Protocol

Development and Pilot Testing of a Combination Intervention to Reduce Heavy Drinking and Improve HIV Care Engagement among Fisherfolk in Uganda

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1. Background and rationale

Alcohol use is inextricably linked to the HIV epidemic in fishing communities on Lake Victoria in Uganda, where HIV incidence among regular drinkers is 5 times higher than among non-drinkers.[1] Fishing communities are an HIV "hotspot;" HIV prevalence in fishing communities is estimated at >25%[2-4] compared to the national prevalence of 7.3%.[5] Prevalent alcohol consumption is also consistently reported across a range of studies with fisherfolk in Uganda[3, 4, 6-8] and hazardous and harmful alcohol use, especially among *fisherfolk men*, is dramatically more prevalent (37%)[6] than in the general population (5.8%).[9] In our preliminary research Among the 61% of men who reported alcohol use, 60.2% had AUDIT scores (>7) indicative of hazardous/harmful alcohol use and 16% had AUDIT scores (>16) indicative of a high level of alcohol problems.[6] Heavy alcohol use is especially problematic among individuals living with HIV as it leads to poor treatment outcomes[10] and is associated with suboptimal antiretroviral (ART) adherence and engagement in care.[11-13]

Like much of Uganda's economy, fishing villages operate on a cash economy; workers get daily cash payments for their work but have limited mechanisms for savings due to a lack of access to traditional banking infrastructure. Poverty and stressful work conditions paired with easy access to alcohol and cash with no means of savings (i.e., access to banks, savings accounts) may be drivers of alcohol consumption among fisherfolk men.[14] Moreover, frequent mobility and work responsibilities, a lack of social support, HIV stigma, and distance to the clinic have been shown to impede access to HIV care services among fisherfolk.[15, 16] Given the unique context of heavy alcohol use and challenges with engaging fisherfolk men in HIV care, a combination intervention, which addresses structural as well as behavioral factors may be needed for this population.

We propose to develop and pilot a brief combination intervention called *Kisoboka* which addresses the key drivers of alcohol use and barriers to HIV care engagement and ART adherence in this population. We address these multi-level factors in an intervention which combines behavioral components to promote behavior change with a structural component which changes the mode of work payments from cash to *mobile money,* to reduce "cash in the pocket," and increase the accessibility of savings through mobile phone-based banking services. For the behavioral components, we will combine and adapt two efficacious alcohol interventions to the cultural and situational context of this population: a brief Motivational Interviewing (MI)-based intervention tested in Kenya[17] and an intervention rooted in behavioral economics.[18] The latter intervention focuses on increasing the extent to which individuals' behavior is motivated by and consistent with their long-term goals such as saving money for the future—in which we will interweave the structural component of the intervention.

2. Specific objectives

Objective 1. Use formative research with fisherfolk men living with HIV and community stakeholders to adapt and develop a behavioral intervention *Kisoboka* ("*It is possible!*") to reduce heavy alcohol use and promote engagement in HIV care and ART adherence among fisherfolk men living with HIV.

> **Objective 1b.** Further refine the intervention through an initial pilot test with 15 participants examining feasibility and acceptability.

Objective 2. Pilot the Kisoboka intervention, randomizing to the *Kisoboka* intervention arm (n=80) or to the control arm (n=80, alcohol screening and referral). We will assess feasibility, acceptability, and preliminary estimates of the potential for the intervention, as compared to control, to decrease heavy drinking frequency and improve HIV care engagement and ART adherence through 6-month follow-up among this key population.

3. Methodology

3.1 Setting and population.

Research setting. The study will be conducted in Wakiso District, Uganda which is on the northern side of Lake Victoria. Our team has conducted several studies in fishing communities in this district. Majority of residents of fishing villages work in the fishing industry and individuals receive daily cash payments for their work. The study will take place at 5 HIV clinics in Wakiso District which serve large populations of fisherfolk. *Fisherfolk* include fishermen, fish traders, fish processors, fish loaders, boat/fishing equipment repairmen, and other workers who engage in work supporting the fishing industry within the fishing communities. As of May 2018, there were over 1,700 adult male patients on ART at these clinics.

Study population. The study population is fisherfolk men aged 18-50 who engage in heavy alcohol use. The age range focuses on men who are the most high risk group for HIV and unhealthy alcohol use.[5, 9]

Inclusion criteria: men aged 18-50; work as a fisherman, fish trader, fish processor, fish loader, related occupation supporting the fishing industry; living with HIV; on antiretroviral treatment for at least 1 month, report missing 1 or more dose of ART in the prior 2 weeks; Alcohol use criteria: consumed 5 or more drinks per occasion 2 or more times in the prior month or have an AUDIT-C (Alcohol Use Disorder Identification Test-Concise) score of ≥4[19]; not planning to move from the area within the next 6 weeks; have their own mobile phone and can be reached via phone (nearly all (>97%) fisherfolk men have their own mobile phones and receive incoming calls is free).

Consuming ≥ 5 drinks per occasion is the definition of heavy episodic drinking or binge drinking, as defined the National Institutes of Alcohol Abuse and Alcoholism (NIAAA). This type of drinking is the most concerning type of alcohol use for individuals who are HIV positive. Recent longitudinal data has shown that greater frequency of heavy alcohol use is directly associated with poor ART adherence and an important clinical outcome (lower CD4 count) and is indirectly associated with higher HIV viral load (via lower adherence).[10] Based on this evidence, we focus on heavy alcohol use for this intervention, and restrict our sample to those reporting recent heavy/binge alcohol use.

Exclusion criteria: visibly intoxicated at the time of enrollment (eligible to enroll when sober); does not speak Luganda or English; unable to read basic Luganda or English; currently receiving work payments via mobile money or currently uses mobile money savings services; occupation is a boat owner or engine owner.

3.2 Study design and procedures

Intervention

Recruitment, eligibility screening, and informed consent.

We will recruit men who are patients at Mildmay's HIV clinics in Wakiso District using two methods.

1) After a male patient checks in for his appointment and his HIV clinic record is pulled, a clinic staff member will review the patient's records to determine if they may be potentially eligible (male, aged 18-50, on ART for at least 6 months, work in the fishing industry, can be reached by phone). After the patient has completed his clinic appointment, clinic staff will refer male patients who are potentially eligible to a research assistant for eligibility screening.

2) Clinic staff will also review clinic records to identify potentially eligible patients and will call the patient to tell him about the study. If the patient is interested, they will seek permission to share his phone number and name with the researchers, provide the contact number for the research assistant, and offer that the patient can come to the clinic to meet the research

assistant to learn more about the study. Study staff will briefly describe the study and seek informed consent to conduct eligibility screening.
Those determined eligible will be offered participation in the study and study staff will obtain written informed consent.

Intervention content and structure
After participants complete the baseline structured interview, the research assistant will refer them to the appropriate counselor who will provide intervention participants with the *KISOBOKA* ("*It is possible!*"). Our proposed brief intervention consists of 4 sessions: 2 individual, 2 group over 6 weeks, plus 2 times weekly text message reminders of life/savings (family prosperity, opportunities for children) and healthy living goals. Through these sessions the combination intervention will address environmental, interpersonal, and individual level factors which are key drivers of alcohol use and key barriers to HIV care engagement and adherence in this population.

Session 1, at enrollment, In-person individual session combining MI-based counseling and goal setting and setting up the structural component of the intervention. During session 1 the counselor will: (1) Set-up the participant to receive payments for work via mobile and (if necessary) helping the participant set up a free mobile money account; (2) discuss short and long term life and healthy living goals, financial planning and savings goal setting (e.g., % of income to reach target savings amount in X time), set goal to transfer X% of daily earnings to a savings account, establish a separate healthcare savings; (3) feedback about AUDIT-C score and assess barriers to HIV care engagement and adherence; (4) MI-based counseling about alcohol use and HIV care engagement and adherence to develop discrepancy between their behavior and savings/life and health goals, engage client in change talk including setting specific goals, discussing barriers, and ways to overcome barriers; (5) discuss alcohol-free leisure activities; (6) provide a diary for participant to track spending and savings and time and money spent drinking.

Session 2, 2 weeks after enrollment, MI-based individual session via phone. Counselors will call participants and will: (1) review progress on alcohol and HIV care engagement and adherence goals, additional counseling as needed to set new goals, overcome barriers or reinforce positive behaviors; (2) review spending and saving diary and progress on savings; (3) review participant's receipt of work payments via mobile money, progress on savings goals, and help troubleshoot any problems.

Sessions 3 and 4, approximately 4 and 6 weeks after enrollment, Group sessions with 4-8 participants per group. Each session will consist of a counselor-led group discussion: (1) encouraging participants to share with the group their life and savings goals, experience with savings, motivations to save, benefits to saving, and long term planning for healthy living; (2) discussing alcohol-free leisure activities and generate motivation to engage in alcohol-free leisure activities; (3) reinforce discrepancy between risky alcohol use and not being engaged in care, not adhering to ART, and long term goals; (4) group "problem solving" about overcoming challenges to reducing alcohol use, including participating in alcohol-free leisure activities, HIV care engagement, and ARV adherence including HIV stigma.

Text message reminders. Intervention arm participants will receive 2 times weekly text message reminders of their goals to increase the salience of delayed rewards of saving money and healthy living. Timing will be approximately 1 hour prior to when the participant reports usually drinking. For confidentiality reasons the text message reminders will not address alcohol, HIV care engagement, or adherence specifically but more broadly focus on "healthy living". We chose the frequency of 2 times weekly based on data showing this frequency is the most acceptable and effective in adherence studies.[20, 21]

Intervention participation incentives. Based on San Diego State University IRB guidance we will compensate participants specifically for the time involved in participation since participation may require them to take time away from work. The intervention arm involves significantly more time commitment (approximately 563 minutes) than the control arm (approximately 195 minutes) and participants will be compensated accordingly. The per hour rate (18,000 Shillings, ~ $5) will be equivalent between study arms. We detail participant incentives below:

Control group: Alcohol screening and referral. Control condition participants will complete the baseline questionnaire, which includes the AUDIT-C screening for risky alcohol use. After completing their baseline assessment, enhanced control condition participants will receive very brief feedback on their AUDIT-C score according to the feedback suggested in the AUDIT brief intervention manual,[22] be provided a referral for alcohol counseling, and briefly engaged in discussion of the importance of HIV care engagement and adherence according to the MOH protocol.[23] The control session will last approximately 20 minutes. The control is an enhanced treatment as usual arm which is recommended for feasibility and preliminary efficacy studies.[24]

Sample size for randomized pilot intervention trial
We will conduct a stage 1b pilot randomized controlled trial of the intervention. As a pilot study, this study is not powered to detect differences in outcomes, but rather to obtain reliable estimates of effect sizes for a subsequent efficacy trial. However, for illustrative purposes we explore power assuming a small effect size (d= 0.2) which is consistent with most brief MI-based alcohol intervention study effect sizes [17, 25-27] as well as care engagement interventions.[28-32] **We plan to enroll 160 participants in the pilot intervention trial** with 80 in each arm i.e., randomizing to the KISOBOKA intervention arm (n=80) or to the control arm (n=80, alcohol screening and referral). To be conservative we anticipate 25% attrition. This will provide 72% power to detect an intervention effect and 85% power to detect a study arm x time effect.

Sampling procedure for the randomized pilot intervention trial (n=160).
The participants recruited (based on the inclusion and exclusion criteria) from the Mildmay HIV clinics in Wakiso District will be requested to share the research assistant's contact details (phone numbers) with their potentially eligible friends. This snowball-sampling procedure will enable us to reach more participants in this hard-to-reach population. Those interested in participating in the study will contact the research assistant who will then take them through subsequent eligibility screening and recruitment procedures. This process will be repeated until the required sample is attained.

Randomization for stage 1b randomized pilot intervention trial.
Individual-level randomization with permuted block assignment balancing 1:1 will be used to create equal size groups for the two study arms. Blocks of 8 or 10 study-generated ID numbers will be created and randomly assigned to intervention or control. Once a participant is screened as eligible and attends an enrollment/baseline visit they will be assigned a study-generated ID number from the pre-randomized list which determined their study arm assignment.

Study variables
Dependent variables
Primary outcomes:
- Phosphatidylethanol (PEth) (alcohol biomarker, blood sample)
- AUDIT-C score[19]
- ART adherence[33]

Secondary outcomes:

- HIV care engagement
- HIV viral load obtained from clinic records
- Frequency of heavy/binge drinking

Potential covariates

- Receipt of instrumental and emotional social support[34]
- Dimensions of HIV stigma:[35] (a) anticipated stigma[36]; (b) enacted stigma[36]; and (c) internalized stigma[37]
- Delay discounting[38]
- Motivation for HIV care engagement[39]
- Income and food insecurity[40]
- HIV status disclosure[28, 34]
- Depressive symptoms[41]
- Subjective health status using the MOS-HIV short form[42]
- Distance/time to the clinic[43]

3.3 Data collection

Stage 1b randomized pilot intervention trial (n=160):

Baseline data collection. After the informed consent process in a one-on-one interview (~60 minutes) using a computerized structured questionnaire, the interviewer will collect demographic information and detailed contact information (e.g., phone numbers, contact details of individuals who would know how to find the participant) to facilitate participant retention, and a venous blood sample for the alcohol biomarker measure (PEth). Interviewers will set the appointments for the 3- and 6-month follow-up.

3 and 6-month follow-up data collection. For participants' convenience the 3-month follow-up interview may be conducted by phone whereas the 6-month follow-up interview must be in person since it involves obtaining a venous blood sample. For the 6-month follow-up, study interviewers will conduct follow-up data collection either at the study office at the clinic or, if requested by the participant, by meeting at a location of the participant's choosing. In our prior work in Uganda, we have found that participants who may have challenges in coming to the study office prefer to have the interviewer come to them. At 3- and 6-month follow-up the interviewers will conduct an individual structured interviewer-administered computer-based interview (~45 minutes duration). At the 6-month follow-up they will also collect 2mls of venous blood for PEth testing. If participants cannot be reached for the blood sample, we will still conduct the interview over the phone. This will allow us to still obtain some 6-month follow-up data from all participants. However, we will continue to follow up with these participants to obtain the venous blood sample even after the phone interview. Follow-up interviewers will be blinded to study arm assignment.

Dried blood spot (DBS) collection and testing. During the baseline and 6-month follow-up interviews, 2mls of venous blood will be collected using sterile EDTA tubes and transported to a laboratory within 6-10 hours from the time of sample collection. At the laboratory, 50µl drops of blood will be placed onto Whatman 903 filter paper (DBS cards), allowed to dry for ≥3 hours, and then stored packaged with a desiccant in a -80C freezer at Mildmay laboratory.[44] Since no laboratories in Africa conduct PEth testing, PEth testing will be done at the United States Drug Testing Laboratories using liquid chromatography-tandem mass spectrometry (LC/MS/MS).[45] We will obtain a Materials Transfer Agreement to ship the DBS to the U.S.

Monitoring intervention fidelity. We will audio record all intervention sessions and randomly select 20% of them to code for fidelity to the intervention protocol.

Training of research assistants and interviewers
To collect baseline and follow-up interview data for the intervention, experienced research assistants/interviewers will be hired for the purposes of the study. These individuals will be trained in the study procedures by one or more of the investigators. Interviewers will be individuals qualified and experienced in performing phlebotomy because they will be responsible for the blood draws and venous blood collection for PEth testing. Clinic staff will also be oriented to the study and the study procedures by the investigators.

Training of counselors in the intervention protocol
Counselors will be trained to deliver either screening and referral (enhanced control) or the *KISOBOKA* intervention. Counselors will have an advanced high school (college preparatory) or college education and have training in general counseling skills. The counselors who will deliver the intervention will undergo a 4-day criterion-based training. In our prior MI-based intervention in Uganda we successfully trained laboratory technicians in MI principles[46] thus we are confident that counselors will be able to learn and become proficient in MI counseling skills through our training. Using highly trained clinical psychologists is not generalizable nor sustainable in this setting since very few of such professionals exist in Uganda.

3.4 Measures
Unless otherwise noted all variables will be assessed at baseline and at follow-up, 3 and 6 months from baseline.

Primary alcohol outcome. We will use an **alcohol biomarker**: phosphatidylethanol (PEth) as the primary alcohol outcomes assessed at baseline and 6-month follow-up. PEth is a phospholipid which is formed only in the presence of alcohol and thus is highly specific.[47] PEth has shown good performance as a medium-term biomarker [48] and in controlled laboratory studies, correlated well with level of consumption (Spearman's r= 0.6-0.8).[49-52]

We will also use the AUDIT-C[19] as another measure of hazardous alcohol use.

ART adherence: We will assess adherence to ART using the AIDS Clinical Trials Group Adherence measures (AACTG),[53] which includes recall questions about ARVs missed for the previous 4 days prior to the interview. It has demonstrated construct validity in Uganda and similar settings[54] and shows strong correlations with HIV VL[55] and moderate correlations with electronic adherence monitoring.[56]

Measures and analysis for assessment of feasibility:
To inform a future larger randomized trial of the *KISOBOKA* intervention we follow Bowen et al.'s suggestions for conducting feasibility studies in preparation for larger RCTs[24] which includes assessing feasibility on the following dimensions: **acceptability**, **demand/use**, **implementation**, and **practicality**. We will document the number of intervention sessions participants attended which will speak to demand for/use of the intervention. To monitor implementation for the individual and group intervention sessions the we will audio record intervention sessions and transcribe and code 20% of sessions to monitor intervention fidelity. Related to the practicality of the procedures, we will assess our retention rate through the 6-month follow-up to determine if we will need to develop additional retention procedures to maximize retention in a larger trial with a longer follow-up.

3.5 Data management and analysis
Data management
Pre-testing: We have used many of these measures in our prior research and already have English and Luganda versions finalized. The remaining measures will be pre-tested with staff

and patients at the participating clinics before the stage 1a pilot intervention. At this stage, we will also pretest the entire follow-up questionnaire to assess the duration of the interview and if necessary, remove measures to reduce the interview length. The stage 1ab pilot intervention will then be used for further pretesting and subsequent revisions to ensure the comprehensibility of each item before the stage 1b trial.

Field editing of data: Except for PEth and Viral load data all data will be entered into the CAPI (computer assisted personal interview) program as it is collected during the assessment interviews. A research assistant will double enter PEth viral load test results into the data file identified only by study ID number.

Qualitative data: Audio recordings of all qualitative data will be transferred to an encrypted and password protected computer. Electronic audio recordings of individual and group counselling sessions will be transcribed within 6 months of the session and the audio recordings will be destroyed once the information from the recordings is written down and double-checked for accuracy.

Quantitative data: Data for the baseline, 3 and 6-month follow-up questionnaires will be entered in real-time using KoboCollect software (A CAPI program). Using the KoboCollect system also eliminates the possibility of any out-of-range responses and therefore, data cleaning is not necessary. Data collected using Kobo is easily exported into SAS and other statistical programs for analysis. A research assistant will double enter PEth test results and viral load test results extracted from clinic records, into the data file identified only by study ID number. Clinical record data will be double entered by the research assistant into this same data file upon receipt. The double entered data will be checked and any discrepancies will be corrected by double checking the clinic records, and by comparisons with the laboratory report.

Data security: Data directly entered from the questionnaire interviews will be automatically encrypted and then uploaded onto a secure server. Only the PIs and data manager will have access to the server. No participant names will be stored in the database. All participants will be identified by a unique identifier, a random number assigned to them at the time of recruitment. In the event of loss of data or theft, all data files will be encrypted, and no outside user would be able to access the data. To ensure that no data that is collected is lost, encrypted data will be backed up on several sources: a separate server and copied to a secondary encrypted database used by the PI and biostatistician for additional processing.

Statistical Analysis Plan

A key objective of this study is to explore the effectiveness of the intervention vs. control and obtain effect size estimates to be used to design a future trial of this intervention. The primary outcomes are PEth scores, AUDIT-C score, and ARV adherence. Different statistical methods will be utilized depending on the type of outcome variable and whether minimum conditions for use of the methods are met. For example, log Gamma models may be used to analyze the difference in PEth scores between intervention and control groups given the expected distribution of PEth scores. An intent to treat approach will be utilized to determine analytic sample. Variables (except PEth which is measured at 2) will be measured at three time points (baseline, 3 and 6 months) so the dependency from the repeated measures must be considered. Information criterion such as AIC and BIC will be used to select the most appropriate covariance structure to address dependance. Generalized estimating equations (GEE) will be built to examine the intervention effect on our outcomes of interest across time points (baseline, 3 and 6 months), adjusting for repeated measurement, using a time*condition interaction term. Potential covariates for each adjusted model will be identified a priori from the literature and added to the model. Correlation matrices will be determined based on model fit. Statistically significant covariates will be retained in final fitted models using an alpha of 0.05.

4 Ethical considerations

Prior to the beginning of the study period, all protocols will be approved by the IRB at San Diego State University (FWA00003782) and the IRB at the Makerere University School of Public Health (FWA00011353), after receiving IRB approvals, Mildmay Uganda will grant administrative clearance. The study will be registered with and granted clearance by the Uganda National Council for Science and Technology.

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