Official Title: Telehealth to Reduce Suicidality and Improve HIV Care Engagement in Tanzania

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General Information

*Please enter the full title of your protocol:		
Telehealth to Reduce Suicidality and Improve HIV Care Engagement in Tanzania		
*Please enter the Short Title you would like to use to reference the study:		
Suicidality and Care Engagement in Tanzania * This field allows you to enter an abbreviated version of the Study Title to quickly identify this study.		

Standard Research Summary

Purpose of the Study

- Objectives & hypotheses to be tested

The overall objectives of the proposed research are to develop a brief telehealth counseling intervention to provide support for suicidality and HIV care engagement, and to reduce the mental health treatment gap in Tanzania. Duke has longstanding collaborations with Kilimanjaro Christian Medical Centre and affiliated HIV clinics, making this an ideal environment for this work.

The investigators hypothesize that a brief telehealth counseling intervention for people living with HIV and experiencing suicidal ideation will be safe (participants in the clinical trial will not have increased risk of suicidal behavior), acceptable (high patient retention and satisfaction, high fidelity), and will demonstrate preliminary efficacy of the intervention (reduced suicidal ideation, improved care engagement, improved mental well-being).

Background & Significance

- Should support the scientific aims of the research

Mental health comorbidities, particularly depression, are key drivers of the global HIV epidemic, contributing to substandard HIV care engagement, reduced quality of life, increased transmission risk, and lower life expectancy among people living with HIV (PLWH).[1–3] Depression is exceedingly prevalent among PLWH[4–6] and suicidal ideation is a common response to an HIV diagnosis, making suicide a leading cause of death among PLWH worldwide.[7,8] However, when PLWH have access to mental health treatment that includes adherence counseling, both mental health and HIV outcomes improve.[9,10] Thus, there is an urgent need to enhance access to quality mental health treatment that addresses the unique needs of PLWH.[11,12]

Throughout much of the world, mental health services are inadequate to meet the needs of the population. In Tanzania, fewer than 300 mental health workers are tasked with providing care coverage for 58 million people, placing it among the world's most underserved nations for mental health care.[13] Counseling services in Tanzania are rare and difficult to access, while inpatient treatment is reserved almost exclusively for severe psychosis, leaving few options for people with suicidal ideation.[14] Meanwhile, rates of death by suicide are extremely high, and more than double among PLWH.[15,16] In the context of such challenges, new approaches are emerging to bridge the mental health treatment gap, including the use of telehealth-delivered counseling.

Phone-based interventions for mental health (telehealth) have expanded rapidly in the COVID-19 era, and are promising approaches for increasing access to care.[17,18] In Tanzania, mobile phone use is widespread and rapidly expanding, with 75% of the population owning a mobile phone and 38% using mobile Internet.[19] These advances create opportunities to extend the reach of health services that are otherwise unavailable to large swaths of the population, including programs to improve HIV care engagement[20], reduce HIV stigma[21], and treat depression and suicidality.[22] However, few studies have attempted to integrate these areas by developing mobile technology interventions for mental health screening and support in the context of HIV treatment.[21]

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Design & Procedures

- Describe the study, providing details regarding the study intervention (drug, device, physical procedures, manipulation of the subject or the subject's environment, etc.). Discuss justifications for placebo control, discontinuation or delay of standard therapies, and washout periods if applicable. Identify procedures, tests and interventions performed exclusively for research purposes or more frequently than standard of care. Include alternative therapies, concurrent therapies discontinued per protocol, risk benefit ratio, and use of tissue/specimens. Discuss monitoring during washout periods if applicable. Include brief description of follow-up, if any.

Study Setting. The study will be located in 4 health centers in Moshi, Tanzania: 1) Kilimanjaro Christian Medical Center (KCMC), a large tertiary hospital, 2) Mawenzi Hospital, a public facility housing the region's only inpatient psychiatry unit, 3) Majengo Health Center, a small urban health clinic, and 4) Pasua Health Centre, a small urban health clinic. KCMC and Mawenzi are the primary referral hospitals for the Northern Zone of Tanzania, covering an area of 122,000 km^2 and 7.7 million people. The adult Care and Treatment Clinics (CTCs) for HIV at these three hospitals currently test more than 300 people for HIV each month and provide HIV care for more than 6,000 PLWH in the region.

IRB and Informed Consent: The study will use Informed Consent forms approved by both the Duke and KCMC IRBs. Because KCMC is the primary government referral hospital in the Kilimanjaro region, the four health centres that will participate in this study all rely on the KCMC IRB for research approvals. Consent forms will be developed and translated in accordance with KCMC's established template and procedures, and will be approved by the KCMC IRB prior to use. Consent forms will be written in English and translated to Kiswahili by a trained bilingual translator, back-translated to English by a second translator, and the forms will be compared and revised to ensure clarity and equivalence in both languages.

Guiding Theoretical Frameworks for the Intervention. Intervention development will be guided by an experimental therapeutic approach[23] targeting untreated suicidal ideation as a contributor to substandard HIV care engagement. The details of the intervention will emerge through Aims 1 and 2 of the proposed research, and will be guided by two theoretical frameworks: cognitive behavioral therapy for depression with adherence counseling (CBT-AD) and MI-SafeCope, a brief model for suicide prevention. The intervention will be culturally-informed, designed for telehealth delivery, and pilot tested in a Stage I pilot feasibility trial.

CBT-AD was developed to treat depression and enhance antiretroviral treatment adherence among PLWH, with promising results in Zimbabwe and South Africa. The intervention involves CBT-based HIV education and problem-solving, isolating unique contributors to depressive symptoms among PLWH to facilitate HIV care engagement. However, CBT-AD is time-intensive at 6 sessions or more, and was not designed to specifically address suicidality. The Duke PI proposes to develop a telehealth intervention that will retain

the foundational components of CBT-AD while integrating a crisis-based model of suicide prevention, a condensed form of care focused on treating acute symptoms and securing the patient's immediate safety.

There are very few brief, validated models for suicide prevention and none have been used in Africa. One promising model with an emerging evidence base is MI-SafeCope, a Motivational Interviewing (MI) intervention that has shown potential to reduce depressive symptoms and increase coping for suicidality in U.S hospitals. The components of MI-SafeCope are 1) developing an individualized safety plan, 2) facilitating social support, and 3) a telephone session to reinforce earlier content. These have direct relevance to my study given the suicide focus, brief delivery model, and precedent for telephone delivery.

Together, CBT-AD and MI-SafeCope, adapted to the context of HIV care in Tanzania, will provide a solid foundation for developing a brief telehealth intervention for suicide prevention, HIV education, and adherence counseling. A preliminary model is described below.

Preliminary Telehealth Model for Intervention Delivery. The proposed intervention will begin with implementing routine screening for depression and suicidality in adult HIV care at the 3 study sites. The screening tools, the PHQ-2 and Columbia-Suicide Severity Rating Scale (C-SSRS), contain 8 items assessing depression and suicidality in the past month, including thoughts, intent, plan, and actions. The PHQ has been validated in Tanzania. We propose to validate several additional study measures in a preliminary validation study with 80 patients living with HIV and experiencing suicidal ideation: the HIV Stigma Scale (HSS), Beliefs About Medicines Questionnaire (BMQ), Illness Cognition Questionnaire (ICQ), Columbia-Suicide Severity Rating Scale (C-SSRS), Self-Efficacy to Avoid Suicidal Action Scale (SEASA), Beck Hopelessness Scale-Short Form (BHS-SF), and Brief Reasons for Living Scale (BRFL).

Patients who endorse depressive symptoms only will receive brief supportive counseling to identify coping strategies and a referral for mental health services. Patients who screen positive for suicidal ideation (respond "yes" to any C-SSRS item) will be eligible for enrollment in the pilot clinical trial.

Once consented, the study team will assist patients to make a video call to the telehealth hub using a mobile phone. Video calls will be made using WhatsApp, a freely available, secure, and widely used mobile application with end-to-end encryption. Calls will be made free of charge (without data charges) using Wi-Fi hotspots made available at each study clinic. Patients who do not have an Internet-equipped phone will use study-owned phones. Private space will be provided in the research offices at each clinic for video calls

The telehealth hub will be located in the KCMC Psychiatry Clinic and will be staffed by two trained research nurses. The two study nurses will answer calls using study-provided tablets and will document patient care electronically, saved on a secure, password-protected electronic database. Nurses provide the majority of health care in Tanzania, including HIV and mental health care, and Moshi is home to many skilled nurses seeking career opportunities. In a setting where specialized mental health training is extremely rare, nurses are a natural fit to deliver a sustainable intervention. The telehealth model will allow for the delivery of all sessions by nurse-counselors at the central hub to efficiently reach patients at subsidiary regional HIV clinics.

Before the first call, the research assistant will gather patients' contact information, preferences for outreach in the event of a missed session, and information for an emergency contact. They will then connect to the telehealth hub and the nurse will begin the first of three counseling sessions. The initial intervention session will be approximately one hour in length, and the second and third sessions will each be approximately 30 minutes in length. Sessions will be held every two weeks to mirror the frequency of HIV clinic appointments for newly diagnosed patients. Patients unable to come to the clinic for follow-up sessions will be given the option to connect via video call or telephone call from the location of their choice. Additional support will be offered through weekly text message check ins and optional phone contacts and booster sessions. At the end of each session, the counselor will re-administer the C-SSRS and patients at acute risk of suicide will be accompanied to a mental health provider for further assessment. If the patient is unwilling to see a provider, the consulting psychiatrist and emergency contact will be called for support.

Aim 1: Identify the desired characteristics of a telehealth intervention for suicidality and HIV care engagement in the Tanzanian clinical context. To refine the intervention model and assess experiences with suicide risk screening and counseling, study personnel will conduct in-depth interviews (IDIs) with stakeholders including PLWH (n=36), clinic administrators (n=20), nurses (n=12), study counsellors (n=4), mental health workers (n=16), and religious leaders (n = 20). For the patient interviews, clinic nurses will assist in identifying adults in HIV care at the study clinics who previously experienced suicidal ideation or completed screening. All study staff will be trained in suicide assessment and safety planning. Administrators and health workers will be recruited from the study clinics. In-depth interviews with healthcare administrators will help inform strategies for future integration of the intervention into the healthcare system, and in-depth interviews with religious leaders will provide insight into their perspectives on the role of religion and spirituality in mental health and suicide prevention, and ways these perspectives might be integrated into the intervention.

Interview guides will be developed with user-centered design in collaboration with the Tanzanian research team and informed by CFIR domains. Participants will first be presented with the core characteristics of the intervention and asked to provide feedback on its adaptability (e.g., potential for tailoring to individual patients, local setting, and acute crisis format), complexity (difficulty of implementation), feasibility (telehealth model), and sustainability (integration into current models of care). Interviews will also explore the outer setting of patient needs and resources, the relative advantage of the intervention compared to other approaches, and external policies and incentives that could impact its scalability. We will also conduct interviews with participants who have completed screening for the study and study counsellors to explore the acceptability of screening, assessment, and counseling. All participants will receive compensation of 10,000 Tanzanian shillings ($4.50) for their time and costs of participation. Interviews will be conducted in Kiswahili or English by a trained research assistant in a private office and audio recorded for later transcription.

Supplementary Aim: First, all study measures will undergo a thorough process of translation, back-translation, and discussion to consensus with a team of bilingual researchers. Using the same recruitment procedures and eligibility criteria described in Aim 1, nurses will implement suicide screening during HIV clinic appointments. Patients (n=80) who screen positive for suicidality (i.e., respond "yes" to any C-SSRS item) will be notified of the research and, if interested, provide informed consent. Eligible participants who are not interested in participating will receive referrals and resources for mental health support. After providing consent, participants will complete the translated survey measures administered by trained study staff. These data will be used to validate the study measures in the Tanzanian clinical context through evaluation of internal consistency (Cronbach's alpha and item-scale correlation), convergent validity among related measures, and confirmatory factor analysis. Participants will receive an incentive of 10,000 TZ shillings ($4.50) to compensate for time and transport. Data collection for this Aim was completed in October 2022.

Aim 2: Refine content for the telehealth intervention with support from a study advisory board in Tanzania. The Duke PI will form an advisory board consisting of PLWH, nurses, mental health workers, administrators and local and regional government officials, to assist in refining the intervention. The advisory board will have approximately 15 members and will convene 3 times: 1) at the conclusion of Aim 1 to assist in refining the intervention prior to piloting by interacting with a prototype model, 2) midway through the clinical trial to review progress, and 3) at the conclusion of the trial to review and assist in interpreting findings. Key members of our previous KCMC advisory boards would be invited to continue their involvement for the current study.

Employing principles of user-centered design and an experimental therapeutic approach, study personnel will invite advisory board members to experience the intervention as a study participant would, by interacting with the intervention technology, counselors, and study surveys. The process will include eliciting continual, iterative feedback on the hypothesized mechanisms of change, to adapt the intervention model to the study-specific context. Board members will observe as a mock patient completes screening and informed consent procedures, then uses a mobile phone to connect with an off-site counselor to participate in a mock counseling session. The board will give feedback on the process and perceived effectiveness of the session, as well as potential drawbacks. Through this process, we will reshape the intervention in real time, identifying opportunities to improve the intervention and increase potential acceptability for both clinic staff and patients.

Using advisory board feedback, the study team will develop a detailed study protocol and intervention manual. Counselors will be trained research nurses with an understanding of mental health and counseling skills. Counselor training will be provided by the Duke PI (a licensed psychologist) and the consulting psychiatrist and will consist of 3 weeks of didactic and mock intervention sessions. This will include instruction in counseling skills, the intervention model, and ethical/safety considerations for research and counseling. During mock sessions, counselor skills and fidelity to the intervention will be assessed by the supervisors using an adapted Therapy Quality Scale (TQS), interrater reliability will be calculated, and disagreement > 1 point will be discussed to consensus. Counselors will be required to attain mean TQS scores ≥ 3 (on a 0-4 scale) in mock sessions prior to contact with participants. They will then complete supervised trial runs with 5 patients from the study clinics, which will be used to refine and finalize the intervention prior to starting enrollment in the clinical trial.

Aim 3: Pilot test the telehealth intervention in a randomized controlled trial to assess feasibility, acceptability, and potential efficacy for reducing suicidality and enhancing HIV care engagement. To evaluate the intervention, the study team will enroll 60 PLWH in a Stage I pilot feasibility trial. Participants will be adults who experienced suicidal ideation in the past month seeking HIV care at one of the 3 study clinics. Using the same recruitment procedures and eligibility criteria described in Aim 1, nurses will implement depression and suicide screening during HIV clinic appointments. Patients who screen positive for depression, but not suicidality, will not be eligible for the clinical trial but will receive a brief supportive counseling module based on WHO's Problem Management+ and a referral for further mental health support. Patients who screen positive for suicidality (i.e., respond "yes" to any C-SSRS item) will be referred to study staff, notified of the research and, if interested, provide informed consent. Eligible participants who are not interested in participating will receive referrals and resources for mental health support.

After providing consent, participants will complete a baseline survey administered by trained study staff. Participants will receive an incentive of 10,000 TZ shillings ($4.50) for each session at the clinic to compensate for time and transport. Participants who connect to calls from a location other than the clinic will receive 10,000 TZ shillings if connecting via video call (to compensate for time and data costs) and 5,000 TZ shillings if connecting by telephone call (as incoming calls will not incur costs to participants). Data collected at baseline will include measures of suicidality, HIV care engagement, and covariates such as stigma, social support, and quality of life. For measures not previously validated in Tanzania, the study team will complete a thorough linguistic and cultural translation process as established by Beaton et al., including back translation, validity checks, and piloting.

Assignment to condition. Upon completion of the baseline survey, participants will be individually randomized to receive either a brief Safety Planning Intervention (n=30), or the 3-session telehealth intervention (n=30). Participants will be randomized at a 1:1 ratio using a block randomization method (4 per block) to ensure equal sample sizes in each condition and to manage the flow of participants to the intervention condition. The allocation sequences will be prepared ahead of time using an online randomization program.

Intervention and control procedures. After randomization, participants will be guided to a private space and assisted to connect by video call to the nurse-counselor (based at KCMC). Upon connecting, control participants will receive the brief (20 minute) Safety Planning Intervention and intervention participants will complete the first of 3 telehealth-delivered counseling sessions. For intervention participants, the remaining sessions will be scheduled at two-week intervals. Patients unable to come to the clinic for follow-up sessions will be given the option to connect via video call or telephone call from the location of their choice. For participants in both conditions, prior to ending the call, the counselor will re-administer the C-SSRS and those at risk of suicide will be directly referred for psychiatric assessment and treatment to ensure their safety. Participants in both conditions will receive text message check ins from the counselors to inquire about their well-being and connect them to additional support as needed. Participants in both conditions will also have the opportunity to contact the telehealth counselors at any time during normal business hours for additional support throughout their participation in the study. These 'booster sessions' will be focused on assessing suicide risk, safety planning, and reinforcing prior session content.

It was clear in the feedback from NIMH that, given all trial participants will have screened positive for suicidal ideation, the study team would need to provide additional support for the control condition and not just "treatment as usual" or a referral for services. A brief safety planning intervention is the most common brief intervention for suicidal ideation. It involves identifying internal coping strategies, external resources for support, and planning formaking the environment safe: https://www.sprc.org/sites/default/files/SafetyPlanningGuide%20Quick%20Guide%20for%20Clinicians.pdf. Safety planning has a strong global evidence base.

Duke's role in the research. As the home institution of the PI, Dr. Knettel, Duke will provide office space and IT services, consultative services, grants and finance management, and library support for the research study. Duke students and postdoctoral associates may take on supportive roles in the reserch and will be added to the IRB protocol as appropriate. Duke IT will assist with procurement and software needs for research computers and tablets. Statistical support will be provided by Duke statisticians at Duke Global Health Institute and the Duke University School of Nursing.

Dr. Knettel's role in the research will be to lead the training of study personnel, including the study coordinator and research assistants and nurse interventionists. Dr. Knettel will help to establish research offices at the clinic sites, establish procedures for data collection and intervention delivery, oversee intervention delivery and data collection to monitor data quality, lead data analysis, and dissemination and reporting of research findings.

Selection of Subjects

- List inclusion/exclusion criteria and how subjects will be identified.

For Aims 1 and 2, clinic nurses will assist in identifying adults in HIV care at the study clinics who previously experienced suicidal ideation. Administrators, nurses and mental health workers will be recruited from the study clinics.

For the supplemental validation study and the Aim 3 clinical trial, clinic nurses will implement screening for suicidality in the clinics using the Columbia-Suicide Severity Rating Scale (C-SSRS), which contains 6 items assessing suicidal thoughts, intent, plan, and actions. Patients who screen positive for suicidality (i.e., respond "yes" to any C-SSRS item) will be notified of the research and, if interested, provide informed

consent for enrollment in the clinical trial. Eligible participants who are not interested in participating will receive referrals and resources for mental health support. Patients who are not eligible for the clinical trial but who screen positive for depressive symptoms will provide informed consent and be offered a brief counseling session focused on Problem Management. Patients who undergo screening for suicide assessment may also be referred for qualitative interviews.

All study participants across all aims will be at least 18 years of age, fluent in Kiswahili or English, and able to provide informed consent to participate.

Subject Recruitment and Compensation

- Describe recruitment procedures, including who will introduce the study to potential subjects. Describe how you will ensure that subject selection is equitable and all relevant demographic groups have access to study participation (per 45 CFR 46.111(a) (3)). Include information about approximately how many DUHS subjects will be recruited. If subjects are to be compensated, provide specific prorated amounts to be provided for expenses such as travel and/or lost wages, and/or for inducement to participate.

For Aims 1 and 2, we will use purposive sampling, asking HIV clinic nurses to identify current clinic patients who previously struggled with suicidal ideation and identifying individuals who have undergone screening for suicidal ideation.

For the supplemental Aim and Aim 3, clinic nurses will screen all adults attending HIV clinic appointments, and all patients who meet the eligibility criteria and screen positive for suicidal ideation will be eligible to be enrolled in the study/clinical trial, with those screening positive for depressive symptoms only being referred for Problem Management+.

All study recruitment will occur in Moshi, Tanzania and will no include DUHS patients. Participants will receive an incentive of 10,000 Tanzanian shillings (approximately $4.50) at each study contact at the clinic to compensate for their time and transportation costs. Intervention participants who connect to calls from a location other than the clinic will receive 10,000 TZ shillings if connecting via video call (to compensate for time and data costs) and 5,000 TZ shillings if connecting by telephone call (as incoming calls will not incur costs to participants).

Subject's Capacity to Give Legally Effective Consent

- If subjects who do not have the capacity to give legally effective consent are included, describe how diminished capacity will be assessed. Will a periodic reassessment occur? If so, when? Will the subject be consented if the decisional capacity improves?

Clinic nurses will assess the participant's capacity to provide consent prior to referring them to the study. Patients who lack the intellectual capacity to give legally effective consent, who are medically unstable, or who are in acute psychiatric distress, will not be enrolled and will instead be referred for appropriate care within the clinics. These participants will be screened for capacity again at their next HIV appointment, and will have the opportunity to enroll at that time if their decisional capacity has improved.

Study Interventions

- If not already presented in #4 above, describe study-related treatment or use of an investigational drug or biologic (with dosages), or device, or use of another form of intervention (i.e., either physical procedures or manipulation of the subject or the subject's environment) for research purposes.

The intervention is described in "Design & Procedures" above.

Risk/Benefit Assessment

- Include a thorough description of how risks and discomforts will be minimized (per 45 CFR 46.111(a) (1 and 2)). Consider physical, psychological, legal, economic and social risks as applicable. If vulnerable populations are to be included (such as children, pregnant individuals, imprisoned persons or cognitively impaired adults), what special precautions will be used to minimize risks to these subjects? Also identify what available alternatives the person has if he/she chooses not to participate in the study. Describe the possible benefits to the subject. What is the importance of the knowledge expected to result from the research?

Ethical considerations for the study will be grounded in recent NIMH guidance on Conducting Research with Participants at Elevated Risk for Suicide. All participants will provide written informed consent prior to participation and a decision not to participate will in no way influence the patient's eligibility for standard care at the clinic. We will continually monitor safety indicators, including suicide attempts and suicide deaths. In the unlikely event of (a) increases in suicidal behavior or (b) greater suicidality in the intervention condition as compared to control, the trial will be discontinued.

Given this close monitoring of safety, we anticipate the risk to participants to be minimal. Potential risks to participants in this study include: 1) negative consequences if confidentiality of information obtained in the study are compromised (including subject identity as a research participant, information collected during assessments, or abstracted information from the medical record review); 2) unintended consequences (e. g., stigma and inadvertent HIV disclosure) resulting from participation in the telehealth intervention; and 3) distress or emotional reactions related to the study assessments or intervention sessions.

Confidentiality is of critical importance, and we will take many precautions to protect against the possibility of a breach of confidentiality. Our research team is very aware of the importance of maintaining strict confidentiality and has extensive experience dealing with sensitive information. All study staff will be well trained and will receive ongoing supervision in confidentiality and data security procedures, specifically in ethical conduct, confidentiality protection, review of medical records, mandated reporting, and other topics of human participant protection. Steps to protect against risks will be implemented as follows:

Prior to any data collection, all study staff will be trained in the protection of human subjects. As this study is specifically enrolling patients who are experiencing suicidal ideation, additional protections will be implemented to minimize risk of suicide. At the conclusion of all Aim 1 interviews and Aim 3 counseling sessions in both conditions (intervention or enhanced standard of care), the nurse-counselor will re-administer the C-SSRS measure of suicide risk. At the first study visit, we will provide all participants with a list of local resources for additional mental health support, including contact information for the health system's inpatient and outpatient psychiatry services.

Any participants at acute risk of harm will be directly referred for further assessment by the study's consulting psychiatrists, Dr. Judith Boshe and Dr. Kim Madundo, or by qualified mental health staff at Majengo Health Centre or Mawenzi Hospital. For participants at acute risk of harm who refuse further assessment or treatment, we will contact the clinic nurse and the participant's emergency contact to inform them of the concern, following the procedures agreed upon by the participant at study enrollment. Dr. Boshe and Dr. Madundo will be available for consultation by mobile phone during all assessment and intervention times, and to see all at-risk participants in the outpatient clinic at KCMC, which offers psychotherapy and psychotropic medication, including antidepressant medication, as well as referral for inpatient treatment at Mawenzi Hospital's Psychiatry Unit if necessary.

Adverse events will be reported to the IRBs according to IRB and NIH policies and appropriate action will be taken to ensure patient safety to the extent of our ability.

The study will not enroll vulnerable subjects. According to Tanzanian healthcare policy, pregnant women living with HIV are seen at a separate Prevention of Mother-to-Child Transmission of HIV (PMTCT) clinic. Prisoners living with HIV receive care within the prison system.

Costs to the Subject

- Describe and justify any costs that the subject will incur as a result of participation; ordinarily, subjects should not be expected to pay for research without receiving direct benefit.

There will be no costs for subjects to participate in the research. Participants will offer their time, and may incur transportation costs to reach the clinic or data costs if they choose to receive follow-up intervention sessions via video call at a location other than the clinic. To defray these costs, participants will receive an incentive of 10,000 Tanzanian shillings (approximately $4.50) at each study contact at the clinic. Participants who connect to calls from a location other than the clinic will receive 10,000 TZ shillings if connecting via video call (to compensate for time and data costs) and 5,000 TZ shillings if connecting by telephone call (as incoming calls will not incur costs to participants).

Data Analysis & Statistical Considerations

- Describe endpoints and power calculations. Provide a detailed description of how study data will be analyzed, including statistical methods used, and how ineligible subjects will be handled and which subjects will be included for analysis. Include planned sample size justification. Provide estimated time to target accrual and accrual rate. Describe interim analysis including plans to stop accrual during monitoring. Phase I studies, include dose escalation schema and criteria for dose escalation with definition of MTD and DLT.

Qualitative data will be analyzed using a thematic approach based on grounded theory and the constant comparative method, a rigorous set of inductive procedures to identify and examine themes from textual data in a way that is transparent and reproducible. Interview transcripts will first be summarized in a qualitative memo, including representative quotes, and organized around *a priori* domains reflecting the components of the interview guides and CFIR. Next, the memos will be uploaded to NVivo software for coding. Within the broader domains, emerging themes from the interviews will be identified and added to a codebook to develop a coding structure. Each memo will be coded by 2 team members, inter-coder agreement will be calculated, and disagreements will be reconciled via consensus discussion with a 3rd team member. After coding, we will produce NVivo queries and analytic memos to synthesize content, compare participant characteristics, and draw deeper meaning on themes. Qualitative results will be synthesized with the input of the Tanzanian research team, developed into at least one research manuscript, and submitted for publication.

Scale validation will include evaluation of internal consistency of each instrument (Cronbach's alpha and item-scale correlation), convergent validity among related measures, and confirmatory factor analysis to assess whether the factor structure of the English version of manuscript is retained in the Tanzaniain clinical sample.

Feasibility and acceptability of the intervention will be described by retention patterns, participant satisfaction, fidelity, and implementation cost. *Participant satisfaction* will be measured using the Client Satisfaction Questionnaire[93] at the 3-month survey and defined as a mean score ≥ 3 on a 1-4 scale. *Fidelit y* to the manual will be measured by TQS and deemed acceptable if mean scores are ≥ 3 on a 0-4 scale. *Co st* of the intervention will be tracked, including the time for training, supervision, and actual costs incurred.

Potential efficacy will be assessed by analyzing differences by condition in primary outcomes (suicidality, HIV care engagement, viral load) and secondary outcomes (depression, social support, quality of life). The trial will not be powered to detect significant intervention effects or stable effect sizes; however, we will conduct these analyses to examine the potential for effects in a larger trial. Mixed-effects regression will be used to model pre-post differences within and between arms using a time by condition model specification (time, condition, and time*condition). Individual-level random intercepts will be used to account for correlation due to repeated measurement. This mixed-effects regression approach allows us to control for baseline outcome values that may not be balanced between groups due to small sample size, and may improve precision of treatment effect estimates. We will also generate parameter estimates and ranges of values to estimate power for a future larger clinical trial study.

Data & Safety Monitoring

- Summarize safety concerns, and describe the methods to monitor research subjects and their data to ensure their safety, including who will monitor the data, and the frequency of such monitoring. If a data monitoring committee will be used, describe its operation, including stopping rules and frequency of review, and if it is independent of the sponsor (per 45 CFR 46.111(a) (6)).

The Duke PI Dr. Knettel will receive guidance on research with patients at-risk of suicide in monthly mentoring meetings with Dr. David Goldston, a recognized expert in the field of suicide prevention research. During these meetings, Drs. Knettel and Goldston will review safety data from the study, including trends in suicidal ideation and any reported instances of suicidal behavior or death by suicide

among participants. In the unlikely event of (a) increases in suicidal behavior from baseline to follow-up survey or (b) greater suicidality in the intervention condition as compared to control as measured in the follow-up survey, the trial will be discontinued.

Participants identified to be in acute crisis at any of the research sites will be referred to Dr. Boshe or Dr. Madundo at the psychiatry service at KCMC, or to mental health staff at Majengo Health Centre or Mawenzi Hospital, in a safe and timely manner. Study research assistants (RAs) and nurse interventionists will be trained in suicide risk assessment using a manual developed by the U.S. Department of Veteran Affairs (2013). This framework incorporates considerations of whether the person has a plan to commit suicide, intent to carry out the plan, access to the means to carry out the plan, or a history of suicidal behavior. Risk assessment will be conducted in each intervention session and whenever emotional distress is communicated outside of sessions (e.g., during weekly text message check-ins).

"Acute crisis" will be defined as a participant meeting more than one of these criteria (plan, intent, means, history). In the event of an acute crisis assessed by a study RA, we will immediately initiate a contact with a psychiatric nurse. If the acute crisis is assessed by a psychiatric nurse, we will notify the consulting psychiatrist (Dr. Boshe or Dr. Madundo). Counseling will be provided, and study staff will maintain contact with the participant until a plan has been made to protect the participant's safety, which may include accompanying them to the psychiatric unit at KCMC or Mawenzi Hospital or contacting a family member or friend to stay with the patient and provide support. If the consulting psychiatrist determines that a participant is able to return home with a family member or friend, a drop in session will be scheduled for the next day to reevaluate risk and progress.