are at risk of death or serious harm, my regular HIV doctor would be notified.	
5.	I agree / that information from this clinic on my laboratory test results, HIV treatment and clinical care can be added to my questionnaire responses.	
6.	I agree to take part in the above study	
7.	I give permission for my GP to be informed of my participation in this study.	

Name of participant	Date	Signature	Contact phone number

Name of researcher	Date	Signature

UCL School of Pharmacy
BMA House
Tavistock Square, London WC1H 9JP
T +44 (0) 20 7753 5800