Home link:

Post hospital care to reduce HIV mortality in South Africa

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INFORMATION LEAFLET AND INFORMED CONSENT FORM: CARE AS USUAL (CAU) AND HOME LINK ARM

PROTOCOL:
HOME LINK: POST HOSPITAL CARE TO REDUCE HIV MORTALITY IN SOUTH AFRICA

SHORT TITLE: Home Link

PROTOCOL NUMBER: Home Link

VERSION: Protocol Version 5.0 dated 05 March 2021
Informed Consent Form Version 4.0, dated 22 April 2021

SPONSOR: National Institute of Mental Health, USA

PRINCIPAL INVESTIGATOR: Prof Neil Martinson

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INTRODUCTION

Good day, my name and surname are _____. I am a _____ (designation) at the Perinatal HIV Research Unit (PHRU). I would like to invite you to consider participating in a research study called Home Link.

Before agreeing to participate, it is important that you read and understand the following explanation of the purpose of the study, the study procedures, benefits, risks, discomforts, and precautions as well as the alternative procedures that are available to you, and your right to withdraw from the study at any time. This information leaflet is to help you to decide if you would like to participate. You need to understand what is involved before you agree to take part in this study and ask the study doctor or staff any questions you may have.

This study is looking for people who were recently admitted to the medical ward of Tshepong Hospital. We are asking you to be in the study because you have spent at least one night in a medical ward of Tshepong Hospital. If you decide to take part in this study, you will be asked to sign this document to confirm that you understand the study. You will also be given a copy to keep.

WHY IS THIS STUDY BEING DONE?

Many people do not continue to receive medical care after they leave the hospital and some people will get sick again and have to return to the hospital. Therefore, we want to find out if doing home visits for people who were recently discharged from hospital for post-care is a good strategy to help people with their recovery after they leave the hospital.

We are therefore comparing two strategies of care to find out which one works best for patients. If you agree to be part of this study you will be randomly assigned to one of the two strategies:

A: Care-as-usual (CAU) study arm: Participants in this arm will receive discharge counseling from a trained counselor before leaving the hospital and will be provided with a follow-up return date (about two weeks later) after leaving the hospital. Discharge counseling will include a review of discharge medications and instructions about follow-up care visits.

B: The Home Link study arm: Participants in the Home Link intervention arm will be discharged from hospital and will receive home visits from the home visit team. The home visit team includes a primary care nurse and counselor who will come to your household after you have left the hospital. A hospital doctor will review your clinic file and will provide guidance to the home visit team. Each Home Link visit will last for approximately 1 hour. Participants in the Home Link arm will be visited by the home visit team at least once and up to 6 times in the 3 months after leaving the hospital.

We want to see which strategy is better (care-as-usual or Home Link) and we want to see how much each strategy costs and if it is value-for-money and acceptable to do such home visits. We would like to ask if you are willing to take part in this study. We are asking you to be in the study because you were recently admitted to Tshepong Hospital. If you agree, we would then randomly allocate you to the CAU or Home Link strategy. You will not be able to choose which strategy you were selected for; it will be like flipping a coin to decide which you got.

WHERE WILL THE STUDY BE DONE?
The study will be conducted by the Perinatal HIV Research Unit (PHRU), at Tshepong Hospital, in the Matlosana Municipality, North West Province.

WHAT WILL HAPPEN TO ME IF I AGREE TO BE IN THE STUDY?
You don't have to be in the study; it is your choice to volunteer. There will be no problems if you decide not to participate.

If you do agree to participate in this study, we will then:

1. Check your clinic or hospital records or your card to see your HIV status and any HIV related tests including viral loads, CD4 counts, and drug resistance testing. We'll also review any TB test results, discharge diagnoses, and any other medical issues and treatment you may have already received. If HIV and TB related test results are not available, we will draw blood and/or collect sputum from you while you are still in the hospital for those tests.
2. For participants living with HIV, we will also collect approximately 10mL of blood for HIV drug resistance testing. HIV drug resistance happens when the HI virus continues to multiply despite the use of ARVs. We will only conduct the drug resistance test if the viral load result is >1000 copies/mL. A viral load tells us how much HIV is in your blood. If you have drug resistance, the ARVs you are taking may not work and a drug resistance test can tell us which ARVs won't work. If drug resistance is found, we will provide those results to your doctor or nurse so that they can make sure you are prescribed the right ARVs.
3. We may use leftover blood from HIV drug resistance testing to repeat the viral load and drug resistance test using a new method. If we do, we would share your most recent HIV viral load result with the researchers but would not share your name.
4. We will ask you several questions about yourself, where you live, the people who you live with, etc. Some of those questions will let us know if you are suitable to be in the study.

If we see that you are able to be included in the study, the study staff member will receive a message to find out the strategy you have been allocated to.

A. If you have been selected for the **care-as-usual strategy,** you will**:**
   - Have in-hospital laboratory and psychosocial assessments;
   - Receive counseling from a trained discharge counselor. Discharge counseling will include a review of discharge medications and instructions regarding follow-up care visits;
   - Be provided with a follow-up return date. This is usually two weeks after leaving the hospital.
   - Be asked to share your contact details with the study team in order to receive up to four, telephonic or in person, follow-ups by a study team member at 8, 12, 26 and 52 weeks after being discharged from hospital.

We will also review your clinic and/or hospital records to collect information on re-admissions, clinic visits, and health status.

B. If you have been selected for the **Home link strategy,** you will:
   - Receive in-hospital laboratory and psychosocial assessments;
   - Be asked to share your address and contact details with the study team for the home visits.
   - Receive up to a total of 6 (for a period of 3 months) follow-up home visits. Visit 1, will be one week after discharge and then every two weeks thereafter until completing 6 visits or after you are discharged from the Home Link intervention based on clinical assessments.
   - At the home visit we will:
     - Assess illness severity by looking at your vitals and will ask you some general medical questions. Based on your results, the home visit team will either: (i) discharge you from having more home visits, (ii) return for another visit in 2 weeks, (iii) contact a doctor at the hospital for further guidance, or (iv) call for an ambulance to take you to the hospital for evaluation and maybe an admission.
     - Review your medication looking at what is prescribed, taken, how often and whether it is available. Counsel on appropriate dosing and address potential adherence barriers (e.g. lack of understanding, lack of medication availability, nausea or other side effects).
     - Provide medications dispensed for you from the hospital pharmacy.
     - Where necessary, collect whole blood, sputum, or urine for transport to the laboratory.
     - Do a household assessment by asking questions on home support.
     - Provide food parcels to households that reported low food security prior to participants discharge from hospital.
     - Provide counselling to address readiness for treatment engagement, depression, and alcohol abuse.
   - During the home visit, we will also do an acceptability questionnaire.
   - We will also conduct interviews with about 40 participants to assess what they thought of the Home Link intervention.

- Up to four, telephonic or in person, follow-ups by a study team at 8, 12, 26 and 52 weeks after being discharged from hospital. These visits will be done during and after the home visits have been completed.
- Review your clinic and/or hospital records to collect information on re-admissions and health status.

WHAT ARE THE BENEFITS OF BEING IN THIS STUDY?
There are no clear benefits to your being in the study. However, if you are in the Home Link arm you will receive household visits and will get your medication delivered by the Home Link team. This study does not provide treatment outside of what is prescribed by your doctor.

WHAT ARE THE RISKS OF BEING IN THIS STUDY?
There are no big risks, as we are not doing anything to you that is harmful. The people working for the study will keep your identity secret. You may have blood collected so one possible risk includes drawing blood which may cause some discomfort, bleeding and or bruising.

WHAT ALTERNATIVES DO I HAVE?
Your participation in this study is entirely voluntary and you can decline to participate, or stop at any time, without stating any reason. Your withdrawal will not affect your access to your normal medical care or other services.

RIGHTS AS A PARTICIPANT IN THE STUDY
As stated above your participation in this study is entirely voluntary and you can decline to participate, or stop at any time, without stating any reason. Your withdrawal will not affect your access to your normal medical care or other services.

WITHDRAWAL FROM THE STUDY
As, stated above, you can leave this study at any time. If you decide to leave the study, please tell the study doctor or research staff that you wish to leave. Again, you do not have to give a reason why you want to leave the study, but any information you provide to study staff will be helpful. The study doctor may also withdraw you from the study if it is considered to be in your best interest.

OTHER INFORMATION

Payment
We will not give any remuneration for taking part in the study.

Protecting privacy and confidentiality
Any information about yourself that you provide to the study will be kept confidential. Study information will be stored on a computer, protected by a password, and will only be seen by people working on the study. We will protect your privacy by only asking you study questions in a private space where others can't hear, or a place that you choose.

NEW FINDINGS
You will be told of any new information learned during the course of the study that might cause you to change your mind about staying in the study. At the end of the study, you will be told when study results may be available and how to learn about them.

WHAT ABOUT CONFIDENTIALITY?
We will make an effort to keep your personal information confidential. We cannot guarantee absolute confidentiality. We may disclose your personal information if required by law. If we publish this study, we will not use your name or identify you personally.

The following people might review your records: University of the Witwatersrand, Human Research Ethics Committee (Wits HREC - Medical), other regulatory bodies, study sponsors, research staff, and study monitors.

WHAT DO I DO IF I HAVE QUESTIONS OR PROBLEMS?
If you have questions about this study or any problems that you think may be related to this study, contact the clinical trial staff on **061 667 7697.**

Ethical Approval
This clinical study protocol has been submitted to the University of the Witwatersrand, Human Research Ethics Committee (Wits HREC – Medical) and written approval has been granted by that Committee. The study has been structured in accordance with the Declaration of Helsinki (last updated: October 2013) which deals with the recommendations guiding doctors in biomedical research involving human participants. A copy may be obtained from me should you wish to review it.

If you have any additional questions about your rights as a research participant, you should contact the University of the Witwatersrand Human Research Ethics Committee (Wits HREC - Medical) who are overseeing the conduct of this study at this clinical research centre. An Ethics Committee is an independent committee established to help protect the rights of research subjects.

Prof Clement Penny, Chairperson
The University of the Witwatersrand
Human Research Ethics Committee
Johannesburg
Telephone number: (011) 717 2301

SIGNATURE PAGE

PERSONAL DOCTOR / SPECIALIST NOTIFICATION:

Please indicate below, whether, you want me to notify your personal doctor or specialist of your participation in this study:

- ☐ YES, I want you to inform my personal doctor/specialist of my participation in this study.
- ☐ NO, I do not want you to inform my personal doctor/specialist of my participation in this study.
- ☐ I do not have a personal doctor/specialist.

STATEMENT OF CONSENT

Before you sign or make your mark on this consent form, make sure of the following:

- You have read this informed consent form, or someone has read it to you.
- This study has been explained to you and you had your questions answered.
- You understand you can ask more questions at any time.
- You understand that it is your decision to join the study and you may withdraw at any time.
- You have understood everything that has been explained to you and you consent to participate in this research study.

Participant's Name and Surname (Print)	**Participant's Signature / Thumbprint**	**Date**	**Time**
Study Staff conducting consent discussion Name and Surname (Print)	**Study Staff Signature**	**Date (dd/mmm/yyyy)**	**Time**

**For participants who are unable to read or write or require a translator, also complete the signature block below:*

***Witness' Name and Surname (Print)**	**Witness' Signature**	**Date**	**Time**

**Witness is impartial and was present for the entire consent process.*

Retain original Informed Consent Form on file. Offer participant a copy. Place a copy in medical records if applicable.