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Testing a Screening, Brief Intervention, and Referral to Treatment Intervention Approach for Addressing Unhealthy Alcohol and Other Drug Use in Humanitarian Settings: Protocol of the Ukuundapwa Chapamo Randomised Controlled Trial

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Abstract

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Conflicts of interests

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Refugees and other displaced persons are exposed to many risk factors for unhealthy alcohol and other drug (AOD) use and concomitant mental health problems. Evidence-based services for AOD use and mental health comorbidities are rarely available in humanitarian settings. In high income countries, screening, brief intervention and referral to treatment (SBIRT) systems can provide appropriate care for AOD use but have rarely been used in low- and middle-income countries and to our knowledge never tested in a humanitarian setting. This paper describes the protocol for a randomised controlled trial to compare the effectiveness of an SBIRT system featuring the Common Elements Treatment Approach (CETA) to treatment as usual in reducing unhealthy AOD use and mental health comorbidities among refugees from the Democratic Republic of the Congo and host community members in an integrated settlement in northern Zambia. The trial is an individually randomised, single-blind, parallel design with outcomes assessed at 6-months (primary) and 12-months post-baseline. Participants are Congolese refugees and Zambians in the host community, 15 years of age or older with unhealthy alcohol use. Outcomes are: unhealthy alcohol use (primary), other drug use, depression, anxiety and traumatic stress. The trial will explore SBIRT acceptability, appropriateness, cost-effectiveness, feasibility, and reach.

Keywords

alcohol use; brief intervention; CETA; humanitarian settings; randomised controlled trial; refugees; SBIRT; substance use; transdiagnostic therapy; unhealthy alcohol use; Zambia

Introduction

Unhealthy alcohol and other drug (AOD) use is prevalent in some refugee and displaced populations (Horyniak, Melo et al., 2016). *Unhealthy AOD use* encompasses a range of AOD terminologies that adversely impact health, including hazardous use, harmful use and AOD use disorder (Saitz, 2005). The risk for AOD use disorder may change for several reasons, including changing access to substances, exposure to potentially traumatic events, chronic adversity and changes to one's social support and resources during displacement (Horyniak, Higgs et al., 2016; Jack et al., 2014; Roberts et al., 2014; Streel & Schilperoord, 2010; UNHCR, 2008). Patterns of AOD use are dynamic and influenced by multilevel factors present within the displacement context (Ezard, 2012; Jack et al., 2014; Weaver & Roberts, 2010), with recent studies suggesting that the prevalence of AOD use disorder among displaced populations converges with that of the host community over time (Harris et al., 2019).

A very few displaced persons with unhealthy AOD use receive evidence-based services (Fine et al., 2022; Harris et al., 2019; Kane et al., 2014). Research on AOD services for displaced populations is sparse, and studies often suffer from methodological limitations, including non-validated measurements, inconsistent recall periods, a lack of focus on other drug use and, notably, lack of rigorous, experimental study designs evaluating AOD interventions (Greene et al., 2019; Jones & Ventevogel, 2021). As a matter of fact, there have not been any published randomised controlled trials (RCTs) in humanitarian settings in which the primary trial outcome was AOD use.

In low- and middle-income countries (LMIC), where the majority of humanitarian emergencies occur and the maximum number of displaced persons reside (UNHCR, 2022), the most often studied AOD treatments have been alcohol brief interventions (BIs) − short one to four session therapies that employ various therapeutic techniques, such as motivational interviewing, psychoeducation and norm referencing (Jonas et al., 2012; Kaner et al., 2007, 2011; Platt et al., 2016; SAMHSA, 2017). BIs are designed to be delivered by a range of providers in diverse healthcare settings (SAMHSA, 2017) to prevent mild or moderately unhealthy alcohol use from becoming more severe. Given their brevity and content, it is unlikely that BIs alone will address AOD dependence or co-occurring mental health problems, such as depression, anxiety, trauma or unhealthy use of other drugs (NIAAA, 2005a; World Health Organization, 2012). Two RCTs conducted in non-humanitarian settings in sub-Saharan Africa found that BIs were no better than control conditions at reducing unhealthy alcohol use (Peltzer et al., 2013; Wandera et al., 2017), possibly due to their inability to address comorbidities. This is a limitation in humanitarian settings, where displaced persons who have unhealthy alcohol use are at high risk of experiencing comorbid mental health or other drug use problems (Greene et al., 2019; Kane et al., 2018). Therefore, BIs may be best used as part of a broader treatment package for unhealthy AOD use.

A screening, brief intervention and referral to treatment (SBIRT) approach is an intervention package that has been effective at addressing unhealthy alcohol use and comorbidities in high income countries (SAMHSA, 2017), although it is rarely tested or implemented in LMIC. With this approach, an individual is: (1) screened for unhealthy alcohol use (and possibly other drug use or mental health comorbidities) using a validated method; (2) provided with an evidence-based BI, if needed; and (3) referred for more intensive treatment, if indicated. In a recent RCT conducted in Lusaka, Zambia, we tested the effectiveness of SBIRT at reducing unhealthy alcohol use among people living with HIV (Kane et al., 2022). The SBIRT package included a BI with referral to a transdiagnostic psychological intervention, the Common Elements Treatment Approach (CETA), as indicated (Kane et al., 2020; Murray et al., 2014). In this study, the BI alone was effective at reducing unhealthy alcohol use among participants without comorbidities. Among participants with severe alcohol use or mental health or substance use comorbidities, the BI followed by referral to CETA was needed for therapeutic impact (Kane et al., 2022). Although promising, the RCT featured a small sample size and was conducted among a clinic-based population in urban Lusaka; therefore, the effectiveness and feasibility of this SBIRT approach in humanitarian contexts are unknown.

Objectives

In this paper, we detail the protocol of an RCT being conducted in an integrated refugee settlement in northern Zambia. The purpose of the trial is to address many of the gaps identified in a UNHCR literature review on AOD interventions in humanitarian settings described above (Greene et al., 2019). SBIRT will be tested in an RCT that aims to evaluate the effectiveness of SBIRT compared to treatment as usual (TAU) in reducing unhealthy AOD use and mental health problems among a group of displaced and host community members aged 15 and older who screen positive for unhealthy alcohol use. We will explore

the acceptability, appropriateness, cost-effectiveness, feasibility, and reach of the SBIRT approach in this humanitarian context.

Methods

Trial Design

Ukuundapwa Chapamo (Bemba for "let's get treated together") is a single-blind, parallel, individually randomised hybrid type 1 effectiveness-implementation trial (Curran et al., 2012). The participants will be refugees from the Democratic Republic of the Congo (DRC) living in the Mantapala refugee settlement or members of the surrounding Zambian host community, 15 years old or older, and who report recent unhealthy alcohol use, defined as reporting an Alcohol Use Disorders Identification Test [AUDIT] score of ≥4 among women or ≥8 among men based on past 3-month alcohol use (Babor et al., 2001). Participants will be randomised to receive TAU or SBIRT (BI and CETA). Assessment of the primary (unhealthy alcohol use) and secondary (other drug use, mental health; see Table 1) outcomes will be conducted at a 6-month follow-up visit, which is the primary endpoint, with an additional follow-up occurring at twelve months post-enrollment. The study design is depicted in Figure 1. The SPIRIT guidelines for reporting clinical trial protocols were used to describe the study methods below (Chan et al., 2013).

Study Setting

The trial will be conducted in the Mantapala refugee settlement and surrounding host communities in northern Zambia. Zambia hosts over 50,000 refugees from DRC, including approximately 18,000 in Mantapala, who have fled ongoing and protracted conflict that began in the mid-1900s. Mantapala, the newest refugee settlement in Zambia, was established in the year 2018 and is situated in Nchelenge, a rural district in Luapula Province along the DRC border. Approximately, 5000 Zambians live in communities around the Mantapala settlement. As Mantapala is an integrated settlement, basic services (i.e., one health centre, two schools, one police station and gender-based violence services) are provided for both the refugee population and Zambian host community members. In this study, we will include both refugees from DRC and members of the Zambia host community as participants. The rationale for this is that hosting communities of refugees also often lack access to certain health and social services, particularly mental health and substance use services. UNHCR recommends implementing inclusive policies that provide support to both the displaced and host community to avoid causing unintended harms (e.g. generating disparities in access to services, which can lead to displaced-host community tensions) (UNHCR, 2011).

Preliminary meetings between the study team and operational partners in Mantapala revealed that unhealthy AOD use was a significant challenge in the settlement and associated with individual, family and community consequences. In July 2019, UNHCR led an assessment of mental health problems among refugees in Mantapala. The community-based convenience sample consisted of 200 people, of whom 35 (18%) had probable alcohol use disorder and frequent cannabis use among people who were drinking alcohol (UNHCR, 2019). Unpublished reports from the province of origin (Katanga, DRC) (UNODC, 2014a)

and host country (Zambia) have also found unhealthy AOD use to be prevalent (UNODC, 2014b). There remains a lack of evidence-based mental health services in Nchelenge district, particularly in and near Mantapala.

Participants

Inclusion criteria will be the following:

1. Living in Mantapala refugee settlement (i.e. Congolese refugee) or member of neighbouring host communities (Zambian).
2. Age ≥15 years.
3. Recent (past 3-month) unhealthy alcohol use (score on Alcohol Use Disorders Identification Test [AUDIT] of ≥4 among women or ≥8 among men) (Kane et al., 2022; NIAAA, 2005b).

Exclusion criteria will be following:

Severe psychiatric illness, high suicide risk (recent attempts and/or ideation with intent and plan) and/or current severe AOD withdrawal that would necessitate immediate referral assessed by the ACASI and/or a trained RA. In these situations, individuals will be immediately liked to an on-site clinical supervisor for further assessment. A referral does not automatically remove the participant from the trial.

Inclusion/exclusion criteria will be assessed by RAs with support from clinical supervisors if warranted. Specifically, RAs will be responsible for identifying signs of alcohol withdrawal and severe mental illness. They have received specific training on identifying these signs. If signs of alcohol withdrawal or severe illness are noted, and/or if the participant flags a suicidal safety question (i.e., “do you have thoughts of killing yourself?”) on the ACASI, a clinical supervisor will be brought in to further assess the withdrawal, mental illness and/or current and previous safety issues. Protocols will be followed to ensure the safety of the participant and the determination to exclude will be made by the clinical team in collaboration with study PIs.

Interventions

Participants randomised to the experimental arm will receive SBIRT, composed of BI and CETA. Participants with moderately unhealthy alcohol use *without* comorbid mental health problems will be classified as “lower risk” and will receive this BI session only and no additional intervention. Participants with severe unhealthy alcohol use and/or comorbid mental health problems will be classified as “higher risk” and will be referred to a counselor to receive the full CETA intervention after completing the BI session. All participants who are randomised to SBIRT will immediately receive a single-session BI (30–45 minutes) based on CETA’s substance use reduction element (Kane et al., 2020). The BI consists of six components, which are summarised in Table 2 as well as a safety component for participants who express suicidal ideation.

CETA is a transdiagnostic treatment based in cognitive behavioural therapy that is delivered using a task-sharing approach (i.e. delivered by lay counsellors without previous mental

health experience) with strong evidence from trials in LMIC and among displaced populations for treating a range of comorbid mental and behavioural health problems, including depression, anxiety, trauma symptoms, functional impairment and unhealthy alcohol use (Bogdanov et al., 2021; Bonilla-Escobar et al., 2018; Kane et al., 2022; Murray et al., 2014, 2020; Weiss et al., 2015) (www.cetaglobal.org), including with displaced populations (Bolton et al., 2014; Murray et al., 2018). CETA is comprised of nine key elements [Table 3] that can be flexibly used in counselling sessions based on a client's symptom presentation and severity.

SBIRT (both the BI and CETA) used the apprenticeship model for training, which includes didactic training in intervention content, modelling and small group role-plays (Murray et al., 2011). Initially, a 10-day live training of lay providers − refugees from DRC and members of the Zambian host community − was conducted in Nchelenge by study authors with interpretation in Bemba. The training was conducted by three CETA trainers (authors K.M., C.F. and M.A.) with 26 lay providers. The highest level of education level attained among the providers was grade nine. The lay providers had range of previous volunteering and work experience, including at the Sexual Gender Based Violence One Stop Center in Mantapala as counsellors, others are church leaders and others volunteered at the settlement health center as community volunteers advocating for safe motherhood practices. None of them, however, had previously received formal training in mental health interventions.

During the initial live training, it was determined by the CETA trainers that it would be necessary to adapt CETA materials from the standard approach (Murray et al., 2014), in part due to education level (in previous CETA studies and programs, providers had a minimum 10^{th} grade education and the ability to read and write in one of the study's primary languages; these criteria were not considered feasible in this context). Materials were adapted into pared-down worksheets that: (1) reduced written text; (2) reduced the number of skills in select elements (e.g. only included three cognitive restructuring techniques instead of the typical five); (3) integrated visual implementation cues; and (4) reduced the amount of content from a typical CETA training. Based on strengths and skills demonstrated during the training, trainees were allocated into roles as BI counselors, CETA counselors, or were assigned to be community outreach workers (i.e. would not provide either BI or CETA in the study) to support participant engagement and retention. It was also determined that additional trainings were needed for the BI and CETA counselors with the new materials and translation available in both Bemba and Kiswahili.

BI counselors attended an additional 7-day live training by two trainers. The training focused on the BI and adapted CETA safety element. Counselors participated in BI and CETA Safety (~2 h/wk) practice groups over a 6-week period. Once the counsellors start using the BI with participants, they will receive weekly supervision until competency is achieved (approximately 5–10 cases) followed by monthly supervision. During each weekly group supervision, trained local supervisors will review the completed BI sessions, including the completed worksheets, detailed notes and objective session reporting by the counselors. Supervisors are trained to detect and address implementation mistakes and then provide session ratings on the counsellor's ability to complete the assessment, follow the manualised steps and overall implementation skill using a Likert scale (scores range from 1=minimal

skill to 5=superior skill). These sessions and ratings are also reviewed on a weekly basis with a CETA/BI trainer to ensure agreement. Once a counsellor has ratings of 4 or 5 across multiple BI sessions, competency is considered to be achieved.

CETA counsellors attended an additional 7-day training with the adapted materials led by two trainers. Following this training, counsellors and supervisors practiced the CETA elements over an intensive 2-week period (15 hours weekly), followed by weekly practice (2–3 hour weekly) for an additional 4 weeks with oversight from a local CETA supervisor. Counsellors continued to attend weekly supervision for 2- to 3-hours per week for review/support of CETA cases. Supervisors met weekly with the CETA trainers for supervision for all active study clients. Supervisors were trained to monitor session fidelity. Fidelity for both BI and CETA sessions is determined by review of session worksheets, detailed session notes and objective reporting in weekly group supervision. Supervisors monitor to ensure that all session steps are followed and correctly implemented. Both counsellors and supervisors receive training in reporting skills to ensure accurate and quality session information.

In the trial, both BI and CETA will be implemented individually (one-on-one format). The cadre of BI and CETA counsellors include both Bemba and Kiswahili speaking individuals to enable delivery of BI and CETA in participants' preferred language. The CETA elements and number of sessions can be flexibly delivered according to higher risk client's symptom presentation and severity. CETA typically consists of 6–12 1-hour sessions, on average. Prior or during the first session, the counsellor and participant will agree on when and where to conduct the subsequent weekly sessions. If sessions are missed, counsellors will follow up via phone (and home-based visit if necessary) to reschedule and assure safety.

Participants randomised to the control condition will receive TAU. In 2019, primary healthcare staff and supervisors were trained in mhGAP to manage priority mental health and substance use conditions (Ventevogel & Mubanga, 2019). However, currently there are no formal mental health services available in the settlement. We will, therefore, provide participants with a referral to the existing health centre within Mantapala to receive routine health services. We will track the number and type of services received by all participants during follow-up assessments. TAU participants will be offered SBIRT following the end of the trial.

The participants (regardless of treatment arm) who endorse having recent suicidal ideation or attempt(s) during research or intervention activities will be immediately seen by an on-site clinical counsellor or supervisor for assessment. The clinical supervisor, in collaboration with an experienced CETA trainer, will be responsible for determining whether the participant can be included or remain in the trial or requires immediate referral to higher level care (i.e. immediate psychiatric or medical services). If a participant is determined to be eligible or can remain in the study, then a safety plan will be created.

Outcomes

Unhealthy alcohol use is the primary outcome of the trial. The focus on unhealthy alcohol use as the primary outcome and inclusion criterion is due to our preliminary research in Mantapala suggesting that alcohol is the main substance of concern, and that other drug use

frequently co-occurs with alcohol use. Secondary outcomes include symptoms of depression (CES-D), anxiety (GAD-7), post-traumatic stress symptoms (HTQ) and other drug use (ASSIST). All measures have been translated into Bemba, adapted and used as outcome measures with good reliability and validity in previous CETA trials conducted in Zambia (Chishinga et al., 2011; Inoue et al., 2021; Kane et al., 2016). In preparation for the current RCT, we conducted cognitive interviews with members of the displaced and host community to ensure they were appropriate for the study population. A summary of the measures for outcomes is provided in Table 1.

Implementation outcomes will be assessed using qualitative in-depth interviews and quantitative costing indicators. Qualitative interview guides were designed to evaluate the acceptability, appropriateness, cost, feasibility and reach of SBIRT, as defined by Proctor's outcomes for implementation research framework (Proctor et al., 2011). We will use expenditure records and interviews to estimate costs of SBIRT over the intervention follow-up period, including start-up, annualised over several years and recurrent costs. For TAU, we will estimate costs of services provided by NGOs and at the health service centres within Mantapala. We will estimate the cost–effectiveness of the intervention and control as a cost per unit change in AUDIT score, by dividing total costs by the total change in AUDIT score at 6 and 12 months. We will assess affordability in the greater context of humanitarian assistance by estimating cost per capita and comparing it with humanitarian funding globally.

Participant Timeline

After interested participants provide informed consent, they will complete the screening assessment. Following the completion of the AUDIT measure, the RA will notify the participant about their eligibility. Eligible participants will complete additional questionnaires for the baseline assessment. Participants who are ineligible for the trial will be thanked for their time and provided with a list of available services for mental health.

Enrolled participants will complete follow-up assessments at 6- and 12-month post-enrollment. The 6-month timepoint is the primary endpoint. We will attempt to complete 12-month assessments with as many participants as possible, recognising that in a humanitarian setting this extended timepoint may not be feasible due to repatriation and mobility. Substance use problems can be chronic with the possibility of recurrence, even after treatment. Thus, we believed, it was important to follow as many participants as possible to 12 months in order to explore the extent to which treatment effects of CETA were sustained.

We will conduct implementation interviews with a subset of RCT participants, counselors and other relevant implementation partners during the follow-up period.

Sample Size

The primary outcome is the difference in change in AUDIT score from baseline to 6-month follow-up between SBIRT and TAU. Using data from the previous SBIRT trial in Lusaka (Kane et al., 2022), we estimated that the sample size required to estimate a moderate treatment effect (Cohen's d=0.5, which was the size of the SBIRT effect found in the previous trial) on change in alcohol use measured by the AUDIT with 90% power would

be 172 (86 per arm). To account for attrition and exploration of putative moderators of treatment effectiveness (e.g. gender, symptom severity, nationality), we inflated our final target sample size to N=400 (200 per group).

Implementation interviews will be completed with RCT participants allocated to SBIRT (n=30), SBIRT or CETA counsellors (n=15), and humanitarian policymakers or program officials whose position has relevance for the implementation of SBIRT in humanitarian settings (n=15).

Recruitment

Research assistants (RAs) will introduce the study during community meetings that will take place at each of the 20 settlement blocks/administrative units in Mantapala and in the surrounding host communities. Community members will be invited to attend by community leaders and outreach workers. The study team will provide information about when and where interested individuals can meet privately with research staff to learn more about the study. We will ask providers from health services and protection programs within the settlement, as well as community members and leaders in each settlement block, to refer individuals who might be eligible and interested in participating to a member of the study team. We will provide the outreach workers with a recruitment script for this purpose and encourage them to recruit people from different ages, genders and ethnic backgrounds. Interested individuals will be given the research team's contact information or can provide their own contact information for the research team to set up an appointment. These community-based recruitment strategies will ensure that only interested individuals will be contacted by the study team. After meeting with the research team, participants who are still interested and provide informed consent will be screened for RCT eligibility.

During the RCT follow-up period, we will purposively recruit 30 SBIRT participants, 15 SBIRT counselors and 15 humanitarian partners to participate in qualitative implementation interviews. Participants will be selected using maximum variation sampling to ensure they represent a range of demographic profiles (age, gender and nationality), baseline AOD use patterns and attendance and intervention response. The 15 SBIRT counsellors will be selected to reflect variation in the following characteristics: type of counselor (BI or CETA), client caseload, community membership (refugee versus host), and competency as identified by the clinical supervisor. Fifteen humanitarian partners (e.g. policymakers and program officials) will be invited to participate based on their knowledge of the project and the relevance of their role in study's implementation.

Allocation

Participants who complete the full baseline assessment and are eligible for the trial will be randomised and enrolled into the RCT. Randomisation will be on a 1:1 basis, stratified by gender (female or male), nationality (Congolese or Zambian) and symptom severity (lower or higher risk). Participants will be randomised to SBIRT or TAU. The RA will allocate participants to treatment arm using a series of sealed, opaque envelopes. The randomisation sequence will be generated using the random number generator in Microsoft Excel before trial commencement by a U.S.-based investigator with no participant interaction. The

randomisation assignments will be recorded on separate pieces of paper and placed inside the envelopes, which are prepared by the study coordinators before the start of the trial and are labelled according to the presenting combinations of the randomisation stratification variables: (1) gender: male, female; (2) nationality: Congolese, Zambian; and (3) risk level: lower risk is defined as unhealthy alcohol use criteria (AUDIT 4–11 among women or 8–15 among men) and do not meet symptom criteria for any of the secondary mental health or substance use outcomes (see cutoffs in Table 1). Higher risk is defined as severe unhealthy alcohol use criteria (AUDIT 12+ for women, and 16+ for men) and/or have met criteria for one or more of the mental health or other drug use comorbidities. The RA will immediately inform participants of their randomisation result.

Blinding

Participants, study counselors, RAs and data analysts will remain blind to randomisation sequence to avoid potential biases in allocation. Due to the nature of the trial and interventions being tested, the study counsellors, participants and RAs will not be blinded after the participant is enrolled. The data analysts will remain blinded to participant treatment arm.

Data Collection Methods

The screening, baseline and follow-up assessments will be administered via an audio computer-assisted self-interviewing (ACASI) program housed on a laptop computer. We have previously developed and implemented an ACASI approach to survey and intervention research in Zambia and found it to be feasible, acceptable and a preferred method by participants for responding to sensitive questions on mental health and substance use (Kane et al., 2017; Kane et al., 2016). Bemba and Kiswahili translators will also be available onsite for assistance with translation and interpretation of questions and RAs will also be available to assist with navigating the laptop computer, if necessary. Questions and response options will be displayed on the laptop screen with an accompanying audio recording. The ACASI will be administered in a private location with headphones to ensure confidentiality.

Qualitative interviews on implementation outcomes will be conducted by RAs and will be audio-recorded with permission from participants. Recordings will be destroyed after interviews are transcribed. Any personal information will be redacted from study transcripts.

Data Management

All qualitative and quantitative data will be stored on an encrypted system with restricted access to essential investigators and staff. Data will be stored without any identifiable information and only the participants' unique study identifier.

Statistical Methods

Primary analyses will be intent to treat (ITT). AUDIT score and other continuous outcomes (CES-D, GAD-7, HTQ, substance specific ASSIST scores) will be separately evaluated with linear mixed models or generalised models if distribution of the outcome is not normal. Fixed effects in the models will include treatment arm, time and interaction terms between treatment arm and time. Random effects will include client ID and counselor ID. Robust

standard errors will be estimated using a sandwich variance estimator (Huber, 1967; White, 1980). Covariates may be included if they differ meaningfully at baseline. In addition to the ITT analysis, we will also conduct a per protocol analysis that includes all participants in the TAU arm and only those participants in the SBIRT arm who completed treatment. We will also explore moderators of treatment effectiveness (e.g. gender, nationality, symptom severity).

Monitoring

In addition to the ethical review boards, the trial will be monitored by a three-person Data and Safety Monitoring Board (DSMB) who have expertise in alcohol and other drug use, global mental health and RCTs. DSMB members will be asked to review and approve the study protocol before trial commencement, and thereafter review twice yearly reports on study progress, enrollment, attrition and adverse events. Meetings between the DSMB and investigators will be convened as needed throughout the study. We will not ask the DSMB to conduct interim analyses.

Research Ethics Approval

The study was approved by the Columbia University Medical Center Institutional Review Board (IRB), the University of Zambia Biomedical Research Ethics Committee and the National Health Research Authority in Zambia and is overseen by a Data and Safety Monitoring Board. The study is being conducted in collaboration with the Zambian Ministry of Home Affairs and Internal Security, and the Ministry of Health. The trial is registered on ClinicalTrials.gov (NCT05471921; Date of registration: 7/25/22).

Protocol Amendments

Any protocol amendments will be reviewed by the DSMB and ethical review boards, as required.

Consent or Assent

Interested individuals will meet privately with a trained RA within a secure, private study location in Mantapala settlement where the RA will review the study information sheet in Bemba, English, or Kiswahili (according to the individual's preference), which includes the study purpose, procedures, risks/benefits and voluntary participation. All participants will provide verbal informed consent/assent given the sensitivity of signing documents in this setting and the increased risk this has for a breach of confidentiality. We will indicate whether informed consent was obtained on confidential screening and enrollment log to which only the research team has access. We will require verbal parental/caregiver permission for participants who are below the age of 18 per Zambian law. Each adolescent will be required to provide permission for the guardian to be contacted. Then, research assistants will seek verbal informed consent from the guardian for their adolescent's participation followed by informed assent from participants who are 15–17 years of age, which will be obtained in private without the parent/caregiver present.

Confidentiality

Study participants will be assigned a unique study identifier. All data will be coded with this identifier and will not include identifiable information. The only place that this code is connected to identifiable information is in a password protected database that only the main study coordinator can access.

Discussion

Access to evidence-based services and research on the effectiveness of existing interventions to treat and prevent AOD use disorder is limited in humanitarian settings (Fine et al., 2022; Hanna, 2017; Kane et al., 2014; Roberts & Ezard, 2015). This study aims to fill critical gaps in evidence on AOD use interventions in humanitarian contexts by testing SBIRT, a package of interventions designed to address unhealthy alcohol use and co-occurring mental health problems. We will evaluate the effectiveness and implementation of SBIRT delivered by lay providers in reducing unhealthy AOD use and co-occurring mental health problems.

Several aspects of this study and its design are innovative. To our knowledge this is the first fully powered RCT evaluating an intervention designed to reduce unhealthy alcohol use in a humanitarian context, although other efforts are currently underway. Second, this study will be conducted within an integrated refugee settlement and aims to reach both Congolese refugees and members of the Zambian host communities and train representatives from these two populations as BI and CETA counselors. Third, this study aims to fill gaps in AOD intervention research conducted in low-resource settings by implementing a package of interventions to address a range of unhealthy alcohol use severity as well as mental health and other drug use comorbidities.

This study has limitations and anticipate challenges. First, the complex and dynamic humanitarian context is likely to present challenges for recruitment and retention of study participants, particularly given active repatriation efforts.

To promote reach and recruitment, we have hired a team of community outreach workers who participated in the first CETA training to engage with hard-to-reach communities about the study and promote recruitment and retention. To mitigate attrition risks, we inflated our sample size to account for high levels of attrition, aimed to identify counsellors who had not expressed interest in returning to the DRC and trained Zambian counsellors who were less likely to relocate outside of the study area. Second, there is very little information on help-seeking for and the acceptability of AOD use disorder services in humanitarian contexts and in the rural Zambia and Congolese refugee populations. We completed a series of qualitative interviews and focus group discussions to determine the most appropriate and acceptable processes for implementing SBIRT within the study context, which informed the procedures described in this study protocol. Third, we experienced challenges during the SBIRT training that led to a series of adaptations to the BI and CETA. Thus, aspects of this model are being implemented for the first time and may present unanticipated challenges to supervision, fidelity and implementation, which we will monitor throughout the study.

If the *Ukuundapwa Chapamo* study finds that SBIRT is effective, this intervention may serve as a model for implementing interventions to address unhealthy AOD use and co-occurring mental health problems in humanitarian settings. The implementation and cost-effectiveness data collected as part of this trial will inform the resource needs and service delivery strategies for SBIRT implementation in similar contexts.

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Key implications for practice

- Unhealthy alcohol and other drug (AOD) use is common in humanitarian settings.
- A screening, brief intervention and referral to treatment (SBIRT) approach is evidence-based for addressing AOD use in high-income countries but has not been tested in low-income humanitarian settings.
- This trial will test an SBIRT intervention featuring the common elements treatment approach (CETA) in reducing unhealthy AOD use among people of concern from Democratic Republic of the Congo and Zambian members of the host communities surrounding Mantapala, an integrated refugee settlement in northern Zambia.

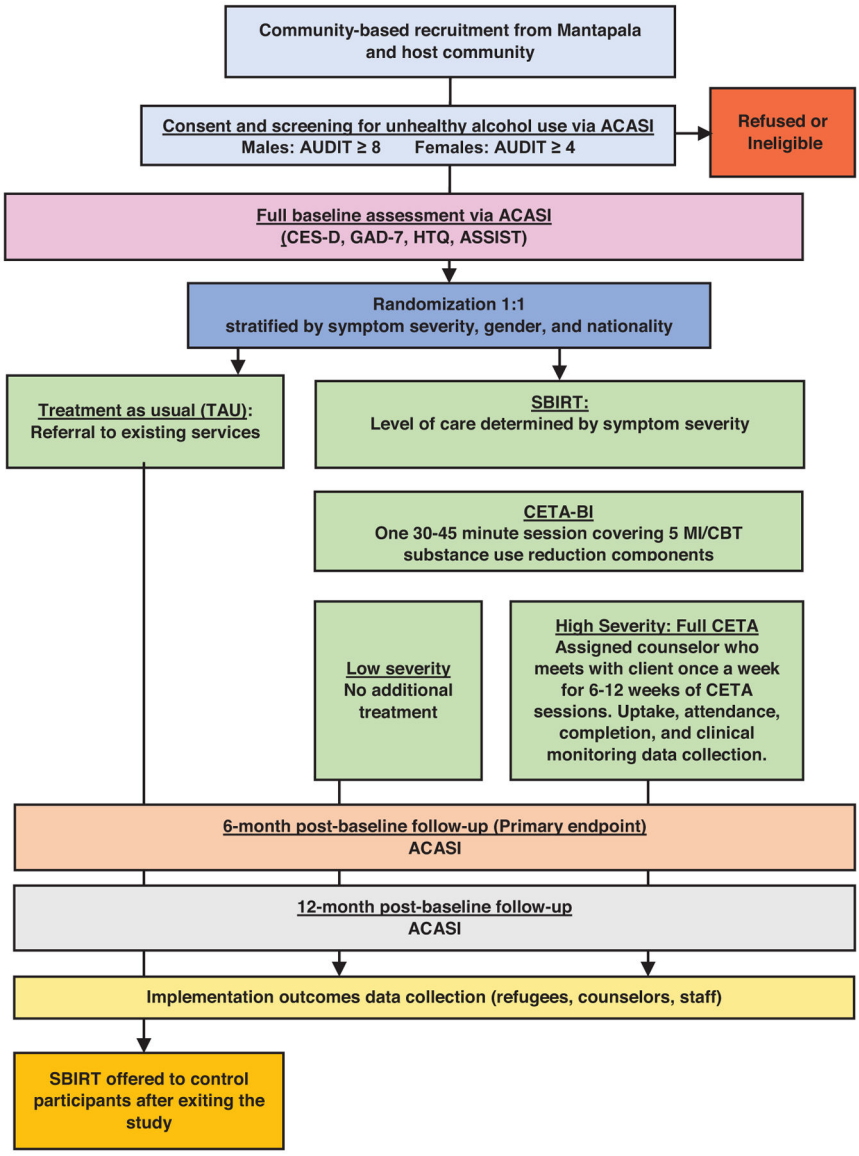

Figure 1.
Study Flow

Table 1

Outcome Measures

Outcome	Measure	Description	Clinically relevant cut-off score to evaluate risk level	Time points (months from enrollment)
Unhealthy alcohol use (primary)	Alcohol Use Disorders Identification Test (AUDIT) (Babor et al., 2001; Saunders et al., 1993)	AUDIT is a 10-item measure of hazardous alcohol use. A total score is calculated across the items with a possible range of 0–40 and higher scores indicating more severe alcohol use problems. The AUDIT was previously validated for use in Zambia (Chishinga et al., 2011)	Initial eligibility for unhealthy use: ≥4 among women or ≥8 among men; eligibility for more severe problem/higher risk of AUD: ≥12 among women or ≥16 among men (Babor et al., 2001; NIAAA, 2005b)	0, 6, 12
Depression (secondary)	Center for Epidemiological Studies-Depression (CES-D) (Radloff, 1977)	CES-D is a 20-item measure of depression symptoms. Participants are asked how often they experienced each symptom over the past week (0 = never or less than 1 day; 1 = 1–2 days; 2 = 3–4 days; 3 = 5–7 days). A total score is calculated with a possible range of 0–60 and higher scores representative of more severe depression symptomatology. The CES-D was previously validated in Zambia. (Chishinga et al., 2011)	CES-D total score ≥16 (Vilagut et al., 2016)	0, 6, 12
Anxiety (secondary)	Generalised Anxiety Disorder-7 (GAD-7) (Spitzer et al., 2006)	GAD-7 is a 7-item measure of general anxiety symptoms. Participants are asked how often they have experienced each symptom in the past week (0 = not at all; 1 = several days; 2 = more than half the days; 3 = nearly every day).	GAD-7 total score ≥10 (Spitzer et al., 2006)	0, 6, 12
Trauma symptoms (secondary)	Harvard Trauma Questionnaire (HTQ) (Mollica et al., 1992)	HTQ is a 39-item scale assessing symptoms of post-traumatic stress. Participants are prompted to respond how often each symptom bothered them in the past week (1 = not at all; 2 = a little; 3 = quite a bit; 4 = extremely). An average item score is calculated with a possible range of 1–4 with higher scores indicative of greater trauma symptoms. A previous study in Zambia demonstrated strong internal reliability of the HTQ (α>.90). (Kane et al., 2017)	HTQ average item score ≥2.5 (Mollica et al., 1992)	0, 6, 12
Substance use (secondary)	Alcohol, Smoking, and Substance Involvement Screening Test (ASSIST) (Humeniuk et al., 2008)	ASSIST is a 7-item measure that evaluates frequency of use, abuse, and dependence symptoms for a range of substance types, including tobacco, alcohol, marijuana, inhalants, cocaine, sedatives, hallucinogens, methamphetamines, and opioids. A specific substance involvement (SSI) score is calculated for each substance type that a participant reports ever having used in their lifetime. An SSI score can range from 0 to 39. The ASSIST was previously validated in Zambia. (Kane, Murray, Bass et al., 2016b)	A non-alcohol/tobacco SSI score on the ASSIST of ≥27 (Humeniuk et al., 2010)	0, 6, 12

Table 2

BI Elements

Element		Description
Assessment	•	Assessing clients current drinking through completion of a 2-week timeline follow back measure
Understanding impacts	•	Reviewing core ways substance use can impact an individual family and communityIdentifying the ways substance use impacts the individual and their family directly
Exploring change	•	Exploring possible ways the client would consider changing or reducing their use
Goal setting	•	Setting a goal for one way the client could reduce in the next few weeks
Identifying the reasons	•	Understanding motivations for using
Skill building	•	Teaching a coping skill to help the client combat one of their primary reasons for use

Intervention (Amstelveen). Author manuscript; available in PMC 2023 May 24.

Table 3

CETA Elements

Element	Simplified name (used in training)	Description
Psychoeducation and engagement	Introduction and Encouraging Participation	• Focus on obstacles to engagement • Linking program to assisting with client's problems • Includes family when appropriate • Program information (duration, content, expectations) • Normalization/validation of current symptoms/problems
Anxiety management strategies	Relaxation	• Strategies to improve physiological stress • Examples: deep breathing, meditation, muscle relaxation, and imagery. Others added by local cultures.
Behavioural activation	Getting active (GA)	• Identifying and engaging in pleasurable, mood-boosting, or efficacy-increasing activities
Cognitive Coping/Restructuring	Thinking in a different way –Part I and Part II(TDW1 and TDW2)	• Understand association between thoughts, feelings, and behaviour • Learn to restructure thinking to be more accurate and/or helpful
Imaginal Gradual Exposure	Talking about trauma memories (TDM)	• Facing feared and avoided memories in detail • Gradual desensitization/exposure
In vivo exposure	Live exposure	• Facing innocuous triggers/reminders in the client's environment • Gradual desensitization/exposure
Suicide/Homicide/danger assessment and planning	Safety	• Assessing client risk for suicide, homicide, and domestic violence • Developing a focused plan with the client and client's family (when appropriate) • Additional referral/reporting when needed
CBT for substance use and relapse prevention	Substance Use Element (SU)	• Utilises motivation and CBT principles and activities to get client buy-in and alter behaviour patterns to change substance use/abuse behaviour.