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Participant Information Sheet and Consent Form for the SUPA Study (Stage 2):

An intervention study looking at the impact of treatment support in ART-naive patients.

Version: 2.0

Date: 04.03.2014

ISRCTN#: 35514212

REC#: 13/EE/0235

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PARTICIPANT INFORMATION SHEET 2 Part 1

You are being invited to take part in a treatment support programme research study. Before you decide whether you would like to take part it is important for you to understand why the research is being done and what it will involve. Please take your time to read the following information carefully. Ask if there is anything that is not clear or if you would like further information. Take time to decide whether or not you wish to take part, and talk to others about the study if you wish.

Summary of the study

- You have in the past been diagnosed with HIV and antiretroviral treatment has been discussed with you by your Doctor or Consultant. Making the decision to start treatment or getting started on treatment may mean big changes in your life.
- We want to find out if a new support programme is useful. The programme helps people with the decision to take HIV treatment, and if they do choose to take treatment, helps people get ready for and adhere (take treatment appropriately) to antiretrovirals.
- The study will randomly divide people into two groups. Half of the people in the study will receive normal care. The other half will receive normal (standard) care plus a support programme for the next 12 months. The programme will be tailored to (adapted to) you as an individual so that you get the most out of the programme. We will compare how well each group does with treatment and this information will help support other HIV positive patients in the future.

What is the purpose of the study?

This study will look at whether providing a support programme for antiretroviral treatment helps people with the decision to take HIV treatment, and if they do choose to take treatment, helps people get ready for and adhere to antiretrovirals. We are particularly interested in whether this helps you take treatment, but we are also looking at psychological well-being (how well you're feeling and what you think about your medicines).

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Why have I been chosen?

We have approached you because you are receiving care for HIV at the Homerton Hospital, King's College Hospital, Queen Elizabeth Hospital or North Middlesex Hospital. It is also because you have been offered antiretroviral treatment. We are looking to include 348 people in this study. This includes men and women, aged 18 and above.

Do I have to take part?

No. It is up to you to decide whether or not you want to take part. If you do, we will ask you to sign a consent form. You can change your mind to participate in the study at any time, without having to give a reason. Your care or HIV treatment will not be affected in any way. If you decide not to take part, you will receive normal (standard) care; 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.

What will happen if I agree to take part?

We are trying to see if a new programme, which supports people with the decision to take HIV treatment and with adhering to their treatment, is more helpful than what people are currently being offered. On your enrolment visit, a researcher will go through this information sheet with you, and you will have the chance to ask any questions about the study. If you do decide to take part in the study, you will be asked to sign the consent form.

Because we don't know if our programme is going to be more helpful than normal (standard) care, we need to make comparisons. You will be randomly selected to join one of two groups. We randomly divide patients into different groups and compare how well they do with antiretroviral treatment. In this study, one group will receive normal (standard) care while the other group will receive our support programme e.g. extra sessions with a specially trained Research Nurse to talk about treatment (what it's like, what you think about it, if you have any concerns, are there solutions to any potential issues, etc). The Research Nurse will be independent of your clinical team. You have equal chances of being included in standard care or the support programme. This is known as **randomisation**. Randomisation is like tossing a coin. Neither you nor the doctor or researcher can choose which group you will join.

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Because the programme involves going to extra sessions, participants will know which group they are in. A person can only belong to one of the groups and not both.

At the end of the study, we will compare how the patients (participants) in the two groups are to see if the support programme helps.

What do I have to do?

Once you have been randomised at your enrolment visit, what you have to do in the study depends on which group you are in.

If you go into the normal care group:

If you are randomised to receive normal care, you will not receive treatment support sessions. The level of care you receive will be the same as if you had decided not to take part in the study. However, you will be in the study for 12 months and you will attend 5 research visits at the hospital or over the phone with a member of the research team to collect data on how you're doing. These visits can be scheduled before or after your regular clinic appointments, or they can be scheduled at another time based on your availability and convenience. The researcher is NOT part of your clinical care team. In addition to your original enrolment visit, the research visits include:

- An initial session with the Researcher within one month of agreeing to take part in the study. You will be asked to fill out questionnaires about how you're feeling about treatment, how you feel generally, and some general questions about yourself and your diagnosis.

- Two further research visits 3 months and 6 months after your first visit to fill out questionnaires. These will be the same as the questionnaires you filled out in the first visit.

- One final visit will take place at 12 months after your enrolment visit. You will be asked to discuss how you're doing with treatment and fill out the same questionnaires as in the previous visits. You will be asked whether you are willing to have a recorded detailed discussion about your experience in the study. This is voluntary.

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You will be given all your antiretroviral medication in a special bottle (sometimes called a MEMS bottle) which records how often you open it to take your medication. You will be asked to use this bottle to store your medication. This bottle is white and not labelled. It does not change the way your medication works. At your research visits, you will also be asked to bring your special bottle in which you carry your medication. A member of the study team will download information from the bottle which will tell him/her how many tablets you have taken and at what time (a bit like putting in a USB stick in a computer). The visit should take 10-15 minutes. This information is NEVER shown to anyone from your clinic team.

If you go into the support programme group:

If you are randomised to receive the support programme you will attend additional visits with a specially trained Research Nurse. They are NOT part of your clinical care team.

If you are randomised to receive the support programme, you will be in the study for 12 months. In addition to your original enrolment visit, you will attend a total of 5-6 research visits within these twelve months. These visits can be scheduled before or after your regular clinic appointments, or they can be scheduled at another time based on your availability and convenience. The visits include:

- An initial session where you will receive treatment support from a trained Research Nurse. This visit should take 60-80 minutes. You will talk about what you think and feel about treatment. For example, you may talk about any concerns you have about treatment or whether you think anything in your life might get in the way of taking treatment. You will be asked to fill out some questionnaires about how you're feeling about treatment, how you feel generally, and some general questions about yourself and your HIV diagnosis. This will also include a short cognitive assessment, which involves brief memory tasks and motor tasks (small movements such as moving your fingers).

- One to two (depending on your needs) follow-up visits within 1 month after the first session. These visits should take 40-60 minutes. These can be done in person at the hospital or over the phone. Just like in session 1, you will talk about what you think and how you feel about treatment. At the last of these sessions you will be asked to fill out some questionnaires including about how you are feeling about treatment.

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- Two further sessions at 3 months and 6 months after your first session. These visits should take 40-60 minutes. These can be done in person at the hospital or over the phone. You will talk about how you're doing with treatment; whether you're having trouble, whether you're doing well, or whether anything has come up that you want to talk about. You will also be asked to fill out some questionnaires, the same as you filled out on your first visit.

- One final visit will take place at 12 months after the first session. You will speak about how you're doing with treatment. You will also be asked to fill out questionnaires about your treatment. These are the same as you filled out in your previous visits. You will be asked whether you are willing to have a recorded detailed discussion about your experience in the study. This is voluntary.

MEMS bottles

You will be given all your antiretroviral medication in a special bottle (sometimes called a MEMS bottle) which records how often you open it to take your medication. You will be asked to use this bottle to store your medication. This bottle is white and not labelled. It does not change the way your medication works. A member of the study team will download information from the bottle which will tell him/her how many tablets you have taken and at what time (a bit like putting in a USB stick in a computer). This information is NEVER shown to anyone from your clinic team.

Audio recording

You may be asked for permission to make an audio recording of your discussions with the Research Nurse. If you agree to this part, you will be given the opportunity to listen to the recording before deciding whether you are happy for us to use it. We would use it to make sure that the Research Nurse is talking to you about the things they need to talk about. This is to evaluate the quality of the care we are providing you. You do NOT have to agree to the recording in order to take part in the main study.

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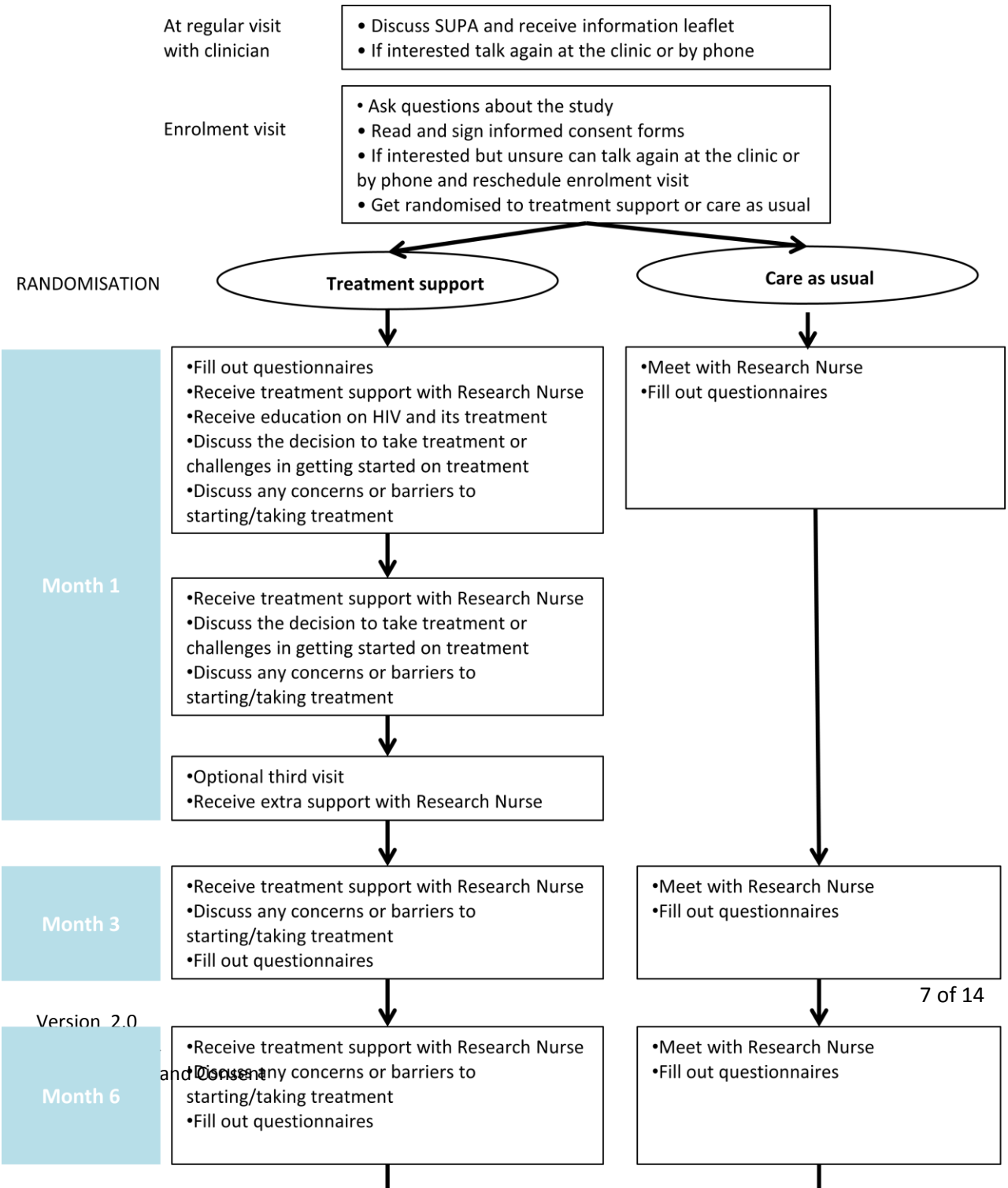
How can I attend the research visits?

Although the initial visit has to be done in person, you will choose whether you want to complete all your other visits in person or over the phone. If you chose to do this over the phone, the Researcher will call you. On the phone, you will choose a 'password' which the Researcher will check with you to make sure he/she is speaking with the right person. You will still need to bring your MEMS bottle in so the Researcher can collect the data, which the Researcher will schedule at your convenience.

Flow chart for study and clinic visits



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For all participants: If you decide to start taking treatment at any visit, a Research Nurse will discuss with you how to use a MEMS bottle to keep your medication.

After you start using your MEMS bottle, you will be asked to bring it in at every visit with the Research Nurse.

Will any other information about me be gathered?

You will be asked if you agree to us recording your routine HIV clinical information (from this clinic only). This is to help us understand whether out treatment support programme is helpful. 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. The information you provide is not shared with your employer or immigration authorities.

How do we compare the two groups?

Your anonymised responses will be added to everyone else's responses, and analysed by computer. We compare the group that received standard care and the group that received our programme. We do this by looking at the information from the questionnaires you filled out, clinical data, and the data from your MEMS bottle. The data will only be analysed for groups and not for individuals. This helps us understand if our support programme is helpful to people. 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).

What are the possible disadvantages or risks of taking part?

We are not aware of any risks from taking part. If you are randomised to receive normal (standard) care, the level of care you receive would be no different from what currently happens. If you are in the group that receives the support programme, you may or may not

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benefit from the extra support: this is what we are trying to find out. It is possible that during the sessions it will be difficult to talk about some things, but the specially trained Research Nurse will not ask you to talk about anything you don't want to.

Everyone taking part will be asked to use a MEMS bottle to store medication. Some people may find this inconvenient. However, the bottle is not labelled and it is not possible to see the tablets stored inside. This bottle is used by many people to store many kinds of treatments (for example, for diabetes, headaches, arthritis, etc.), not just treatment for HIV.

Potential benefits of taking part

If you are in the group that receives the support programme, you might feel better about taking treatment and find taking treatment easier. We do not know whether this will happen or not and this is why we need find out from this study. If you agree to take part, you will have equal chances of been selected into one of the groups.
If you are randomised into the standard care group, you will not get any additional direct benefits. However you will be helping us understand whether a support programme is helpful, and this may help many people in the future.

Will my taking part in the study be kept confidential?

Yes. All the information about your participation in this study will be kept confidential. The details are included in Part 2.

Contact details

If you would like any further information or to discuss any issues relating to this study, you can contact:
[INSERT]
This completes Part 1 of the Information Sheet. Part 2 tells you about some of the safeguards we have put in place to make sure that this research is carried out according to existing guidelines.

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APPENDIX 2: PARTICIPANT INFORMATION SHEET 2 Part 2

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

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

What if there is a problem?

If there is a problem with either members of staff involved in the research study or what you are being asked to do then you can report this. If you have concerns about any aspect of this study, ask to speak with the researchers. They will do their best to answer your questions. Alternatively you can contact the Patient Advice and Liaison Service (PALS) between 09:30 and 17:00 hours, Monday to Friday at:

The Homerton Hospital on 020 8510 7315
or
King's College Hospital on 020 3299 3625
or
North Middlesex Hospital on 020 8887 4172
or
Queen Elizabeth Hospital on 020 8836 4592
or
Lewisham University Hospital on 020 8333 3355

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

Will my taking part in the study be kept confidential?

Yes, all the information about your participation in this study will be kept confidential. 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.

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If you join the study, some parts of your medical records and the data collected for the study may be looked at to check that the study is being carried out correctly. This would be by authorised people from regulatory authorities or from the NHS Trusts involved. They will have a duty of confidentiality to you as a research participant.

All information that you provide will be stored securely with a randomly generated number instead of your name. This is NOT your hospital number. It will not be possible for people to match/link the information you provide with you.

All identifying data will be destroyed after 15 years, to follow good clinical practice (GCP). A completely anonymised version of the data 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.

Involvement of your General Practitioner/Family doctor (GP)

If you decide to take part, we will inform your GP, but only with your permission. You do not need to tell your GP that you are participating in this study. If you do not want to tell your GP that you are participating in this study, please leave Section 7 on the Consent Form blank.

What will happen to the results of the research?

The results of the research will be reported to members of staff in the hospital, at research conferences and will be published in scientific journals. The results will also be published on the study website www.supaprogramme.co.uk

Since your data is anonymised and evaluated with others as a group, you will not be identified in any way in study reports or publications.

If you wish to obtain a copy of the published results, please tell a member of our research team and he/she will be happy to supply you with one. A summary of the overall study results for participants will be produced once the study has been completed and analysed.

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Who is organising and funding this study?

This study is being organised by the UCL School of Pharmacy, and overseen by Brighton and Sussex University Hospitals NHS Trust. It is funded by the National Institute for Health Research.

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.

Contact for further information

If you have any further questions concerning the study or if any problems arise during the study please contact:

King's College Hospital	Dr Frank Post	frank.post@kcl.ac.uk 020 7848 5779
Homerton University Hospital	Prof Jane Anderson	janderson@nhs.net 020 8510 7983
North Middlesex Hospital	Dr Jonathan Ainsworth	jonathan.ainsworth@nmh.nhs.uk 020 8887 4236
Queen Elizabeth Hospital	Dr Stephen Kegg	stephen.kegg@nhs.net 0208 836 5760
Lewisham University Hospital	Dr Charles Mazhude	c.mazhude@nhs.net

Or, you can contact our sponsor at Brighton and Sussex University Hospitals NHS Trust. trial.monitors@bsuh.nhs.uk

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Who else can I talk to?

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:

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

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.

If you agree to take part you will be given a copy of the signed consent form and this information sheet to keep. Thank you for taking the time to read this information and for considering taking part in this study.

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CONSENT FORM

An intervention study looking at the impact of treatment support in ART-naive patients

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 I 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 publication. I understand that all information will be stored confidentially and securely as explained in the Participant Information Sheet Part 2.	
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 understand that relevant sections of my medical notes and data collected during the study may be looked at by individuals from the UCL School of Pharmacy, from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my medical/clinic records.	
6.	I agree to have one or more of my sessions with the specially trained Research Nurse audio-recorded.	
7.	I give permission for my GP to be informed of my participation in this study.	

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8.	I understand that only my SUPA participant trial number and date of birth will be used to identify me on the Case Report Forms that are sent to University College London, School of Pharmacy / stored at the site where I am participating in the trial.	
9.	I agree to take part in the above study.	

Name of participant	Date	Signature	Contact phone number

Name of researcher	Date	Signature