Document Coversheet

Study Title: Technological Intervention for Reducing Alcohol Use Among People Living With HIV/AIDS (TRAC)

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STUDY PROTOCOL

1. Introduction/Background Information/Scientific Rationale

People living with HIV/AIDS (PLWHA) are almost twice as likely to use alcohol as those in the general population,[1] and as many as half of PLWHA have a history of alcohol-related problems.[2] Alcohol can have severe negative effects on PLWHA by way of several mechanisms, but it has an especially negative impact on highly active antiretroviral therapy (HAART) adherence. On days when individuals have one or more drinks of alcohol, they are almost nine times more likely to be non-adherent to their medication regimen.[3] One study found that alcohol consumption was the strongest predictor of HAART adherence, having larger effects than depression, social support, heroin use, cocaine use, dosage amount, age, gender, or race/ethnicity.[4] It is clear that alcohol consumption must be addressed to increase HAART adherence and survival among PLWHA.

The strong link between alcohol consumption and treatment use and outcomes has led to interventions to reduce alcohol use among PLWHA, using methods including motivational interviewing and cognitive behavioral therapy. These interventions have had mixed results, with some leading to decreases in alcohol consumption and others yielding no significant effects.[5] Researchers have suggested that the use of technology to extend and enhance intervention effects may be a useful tool for improving effectiveness.[5] Hasin et al.[6] tested a brief intervention among PLWHA using motivational interviewing combined with daily self-monitoring using telephone-based interactive voice response. This combination led to decreases in drinking among problem drinkers as compared to control and a motivational interviewing-only conditions, suggesting the potential for using phone-based methods. This study was limited, however, by relying on self-reported measures of alcohol consumption and by requiring multiple visits to an urban HIV clinic. Considering that many HIV/AIDS case workers report that transportation is a significant issue for their clients,[7] it is likely that many of the previously tested interventions have had limited reach to those outside of urban areas.

The proposed study builds on previous literature aiming to reduce alcohol consumption among PLWHA by developing a new technology-based intervention and testing methods of delivery that may help to mitigate alcohol-related adherence issues. Members of the research team have previously conducted studies exploring alcohol reduction interventions for PLWHA (see U01AA020795, R01AA020031), which will guide the content for a new behavioral skills and self-monitoring intervention, Tracking and Reducing Alcohol Consumption (TRAC). To address issues of accessibility and transportation raised by previous research, TRAC will be exclusively delivered via technology, including smartphones and videoconferencing-based telemedicine. Counselors for this study will deliver the eight-session intervention to PLWHA through a combination of live interactive video and phone-based conversations, allowing patients throughout the state to access alcohol reduction counseling without traveling long distances. This intervention is based on theories of motivational enhancement and the technique of motivational interviewing, and is designed to be delivered by health educators in a variety of community settings. Thus, it does not require delivery by a licensed social worker or counselor, increasing the generalizability of the intervention. The proposed research will also utilize smartphones for self-monitoring of alcohol consumption and medication use, using mobile questionnaires and innovative Bluetooth-enabled breathalyzers. The use of breathalyzers means that researchers no longer have to rely solely on self-report for alcohol use data, but can have intoxication indicators transmitted wirelessly to online databases. This makes self-monitoring easier for participants by automating the process, while also increasing the validity of the measures. Overall, this technologically-enabled intervention will seek to improve access to alcohol reduction counseling for PLWHA by using telemedicine to extend reach to rural areas, while also allowing for automated collection of alcohol use data to support self-monitoring.

2. Hypothesis/ General Research Questions

This study will explore the following research questions:

- Is a technology-based alcohol reduction intervention feasible and acceptable for delivery to PLWHA?
- Do participants in the TRAC intervention adhere to self-monitoring tasks?
- Does participation in the TRAC intervention lead to reductions in alcohol consumption?
- Does participation in the TRAC intervention lead to improvements in medication adherence?

- Does participation in the TRAC intervention impact other clinical HIV outcomes, including CD4 count and viral load?

3. Study Objectives

The aim of the study is to conduct a pilot randomized controlled trial of the TRAC intervention among PLWHA:

- Two-month, randomized-controlled waitlist trial with 2-month follow-up (*N*=50)
- Feasibility evaluation, focusing on recruitment, engagement, and adherence
- Evaluation of effects on overall alcohol consumption, HAART adherence, and clinical outcomes

4. Study Design

Description of relevance to the VA

HIV occurs among veterans at a higher rate than among those in the general population. Moreover, many veterans struggle with alcohol use disorders, which can impact their health and overall quality of life. The TRAC intervention, which aims to reduce alcohol use among people living with HIV/AIDS, thus meets two important needs among the VA patient population.

Study Population and patient selection

Subject Inclusion Criteria: To be eligible to participate in the intervention, patients must be 1) HIV-positive, 2) 18 years and older, 3) an at-risk drinker as identified through a screening procedure, 4) currently taking HIV medication and 5) a patient receiving care at one of the study recruitment sites. Based on NIAAA's screening recommendations, every person living with HIV who reports to participating clinics will complete a short screening procedure. Clinical data of interest including alcohol dependency diagnoses and prescription use will be pulled from CDW via VINCI, CCR and HAVACS. These clinical indicators will be used to create a list of eligible patients with appointments in the coming month for screening. The list of eligible patients will be stored in the secure VINCI project folder and then downloaded to the secure local VA drive for use by study coordinators. The only two locations in which the list will be stored are within VINCI and on the secure local drive. After a list of patients has been created, the study coordinator will screen the patient EMR (CPRS/VISTA) for inclusion criteria.

Patients who are identified as eligible will be screened using a survey if they are interested in participating. First, they will be asked if they sometimes drink alcoholic beverages. If yes, they will be asked how many times in the past month they have had 5 or more drinks in a day (for men) or 4 or more drinks in a day (for women). They will also be asked if, on any week in the past month, they have had more than 14 drinks (for men) or more than 7 drinks (for women). If they answer yes to either of those questions, they are considered to be an at-risk drinker and will quality for the study. This screening may also be conducted over the phone if the participant indicates interest in the study but is unable to complete the screening procedure while visiting the clinic. If the screening procedure indicates that the participant is eligible, they may begin the study within 30 days time.

Subject Exclusion Criteria: Individuals who are HIV-negative, less than 18 years of age, who are not identified as an at-risk drinker through the alcohol screener, or who are not currently prescribed HIV medication will not be eligible to participate. For the randomized controlled trial, participants who have not had their viral load tested within the 3 months prior to beginning the intervention (3 months before baseline for the Intervention group, 3 months before the 8-week time point for the Waitlist-Control group) will not be eligible to begin the study until they have had bloodwork completed. Additionally, participants will take the AUDIT questionnaire as part of the study screener. If they score a 20 or higher, indicating alcohol dependence, they will not be eligible for study participation.

Study Recruitment

After screening, patients who are deemed eligible for the study may be recruited in the following ways:

- An IRB approved letter mailed to the patient and then after two weeks the patient may be contacted over the phone or in person at a clinic visit about the study unless they decline
- Through an approved study flyer or direct patient initiated contact to the study coordinator
- A clinic provider refers patient to study or gives patient study flyer at clinic visit

- Direct patient contact in the clinic at clinic visit
- Outreach to a patient who has previously signed an informed consent form for another research study which allowed for future contact

Study Intervention/Investigational Product
The TRAC intervention focuses on increasing motivation and building skills for avoiding triggers and managing situations that encourage drinking. It requires eight 30-minute sessions with a counselor using videoconferencing and mobile phones. There is also a short booster session conducted via phone 4 weeks after the participant completes the 8th session. The counselor will have training in motivational interviewing and receive credentialing through the VA. The intervention is designed for delivery by health educators in community settings and does not utilize any cognitive behavioral therapy, so it does not require a licensed social worker or counselor. Specifically, the content of the intervention will cover the following topics:

Session Emphasis	**Session Content**
Session 1. Study Introduction	1. Study Introduction 2. Self-monitoring and phone training 3. Breathing awareness exercise
Session 2. Developing a Change Plan	1. Increasing Motivation 2. Developing a Change Plan
Session 3. Triggers for Drinking Alcohol & Distraction techniques	1. Urges and Cravings 2. Emotional triggers 3. Situational and Environmental Triggers 4. Social Triggers 5. Distraction techniques 2. Personal distraction techniques
Session 4. Skill Building: Managing Urges and Cravings	1. Delay before acting 2. Negative consequences of drinking 3. Positive consequences of not drinking
Session 5. Skill Building: Managing Emotional Triggers	1. Improve the moment 2. Do something relaxing
Session 6. Skill Building: Managing Social Triggers	1. Drink refusal 2. Seek social support 3. Seek spiritual support
Session 7. Skill Building: Managing Situational and Environmental Triggers	1. Consuming alternate food or drink 2. Engaging in alternate behavior 3. Avoiding the situation or environment
Session 8. Looking Ahead	1. Summative self-assessment 2. Planning for the future
Booster Session	1. Review of drinking goals 2. Refresher of triggers and management strategies

The counselor will stick to a pre-written script in delivering the intervention content, while also allowing for some time to discuss the participant's drinking behavior over the past week and address any questions the participant might have. In addition to receiving the eight sessions of intervention content, participants will complete smartphone-based self-monitoring of medication adherence and alcohol consumption, which will be discussed during intervention sessions. Each day, they will be texted at two random times to complete a breathalyzer reading using a BACtrack Mobile Pro, which is sold by a company with FDA clearance and utilizes law enforcement-grade sensors for determining blood alcohol level. It connects wirelessly to phones via Bluetooth, automatically uploads readings, allows the user to view their current and past readings with a mobile app, and allows them to share their readings with counselors. At the time of the breathalyzer reading, participants will also be asked to indicate via survey how many drinks they have consumed and their medication use for the day. During intervention sessions, the counselor will discuss the patients' alcohol use reports from the previous week.

Study Procedures/Evaluations

Step 1: Patient recruitment and screening (Goal=50 patients total)

1. Three weeks ahead of patient medical visits, the VA research coordinator will send out a letter detailing the study information and informing the patient that they will have a chance to learn more and/or enroll at their next medical appointment
2. One week before the appointment, the VA coordinator will call the patients to tell them about the study and inform them that they will have a chance to enroll during their next appointment (see recruitment script)
3. Following a medical visit at the VA clinic, patients will be offered the chance to speak to the research coordinator about the study
4. The research coordinator will briefly explain the study (see recruitment script) to the patient.
5. If the patient is interested, they will be given a tablet to complete a screening assessment.
    a. Alternatively, the patient may elect to complete the screening assessment over the phone at a later time
6. The screening assessment will examine:
    a. Risky drinking behavior
    b. Medication adherence (single item asking about percentage of doses taken within the previous month)
    c. Age
    d. HIV status
7. The research coordinator will check to see if the following inclusion criteria are met:
    a. HIV-positive
    b. 18 years or older
    c. An at-risk drinker as identified by the alcohol screener
    d. Currently taking HIV medication
    e. A score less than 20 on the AUDIT questionnaire
        i. Score is displayed on the final page of the questionnaire. If above 20, see step 9 below for further direction.
8. If patients are eligible, the research coordinator will provide them with a TRAC flyer and consent form
    a. If the patient wants to enroll in the study, the coordinator will proceed with enrollment (see next section)
    b. If the patient does not want to enroll today, they can take the TRAC flyer and consent form with them. If they want to enroll at a later date, they can call the VA coordinator.
    c. They are eligible to begin the study if they enroll within 30 days. If they would like to join the study after that date, they will need to be re-screened.
9. If patients are ineligible because of a score of 20 or higher on the AUDIT questionnaire, a note will be made in their chart and a referral made to their clinical team for follow-up regarding concerning levels of alcohol use.
10. Screening activities will not collect any data to be used in the study.

Step 2: Patient Enrollment

1. The coordinator will go through the consent form and HIPAA form with the participant, discussing:
    a. The overall purpose of the study
    b. The time commitment of the study
    c. Their expectations as a participant
    d. The incentives they will receive
    e. Any questions the participant has
2. Once the participant has demonstrated sufficient understanding of the consent and HIPAA forms, the research coordinator will obtain consent and a signature on the HIPAA form.
3. The research coordinator will assign the participant a numeric identifier and record it in the secure code key
    a. The research coordinator will inform the participant that if they forget their study ID at any time, they can contact the researchers to learn what it is.
4. Only researchers will have access to this key, which will be kept in a password-protected file

5. The research coordinator will then check the randomization spreadsheet (pre-generated set of random numbers for each participant ID assigning them to the intervention or waitlist-control group)
    a. If they are in the intervention group (Group 1):
        i. The research coordinator will check the participant's medical record to make sure they have had their viral load tested within the previous 3 months. If not, their entry in the study will be delayed until after they have obtained viral load testing.
        ii. The research coordinator will inform the participant that they have been placed in the Intervention group.
        iii. The coordinator will schedule the participant's first videoconferencing session (1 ½-2 hours) with the study interventionist using the shared calendar, where they will receive their smartphone (if needed) and breathalyzer
        iv. The research coordinator will provide the participant with a copy of the Participant Manual, which includes instructions for downloading the breathalyzer app on to their own phone, if they choose to use it.
        v. The coordinator will encourage the participant to try downloading the app, and tell them that the interventionist will be in touch soon and can help them to install the app if need be
    b. If they are in the waitlist-control group (Group 2):
        i. The research coordinator will check the participant's medical record to make sure they have had their viral load tested within the previous 1 month (within 3 months of the intervention starting), or has plans to get it tested within the following 2 months. If not, their entry in the study will be delayed until after they have obtained viral load testing.
        ii. The research coordinator will inform the participant that they have been placed in the waitlist-control group
        iii. The participant will be provided the chance to complete the baseline assessment at that time on a laptop computer. If they choose not to complete it, the interventionist will call them to provide introductions and give them the web address for completing the questionnaire. This web address will also be provided to the participant on a handout.
6. The research coordinator will ask the participant the following questions about their cell phone:
    a. Do you prefer to use a study phone or your own phone? (Study Phone/Own Phone)
    b. If they prefer to use their own phone:
        i. Do you own a smartphone? (Y/N)
            1. If no, inform participant that they must use a study phone, which will be provided at their first appointment
        ii. What type of phone is it? (Android/iPhone/Windows/Other)
    c. Have you ever had to cancel or shut off your cell phone service for a period of time because the cost of maintaining the service was too expensive? (Y/N)
        i. If yes, how recently did this occur? (More than a year ago/Less than a year ago)
            1. If less than a year, inform participant that they must use a study phone, which will be provided at their first appointment
    d. Do poor or dropped signals prevent you from using your cell phone? (Y/N)
        i. If yes, inform the participant that they may need to use a study phone. The interventionist will contact them before their first appointment to determine if one is needed.
    e. How often do you reach the maximum amount of data you are allowed to use as part of your cell phone plan? (Frequently/Occasionally/Rarely/Never)
        i. If "frequently" or "occasionally," inform the participant that they must use a study phone, which will be provided at their first appointment.
    f. If responses indicate that they can use their own phone: Ask the participant to view the instructions for downloading the BACTrack app in the Participant Manual and ask them to download it to their phone before coming in for the initial meeting.
7. After the research coordinator asks these questions they will also ask the participant to provide information on their best emergency contact. The participant will be notified that this emergency

contact will only be called if necessary and that all information regarding their involvement in the study will be kept confidential.
    a. If it is an emergency and a patient cannot be reached, study staff will reach out to the emergency contact
8. The research coordinator will then notify the study interventionist through email of the newly-recruited patient by providing the Study ID number only.
9. The interventionist will be notified of a patient's intial appointment time through the shared calendar.
10. One day before the videoconferencing session, the interventionist will contact the participant to remind them of their appointment.

Step 3: Intervention Delivery

3a. Intervention group

1. One day before the videoconferencing session, the interventionist will contact the participant to remind them of their appointment.
    a. If they are using their own phone and were not able to download the app before the last contact point, check in regarding the app installation at this point
2. Upon arrival to the clinic for the first intervention session, the patients will be shown to a private room to begin their first videoconferencing session
3. The patient will be given a laptop to complete the initial assessment battery
4. If the participant is in need of a study phone, the VA coordinator will provide this phone, along with the breathalyzer, to the participant
5. Participants will begin the first intervention session, which will consist of the following content/tasks:
    a. Introductions and orientation to the technology (smartphone and breathalyzer, stored at the clinic; tutorial handouts provided)
    b. Review of self-monitoring procedures and setting of "do not disturb" hours
    c. Review of breathing awareness exercise
    d. Scheduling follow-up intervention sessions for weeks 2-8, conducted via mobile phone
    e. A short post-session satisfaction survey, delivered via text message and completed immediately following the session.
6. The day after the first session, participants will begin self-monitoring their alcohol, medication use, and mental health
    a. They will be texted at two random times each day using an automated software to complete a breathalyzer reading and finish a survey
    b. If participants do not respond to the request within 30 minutes, a text reminder will be sent, followed by another an hour later.
        i. If the participant is in a situation where they are unable to complete the breathalyzer test, they will be able to respond to the text message and request a follow-up reminder two hours later.
    c. If participants wish to go to sleep for the night and have not yet received their evening reminder, they can elect to complete a breathalyzer reading and survey before going to bed.
    d. Self-monitoring will continue through the end of week 8 (until they return to the VA to complete their post-test and return their equipment)
    e. Participants will be instructed to call the interventionist if they have any technical difficulties throughout the course of the study
7. Sessions 2-8 of the intervention will be conducted via phone call, with patients instructed to find a private room at home from which to speak with their counselor.
    a. After each session, the participant will complete a short post-session satisfaction survey, delivered via text message and completed immediately following the session
8. During Session 8, the interventionist will schedule the following appointments, contacting the patient one day before all subsequent tasks to remind them:
    a. Post-intervention appointment at the VA to complete assessment and return equipment (1 week later)
    b. Booster session (to be completed via phone 5 weeks later)
    c. Questionnaire #3, to be completed 9 weeks later
    d. Questionnaire #4, to be completed 17 weeks later
9. The final session at the VA (Week 8) will include the following tasks:

a. Returning of mobile phones (if applicable) and breathalyzers
b. Post-intervention assessment battery, completed using a laptop
c. Reminder of all subsequent appointments/tasks for the study

10. At 12 weeks, the interventionist will contact the participants to complete a 30-minute intervention booster session via phone. This session will review the participant's drinking goals and provide a refresher on the different types of triggers and strategies to address them.
11. At 16 weeks, the interventionist will contact the participants and ask them to complete a follow-up assessment battery at home (on a computer, tablet, or mobile phone—no clinic visit will be required)
    a. Participants will be given the option to come to the VA to complete the questionnaire if desired
    b. If assessment is not done within a week, researchers will contact the participant to encourage participation and ensure that no adverse events had occurred
        i. If patients cannot be reached, researchers will attempt to contact them three additional times (one day later, three days later, and one week later). If they cannot be contacted by the third attempt, they will be considered lost to follow-up and will not be contacted again.
12. At 24 weeks, the interventionist will contact the participants and ask them to complete an additional follow-up assessment battery at home (on a computer, tablet, or mobile phone)—no clinic visit will be required
    a. Participants will be given the option to come to the VA to complete the questionnaire if desired
    b. If assessment is not done within a week, researchers will contact the participant to encourage participation and ensure that no adverse events had occurred
        i. If patients cannot be reached, researchers will attempt to contact them three additional times (one day later, three days later, and one week later). If they cannot be contacted by the third attempt, they will be considered lost to follow-up and will not be contacted again.
13. After the participant completes the study, a retrospective chart review will be conducted to obtain viral load measurements (minimum of 2) from the participant during the time period beginning 3 months prior to their entry ino the study and up to 6 months after their entry into the study.

3b. Waitlist-control group

1. After randomization and enrollment, the participant will complete the baseline assessment either at the time of enrollment, at home, or durng a subsequent appointment within the next 30 days
2. The interventionist will call the participant after enrollment and do the following:
    a. Introduce themselves to the patient
    b. Describe the study timeline
    c. Discuss follow-up contact times and encourage the participant to stay in contact
    d. Remind participant of incentives they will receive for participating
    e. Provide information about the baseline assessment (if the participant has not already completed it)
3. The interventionist will contact participants using their chosen method of communication after 4 weeks to maintain contact and ensure that no adverse events have occurred
4. At 7 weeks, the interventionist will contact participants to obtain their availability for the next week to schedule the first intervention content session based on the shared calendar
5. One day before the videoconferencing session, the researcher will contact the participant via the participant's chosen method of contact to remind them of their appointment
6. At 8 weeks, the patient will come into the clinic to begin the intervention.
7. The patient will be given a laptop to complete the initial assessment battery
8. If the participant is in need of a study phone, the VA coordinator will provide this phone, along with the breathalyzer, to the participant
9. The participant will begin the first intervention session, which will consist of the following content/tasks:
    a. Introductions and orientation to the technology (smartphone and breathalyzer, stored at the clinic; tutorial handouts provided)

    b. Review of self-monitoring procedures and setting of "do not disturb" hours
    c. Review of breathing awareness exercise
    d. Scheduling follow-up intervention sessions for sessions 2-8, conducted via mobile phone.
    e. A short post-session satisfaction survey, delivered via text message and completed immediately following the session.
10. The day after the first session, participants will begin self-monitoring their alcohol, medication use, and mental health
    a. They will be texted at two random times each day using an automated software to complete a breathalyzer reading and finish a survey
    b. If participants do not respond to the request within 30 minutes by replying with "C" to confirm they completed the tasks, a text reminder will be sent, followed by another an hour later.
        i. If the participant is in a situation where they are unable to complete the breathalyzer test, they will be able to respond to the text message and request a follow-up reminder two hours later.
    c. If participants wish to go to sleep for the night and have not yet received their evening reminder, they can elect to complete a breathalyzer reading and survey before going to bed.
    d. Self-monitoring will continue until the day of the final intervention session
    e. Participants will be instructed to call the interventionist if they have any technical difficulties throughout the course of the study
11. Sessions 2-8 of the intervention will be conducted via phone call, with patients instructed to find a private room from which to speak with their counselor
    a. After each session, participants will complete a short post-session satisfaction survey, delivered via text message and completed immediately following the session
12. During Session 8, the interventionist will schedule the following appointments, contacting the patient one day before all subsequent tasks to remind them:
    a. Post-intervention appointment at the VA to complete assessment and return equipment (1 week later)
    b. Booster session (to be completed via phone 5 weeks later)
    c. Questionnaire #4, to be completed 9 weeks later
13. The final session at the VA (Week 16) will include the following content/tasks:
    a. Returning of mobile phones and breathalyzers
    b. Post-intervention assessment battery, completed using a laptop
    c. Reminder of all subsequent appointments/tasks for the study
14. At 20 weeks, the interventionist will contact the participants to complete a 30-minute intervention booster session via phone. This session will review the participant's drinking goals and provide a refresher on the different types of triggers and strategies to address them.
15. At 24 weeks, researchers will contact the participants and ask them to complete a follow-up assessment battery at home (on a computer, tablet, or mobile phone)—no clinic visit will be required.
    a. Participants will be given the option to come to the VA to complete the questionnaire if desired
    b. If assessment is not done within a week, researchers will contact the participant to encourage participation and ensure that no adverse events had occurred
        i. If patients cannot be reached, researchers will attempt to contact them three additional times (one day later, three days later, and one week later). If they cannot be contacted by the third attempt, they will be considered lost to follow-up and will not be contacted again.
16. After the participant completes the study, a retrospective chart review will be conducted to obtain viral load measurements (minimum of 2) from the participant during the time period beginning 1 month prior to their entry ino the study and up to 8 months after their entry into the study (6 months after beginning the intervention sessions).

Protocol deviation in case of COVID-19 concerns:

If the providers within the ID clinic or the VA as a whole determines that attending study visits puts participants' health at risk due to the spread of COVID-19, then TRAC participants will be given the option

to complete all study tasks remotely. The following changes to the protocol will occur until the risk of attending study visits is determined to have been returned to an acceptable level:

1. All screening will occur via phone (study screener and cell phone screener)
2. If participants are eligible and interested in the study, the consent form and HIPAA release will be sent via mail to participants. The interventionist will call participants to review both documents and answer any questions. Once they are signed, participants will use a pre-paid envelope to send them back to the VA.
3. Following receipt of the consent and HIPAA forms, participants will be shipped study equipment (breathalyzer and cell phone, if applicable), participant manuals, and ClinCards, and the interventionist will reach out to schedule the initial appointment.
4. The first visit will be conducted using videoconferencing on the particpants' mobile phone, and if that is not possible due to phone or data limitations, a traditional phone call will be held.
5. The remaining part of the study will continue as originally scheduled, and participants will not return to the VA for the Week 8 visit. They will use a pre-paid shipping box to send study equipment back to the VA.
6. Once the equipment is received by the study team, participants will receive compensation owed for the final visit.
7. Participants will also complete all study questionnaires remotely using their own phone or computer, with the option to complete paper questionnaires if needed (mailed to participants' homes).
8. All assessments (daily surveys and study questionnaires) will contain questions related to COVID-19 attitudes, COVID-19-related behaviors, and COVID-19 experiences/exposure.

Step 5: Incentive Distribution

Throughout the intervention, the participant will receive money deposited to a ClinCard debit card or mailed to the participant by check on the following schedule. On the rare occurrence that a study visit is delayed, the participant may receive additional compensation equivalent to the monitoring tasks completed, but no more than $30:

Intervention Group

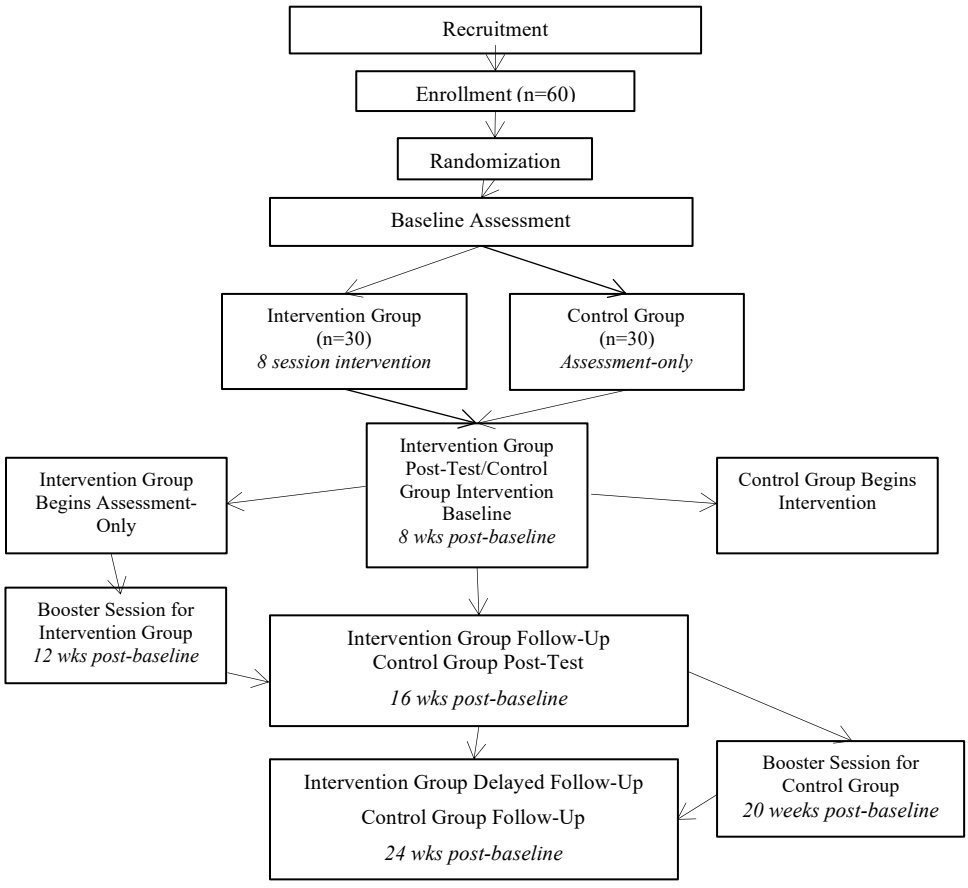
- After Session 1: $20 for in-person session, $30 for questionnaire
- After Session 2: $20 for phone session, up to $15 for daily monitoring
- After Session 3: $20 for phone session, up to $15 for daily monitoring
- After Session 4: $20 for phone session, up to $15 for daily monitoring
- After Session 5: $20 for phone session, up to $15 for daily monitoring
- After Session 6: $20 for phone session, up to $15 for daily monitoring
- After Session 7: $20 for phone session, up to $15 for daily monitoring
- After Session 8: $20 for phone session, plus up to $15 for daily monitoring
- After Week 8 visit to the VA: $40 for questionnaire, plus up to $15 for daily monitoring
- After Week 12 Booster Session: $20
- After week 16 questionnaire: $40
- After week 24 questionnaire: $40

Control Group

- After baseline questionnaire: $30
- After Session 1: $20 for in-person session, $40 for questionnaire
- After Session 2: $20 for phone session, up to $15 for daily monitoring
- After Session 3: $20 for phone session, up to $15 for daily monitoring
- After Session 4: $20 for phone session, up to $15 for daily monitoring
- After Session 5: $20 for phone session, up to $15 for daily monitoring
- After Session 6: $20 for phone session, up to $15 for daily monitoring
- After Session 7: $20 for phone session, up to $15 for daily monitoring
- After Session 8: $20 for phone session, plus up to $15 for daily monitoring

- After Week 16 visit to the VA: $40 for questionnaire, plus up to $15 for daily monitoring
- After Week 20 Booster Session: $20
- After Week 24 questionnaire: $40

Study Schedule
Participants in the waitlist-controlled trial will be enrolled in the study for a total of 24 weeks (168 days), whether they are in the intervention or waitlist-control group. They will participate in eight intervention sessions and one booster session. The first and last sessions will take 1.5-2 hours, depending on how long the participants take to complete the surveys. Sessions 2-8 and the booster session will take 30 minutes each. After each intervention session, they will complete a short 5-minute questionnaire on their mobile phones. During the intervention, they will also complete two daily assessments, which will take approximately 20 minutes total. Each participant will also complete two additional assessment batteries, which will take 45-60 minutes. Thus, the total time commitment is approximately 27-28 hours. On the rare occasion when study visits may be unexpectedly delayed, visits will not be delayed more than 1 week. See the following flowchart for detailed information about the participant timeline.



Patient Compensation
Participants will receive the following:
- $20 for attending all intervention sessions via videoconferencing or phone (including booster session – 9 sessions)
- $1 for each completed breathalyzer reading (up to 14/week, with $1 bonus for completing all readings)
- $30, $40, $40, and $40 for completing health questionnaires
- TOTAL POSSIBLE: $450

5. Data

Collection and record keeping

Both intervention and waitlist-control groups will complete an extensive assessment battery at baseline, 8 weeks, 16 weeks, and 24 weeks. They will also complete daily monitoring of alcohol and medication use during their 8-week intervention period. The following outcome variables will be explored via the listed methods of data collection:

Confidential online questionnaires, completed on tablets or mobile phones at baseline, and 8-, 16-, and 24 week follow-ups, concerning the following variables:

- Post-Traumatic Stress Disorder Symptoms
- Alcohol and drug use
- Alcohol-related beliefs
- Mental health status (anxiety, depression, stress, history of mental health diagnoses)
- Coping processes
- Emotion regulation
- Coping self-efficacy
- Quality of life
- Perceived social support
- Perceived HIV stigma
- HIV diagnosis date and transmission source
- Technology use
- Technology attitudes
- Health literacy
- Demographic information
- COVID-19-related history, protective behaviors, attitudes, and beliefs
- Knowledge of intervention materials (follow-up only)

Confidential online questionnaires and correspondence, completed on mobile phones twice daily, concerning the following variables:

- Alcohol intake, via survey response
- Medication use, via survey response
- Engagement in COVID-10 protective behaviors and COVID-19 related stress, via survey response
- Blood alcohol content, via breathalyzer reading sent to study coordinator
- Anxiety and depression, via survey response

Confidential online questionnaires, completed on tablets or mobile phones immediately following each of the 8 intervention sessions and concerning the following variables:

- Ratings of session experiences
- Attitudes toward session
- Perceived therapeutic alliance
- Open-ended reaction to the session

Retrospective chart review of viral load based on blood draws conducted as part of routine clinical care.

Data Storage

All survey and questionnaire data will be collected using Qualtrics survey software, which encrypts data and utilizes password-protected accounts. The "Anonymize Responses" option will be selected to avoid collection of IP addresses. Participants will only be asked to include their numeric study ID as part of their survey response, and will not need to provide any other identifying information. Any downloaded data will be kept on password-protected computers. Once data collection is completed and data files have been downloaded to a local computer, the data on Qualtrics will be deleted. The Qualtrics surveys will be housed

on the University of Georgia's Qualtrics account, which is used by the study interventionist and coordinator. The funder PI, Dr. Carolyn Lauckner, is at the University of Kentucky and will have shared access to the de-identified datasets.

Audio recordings of interviews will not include the respondent's name or demographic information, and will be identified only by the participant's numeric study ID. Additionally, all audio recordings will be deleted following transcription. During the transcription process, any identifying information that was incidentally revealed during the interview will be left out of the record. If audio recordings need to be shared among the research team to facilitate transcription, a secure file sharing service will be used. If a given recording happens to contain identifying information, only VA-credentialed researchers will be provide access to it.

Daily breathalyzer responses will be texted to the interventionist's study phone from the participants. On a weekly basis, the interventionist will transfer these readings to a secure database housed on a password-protected computer and delete them from her mobile device. Participants will be provided guidance (in the form of a handout) about how to delete the readings from their own phones (or the study phones).

Local computers containing research data will be password protected and encrypted using either FileVault (Mac) or BitLocker (Windows). If research files are shared among the research team, an encrypted file sharing service will be used.

Data security Plan
All questionnaire-based assessments, including the post-session questionnaires for the open trial, the baseline and follow-up assessments for both the open trial and the intervention, and the surveys used for daily self-monitoring for the open trial and intervention, will be delivered in an electronic format. The surveys will be programmed and delivered using Qualtrics, which houses data and responses on a secure, password-protected site.

For questionnaires completed in the clinic, the tablets will be pre-loaded with links to the online surveys. For surveys conducted via mobile phone, participants will be texted a link to the assessments, which they can then open and complete using a mobile browser. At the beginning of the survey, participants will enter a unique identifier assigned to them at enrollment, which they can ask the interventionist for at any time in case they forget. Any data files containing contact information and identifiers will be kept separate from the survey responses on a secure, password-protected computer. Following the completion data collection, identifying information will be permanently removed from all electronic files. Participants will be trained regarding how to secure their mobile phone using a password, and the mobile phone used by the counselor will also be secured.

The interviews following the open trial will be conducted only by researchers affiliated with the project and not by individuals working at the VA. Responses will be recorded digitally. Recordings will then be transcribed by a research assistant and any identifying information will be removed, with pseudonyms used if necessary. Following the transcription of all files, which will be kept on password-protected computers, the recordings of the interviews will be deleted. The transcripts will be stored with all other research data and kept for 6 years before being destroyed.

The twice-daily self-monitoring completed by participants involves breathalyzer readings collected via text message. Each phone will be pre-loaded with contact information for the study coordinator's dedicated cell phone to reduce any chances of confusion or sending the information to the wrong individual. Both the participants' and coordinator's phones will be secured using a password, and coordinators will manually upload readings to a computer using a USB cable. After they are uploaded, the coordinator will delete readings from their phone. Study phones will likely be used by multiple participants throughout the rolling enrollment procedure of the intervention, so each phone will undergo a factory reset to avoid compromising any previous participants' data. This will not be necessary if participants choose to use their own phones for the study.

To protect against loss of confidentiality, we will follow strict data management procedures. Access to data will be permitted only to the researchers and counselors, who will be trained in HIPAA procedures and will sign confidentiality agreements. Any contact information will be stored separately from responses and permanently deleted following the completion of data collection. Consent and HIPAA Authorization forms, which will be the only physical forms with identifying information, will be kept in a locked file cabinet in the coordinator's office. Moreover, members of the research team (e.g., research assistants) will be required to participate in training in the areas of ethics, confidentiality protection, and human subject participants. They will also be trained on a protocol regarding how to avoid identifying research participants who are seen out of the research setting.

To secure data on mobile phones, respondents will be taught how to delete messages or photos if they are worried about their information being compromised. Both respondents and counselors will be trained regarding and required to secure their phone using a password. A web-based service that allows complete control over data will be chosen to deliver the self-monitoring reminders, and any data collected during this process will be downloaded to a secure computer and deleted from the website following the completion of data collection. Finally, all phones will be capable of being remotely wiped in the case of loss or theft to protect participants' information. After each participant concludes with the intervention, the phone will undergo a factory reset to remove any traces of data or identifying information. Together, these steps are more than adequate to minimize and protect against risk.

6. Potential benefits/risks

Participants in the proposed research will benefit primarily by receiving free alcohol reduction counseling, which has potential to not only reduce their alcohol use, but improve their HIV medication adherence and, in turn, their overall health. The self-monitoring aspect will also increase their own awareness of their behaviors and potentially improve their ability to recognize contextual predictors that encourage alcohol use or a lack of medication adherence. Finally, participants will receive financial compensation for their participation. All participants will receive these benefits with minimal effort, as the intervention requires few in-person visits, while the rest can be received via mobile phone.

For all participants, there is the potential risk of anxiety or discomfort when reporting opinions or receiving educational intervention content. The interviews and surveys will address sensitive information or information that may cause embarrassment, such as substance use behaviors and mental health status. Additionally, there is also the risk of loss of confidentiality, as identifying information will be collected in order to monitor participants' data throughout the course of the planned research, as well as to obtain their HIPAA authorization.

There are also inherent risks in using communication technologies for delivering a health intervention. The videoconferencing sessions of the intervention will occur over a HIPAA-compliant secure network, so they will pose no risk. However, any of the activities done using mobile phones, including intervention sessions and self-monitoring, are inherently less secure. Participants and study personnel will receive thorough training on how to secure their mobile phones to prevent any unauthorized access to data, and each phone will have the potential to be remotely wiped in case of theft or loss. The study coordinator will explain this issue carefully and get consent of understanding as part of the study protocol.

In the event that identifying information is released to an unauthorized party, the serostatus of participants could be revealed to unwanted individuals. This could potentially cause harm, but is unlikely considering the careful plans in place regarding data management and protection. All possible measures will be taken to protect information provided through surveys, interviews, and intervention participation, and confidentiality will be respected. Following completion of data collection, responses will become anonymous as identifying information is permanently deleted. For these reasons, we estimate that this minimally-invasive project poses minimal risk.

STATISTICAL ANALYSIS PLAN

For the randomized controlled trial, data analytic methods will be focused on examining acceptability and feasibility, as well as effects on alcohol intake, HAART adherence, and HIV-related medical outcomes (CD4 count and viral load). Intervention adherence, daily monitoring adherence, and session acceptability will be described using descriptive statistics. Session attitudes will be assessed using several 5-point semantic differential attitudinal measures rating the session, including Boring/Interesting, Unpleasant/Pleasant, Bad/Good, Useless/Useful, and Negative/Positive. Scores on the session attitude semantic differential measures will be reverse-coded where required and averaged to form an overall attitude score, with "0" being "neutral."

We will provide descriptive summaries for the outcome variables, including mean, median, and standard deviation for continuous variables and counts and percentages for categorical variables. We will summarize the outcome variables overall and across the intervention groups. In assessing the differences in alcohol use and medication adherence between the two groups during the 8-week intervention period, we will utilize the Kruskal–Walli's test, a non-parametric statistical approach, to compare the distribution of outcome variables. The general linear model (ANOVA) will be used to estimate the difference between alcohol use and medication adherence among the groups, and the estimation of the effect size (Cohen's D) at the end of the 8-week intervention period. While this study was not powered to detect significant differences, the goal of these analyses is to observe changes and effect sizes that may provide preliminary evidence of efficacy.

To examine intervention effects as assessed through daily surveys, we will examine responses to the morning survey question asking if participants had consumed alcohol on the previous day (yes/no), whether or not they reported a positive breathalyzer reading (> 0.0), and if they had taken all of their HAART on the previous day (yes/no). Within the 8-week intervention period and using the daily data, we will assess the change in the proportion of participant's alcohol use, the proportion of positive breathalyzer readings, and the proportion of their medication use from the beginning of week 1 to the end of week 8 using McNemar's matched pair test. This test will allow us to address the interdependency in the repeated measurements. We will account for missing survey responses by considering two scenarios: First, assuming they were missing completely at random and remained missing, and second, that missing values were indicative of alcohol use/medication nonadherence and were thus filled in as drinking days/positive breathalyzers/nonadherent days (a conservative approach).

All participants will have received the intervention by the end of the 8 week (2-month) post-intervention period. To examine long-term intervention effects, participants from both the waitlist-control and intervention group will be combined into a single dataset. A generalized linear model (via SAS GENMOD PROCEDURE) and a multiple linear regression model will be fit to the change from baseline for each outcome measure. Change from baseline is the difference between the baseline value and values obtained at subsequent time points: 8 weeks (immediate post-intervention; T2 for intervention group and T3 for waitlist-control), and 16 weeks (2 months post-intervention; T3 for intervention group and T4 for waitlist-control) for each outcome measure. The rationale for fitting the change from baseline is that this model removes the effect of baseline differences that may exist from the model. All statistical hypothesis tests will be conducted used the standard 5% significance level. SAS Version 9.4 (TS1M1, SAS Institute, Cary, NC), will be used for all analyses.

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