SYV: A Mental Health Intervention to Improve HIV Outcomes in Tanzanian Youth

Duke IRB # Pro00109309

CT.gov # NCT05374109

Principal Investigator: Dorothy Dow, MD

Consent form attached

Form
M0345

TUMAINI UNIVERSITY KILIMANJARO CHRISTIAN MEDICAL COLLEGE

K.C.M.C Kilimanjaro Christian Medical Centre

Duke University Health System

Minor Consent Form English

Consent to Participate in a Research Study
SYV: A Mental Health Intervention to Improve HIV Outcomes in Tanzanian Youth
Study Version 2 dated July 28 2022, Consent Form Version Date: August 3, 2022,

INTRODUCTION
You are being asked to allow your child to take part in this research study because he/she has HIV and attends the local adolescent HIV clinic. Research studies are voluntary and include only people who choose to take part. Please read this consent form carefully and take your time making your decision. As your study doctor or study staff discusses this consent form with you, please ask him/her to explain any words or information that you do not clearly understand. We encourage you to talk with your family and friends before you decide to allow your child to take part in this research study. The nature of the study, risks, inconveniences, discomforts, and other important information about the study are listed below. Please tell the study doctor or study staff if your child is taking part in another research study.

Who will be my child's study doctors?
Dr's Blandina Mmbaga, Aisa Shayo, and Dorothy Dow will conduct the study and it is funded by the National Institutes of Mental Health. of the United States of America.

WHY IS THIS STUDY BEING DONE?
The purpose of this study is to evaluate if a mental health and life skills intervention helps to improve mental health, coping with stressors, and helps youth take their antiretroviral therapy (ARVs). The study will continue to assess mental health needs and invite caregivers or another trusted adult chosen by the youth to come to a few of the lessons. The ultimate goal is to improve overall health and ART adherence of HIV positive youth.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?
Approximately 175-200 youth will take part in this study at this site. The study is taking place across four sites in Tanzania (Kilimanjaro, Mwanza, Mbeya, and Ifakara) and therefore a total of 700-800 youth.

WHAT IS INVOLVED IN THE STUDY?
If you agree for your child to be in this study, you will be asked to sign and date this consent form. By allowing your child to participate, he/she may will be randomly assigned to either the SYV study lessons plus regular care or continue your usual regular care (no additional lessons). We will assign your child to one of these groups using a computer. Your child will have a 1 in 2 chance of receiving the lessons, but will be asked to attend all the study visits.

1. If your child is randomized to participate in the SYV study lessons, he/she will be asked to attend each lesson lasting approximately 90 minutes every week for 12 weeks. This includes 10 group study lessons and 2 individual meetings as well as a final celebration. He/she will continue to attend the regular HIV clinic. After 12 months, your child will be invited to return to receive a brief reminder about the lessons learned (a booster session).
2. All study participants will be asked to attend study visits. As part of the study visits, your child will be asked questions about adherence, stigma, and mental health issues regarding depression, coping, and trauma in the form of a survey. We will obtain 5-10 mL of blood to be stored at your local laboratory and used for HIV RNA and potentially resistance (genotype) testing and any markers of inflammation. We will also ask to take a hair sample, (20-30 strands of hair; note, you naturally lose more hair than this every day). The hair sample will be used to measure the amount

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of ARV in the body and potentially any markers of inflammation. This same process will take place at enrollment, after the randomized group completes study lessons (4 months), and 6 months, 12 months, and 18 months after the intervention began. Travel costs will be reimbursed and food or a food coupon equivalent provided at each study visit.

3. We may also invite your child to participate in an in-depth interview or focus discussion group to share their experiences as part of the study.

As part of participation, your child's chart will be reviewed for medical information, for example adherence, prior CD4 and viral load studies, which have been drawn as standard of care or for other research studies.

Please note participation is voluntary. Refusal to participate will involve no penalty or loss of benefits to which your child is otherwise entitled. If you do not sign this consent , your child will continue to receive care, but not as a part of this study.

HOW LONG WILL MY CHILD BE IN THIS STUDY?
Your child will be in this study for approximately 18-24 months. Your child's participation includes potentially receiving the study lessons, five study visits and potential focus group discussions or in-depth interviews. If he/she decides to stop participating in the study, we encourage you and your child to talk to your research doctor first.

WHAT ARE THE RISKS OF THE STUDY?
Physical risks involved in this study are minor. As with any blood draw, the risk of having to repeat the blood draw is possible and bleeding or bruising may occur. These risks are no more than that for routine standard of care lab tests. There is very minimal risk to the hair sample as the study nurse or research assistant will simply cut with scissors (no razors) a few strands of hair near your child's scalp. Psychological trauma is also a possibility as some of the questions and or lessons could bring up uncomfortable memories. Your child may refuse to answer any of the questions and you may take a break at any time during the study. While we will periodically remind all study participants to respect confidentiality, we cannot guarantee complete confidentiality of any information you share with other study participants.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?
There may be direct medical benefit to your child in the form of decreased stress, improved coping skills and wellness, and improvement in adherence to medication (ARVs). The information learned from this study should benefit our knowledge of the impact of the study lessons on your child's mental and physical health. The early data showed the lessons helped participants take their medication and their virus to be suppressed. If your child is experiencing depressive, anxiety, or trauma symptoms, a health care professional will be immediately available to discuss these symptoms.

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WILL MY CHILD'S INFORMATION BE KEPT CONFIDENTIAL?
Study staff will protect your child's information closely so no one without proper authorization will be able to connect your child's responses to any other information that identifies your child. But, if your child tells us about an intention to harm him- or herself or others, or we learn about abuse, we need to follow Tanzanian guidelines and may need to break confidentiality so we can immediately link your child to mental health support or social services.

This study will collect Personally Identified and Personally Unidentified Study Data. Personally Identified Study Data includes name, contact information, and any other information that could directly identify your child. Personally Unidentified Study Data includes all other information that does not directly identify your child, such as health information your child provides to the study. In addition to data, we also collect the blood and hair samples described above.

Every effort will be made to keep your child's Personally Identified Study Data confidential. During the study, data will be kept in protected files that only the research staff can access. Any Personally Identified Study Data will be removed or changed ("de-identified") before files are shared with other researchers or results are made public. We may have to share Personally Identified Study Data in order to meet laws or regulations.

After the study concludes, Personally Identified Study Data will be retained by Duke University for 6 years; and Kilimanjaro Christian Medical Center and Tumaini University-Kilimanjaro Christian Medical University College in accordance with Tanzanian laws pertaining to data protection and their data retention policies. Personally Unidentified Study Data will be stored in the NIMH Data Archive and potentially other data archives. None of your child's Personally Identified Study Data will be stored in any data archive. Blood samples will be kept at your local lab after the study ends so they can be used for other research purposes. Hair samples will be sent to a lab at University of California San Francisco to be analyzed for this study, then destroyed. While the labs will not have any Personally Identified Study Data about your child, there is a theoretical possibility that your child could be identified later from any genetic data contained in a sample.

The study consent form will be retained in your child's research record for at least six years after the study is completed. Your child's viral load (HIV RNA) results will be made available in your medical record indefinitely.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

WHAT ARE THE COSTS?
There will be no additional costs to your child as a result of being in this study.

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Your child will be reimbursed for travel expenses related to his/her participation and food or a food coupon equivalent for a meal (5,000 tsh, $2.25 value) will also be provided.

WHAT ABOUT MY RIGHTS TO DECLINE PARTICIPATION OR WITHDRAW FROM THE STUDY?
You may choose not to allow your child to be in the study, or, if you agree for your child to be in the study, your child may withdraw from the study at any time. If your child withdraws from the study, no new data about your child will be collected for study purposes other than data needed to keep track of your withdrawal. Data already entered into the study database cannot be withdrawn.

Your decision not to allow your child to participate or a decision to withdraw from the study will not involve any penalty or loss of benefits to which your child is entitled, and will not affect your child's access to health care. If your child does decide to withdraw, we ask that you contact Drs. Blandina Mmbaga, Aisa Shayo, and/or Dorothy Dow to let a doctor know that your child is withdrawing from the study. A doctor should be notified in writing, in the case of study withdrawal and withdraw notification can be sent to KCMC-Duke Collaboration, P.O. Box 3010, Moshi Tanzania. We will tell you about new information that may affect your child's health, welfare, or willingness to stay in this study. Your doctor may decide to take your child off this study if your child's condition gets worse, if your child has serious side effects, or if your study doctor determines that it is no longer in your child's best interest to continue.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?
For questions about the study or a research-related injury, or if you have problems, concerns, questions or suggestions about the research, contact Drs. Blandina Mmbaga, Aisa Shayo, and Dorothy Dow.

For questions about your child's rights as a research participant, or to discuss problems, concerns or suggestions related to the research, or to obtain information or offer input about the research, contact the KCMC Ethics Committee at 27-275-3616 or National Health Research Ethics Committee at NIMR: 22-212-1400 during regular business hours.

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Parent/Guardian Initials _____

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STATEMENT OF CONSENT
"The purpose of this study, procedures to be followed, risks and benefits, have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have questions, to discuss problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research. I have read this consent form and agree for my child to be in this study, with the understanding that he/she may withdraw at any time. I understand that by signing I am authorizing the use and release of my study data as described in this consent form. I have been told that I will be given a signed and dated copy of this consent form."

☐ I consent for my child to participate in the Sauti ya Vijana Study

☐ I consent to blood sample from my child being stored in my local laboratory for possible future research testing.

_____ _____
Signature of Subject Date and Time

_____ _____
Signature of Person Obtaining Consent Date and Time

DUHS IRB
IRB NUMBER: Pro00109309
IRB REFERENCE DATE: 08/30/2022
IRB EXPIRATION DATE: 02/09/2024

Parent/Guardian Initials _____