Informed Consent Form

Title: InTSHA: Interactive Transition Support for HIV-infected Adolescents Using Social Media

NCT Number: NCT03624413

IRB Approval Date: March 6, 2021

ADOLESCENT CONSENT TO ACT AS A RESEARCH PARTICIPANT (AGES 18-19)

InTSHA: Interactive Transition Support for HIV-infected Adolescents Using Social Media

This document is to inform you of the purpose of this research, and to give you a description of the procedures to be followed, possible risks and discomforts, possible benefits and the basic ground rules, which will govern this research study.

STUDY INVESTIGATORS

Investigator(s): Brian Zanoni, MD, MPH
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Staff: Thobekile Sibaya
Nompumelelo Ndela

WHY IS THIS STUDY BEING DONE?

The research study is to develop a social media-based program to assist with transition care for adolescents living with HIV.

You are being asked to be in this study because you are an adolescent living with HIV who will transition to adult care.

Up to 80 adolescents will be enrolled in the study.

WHAT IS INVOLVED?

If you agree to be in this study, your participation will consist of completing questionnaire and having your blood drawn at enrollment to check your viral load. In addition, we will review your medical record for demographic and health information. You will be randomly assigned to be in the intervention group or standard of care. Consent begins with the signing of the informed consent form. A research assistant will have you complete a questionnaire about your experience with HIV, transitioning to adult care, peer support, mood, self-esteem, and connection to the clinical staff. If you are in the intervention group, you will participate in one in-person introduction meeting followed by at least 10 twice weekly virtual WhatsApp closed discussion groups with adolescents and healthcare providers. Discussions will include topics such as stigma, disclosure, and self-esteem among others. If you are not selected for the intervention, you will receive standard of care. After 6 months you will complete an additional questionnaire and have another blood draw for viral load. If you are in the intervention group you will also participate in a one-on-one interview asking about the intervention. You also have the option of completing an additional interview or focus group about the stigma session. All conversations will be recorded and later copied down. Your responses will be anonymous and your name will not be recorded.

WHAT ARE THE RISKS OF THE STUDY?

Participating in the questionnaire, interview, or WhatsApp discussion group may cause you to feel anxious. You may take breaks at any time and you may refuse to answer any questions. This will not affect your participation in the study. If you have concerns, we can help you get counseling.

Participation in any research study involves the risk of loss of privacy. To protect against this risk, we will conduct all study-related activities in a private space. We will not permanently record any personal identifying information. We will not use your name. Your information will be linked to a code. All electronic data will be kept on password protected, encrypted computers. Paper documents will be kept in a secure, locked cabinet. The researchers will not discuss any information about you with anyone other than study investigators. We will ensure that your cell phone and What's App conversations are password-protected.

There is one in person introduction session that could expose participants to COVID. However, all participants will be required to use masks (provided), be physically distant, and use hand sanitizer (provided) during the session.

For the blood draw there is a risk of pain, infection, or blood clots. This risk is not different from blood draws for clinical purposes.

Participation or non-participation will not influence your care provided by the clinic.

WILL YOU BE COMPENSATED?

You will not be charged any fees or expenses related to this study. You will receive R250 on the day you complete the questionnaire and blood draw to cover transport costs. At the end of the study, you will receive an additional R250 for completion of the follow-up questionnaire and blood draw. If you are in the intervention group, you will receive an additional R150 for participating in each additional interview. You will also receive airtime/data to allow your continued participation in the intervention.

ARE THERE BENEFITS TO TAKING PART IN THIS STUDY?

There is no medical benefit to you for participating in this study. You may benefit from the education and experiences in the discussion group. The information we get from this study may help us to improve the treatment for adolescents living with HIV as they transition to adult based care.

CAN YOU BE REMOVED FROM THE STUDY WITHOUT YOUR ASSENT?

Your participation in this study is entirely voluntary. You may decide not to participate, or you may end your participation at any time without harming your future medical care or losing any benefits to which you are entitled.

The study staff may end your participation at any time if it is felt to be in your best interests or if you do not follow the instructions of study personnel.

WHAT ABOUT CONFIDENTIALITY?

Your personal identity, name, address, and other identifiers will remain confidential. In the database, you will only be referred to by a code number. The study doctor can use the study results as long as you cannot be identified.

WHO DO YOU CALL IF YOU HAVE QUESTIONS OR PROBLEMS?

Dr. Zanoni and/or Thobe Sibaya have explained this study to you and answered your questions. If you have any questions, feel free to ask them. If a study-related problem should occur, or if you have any questions or concerns regarding the study at any time you may contact the following study staff:

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[redacted]

Co-Investigator:
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[redacted]
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[redacted]

PARTICIPANT ACKNOWLEDGEMENT:

☐ You have been told that your participation in this research study is voluntary. You have read the information above describing this study and all of your questions have been answered to your satisfaction. You voluntarily give your consent to participate in this research study.

☐ I agree to be contacted for clarification, follow up questions, and/or to participate in additional studies that may arise.

Contact number:_____

Name of Participant	Age
Signature of Participant	Date
Signature of Person Conducting	Date
Signature of Witness (if participant is illiterate)	Date