TUMAINI UNIVERSITY KILIMANJARO CHRISTIAN MEDICAL COLLEGE

Kilimanjaro Christian Medical Centre

DUKE UNIVERSITY HEALTH SYSTEM

Minor form, English

Consent to Participate in a Research Study

Integrating Mental Health into a HIV Clinic to Improve Outcomes Among Tanzanian Youth

Version 1, February 2015 Protocol ID: 540 (KCMC)

INTRODUCTION

You are being asked to allow your child to take part in this research study because he/she has *HIV* and attends Teen Club at KCMC or Mawenzi CTC every month. 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?

Drs Blandina Mmbaga, Aisa Shayo, and Dorothy Dow will conduct the study and it is funded by the National Institutes of Health, Fogarty International of the United States of America.

WHY IS THIS STUDY BEING DONE?

The purpose of this study is to develop a tool kit for adolescent HIV clinics including a HIV curriculum and cognitive behavioral therapy intervention and to implement the intervention as part of the youth clinic. The study will continue to assess mental health needs among HIV-positive youth and include the caregiver perspective to understand how these mental health problems affect the ability to take HIV medication every day. The ultimate goal is to improve overall health and ART adherence among HIV positive youth.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

Approximately 250 youth will take part in this study from Kilimanjaro Christian Medical Centre (KCMC) and Mawenzi CTC. We hope to also enroll 50 caregivers of enrolled youth to participate in information gathering sessions about the caregiver perception of youth adherence and mental health.

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 be asked to attend a small focus group session to discuss depression, anxiety and trauma and to help modify the cognitive behavioral therapy and HIV curriculum. Your child will be randomly assigned to either participate in the cognitive behavioral therapy sessions in addition to his/her regular care or receive just his/her regular care (no cognitive behavioral therapy sessions). We will assign your child to one of these groups by flipping a coin. Your child will have a 1 in 2 chance of participating in the cognitive behavioral therapy sessions.

1. If your child is randomized to participate in cognitive behavioral therapy, he/she will be asked to attend each session lasting approximately 2 hours, 3 weeks per month for 4 months inclusive of 12 sessions. He/she will receive the regular HIV educational curriculum as part of routine clinic. He/she 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 3-5 mL of blood to be used for HIV RNA and potentially resistance testing. We will also ask to take a hair sample, (20-30 strands of hair; note, you naturally lose more hair than this every day). This same process will take

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place at enrollment, before the cognitive behavioral intervention, and 3 months, 12 months, and 24 months after the intervention has completed. Travel will be reimbursed and food or a food coupon equivalent provided at each visit.

2. If your child is assigned to receive the regular HIV educational curriculum, he/she will still be asked questions about adherence, stigma, and mental health issues regarding depression, coping, and trauma in the form of a survey. We will obtain 3-5 mL of blood to be used for HIV RNA and potentially resistance testing. We will also ask to take a hair sample, (20-30 strands of hair; note, you naturally lose more hair than this every day). This same process will take place at enrollment, before the cognitive behavioral intervention, and 3 months, 12 months, and 24 months after the intervention has completed. Travel will be reimbursed and a food or a food coupon equivalent will be provided.

As part of participation, your child's chart will be reviewed for information on 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 form 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 28 months. Your child's participation includes a potential focus group discussion of the questions used in the cognitive behavioral therapy and HIV educational curriculum to make sure they are relevant and make sense. After enrollment your child will be asked to complete a preliminary visit, and 3 visits at 3 months, 12 months, and 24 months after his/her cohort completes the intervention. The study could last up to four years requiring only 3 visits after the intervention is complete. If he/she decide 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 as is bleeding and bruising. 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 will simply cut with scissors (no razors) a few strands of hair near your scalp. Risk includes accidental cutting too close to the scalp or a loss of a braid. Psychological trauma is also a possibility as some of the questions and or sessions could bring up uncomfortable memories. Your child may refuse to answer any of the questions and you may take a break and even stop at any time during the study.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?
There may be direct medical benefit to your child in the form of decreased stress and improved mental wellness. The information learned from this study should benefit our knowledge of the impact of cognitive behavioral therapy on mental health and coping skills and in turn help you transition to a more productive

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adult life. If your child is experiencing depressive, anxiety, or trauma symptoms, a health care professional will be immediately available to discuss these symptoms. Your child will receive free virologic monitoring not currently available as standard of care. This information will be available to you and to your doctor and will help in decisions about your child's medication. Hair samples will be used for research purposes to inform best drug dosing and ways to improve adherence.

WILL MY CHILD'S INFORMATION BE KEPT CONFIDENTIAL?
Every effort will be made to keep your child's information confidential. Study records that identify your child will be kept confidential. Privacy Regulations provide safeguards for privacy, security, and authorized access. You will not be identified by name, hospital number, address, telephone number, or any other direct personal identifier in any study records disclosed outside of Kilimanjaro Christian Medical Centre (KCMC) or Mawenzi Hospital. For records disclosed outside of KCMC or Mawenzi, your child will be assigned a unique code number. The key to the code will be kept in a secure, password protected electronic file.

Your child's records may be reviewed in order to meet federal or state regulations. If any of these groups review your research record, they may also need to review your child's entire medical record. Reviewers may include the Kilimanjaro Christian Medical Centre (KCMC) Institutional Review Board and the Duke University Health System Institutional Review Board.

The study results will be retained in your child's research record for at least six years after the study is completed. At that time either the research information not already in your child's medical record will be destroyed or information identifying you will be removed from such study results at KCMC. Your child's viral load results will be made available and remain in your child's medical record indefinitely. While the information and data resulting from this study may be presented at scientific meetings or published in a scientific journal, your child's identity will not be revealed.

WHAT ARE THE COSTS?
There will be no additional costs to your child as a result of being in this study.
You will be reimbursed for travel expenses related to your participation and food or a food coupon equivalent for a meal (4,000 tsh value) at the local Canteen will also be provided.

Reimbursement:
Moshi Urban: TSH 2,000
Moshi Rural: TSH 4,000
Hai: TSH 5,000
Siha: TSH 10,000
Mwanga Urban: TSH 7,000
Mwanga Rural: TSH 12, 000
Same Urban: TSH 8,000
Arusha: TSH 10,000
Rombo: TSH 10,000

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WHAT ABOUT MY RIGHTS TO DECLINE PARTICIPATION OR WITHDRAW MY CHILD 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 to 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 Dr. Blandina Mmbaga, Dr. Aisa Shayo or Dr. 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 Dr. Aisa Shayo (0754298894), or Dr. Dorothy Dow (0762431127).

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 Kilimanjaro Christian Medical Centre (KCMC) Institutional Review Board or KCMC ethics committee (phone number 027 27-53909).

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STATEMENT OF CONSENT

"The purpose of this study, procedures to be followed, risks and benefits have been explained to my child and 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 I may withdraw my child at any time. We have discussed the study with my child, who agrees to be in the study. I have been told that I will be given a signed and dated copy of this consent form."

_____	_____	_____
Signature of Subject	Date	Time
_____	_____	_____
Signature of Parent/Guardian	Date	Time
_____	_____	_____
Signature of Person Obtaining Consent	Date	Time