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Couples motivational interviewing with mobile breathalysers to reduce alcohol use in South Africa: a pilot randomised controlled trial of Masibambisane

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ABSTRACT

Introduction Heavy alcohol use among people living with HIV in sub-Saharan Africa can hinder the success of HIV treatment programmes, impacting progress towards United Nations Programme on HIV/AIDS goals. Primary partners can provide critical forms of social support to reduce heavy drinking and could be included in motivational interviewing (MI) interventions to address heavy drinking; however, few studies have evaluated MI interventions for couples living with HIV in sub-Saharan Africa. We aim to evaluate the feasibility and acceptability of a couple-based MI intervention with mobile breathalyser technology to reduce heavy alcohol use and improve HIV treatment outcomes among HIV-affected couples in South Africa.

Methods and analysis We will employ a three-arm randomised controlled trial to assess the efficacy of couple-based MI (MI-only arm) and in conjunction with mobile breathalysers (MI-plus arm) to address alcohol use and HIV outcomes, as compared with enhanced usual care (control arm). We will enrol heterosexual couples aged 18–49 in a primary relationship for at least 6 months who have at least one partner reporting hazardous alcohol use and on antiretroviral therapy for 6 months. Participants in both MI arms will attend three manualised counselling sessions and those in the MI-plus arm will receive real-time feedback on blood alcohol concentration levels using a mobile breathalyser. Couples randomised in the control arm will receive enhanced usual care based on the South African ART Clinical Guidelines. Feasibility and acceptability indicators will be analysed descriptively, and exploratory hypotheses will be examined through regression models considering time points and treatment arms.

Ethics and dissemination The study was approved by the University of California, San Francisco (HRPP; protocol number 21-35034) and Human Sciences Research Council Research Ethics Committee (REC: protocol number 1/27/20/21). We will disseminate the results at local community meetings, community-level health gatherings and conferences focused on HIV and alcohol use.

Trial registration number NCT05756790.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ Intervention was developed and tailored to the cultural context of heterosexual couples in a rural setting of KwaZulu-Natal.
⇒ Uses a dyadic approach to intervene to collect and analyse intervention effects on both partners.
⇒ Incorporates an alcohol biomarker to mitigate the limitations of self-reported drinking behaviour.
⇒ Small pilot study not powered to detect changes in behavioural outcomes.
⇒ Relatively short follow-up period of 6 months does not allow for the assessment of long-term health effects.

INTRODUCTION

Background

In sub-Saharan Africa (SSA), alcohol use is described as 'adding fuel to the fire' for people living with HIV (PLWH),[1] threatening the success of HIV treatment programmes and progress towards United Nations Programme on HIV/AIDS goals.[2–5] South Africa is severely impacted by HIV, particularly in KwaZulu-Natal (KZN) where 27% of adults are infected with HIV.[6] At 11 L of pure alcohol per year, South Africa has some of the highest levels of per capita drinking in the world.[7] Among PLWH who drink in South Africa, 50%–90% report heavy alcohol use.[8–10] Notably, South Africa also has some of the highest rates of gender-based violence worldwide,[11 12] which is closely linked to heavy alcohol use.[13 14] For PLWH, alcohol use contributes to poor adherence to antiretroviral therapy (ART) and retention in HIV care.[15–17]

Our research in SSA suggests that primary partners are key to the success of alcohol interventions given their critical role in helping people reduce alcohol use and the couple dynamics that intersect with alcohol

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use.[18–21] In South Africa, partners mitigate the harms of alcohol use by helping drinkers manage their alcohol use while maintaining adherence to ART[19]; however, communication around reducing alcohol use is not always effective and can be limited by gender-based power imbalances. This suggests the need for interventions to build couples' communication skills and shared decision-making around alcohol use.[20] Harnessing this powerful form of social support is critical in a setting where clinical services for alcohol misuse are inadequate and can be costly for patients.

One approach that has been effective at reducing alcohol use among PLWH is motivational interviewing (MI) in conjunction with mobile technology for real-time feedback on drinking levels.[22–29] MI is a collaborative, goal-oriented style of communication with particular attention to the language of change.[30] It is designed to strengthen personal motivation for and commitment to a specific goal by eliciting and exploring the person's own reasons for change in an atmosphere of acceptance and compassion.[30] Few MI approaches with couples have been developed for alcohol use, particularly in the African context.[21 31–33] Although Starks articulated a comprehensive framework for MI practice with couples,[34] most of the research on feasibility and acceptability (F&A),[21 35] and preliminary efficacy[32 36] of the approach has come from the study of male couples in the USA.

In studies with individuals, daily monitoring of drinking levels, when paired with MI, has a greater effect on drinking than MI alone[27–29] and we hypothesise that monitoring may have additional benefits with couples. Although primary partners are generally aware of a person's alcohol use, they may have inaccurate knowledge of drinking amounts and frequency if not drinking together. Accurate knowledge of drinking levels in real time is critical to trigger couples' communication as well as timely and tailored social support. Mobile breathalysers have been shown to be a feasible and acceptable strategy for self-monitoring alcohol use in studies with individuals and new products have been developed for dyads that allow for sharing of blood alcohol concentration (BAC) levels with support partners via a mobile app.[37–39] In sum, mobile breathalysers can provide real-time feedback and support, which can be synergistic with an MI approach with couples that fosters couple communication and problem-solving skills to effectively engage with the breathalysers and work together to reduce alcohol use.

Objectives

The main aim of this study is to evaluate the F&A of a couples-based intervention for heavy alcohol consumption among HIV-affected couples (Masibambisane, "Let's work together" in isiZulu). Our primary hypothesis is that Masibambisane will be feasible and acceptable. As exploratory hypotheses, we expect that participants who receive the intervention will report lower number of drinking days and heavy alcohol use (a combined measure of self-report and an alcohol biomarker), and greater rates of viral suppression and adherence to ART at follow-up visits.

METHODS AND ANALYSIS

Trial design

We will conduct a three-arm randomised controlled trial (RCT) with couples randomised to the following arms: (1) an enhanced usual care (EUC) control condition; (2) couple-based MI (MI-only arm) and (3) couple-based MI with mobile breathalysers (MI-plus arm). Couples in arm 2 and 3 will receive three MI sessions over a 60-day period with an experienced counsellor to help strengthen communication and problem-solving skills around alcohol use. Couples in arm 3 will use a mobile breathalyser and app for 60 days and receive the same MI sessions, which will incorporate feedback on BAC results into the sessions. This design will allow us to assess the efficacy of couple-based MI alone and the added synergistic effect of the mobile breathalysers on alcohol use and HIV outcomes (eg, adherence to ART, viral suppression).

Study setting

The Masibambisane study will be conducted by the Human Sciences Research Council (HSRC) in the Sweetwaters community, a rural area west of the capital of KZN, Pietermaritzburg, South Africa.

Eligibility criteria

Couples will be included in the study if they are: (1) in a primary relationship for at least 6 months; (2) aged 18–49 and (3) have at least one partner (the 'index patient') with a positive Alcohol Use Disorders Identification Test (AUDIT-C) screen (score of 3 or more for women and 4 or more for men; modified to cover the prior 3 months)[40] and on ART for at least 6 months. We expect all participants to be on oral ART regimens as long-acting ART was not available at the time of this study in South Africa. All participants living with HIV will be required to have disclosed their HIV status to their partner in the study. Lastly, both partners will separately agree to participate in order for the couple to be enrolled.

We will exclude participants with an AUDIT-C score greater than 12, indicating risk of severe alcohol use disorder. Participants with severe drinking issues may not benefit from a short-term counseling-based intervention and may need more intensive treatment than our study can provide. Our intervention may also not be appropriate for couples experiencing severe intimate partner violence (IPV). Thus, we will exclude those who fear for their safety by participating in the study and/or report severe IPV in the past 3 months. IPV is assessed using the WHO measure for South Africa, which assesses physical, sexual and emotional violence, and determines whether it is mild, moderate or severe.[41] This trial does not place restrictions on concomitant receipt of care for alcohol use or HIV care and treatment.

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Patient and public involvement

We adapted the Masibambisane intervention from the three-session couples MI intervention protocol originally developed by Starks *et al* for use in the Couples Health Project.[36] The original intervention was intended to reduce drug use and enhance primary HIV prevention among male couples in the USA. In contrast, the Masibambisane intervention will address heavy alcohol use among heterosexual couples in South Africa in which at least one partner is living with HIV. The adaptation process therefore had to consider: (1) cultural and linguistic context; (2) reformulation of the new target behaviour (ie, to heavy alcohol use) and (3) integration of the mobile breathalyser component.

We followed the ADAPT-ITT framework[42] to arrive at the final version of the Masibambisane intervention. Consistent with step 5 in the ADAPT-ITT framework, we conducted focus group discussions (FGDs) with 36 key stakeholders to gain feedback on the intervention content and activities, including perceptions of the mobile breathalyser technology. Key stakeholders included HIV care providers, alcohol vendors, community leaders and couples who drink alcohol. This feedback was integrated in the creation of a modified intervention manual (ADAPT-ITT step 6). The revised manual was reviewed by 8 members of the research team during the intervention training process (ADAPT-ITT step 7)—including the counsellors who would deliver the intervention. Their feedback was used to refine and finalise the Masibambisane manual to maximise usability and enhance cultural relevance.

Masibambisane intervention arms

Participants in the MI-only and MI-plus arms will receive three in-person manualised MI sessions as a couple with a trained counsellor in the language of their preference (either *isi*Zulu or English). Sessions take place approximately 30 days apart over a period of 2 months. In addition, the index participant in the MI-plus arm will make use of the mobile breathalyser and companion app, which will deliver real-time feedback on the index participant's BAC levels to both partners for 2 months. The couples randomised to MI-plus will receive brief technology training on how to operate the mobile breathalyser and app followed by a short trial period to become familiar with the technology before starting intervention activities. All sessions are conducted with both partners together and each lasts 60–75 min. The manual will provide guidance on sequencing of content. It is executed in a manner consistent with the spirit, processes and techniques of couples MI outlined by Starks.[34 36]

Session 1

The counsellor first orients the couple to the structure and nature of the intervention and reminds them about the limits of confidentiality. After initial engagement and rapport building, the counsellor invites the couple to reflect on communication strengths and weaknesses before engaging in strengths-based communication skill building. The topic of alcohol use is introduced through the use of a calendar activity developed for Starks' previous studies.[32 36] Partners who report heavy alcohol use at baseline complete the calendar by indicating days they consumed alcohol in the past 30 days. This serves as an immediate feedback tool that the counsellor uses to catalyse a conversation about alcohol use and evoke relevant change talk. This discussion culminates in the couple identifying what they would like alcohol use to look like in the coming month and developing a shared plan to accomplish that goal. The session ends with the counsellor inviting the couple to notice communication successes and challenges and to schedule a pleasant event together in the coming month (in addition to summarising the couple's alcohol-related goals and plans).

Session 2

The session begins with a check-in on recent communication and goals from the previous session. The couple then completes a values card-sort exercise highlighting shared values and joint goals. For Masibambisane, the standard values card sort deck[43] used in previous MI interventions with couples[36] was modified to increase cultural relevance and translated into isiZulu. Following the card-sort exercise, counsellors refocus the conversation on alcohol use by completing another calendar activity. For participants randomised to couples MI, this procedure mirrors that used in session 1. For couples randomised to MI-plus, the counsellor presents the couple with breathalyser data for the index partner from the prior month, presented in a calendar format. Data for the non-index partner (if also reporting heavy alcohol use at baseline) are added to this calendar. In addition to debriefing the calendar, couples in the MI-plus condition discuss their experiences using the breathalyser and receiving the BAC readings of their partner. After the calendar is created and debriefed, the counsellor further evokes change talk with a series of questions about potential consequences of drinking. Similar to session 1, the discussion culminates in the couple identifying what might be reasonable drinking limits for the coming month and developing a shared plan to accomplish that goal. The session ends with the counsellor inviting the couple to notice communication successes and challenges and to schedule a pleasant event together in the coming month (in addition to summarising the couple's alcohol-related goals and plans).

Session 3

The session begins with a check-in on recent communication and goals from the previous session. Similar to session 2, counsellors then refocus the conversation on alcohol use by completing another calendar activity. As in session 2, participants randomised to MI-only complete the calendar following session 1 procedures. Those randomised to MI-plus are presented with a calendar containing prior month breathalyser data. After the calendar is created and debriefed, the counsellor further

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evokes change talk with a series of questions about potential consequences of drinking specifically for HIV-related healthcare outcomes and the couple's communication and sexual interactions. Similar to session 1, this discussion culminates in the couple identifying their drinking goals for the coming month and developing a shared plan to accomplish that goal. Finally, counsellors engage in a termination discussion. This begins by inviting the couple to reflect on their experiences over the past 2 months while engaged in the intervention. The couple then looks ahead and considers long-term goals—including specific goals for limits on alcohol use—and constructs a shared plan to accomplish them.

Mobile breathalyser and app

We will use BACtrack View, which consists of a handheld commercial-grade breathalyser and accompanying mobile app. Index patients will receive twice-daily Short Message Service (SMS) message requests to complete a breathalyser reading at 11:00 hours and again at 20:00 hours. Given the frequent power outages in South Africa, which often result in a loss of cellular service, participants will be allowed to complete missed tests as soon as the power returns. To avoid disruptions in cellular service by having to manually purchase data, we will automatically provide cellular data to perform the tests. We will also provide phones to participants who do not have compatible smartphones and power banks to keep phones and breathalysers charged during power outages.

To complete a breathalyser test, the participant will log into the mobile phone app and follow a series of prompts to blow into the breathalyser in front of the phone camera, which displays the BAC value, and transmits the BAC value and photo of the participant taking the test to the BACtrack View server for storage. After successfully completing the test, the partner will receive an SMS message informing them of the BAC value from the index patient. The study coordinator is notified of BAC results and/or missed tests and can log into the BACtrack View app to view all tests results completed over a monthly period. A trained technology navigator will be assigned to each couple, who will reach out to couples who are missing tests and will be available for support as couples are getting started with the BAC tests. At the end of each 30-day period, BAC results are mapped onto monthly calendars and used in subsequent MI counselling sessions.

Control arm: EUC

Couples in the control arm will receive EUC, with usual care defined by the South African national 2019 ART Clinical Guidelines.[44] As part of clinical care for HIV, the harms of alcohol use are briefly discussed during the morning health talks in the waiting rooms of HIV clinics. HIV clients are advised that alcohol intake should be fewer than two standard drinks/day for men and one for women, and drinking should not occur daily (at most 5 out of 7 days per week). After randomisation, couples in the control arm will receive additional alcohol counselling modelled on WHO guidelines and Conroy *et al*'s intervention in Malawi, which uses participants' baseline AUDIT scores for messaging around alcohol reduction and lasts 10–15 min.[45] In selecting the control, we chose to balance our ethical obligation to provide basic health information on alcohol use (minimal in this setting), while maximising the generalisability of our findings to inform a future RCT, which will employ a EUC control group. Clinical trial experts recommend the usual care condition over other designs such as a time-and-attention control (TAC) when the long-term goal is to inform implementation science and scale-up.[46 47] Our long-term goal will be to test the effectiveness of a scalable alcohol intervention. Moreover, because TAC designs have an active but different intervention, there is the risk of positively biased intervention results because the comparison arm can distract participants from making reductions in alcohol use they would have otherwise made.[46 47]

Training of staff

Given the skills required to deliver MI, we will hire certified HIV testing counsellors with 2+ years of counselling and/or facilitation and community experience. Facilitators and the HSRC research manager will attend a week-long didactic training workshop (in-person, at the HSRC) with Starks *et al*. Starks is a licensed clinical psychologist and an MI-trainer certified by the Motivational Interviewing Network of Trainers.

The training workshop will begin with a 1-day introduction to individual MI skills.[30] This workshop will focus on the spirit of MI, engaging skills (open questions, affirmations, reflections and summary statements), and recognising change talk (expressions of desire, ability, reasons, need, commitment, activation and taking-steps to change). The first training day will end with a demonstration of couples MI delivered in *isi*Zulu (through a translator) by Starks. Days 2–5 will focus on the spirit, processes and skills of MI with couples. Activities will consist of brief didactic presentations of content interspersed with worksheets to reinforce knowledge acquisition and a wide variety of role-play activities permitting practice. Beginning in day 3, role play activities will be used to introduce counsellors to key aspects of the intervention protocol and facilitate practice with immediate feedback from Starks.

Following the training workshop, all interventionists will complete a series of training mock sessions to practice the intervention content. These will be completed in English, recorded and reviewed by Starks. Counsellors will receive written feedback and meet biweekly with Starks to discuss progress in the mock session process and review relevant skills. All interventionists will complete a minimum of two mock sessions for each intervention component before being cleared to deliver the intervention to participants.

We will also train a pair of interviewers to recruit couples and conduct assessment visits, who will be gender-matched to partners. AAC and RB will lead additional training with

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staff, covering topics on couples counselling, the mobile breathalyser technology, how to handle ethical issues with couples, health education around alcohol use and HIV, the intervention manuals and procedures, and professional conduct.

Fidelity monitoring and supervision

Once cleared, interventionists will meet monthly (via Zoom) with Starks for group supervision while sessions are ongoing during the trial. These meetings will provide an opportunity to present and discuss cases, review relevant skills and discuss ongoing challenges to protocol delivery.

Given the large number of sessions conducted, we will select a sample of sessions (around 15%) to perform additional fidelity checks giving equal attention to all counsellors and all sessions. For these sessions, a peer facilitator (ie, another counsellor) or the research manager will complete a checklist using either transcripts or audiorecordings to ensure each activity in the manual was covered. Intervention sessions will be audiorecorded. Self-assessment forms will contain rating for key MI components (eg, collaboration, respect). A separate space on the checklist and self-assessment forms will be provided for written comments. After each session, counsellors will complete the self-assessment form. Completed forms will be discussed in regular Zoom calls with the team to discuss areas where further guidance is needed and to help problem-solve challenges. Finally, Starks will listen and provide feedback on any sessions conducted with English-speaking couples as an additional check on fidelity to the intervention protocol.

Recruitment

Community-based recruitment will be used to identify index patients at community-based organisations or locations in the community where people who drink alcohol can be found. Recruiters will use procedures established at HSRC to identify and recruit participants using a community mobilisation approach. A team of recruiters will target individuals and couples in public areas in the community, including alcohol venues (eg, shebeens, bottle shops), markets, sports grounds, taxi ranks, HIV clinics and community events. Though couples will be targeted together if possible, couples may not be together in public[48] and this could hinder successful recruitment of couples into research studies in the area.

Passive recruitment will also be used. This includes distributing community flyers describing the study and encouraging interested individuals to contact the project staff by calling or sending a free 'please call me' SMS text message to the listed cellular phone number. Recruiters will respond to these messages as soon as possible, typically no later than the next working day. Passive recruitment will further be employed through flyers placed at the clinics. Clinic-based outreach teams and care providers will assist in identifying HIV patients who use alcohol use and have been on ART for at least 6 months, referring them to HSRC recruiters. In all recruitment approaches, recruiters will ask potential participants if they would like to hear about the study and explain the nature of the study using standard recruitment scripts.

Screening for participation

Screening will be a two-step process. The initial screener will be delivered either in-person or over the phone. If recruited in person, the screener will take place in a private location identified by the recruiter. Partners in a couple will be screened separately to ensure confidentiality. If the participant cannot complete the initial screener in the field, the recruiter will record their contact information for a later phone screening. Once deemed eligible to continue, the recruiter will inform the index participant that their partner must also be screened. Contact information for the recruited partner will be collected and permission to call them will be obtained. Alternatively, the partner can initiate contact via a 'please call me' SMS text message. The index participant will be provided with study information to share with the partner.

Couples meeting initial eligibility criteria will be given a secondary screener in person that asks a variety of questions not limited to IPV. The members of the couple will be screened simultaneously but separately by gender-matched interviewers. The goal is to screen out illegitimate couples or those who experienced severe IPV in the past 3 months or have safety concerns. In case a couple is deemed ineligible due to IPV, they will not be informed of the reason for ineligibility to minimise any unintended harms. As part of the second screener, questions about how the couple met will be asked (with the answer not recorded). After completing the second screener, the two recruiters will compare their notes and determine if the couple is legitimate. If not, the recruiters will inform the couple of their ineligibility without providing a specific reason.

During this screening interview, staff will use a rapid HIV test to confirm HIV status for all participants who reported living with HIV. If the index patient tests negative for HIV on the point-of-care HIV test, they will be considered ineligible. Both partners must be eligible for the couple to be considered eligible for the study.

If both members of the couple report heavy alcohol use during screening and are on ART, the male partner will be assigned to be the index patient given that drinking among men is generally more frequent than women in similar types of couples.[18 49] For the MI-plus arm, only the index patient will receive the breathalyser and mobile app as the tester; their partner will only receive SMS text notifications of their BAC levels.

Randomisation

After informed consent and the baseline assessment, couples will be randomised to the control arm, the couple-based MI arm or the couple-based MI with mobile breathalysers arm (MI-plus). We will use randomly permuted block sizes (eg, 3, 6 and 9) generated using

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a computerised and secure process. The University of California San Francisco (UCSF) project coordinator and the HSRC data manager will use the table that the study statistician created to print documents that assign participants to one of the three arms. These documents will be placed in sealed envelopes ordered sequentially in a box and maintained by the HSRC data manager in a locked cabinet. HSRC interviewers will take a small subset of envelopes into the field with them and will be trained to administer random assignments following the order of the envelopes. At the end of the baseline survey, the index patient will be given the envelope that contains the random assignment. Couples will receive an appointment card with a date for their next study visit following randomisation.

Blinding

Counsellors delivering the intervention cannot be blinded to the intervention condition. Assessment staff are different from the staff who delivered the intervention to a given couple. However, because the assessment staff work in close collaboration with the counsellors in tracing couples and assisting with technology navigation for those in the MI-plus arm, we cannot fully guarantee that assessment staff will be blinded from the intervention condition as well. Participants will also not be blinded to the intervention condition and will be informed during randomisation of their assigned group.

Data collection

Study assessments will occur at baseline, 2 months and 6 months postintervention initiation. The 2-month visit will occur after completion of the MI sessions. All surveys will be delivered in-person using same-sex interviewers who are fluent in both English and *isi*Zulu to be able to use the participants' preferred language. Study staff will enter data directly into REDCap using a mobile tablet. The REDCap mobile app is designed to be used without internet access, so it is suitable for areas with an internet connection.

Laboratory testing

At the 2-month visit, dried blood spot (DBS) samples will be collected from all participants who reported heavy alcohol use at baseline to test for Phosphatidylethanol (PEth), an alcohol biomarker that is well correlated with total alcohol consumption in the prior 2–4 weeks.[50 51] Additionally, at the 2-month visit, DBS samples will be collected for all index patients living with HIV to test for viral load. We will prepare DBS by pipetting whole blood onto Whatman 903 cards. DBS cards for PEth will be stored at room temperature in locked cabinets and transported to a commercial laboratory in the USA for PEth quantification (16:0/18:1 analogue), with lower limit of quantification of 8 ng/mL.[52] PEth is well correlated with breathalyser-assessed number of days drinking over 21 days[53] and the volume of alcohol consumed in the past 21 days.[51] DBS cards for viral load will be transported on a daily basis to an accredited laboratory in South Africa and processed using the Panther System with a lower limit of detection of 883 copies/mL.

Data management

We will use built-in controls within REDCap to restrict out of range values and prompts will be given to alert the user to missing data or unusual entries. The mobile application displays questions on the screen and then gives interviewers the ability to enter responses directly into the mobile phone or tablet. Once complete, the research instrument (ie, survey, baseline interview) is temporarily stored in a non-readable encrypted file on the device/tablet. When in an area with network coverage or back at the research office, completed forms are uploaded and removed from the tablets approximately every 60 s. If no network signal is present, the data are stored on the mobile device until such time that it detects a network signal. Checks will be placed to ensure correct information has been entered by the HSRC Research Manager. Information from the research instruments is then uploaded to a secured server. The data undergo both internal and external quality checks, conducted by the UCSF Research Manager and the HSRC Data Science Unit. Additionally, incoming data will be monitored daily to identify any unusual or unexpected entries. In cases where such entries are detected, data queries will be generated, and the HSRC team will be contacted to address and resolve these queries.

Retention

On enrolment, we will obtain contact information (eg, two cell phone numbers, directions to households and contact information for up to three other individuals) to facilitate tracking. Participants will be contacted regularly (eg, twice a month) to update contact information and check on location. Prior to the assessment visits, reminder calls and SMS messages will be made to both partners 1 week before the appointment and again 1–2 days prior. For participants who miss appointments, we will limit the number of phone call attempts to 3–4 to respect privacy and the right to refuse. There may be special circumstances when outreach workers will be dispatched to participants' communities (with their prior consent) such as when calls do not go through.

We anticipate that we will lose a very small percentage of couples due to break-ups, deaths and migration (<5%), which we have accounted for in recruitment and analysis plans. One assessment will be conducted with each partner separately following the break-up to understand when the couple broke up, whether study participation contributed to the break-up, and if not, other reasons for why the couple broke-up.

The breakup assessment will also allow us to identify any negative effects of participation on couples. If the study contributed to the break-up or the break-up was a negative experience, we will follow the adverse event logging process. We will continue to follow each partner

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individually and administer study assessments given that our study outcomes (eg, alcohol use) are at the individual level. This will allow us to explore whether participation in the study, despite the break-up, had any effect on their alcohol use; however, couples who break-up before participation in the intervention will exit the study.

STUDY OUTCOMES

Primary F&A outcomes

The primary goal of this pilot trial is to assess F&A of Masibambisane. The primary F&A outcomes and corresponding targets are: enrolment rate (proportion of eligible couples who enrol in the study; target: 80%) and retention rate (proportion of couples who complete the 6-month follow-up survey; target: 85%).

Secondary F&A outcomes

Secondary F&A outcomes are: satisfaction rate (proportion of couples who report being satisfied or very satisfied with Masibambisane at the 2-month follow-up: target: 75%), midpoint survey completion rate (proportion of couples who complete the 2-month follow-up survey; target: 85%), session completion rates (proportion of couples who attend 100% of sessions; target: 75%) and breathalyser test completion rate (proportion of tests taken after prompted; target: 70%).

We will also assess fidelity to the intervention by having the manager or facilitators complete detailed checklists after each session to document activities conducted. As a second check, we will audiorecord all sessions and have an independent research assistant listen to a subset of recordings and complete the same checklists. We set a target of 80% fidelity.

Secondary health outcomes

Although we are not powered to examine treatment effects, we will explore the effect of Masibambisane on the alcohol use among the partner reporting hazardous alcohol use at baseline: number of drinking days in the past 30 days (assessed via the timeline follow-back, assessed at 2 months and 6 months), non-heavy alcohol use (ie, a composite measure consisting of a negative AUDIT-C score[40] in the past 3 months and PEth value <35 ng/mL, a recommended cut-off value,[54] both assessed at 2 months), and raw AUDIT-C score (0–12); and among the partner with HIV: optimal ART adherence (95% or higher on the Visual Analogue Scale[55]), and viral suppression (less than 1000 copies/ml per HIV clinical guidelines).[44]

Additional exploratory outcomes include relationship dynamics such as constructive communication (communication patterns questionnaire[56]; alpha=0.69–0.72); alcohol-specific partner social support (adapted based on the social provision scale[57]; alpha=0.84), trust (dyadic trust scale[58]; α=0.82), intimacy (emotional intimacy subscale of Sternberg love scale[59]; alpha=0.90), unity (inclusion of self-in-other measure[60]), relationship satisfaction (couple satisfaction index,[61] single item) and sexual satisfaction (couple sexual satisfaction scale[62]; alpha=0.89). Because we expect that reductions in alcohol use and improvements in relationship dynamics may reduce IPV, we will also explore effects on physical, sexual and emotional violence as measured by the WHO domestic violence module.[63 64] All relationship dynamics and IPV types will be modelled as continuous variables.

Sample size

Formal tests of health outcomes or attempts to obtain valid estimates of effect sizes are not statistically justified for the proposed study.[65–69] Pilot studies, by design, cannot definitively test hypotheses due to their smaller sample sizes and the frequent design adjustments necessary to maximise recruitment, retention and quality assessment of outcomes.[65–69] Effect size estimates are not sufficiently reliable given the breadth of the confidence intervals; however, to supply additional information, we conducted several power analyses using NCSS PASS. In sum, our study is powered to detect small to medium distances to confidence limits for descriptive statistics and medium to large longitudinal analysis effects, though, as noted above, formal hypothesis testing will not be the focus of this pilot study.

Data analysis plan

F&A data analysis

The primary analyses will include descriptive statistics of F&A indicators, comparing each statistic (eg, percent retained) to the threshold described above. Above-threshold findings will suggest a reasonable level of F&A while below-threshold findings would suggest that remedial modifications to study procedures and/or design would be required prior to moving forward with a full-scale trial. We will stratify the statistics by gender to consider sex as a biological variable.

Exploratory hypotheses and analyses

Although the primary objective is to assess F&A rather than to conduct formal hypothesis tests, we will evaluate exploratory hypotheses as part of the assessment process. For example, we expect that: (1) participants in the MI-only arm will report a greater reduction in the number of drinking days and in lower odds of engaging in hazardous alcohol use than participants in the EUC control arm; (2) participants in the MI-plus arm will report a greater reduction in the number of drinking days and lower odds of engaging in hazardous alcohol use than participants in the MI-only arm. Secondarily, we anticipate that intervention participants will report higher odds of adherence to ART and viral suppression than those in the EUC arm. We also anticipate the intervention participants in both arms will report higher (indicating more positive) scores on relationship dynamics and lower scores on IPV than those in the EUC arm.

We will compute descriptive statistics to capture measures of central tendency for continuous variables and proportions for binary variables, by visit and by

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treatment arm. To explore the effect of Masibambisane on the secondary outcome of number of drinking days, we will use mixed-effects negative binomial regression models including all three time points. Negative binomial models are recommended for count-based outcomes like drinking days.[70] For the AUDIT-C score, we will use linear mixed-effects models including all three time points. For optimal adherence to ART, we will use mixed-effects logistic regression models including all three time points. Models will include random effects for participants and couples, and fixed effects for time point and study arm, interaction of time and arm and sex of the index patient. We will also explore the whether the effects are moderated by respondent type (ie, index patient vs partner).

To explore effects on biomarker-based outcomes captured only at 2 months (eg, heavy alcohol use, viral suppression) and only on index participants, we will use logistic regression models with treatment arm as the main predictor. For heavy alcohol use, which will be collected on both members of the couple, we will cluster based on couple ID to account for non-independent drinking levels within dual-drinking couples. All analyses will use an intention-to-treat approach to include every participant within the analysis based on their original randomisation group. Statistical analyses will be conducted in Stata V.18. If missing data exceed 5%, we will use multiple imputation via chained equations following methods in our prior studies.[71]

ETHICAL CONSIDERATIONS AND DISSEMINATION

Informed consent

Participants will provide written informed consent for the following activities: (1) to participate in the second screening interview, which asks personal questions about IPV; (2) to participate in the RCT and all procedures, including providing blood samples for PEth and viral load testing and (3) to export alcohol biomarker DBS samples to the US laboratory for testing. Partners will be consented individually in a private interview room by a gender-matched interviewer in the isiZulu or English, depending on the participant's preference. The consent process will cover topics on the purpose of the study, study procedures, potential risks and benefits, how confidentiality will be ensured, voluntary participation, the funding agency and study investigators, and contact information for the study PIs. The interviewer will go over all aspects of consent verbally and address any questions that the participant has about participation. We will capture signed consent using the REDCap mobile app. Participants will be given a paper copy of the consent forms. If participants are unable to read and write (as assessed by a brief reading comprehension tool), the interviewer will have a witness monitor the informed consent process and sign the consent form.

Confidentiality and privacy

Participants may face a loss of confidentiality, which could lead to social stigma, discrimination or physical and psychological harm due to their HIV status and alcohol use. To protect confidentiality, various measures will be taken, including staff training, using research identification numbers instead of names and secure data storage. There is also a risk of loss of privacy, especially when discussing sensitive topics such as HIV and alcohol use. Privacy will be maintained by using coded language and providing participants with strategies to protect their privacy, such as using discreet covers for breathalyser devices and phones. Participants will be assured that their responses will not be shared with their partners, and steps will be taken to address coercion or violence, including referrals to appropriate services.

Data safety and monitoring

This study protocol was approved by the HSRC Research Ethics Committee (REC: protocol number 1/27/20/21), the UCSF Human Research Protection Programme (HRPP; protocol number 21-35034) and is registered with ClinicalTrials.gov (NCT#05756790). A data safety and monitoring board (DSMB), composed of three independent experts in the field of HIV and alcohol abuse, has been convened in accordance with NIH policy. They reviewed and approved the study procedures for trial monitoring on 15 November 2022. The DSMB will convene every 6 months and also in response to the occurrence of any serious adverse events. Data on anticipated adverse events, including couple dissolution and IPV, will be gathered throughout the study and reported to the DSMB at biannual meetings. Unanticipated events and events reported spontaneously will also be summarised and reported at the meetings.

Trial modification and discontinuation

Trial modifications will be allowed given that this is a pilot study designed to maximise F&A; however, major changes such as to eligibility criteria or key aspects of the trial design will require approval from the study sponsor and DSMB. In the case of major changes, amendments would be filed with the UCSF and HSRC institutional review boards and the ClinicalTrials.gov record would be updated. Adverse events will be monitored by the DSMB, who could recommend pausing or halting of the study if needed. We have no plans to conduct any interim analyses for this small pilot study other than preliminary analyses of baseline data.

Ancillary and post-trial care

Participants will be provided with a list of resources for community-based services for HIV, couples and behavioural health at the start of the study. Participants who are flagged for suicidality, IPV or serious mental health concerns will be referred by the research staff to Lifeline (ie, a local organisation that handles psychosocial or mental health issues and has expertise in couples

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counselling) or other mental health services. The research team will contact the service provider to set up an appointment and then inform the participant of their appointment schedule. The team will follow-up with the participant later to ensure they were linked into services if they expressed an interest in obtaining help.

Dissemination

Sharing of data and results generated by this project will be carried out in several ways. The study findings will be made available on ClinicalTrials.gov. We will also deposit deidentified data in the US National Institute of Mental Health (NIMH) data archive (NDA) as required by the terms of the award. In collaboration with the HSRC community outreach team, results will be presented at local community meetings attended by participants and key stakeholders such as alcohol vendors. Results will also be presented at community-level meetings held by district and local health officials in collaboration with local HIV care clinics to ensure findings are disseminated to HIV policy-makers. Finally, results will be presented at HIV and alcohol use conferences and published in peer-review journals with authorship based on intellectual contribution and guided by American Psychological Association guidelines.

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Contributors AAC serves as the principal investigator for the Masibambisane study and oversaw the completion of this manuscript. RB, LM, BC and HH were contributing authors and served as project managers overseeing the implementation of the study protocol. TJS, AvH, JAH and TBN are study coinvestigators. All authors have read and approved the final manuscript.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

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