Informed Consent Form

Interactive Transition Support for Adolescents Living with HIV Comparing Virtual and In-person Delivery Through a Stepped-wedge Cluster Randomized Clinical Trial in South Africa (InTSHA VIP)

IRB Approval Date: October 30, 2023

NCT06035445

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

InTSHA VIP: Interactive Transition Support for Adolescents livening with HIV – Virtual or in-person

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
Moherndran Archary, MBChB, PhD
Maryam Shahmanesch, MD, PhD
Kathy Baisley, Msc
Jessica Haberer, MD, MS
Vincent Marconi, MD

Staff: Thobekile Sibaya
Nompumelelo Ndela

WHY IS THIS STUDY BEING DONE?

The research study is to compare in-person or virtual support groups 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.

Approximately 600 adolescents will be enrolled in the study.

WHAT IS INVOLVED?

If you agree to be in this study, your participation will consist of completing questionnaires 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 in-person or virtual intervention groups 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 one of the intervention groups, you will participate in either monthly in-person adolescent-friendly peer support groups or twice monthly virtual WhatsApp closed group discussions with other adolescents. Each intervention will last approximately nine months. 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 9, 18, and 24 months you will complete a questionnaire and have a blood draw for viral load. If you are in the intervention group, you may also participate in a one-on-one interview asking about the intervention. 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 in-person or WhatsApp discussion groups 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 personally 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 the study investigators. We will ensure that your cell phone and What's App conversations are password-protected.

The in-person sessions could expose participants to COVID. However, all participants will be required to use masks (provided), 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 the 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 R350 on the days you complete the questionnaire and blood draw to cover transport costs (at study entry, 9 months, 18 months and 24 months after study entry). If you are in the intervention group, you will receive an additional R350 for participating in each additional interview. You will also receive airtime/data and/or transportation reimbursement 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 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.

Certificate of Confidentiality

There is a Certificate of Confidentiality from the United States National Institutes of Health for this Study. The Certificate of Confidentiality helps us to keep others from learning that you participated in this study without your permission. However, the Certificate of Confidentiality may not be effective for data held outside of the United States.

Confidentiality

Your child's identity, medical records and participation in this research will be strictly confidential, i.e. your child's name will not appear with the information, except here in the hospital. No information identifying your child will be sent to the United States. At the end of the study, we will write a report about the results of the study and publish the results of this study so that other doctors can learn about it. These reports will not include any information relating to you or your child personally, e.g. your child's name or where you live. We ask your permission for authorised medical staff, clinical monitors or auditors, the study sponsors and the University of KwaZulu-Natal's Biomedical Research Ethics Committee (BREC) to have access to this information to ensure that the study is being conducted correctly. By signing this written informed consent form, you are giving permission for this to be done.

WHO DO YOU CALL IF YOU HAVE QUESTIONS OR PROBLEMS?

Drs. Zanoni/Archary and/or Ms Thobekile 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:

Principal Investigators:

Brian Zanoni, MD
[redacted]

Moherndran Archary, MBChB
Pediatric Infectious Disease,
King Edward VIII Hospital
[redacted]

Research Assistant:
Thobe Sibaya
[redacted]

BIOMEDICAL RESEARCH ETHICS ADMINISTRATION
Research Office, Westville Campus
Govan Mbeki Building
University of KwaZulu-Natal
[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 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