Form
M0345

Duke University Health System

**Consent To Participate In A Research Study**
Informing, Designing, and Testing a Telehealth Intervention to Address Mental Health and HIV in Tanzania
**Version: 3 – Clinical Trial**
**Version Date: 7 August 2023**

Telehealth to Reduce Suicidality and Improve HIV Care Engagement in Tanzania

NCT04696861

Unique Protocol ID: Pro00107424

K08MH124459 [U.S. NIH Grant/Contract Award Number]



Subject Initials:_____

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## INTRODUCTION

The purpose of this research is to develop a brief telehealth counselling intervention to provide support for suicidality and HIV care engagement. This phase of the study will be testing the counselling intervention. Potential risks to participants in this study include unintended consequences such as stigma if others come to know that you are participating in the research, and emotional reactions related to talking about HIV and mental health challenges. All of the research activities are completely optional and will not influence your ability to receive care at the clinic. If at any point you are feeling unsafe, including feeling that you might harm yourself, we strongly encourage you to contact mental health professionals at KCMC Hospital, Mawenzi, or Majengo for support.

This form will give you an explanation of the research. I will read this consent form with you and allow you to take time making your decision. Please ask if there are words or information that you do not clearly understand. This study is being conducted together by Dr. Brandon Knettel at Duke University in the United States, with the support of Dr. Blandina Mmbaga at Kilimanjaro Christian Medical Centre.

## WHY IS THIS STUDY BEING DONE?

The purpose of this research is to develop a brief telehealth counselling intervention to provide support for suicidality and HIV care engagement. In this phase of the study, we will be assessing whether the counselling program we developed can be implemented in two clinics in the Kilimanjaro region, and how the counselling program affects the well-being of people who participate.

## HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

This phase of the study will include approximately 60 people. Participants will be people living with HIV who are 18 years or older and who endorse having recent thoughts of suicide. 20 participants will be invited to complete an interview about their experience.

## WHAT IS INVOLVED IN THE STUDY?

Participation in this study is entirely voluntary, and you are free to leave the study at any time. After signing and dating this consent form, you will be asked to complete an interviewer-administered structured survey, conducted by a research assistant in a private space. The survey will take approximately 60 minutes.

We do not know yet how different types of counseling may help people with suicidal thoughts. For this reason, you will be randomly placed in one of two groups after you complete the survey. You will receive either: (1) a brief approximately 20-minute counselling session to make a plan for your safety; or (2) the three longer counselling sessions, held every two weeks, aimed at building skills to cope with HIV and suicidal thoughts. The first session today will be up to one hour long. The other sessions will be 30 minutes. We will decide your group randomly, like when you toss a coin. You cannot choose which part of the study you will be selected into. Counselling sessions today will occur in a private space in the clinic using a WhatsApp video call on a mobile phone provided by the study staff. You will



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use the phone to connect with the counsellor, a nurse based at KCMC. If you receive the additional counseling sessions, you will have the option to come back to the clinic for future sessions using our phone, or you can choose to receive a phone call or WhatsApp call on your own phone.

With your permission, counseling sessions will be audio recorded. This will help our counselors improve their training. We may also use the recordings to write a paper to understand and improve how people will benefit from counseling. If we do this, all identifying information such as names or places will be removed from the transcripts of the recordings.

After today's session, participants in both groups will receive text messages once per week to check in on you and ask how you are feeling. You may also call the study staff to request additional counselling support at any time during normal business hours while you are in the study. If at any point you are feeling unsafe, including feeling that you might harm yourself, we strongly encourage you to contact mental health professionals at KCMC Hospital, Mawenzi, or Majengo for support.

You will be asked to complete a follow-up survey in three months. The survey will take place in a private room here at the clinic or will be conducted by phone and will take approximately 60 minutes. We will also collect information from your medical record during the study period in order to record how often you come to the clinic and other information about your clinical care.

You may also be invited to do an additional one-on-one interview. If you chose to do this interview, you will be asked about your experiences with the counseling sessions. With your permission, the interview will be audio recorded and we will use the voice recording to write down our conversation. All names and identifying information will be removed from the transcript.

At the time of each study activity, the procedure for that activity will be clearly explained to you. You have the option to decline participation in any study activity at any time. In order to keep in touch with you between the study activities, we will collect your name, phone number and address, as well as the contact information of someone close to you who we can contact in cases of emergency or if we are unable to reach you. This information will be stored separately from study information we collect and will be kept private.

**HOW LONG WILL I BE IN THIS STUDY?**
The total length of time you will spend in the study is up to 3 months. You can choose to stop participating at any time without penalty or loss of any benefits to which you are entitled.

**WHAT ARE THE RISKS OF THE STUDY?**
The study procedures that have been selected have only minimal risk. Nevertheless, the protocol raises two general areas of human subjects concerns:



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Confidentiality. Every effort will be made to keep your information confidential and protected. No personal information will be shared with anyone outside of the study team, except in the case of an emergency. If the study team has immediate concerns about your safety, we may inform medical providers or your trusted contact. Identifying information such as consent forms and your name will be always be kept separate from study data so that interview data are kept private.

Discomfort. This study may make you feel uncomfortable as you talk about topics such as mental health and HIV. You may feel embarrassed or shy, and sometimes it may bring up personal information that makes you feel emotional.

**ARE THERE BENEFITS TO TAKING PART IN THE STUDY?**
You may get some benefit from the study by receiving the counselling. Additionally, research projects like these are done to gain scientific knowledge that will help others. We expect that the results of this study will inform the development and delivery of counselling services for people living with HIV in Tanzania and similar settings in the future. You will help us learn information that will help us improve services for people living with HIV.

**WILL MY INFORMATION BE KEPT CONFIDENTIAL?**
All documents and audio-recordings will be stored in a locked filing cabinet or on a password protected computer. Study information will be identified only by a number, not your name. The key to the code will be stored in a separate password protected document on a password protected computer, to which only essential study staff will have access. Any documents containing your name and personal information will be kept separate from other study records, and will be stored in a secure way. Your records may be reviewed by the sponsor of the study (U.S. National Institutes of Health) and their representatives, Duke University or Kilimanjaro Christian Medical Center institutional ethical committees, and study staff.

If we write about this work, your identity and personal information will remain anonymous. If requested, we may share de-identified data with other researchers. We will not include any information that could identify you.

**A description of this clinical trial will be available on 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 costs to you as a result of being in this study.



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**WHAT ABOUT COMPENSATION?**
You will receive 10,000 TSh at each counselling session and the 3-month survey time point at the clinic to compensate you for your time and the cost of transportation to the clinic. If you choose to complete a counseling session from another location using a video call, you will receive 10,000 TSh for your time and the cost of data. If you choose to receive a phone call for counseling, we will call you at no cost to you, and you will receive 5,000 TSh for your time. If you participate in the additional one-on-one interview at the clinic, you will receive an additional 10,000 TSh.

**WHAT ABOUT MY RIGHTS TO DECLINE PARTICIPATION OR WITHDRAW FROM THE STUDY?**
You may choose not to be in the study, or, if you agree to be in the study, you may withdraw from the study at any time. If you require additional time to make a decision about whether to participate, you may request to enroll at a later date. If you enroll and later decide to withdraw from the study, no new data about you will be collected for study purposes. Your decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits to which you are entitled. If you do decide to withdraw, we ask that you contact Dr. Blandina Mmbaga in writing and let her know that you are withdrawing from the study. Her mailing address is Dr. Blandina Mmbaga, KCMC 3010, Moshi, Tanzania, and her email is blaymt@yahoo.com.

**WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?**
For questions about the study, a research-related injury, or if you have complaints, concerns, or suggestions abut the research, contact Dr. Blandina Mmbaga at KCMC 3010, Moshi, Tanzania, or phone number 0768-435-116.

If at any point you are feeling unsafe, including feeling that you might harm yourself, we strongly encourage you to contact mental health professionals at KCMC Hospital, Mawenzi, or Majengo for support. The main operator at KCMC can be reached at +255 27 2754377 or +255 27 2754380. Dr. Kessy at Mawenzi can be reached at +255 76 3755419. Dr. Mariki at Majengo can be reached at +255 75 5821679.

If you wish to contact someone outside of the study team about your rights as a research participant, to obtain additional information, or with problems, concerns or suggestions related to the research, you can call the Ethics Committee of KCMC at the phone number +255-27-2753616 or you can contact the Duke University Health System Institutional Review Board (IRB) Office at +1-919-668-5111.

A description of this clinical trial is available on www.ClinicalTrials.gov (Protocol # NCT04696861). 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.



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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 to be in this study, with the understanding that I may withdraw at any time. 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 Person Obtaining Consent | Date | Time |