INFORMATION SHEET AND INFORMED CONSENT FOR PARTICIPATION IN MAIN STUDY

AUR2-4-240-□□□-□□□□□-□ NCT Number: 03340428

TITLE: Corrections2Community: Post-Release Retention in HIV Care for Ex-Inmates In South Africa

The investigators doing this study are:
Dr Salome Charalambous and Mr Tonderai Mabuto from The Aurum Institute, South Africa
Dr Christopher Hoffmann from Johns Hopkins University, USA

Introduction

Hello, my name is [__insert name of study personnel__]. I am part of a research study team at [__insert name of institution__]. We would like to invite you to take part in the "Corrections2Community" Study.

This paper tells you about the study. Before volunteering to participate in this study, it is important that you read and understand the following explanation of the purpose of the study, the study procedures, benefits, risks, and your right to withdraw from the study at any time. The study staff will also talk with you about this information. We want you to ask ANY questions about ANY part of the study that you do not understand. After you understand the study, we will ask you to decide if you want to be in any part of it, or not.

If you agree to take part in this study, you will be asked to sign or place your thumbprint on some pages of this document. You will receive a copy of this document (Study Information Sheet) and the pages that you sign (Consent Forms) to take home with you for your records.

Purpose of the study

- The purpose of this study is to find out ways of supporting inmates to continue with HIV treatment after release.
- In our previous work, ex-inmates face several challenges such as: knowing where and when to receive care, long queueing times at the clinic, family abandonment, being treated differently in their communities, lack of money to support themselves, and substance use. One of the solutions suggested by ex-inmates that we have talked with is the idea of having support groups of ex-inmates on HIV treatment to where people can receive their medication and talk about their challenges with continuing treatment.
- In this study we want to test if the idea of these support groups will work, and check if it people who attend these groups are able to continue with treatment much better than those who go straight to the clinics. These support groups are also called community adherence clubs.
- In order to test if this idea will work, you will be asked to join one of two groups. The type of group you will be assigned will be decided by chance (like the lotto). People in one group will participate in the support groups after release, and people in the other group will not be part of the support groups (care as usual).
- You must agree to stick with the type of group that we give you. You cannot change to another type of support.
- About 120 participants will be assigned to Group 1 and 60 participants will be assigned to Group 2. Participants 18 years and above will be asked to participate from correctional facilities in Kgosi Mampuru II and Modderbee Management Areas in Gauteng Province.

What will happen if you are assigned Group 1 (support groups/adherence clubs)?

- We will ask you to go to a support group in the area that you have been released.
- We will ask you to attend the support groups every month. The group sessions will last for approximately 2 hours.

- During each group session, our study staff will check your general health, and provide you with pre-packaged HIV medication.
- During each group session, we will also talk about different topics such as substance use, alcohol use, adherence to treatment, family and community relationships, and financial insecurity.
- We will encourage all the people in the group to share their experiences on these different topics.
- We will ask you to attend the group sessions for up to 6 months. After 6 months, we will encourage you to continue with your treatment using similar adherence clubs that are managed by the clinics in your local area.

What will happen if you are assigned to Group 2 (care as usual)?

- You will receive your HIV treatment and support from the clinic to which you will be referred to by the nurses in this correctional facility.
- You will not be assigned to a support group or adherence club as part of this study.

What will happen for all participants before release (Group 1 & 2)?

- We will collect information about your time in this correctional facility, your general health, the treatment you are taking, your experiences with living with HIV, and information on your family and friends who form part of your support structures.
- A person from our team will met with you to explain any questions you have about the study. They will also discuss with you any questions or issues you may have about continuing with your treatment after you get released.
- We will ask your permission for our study staff to contact you once you leave the correctional facility and are back in the community.
- We will also ask you to provide us with an address of where you think you will go after release, and phone numbers of any people who may help us find you. We would also like you to give us permission to contact you, using these people. We will not mention anything about your condition or participation in this study. We will leave our names and ask you to send “call-me-back” messages on a number that we will give you.
- We will also ask for your permission for our study staff to visit your home and find out how you are doing if we are unable to contact you directly or through your next of kin. We would also like you to give us permission to work with Community Corrections Officers to contact you if we are unable to do so ourselves.
- We would also like to you to allow us to access and record information from your clinic and hospital records to check; your medical history, the medication you are taking, and how you are doing on treatment. All this information will be kept secret by our study staff.
- We will provide information on services to help you succeed with continuing your treatment out of the correctional facility.

What will happen for all participants after release (Group 1 & 2)?

- We will contact you at about 2 weeks to check where you have been released to and get more contact details.
- We will call you again at 1, 3 and 6 months from the date you are released from the correctional facility. We will ask; how it is going with your treatment, and if you have gone to a clinic or hospital to continue treatment.
- We will do this follow up over the phone, unless you think it may be better for us to meet you face-to-face, in which case we have to arrange for a place where we can meet.
- We will also send you short messages (sms) so that we can keep in touch with you.
- If you go to the clinic, we will ask to see your clinic records to know what help you will be getting. We will also be interested in knowing if you keep on going to the clinic or hospital for treatment.

- You will be asked to provide a blood sample at about 6 months from the time you get released from this correctional facility. The blood sample will be up to 8mL (2 teaspoons). The blood will be collected from your arm by a trained study staff member.
    - The blood will be sent to an outside laboratory. The laboratory will check the amount of HIV in your blood (viral load) and if there are any signs of medication used to treat HIV in your blood.
    - No names or other identifying information will be written on blood samples that will be sent to the laboratory.
    - The blood we send to the laboratory will be stored until the study is complete, after which it will be destroyed.

What are the risks and discomforts of being in this study?

- Someone might find out that you are taking part in this study. If this happens, this may result in you being treated differently by some people in the community. However, our study staff will keep information about your participation in this study confidential/kept secret.
- If you are assigned to the group that will attend the adherence clubs, you may know (or be known by) other participants in the group. We will request that all participants in the group discussion treat all identities and information shared in the discussion strictly confidential. However, as this is a group discussion, confidentiality cannot be guaranteed, as the study team does not have control over whether a participant chooses to disregard this.
- The study involves asking questions regarding your life and experiences. Talking about these things can be disturbing. You may feel uncomfortable answering a question. If you do not feel comfortable then you can refuse to answer the question.
- If you feel, you need psychological /mental and emotional support because of study procedures we will refer you to correctional centre health staff whilst you are in the correctional facility and once you have been released, this will be provided by study staff, including a Clinical Psychologist who is contracted to Aurum Institute.
- We do realise the concern and risk of others knowing about your health status. Again, all results are strictly confidential/kept secret and will only be made known to you and the study staff.

What are the benefits of being in the study?

- There may be no direct benefit to you from participating in this study. If you are assigned to the group that will attend adherence clubs, you may benefit from the support and the additional services that are provided in this group. Whether participation in these groups will truly beneficial, is what we are trying to find out from this study.
- The results of the study will help us know how best to continue with HIV care, and so it will help other inmates in the future.

What are your rights as a participant in this study?

- We cannot do this study without your authorization / permission to use information collected in this study. We would need your permission / authorization. If you do not, then you may not join this study.
- Your participation in this study is entirely voluntary (your own free will). You may decline/ to choose not to participate. You may also stop at any time, without stating any reason. You may revoke (cancel) your permission to use the information you give us in this interview at any time by notifying the study staff. If you do cancel your authorization to use the information you provide, your part in this study will end and no further information about you will be collected.
- Your withdrawal will not affect any healthcare or any other services you may be receiving.

How is the information collected during this study going to be kept confidential?

- All information collected during for this study will be secure and confidential/kept secret. Your personal information is protected by South African law and by regulations from the funder (the National Institutes of Health). This means that researchers cannot be forced to disclose your personal information. However, if we learn about something that could put your or others health at risk right now we may need to report it to appropriate professionals. All personal information (including recordings) is only available to study staff. Study staff will keep this information in locked-secured cabinets or password protected computer devices.
- We will also write your name on the form that you sign when you agree to participate. In order to keep all other information secret, we will assign you a number or code that only the study staff can trace back to you.
- When we make reports on data from this study, we will not include any information that identifies you as a participant in this study.
- The study has been structured in accordance with the Declaration of Helsinki (last updated: October 2013), which deals with the recommendations guiding research involving human participants. A copy may be obtained from me should you wish to review it.

Reimbursement

- You will not be paid for participation in this study.
- If you are allocated to attend the adherence clubs, we will reimburse you R100 for each monthly attendance to the adherence club.
- If you are in the care as usual group we will give you R50 worth of airtime for two successful follow up visits that we are able to make with you after release. The airtime will allow you to keep in contact with the study team, or other people who will support you with continuation of HIV treatment after release.
- In addition, we will also reimburse you R100 when we meet you to collect a blood specimen, about 6 months from the time of your release.

Ethical approval

- This study protocol has been submitted to the University of the Witwatersrand, Human Research Ethics Committees, and the Institutional Review Board of the Johns Hopkins University in the United States. These committees have given us written permission to go ahead with this study, and may request to check records for this study to make sure that that people taking part in the study are protected and that accurate information is being recorded. These records will be utilised by them only in connection with carrying out their duties relating to this research study.
- The study has been structured in accordance with the Declaration of Helsinki (last updated: October 2013), which deals with the recommendations guiding people conducting research involving human participants. A copy may be obtained from me should you wish to review it.

Source of additional information

- If you have any questions about this study, please ask us now. If you have any questions later, you may also telephone, Mr. Nieser Seatlholo - Study Coordinator on 0105901401 or Email: nseatlholo@auruminstitute.org
- If you want any information regarding your rights as a study participant, or complaints regarding this study, you may contact The Chairperson of the University of the Witwatersrand, Human Research Ethics Committee (HREC) at (011) 717 2301.

Participant questions

Did the participant have any questions? Yes/No

If yes, what were they and what responses were provided?

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INFORMED CONSENT FORM FOR PARTICIPATION IN MAIN STUDY

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Dr Christopher Hoffmann from Johns Hopkins University, USA

- I have read the information sheet about this study (or the information sheet about this study has been read to me) and I understand what will be required of me and what will happen if I take part in the study.
- I have also received, read and understood the above written information regarding the study.
- I may, at any stage during the study, withdraw my consent and participation in the study without giving a reason and without this affecting my normal care and management.
- I have had sufficient opportunity to ask questions and (of my own free will) declare myself prepared to participate in the study.
- By signing this consent form, I agree to participate in the study.

STUDY PARTICIPANT:

Printed Name	Signature/mark/thumbprint	Date

STUDY STAFF:

I herewith confirm that I have explained to the participant the study purpose and procedures and we have discussed all the risks that are involved. I have answered questions to the best of my ability that the participant had.

Printed Name	Signature	Date

TRANSLATOR /OTHER PERSON EXPLAINING INFORMED CONSENT:

Printed Name	Signature/mark/thumbprint	Date

WITNESS (If applicable):

Printed Name	Signature/mark/thumbprint	Date