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Opinion paper

Telehealth interventions to reduce alcohol use in men with HIV who have sex with men: Protocol for a factorial randomized controlled trial

Christopher W. Kahler^{a,*}, Anthony Surace^a, Ayla Durst^a, David W. Pantalone^{b,c}, Nadine R. Mastroleo^d, Maria Jose Miguez^e, Diego Bueno^e, Tao Liu^f, Peter M. Monti^a, Kenneth H. Mayer^{b,g}

^a Center for Alcohol and Addiction Studies and the Department of Behavioral and Social Sciences, Brown University School of Public Health, Providence, RI, USA

^b The Fenway Institute, Fenway Health Boston, MA, USA

^c University of Massachusetts - Boston, Boston, MA, USA

^d College of Community and Public Affairs, Binghamton University (SUNY), Binghamton, NY, USA

^e Florida International University, Miami, FL, USA

^f Center for Statistical Sciences and Department of Biostatistics, Brown University School of Public Health, Providence, RI, USA

^g Beth Israel Deaconess Medical Center/Harvard Medical School, Boston, MA, USA

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ABSTRACT

Background: Heavy alcohol use is prevalent among men who have sex with men (MSM) living with HIV and is associated with reduced antiretroviral therapy adherence, reduced HIV viral suppression, and reduced survival. We recently found that compared to HIV treatment as usual, three sessions of in-person motivational interviewing (MI) substantially reduced drinking in MSM with HIV. In an effort to enhance the effectiveness and efficiency of this intervention, the present study will test whether MI is more effective than brief intervention when delivered by videoconferencing, whether interactive text messaging (ITM) can enhance the effects of alcohol intervention, and whether extended duration of intervention is more effective than brief duration. *Methods*: Using a $2 \times 2 \times 2$ factorial design, we will randomly assign 224 heavy-drinking MSM with HIV to: MI or brief intervention (BI); ITM or no ITM; Standard or Extended intervention (EI). All participants will receive intervention immediately after baseline assessment via videoconferencing and at 1-month post baseline via telephone. Participants randomized to EI will receive daily interactive texts about alcohol use for 1 month, with those randomized to EI receiving weekly interactive texts through 9 months. Alcohol and HIV-related outcomes will be assessed at 6 and 12 months post baseline.

Conclusion: By testing the combinations of interventions that can most effectively reduce alcohol use among MSM with HIV, this study will set the stage for wider-scale implementation of an optimized intervention combination.

1. Introduction/background

Up to 20% of HIV-infected men who have sex with men (MSM) drink heavily (i.e. drinking 5 + drinks in a day) at least once a week [1], and rates of alcohol/substance use disorders amongst HIV-infected MSM have been estimated to be as high as 48% [2]. Heavy drinking in people with HIV is associated with low antiretroviral therapy (ART) adherence [3–5], uncontrolled plasma viremia, lower CD4 cell counts [4–6], and reduced survival [7]. Moreover, heavy drinking has been associated with condomless sex amongst MSM with HIV, potentiating the risk for further HIV spread [8,9]. Thus, there is a pressing need to develop scalable interventions to reduce heavy drinking among MSM with HIV.

We recently conducted the first randomized controlled trial of motivational interviewing (MI) with personalized feedback tailored for heavy-drinking HIV-infected MSM recruited and counseled within an HIV primary care clinic [10]. Participants randomized to receive three in-person sessions of MI over a 6-month period, compared to an assessment-only HIV treatment-as-usual control, reported significantly less alcohol use at 6 and 12 months post baseline with effect sizes in the small to medium-sized range. Furthermore, among participants

* Corresponding author. Center for Alcohol and Addiction Studies, Brown University, Box G-S121-4, Providence, RI, 02912, USA. *E-mail address:* Christopher_Kahler@brown.edu (C.W. Kahler).

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Received 20 June 2019; Received in revised form 15 October 2019; Accepted 16 October 2019 Available online 18 October 2019 2451-8654/© 2019 The Author(s). Published by Elsevier Inc. This is an open access article under the CC BY-NC-ND license (http://creativecommons.org/licenses/by-nc-ad/4.0/). reporting condomless sex with non-steady partners at baseline, MI resulted in significantly greater reductions in condomless anal sex than treatment-as-usual.

The current study expands upon research using MI for heavy drinking MSM with HIV in three key respects. First, our prior trial utilized a treatment-as-usual control. Brief interventions (BI) to reduce drinking have shown promise in a variety of medical settings including in people with HIV [11–13]. Since MI requires more training and time to deliver than BI, this study will test whether MI produces greater reductions in drinking than BI.

Second, this study examines the duration of intervention that most efficiently produces substantial, sustained reductions in drinking. Although our prior results indicated that men made continued changes in drinking over a 6-month intervention period [10], Hasin et al. [12] found that interventions over just two months also resulted in lasting changes in drinking. The present study will examine whether extended intervention (EI) that monitors and intervenes with participants for 9 months results in greater reductions in drinking compared to intervention that lasts only 1 month.

Third, to increase scalability of MI, this study will examine two technological enhancements: (1) delivery of interventions using video-conferencing and (2) interactive text messaging (ITM) to maintain/ support behavior change. Both telehealth and ITM have shown promise as behavior intervention modalities that may increase intervention reach and cost-effectiveness [14–19].

The current trial utilizes a 2 (BI vs. MI) \times 2 (no ITM vs. ITM) \times 2 (no EI vs. EI) randomized factorial design in which 224 heavy drinking MSM with HIV will be enrolled from study sites in Boston and Miami and randomly assigned to one of the eight possible intervention combinations formed from the fully factorial design. Both BI and MI will be delivered by interventionists at Brown University using a HIPAA-compliant videoconferencing system. Outcomes will be assessed at 6 and 12 months after the initial intervention session.

2. Methods

2.1. Study setting

Participants will be recruited from HIV clinics and the local community around Florida International University in Miami, FL and Fenway Health in Boston, MA.

2.2. Participants

A total of 224 heavy drinking HIV-infected MSM will be enrolled in the study over approximately 3 years. Eligible participants will: (1) be at least 18 years of age; (2) report an average of one or more heavy drinking (\geq 5 drinks) episodes per month or drinking more than 14 drinks per week over the past 3 months; (3) have a confirmed diagnosis of HIV; (4) identify as cisgender male; and (5) report having sex (i.e. oral or anal) with a male partner in the past 12 months and/or identify as gay or bisexual. Treatment-experienced participants will have to be on the same ART regimen for at least 3 months prior to study enrollment, so that changes in functioning and health outcomes can be more clearly ascribed to intervention rather than recent changes to medication regimen.

Participants will be excluded if they: (1) report any intravenous drug use within the past 3 months; (2) display psychosis, active suicidal ideation, or mania; (3) are receiving treatment or received treatment for an HIV-related opportunistic infection within the past 3 months; (4) are currently receiving treatment for an alcohol or drug use disorder; or (5) cannot commit to the study's 12-month duration. We also will exclude participants who might need supervised alcohol detoxification, specifically, those having a history of severe withdrawal symptoms such as hallucinations, seizures, or delirium tremens. Prior to baseline assessment, participants will be asked to remain abstinent from alcohol overnight. Participants must present to their baseline assessment with a breath alcohol concentration (BrAC) of 0.00 g/dl. Withdrawal symptoms will be assessed using the Clinical Institute Withdrawal Assessment for Alcohol, revised [20], and those with scores over 7 will be excluded. Participants will not be required to use text messaging to participate, and all participants will be included in intent to treat analyses.

2.3. Outcome variables

2.3.1. Primary outcome measures

The primary alcohol consumption outcomes are: (1) the number of standard alcohol drinks consumed and (2) the frequency of heavy drinking days in the past 30 days as assessed by the Timeline Followback [21] at 6- and 12-month follow-ups.

2.3.2. Secondary outcome measures

The secondary outcomes assessed a 6- and 12-month follow-ups are: (1) the number of days engaging in condomless sex with a non-steady partner in the past 30 days, (2) past 30-day ART adherence (i.e. percentage of days taking all prescribed ART doses), and (3) HIV viral suppression (i.e. <20 copies/ml).

2.4. Procedure overview

2.4.1. Recruitment & screening procedures

Participants will be recruited through passive (e.g., fliers posted at HIV clinics and relevant community sites and online advertisements) and active (e.g., in-clinic screening and recruitment by research staff when patients arrive for routine HIV care appointments) recruitment strategies. Patients who express interest in participating will complete a brief screening to confirm they meet primary inclusion criteria (see section 3.2). Participants who meet criteria will be scheduled for a baseline interview to confirm eligibility where they will complete an informed consent approved by the local IRB (i.e., either Florida International University or Fenway Health).

2.4.2. Assessment procedures

At baseline and each follow-up visit, participants will complete a series of structured interviews, questionnaires, and neurocognitive tests. After the baseline assessment and intervention, participants will return to the clinic at 6 and 12 months for follow-up interviews.

Alcohol/Substance Use. At baseline, current and past alcohol and substance use disorders (as well as screening for mania and psychosis) will be assessed using the Mini International Neuropsychiatric Interview (MINI) [22]. The Short Inventory of Problems [SIP; 23] will be used to assess the extent to which participants have experienced problems related to their alcohol use in the 3 months prior to each interview. The SIP assesses 15 negative consequences of alcohol use and has good psychometric properties [23,24]. In addition to providing a breath sample for alcohol concentration analysis at each in-person assessment, participants also will provide a urine sample for testing for recent drug use: PCP, ecstasy, barbiturates, methadone, oxycodone, benzodiazepines, methamphetamine, THC, opioid, and cocaine. As a biomarker of alcohol use, a dried blood spot will be obtained to allow assaying of phosphatidylethanol (PEth), a phospholipid that appears on red blood cell membranes as a result of exposure to alcohol [25]. The quantity of PEth produced is directly proportional to the concentration of alcohol [25] and will serve as a secondary measure of recent alcohol consumption.

Timeline Followback (TLFB). The TLFB interview [21] is a valid and reliable calendar-assisted structured interview, which provides a way to cue memory so that accurate recall is enhanced [26–28]. Utilizing a past 30-day timeframe, the TLFB will provide daily data on amount of alcohol consumed, which will be summarized to provide total number of drinks consumed and number of heavy drinking days. The TLFB also will be used to provide a valid assessment of drug use behavior [29]. Sexual

risk taking will also be assessed via the TLFB with detailed information on the type of partner (primary, casual, or anonymous); HIV status of partner (positive, negative, or unknown); type of sexual activity (oral, anal, insertive or receptive); condom use; and whether the participant was under the influence of alcohol and/or other substances. Three variables will be derived from this measure: number of days reporting sex under the influence of alcohol or drugs, occasions of condomless sex, and occasions of condomless sex with a non-steady partner. The TLFB also will be employed to assess ART adherence; participants will review each day of the TLFB calendar and indicate the number of doses prescribed and taken. The TLFB has been shown to be a valid measure of adherence [30,31] and facilitates examination of alcohol-adherence associations on a daily basis [32–34]. The dependent variable will be the percent of days with no missed ART doses.

<u>Measures of Neurocognitive Functioning.</u> A brief battery of neurocognitive tests will be performed at baseline and follow-up assessments. The tests were selected because they are sensitive to the effects of HIV and heavy alcohol consumption. Results from the baseline neurocognitive battery will be part of the feedback report for those in MI. The battery takes a total of 20 min to complete and includes the Wechsler Test of Adult Reading [WTAR [35,36]], Trails A and B [37], Symbol Digit Modalities [38], Hopkins Verbal Learning test [39–41], and the Controlled Oral Word Association Test [42–44]. All of these measures are well-established neurocognitive measures that have each been widely used in numerous studies of HIV [45–49] and alcohol [50–63] effects on brain functioning.

<u>Computer-Assisted Self Interviewing (CASI)</u>. A brief CASI will also be used to capture alcohol use, drug use, sexual behavior, and ART adherence data. CASI may reduce under-reporting of stigmatized behaviors due to social desirability [64]. The CASI queries behavior over the prior 3 months at baseline and each follow-up providing a secondary assessment of our behavioral outcomes. The sexual behavior assessment queries the number, gender, and HIV status of anal or vaginal sex partners. The CASI uses a graduated frequency measure to assess alcohol use [65], assesses frequency of use of marijuana, cocaine/crack, methamphetamine, inhalants, psychedelics, and opioids, and assesses ART adherence using a well-validated questionnaire [66]. These will serve as secondary outcomes.

<u>Clinical Assays.</u> At baseline, 6, and 12 months, we will collect serum samples from all participants. To ensure that all participants are in HIV care, all participants are required at baseline to provide documentation of a plasma HIV RNA ('viral load') test within the past 6 months. At baseline and the 12-month follow-up visit, we will request medical records to document current viral loads, CD4 cell counts, and liver function tests. For participants without a viral load or CD4 test within the past six months or liver function tests within the past one month, we will run these assays using the blood samples provided.

2.5. Randomization procedures

At the conclusion of the baseline interview, the research assistant (RA) at the recruitment site will enter alcohol use and clinical information into a computer program to generate a MI feedback report. Participants will then be randomized by computer so that only the interventionist knows condition assignments prior to the intervention session. The program uses block sizes of 16 (two assignments of each of the eight potential combinations of treatment conditions) for randomization to ensure that all conditions and combinations of conditions remain balanced for each study site. The RA will connect participants through a secure videoconferencing portal to the Brown-based interventionist and leave the room before the session begins. The interventionist will conduct the BI or MI session, enroll those assigned to ITM in the ITM system, and explain the procedures for future counseling sessions based on assignment to EI or no EI.

2.6. Details of the intervention and control

2.6.1. Videoconferencing

Baseline and 6-month intervention sessions will be conducted via SecureVideo, a high-definition HIPAA compliant videoconferencing system [67]. Although it is unlikely that BI delivery would occur via telehealth in the context of routine clinical practice at present, we chose to deliver both interventions using this modality to ensure masking of RAs at the recruitment sites and to match MI and BI on counselors and delivery format.

2.6.2. Interventionist training

Interventionists will be master's- or doctoral-level treatment project staff, with previous experience working with HIV-infected MSM in clinical or research settings. We will always have at least two interventionists available to deliver counseling, and we anticipate up to six interventionists will deliver counseling. Interventionists will receive roughly 20 h of training in MI, including reading and participating in role-playing exercises. Interventionists will be provided with highly detailed treatment manuals and will deliver counseling in both MI and BI. The manuals provide interventionists with a standardized list of procedures to follow with participants and allows for consistent treatment delivery across staff. All intervention sessions will be audio recorded.

2.6.3. Interventionist supervision

Interventionists will attend bi-weekly clinical supervision meetings, in which staff discuss current cases and receive feedback based on review of audio recorded sessions. In addition all audio recorded treatment sessions will be coded to evaluate MI integrity and fidelity using the Motivational Interviewing Skill Code Version 2.5 [MISC [68]]. Each session will be parsed and coded by independent raters.

2.6.4. Brief intervention (BI)

The BI entails a relatively scripted intervention session lasting 5-15 min that is consistent with clinical guidelines for counseling primary care patients regarding unhealthy drinking [69]. The interventionist will inform the participant that they are drinking more than is medically safe and that continuing to drink at their current level could lead to health problems. The interventionist will emphasize the importance of staying within National Institute of Health's recommended limits for individuals with chronic health conditions [7], and will inform participants that alcohol increases risk for health problems and mortality at lower levels of consumption for people with HIV compared to those without HIV [7]. The interventionist will then ask the participant what changes, if any, he would like to make to his alcohol use. For those participants interested in change, the interventionist will help them decide on a specific goal and offer advice on reaching said goal (e.g. joining self-help groups). For participants not interested in changing their current alcohol use, the interventionist will reaffirm their autonomy and discuss their reasons for not wanting to change their drinking at this time.

2.6.5. Motivational interviewing (MI)

The MI intervention closely follows the procedures from our recent clinical trial [10], which draws heavily from techniques of Motivational Interviewing [70] to facilitate behavioral change through support and guidance. First, interventionists explore participants' perceived benefits and deterrents to drinking and focus on how drinking relates to their HIV treatment. Interventionists will reflect back and amplify participant statements supporting behavior change. Interventionists will then provide personalized feedback on the participant's drinking compared to derived norms from a national sample of urban MSM [71]. Next, interventionists will provide feedback on the health impact of alcohol on several major areas of functioning (i.e., ART adherence, liver functioning, viral load/CD4 counts, cognitive functioning, sexual risk taking,

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and other substance use). Interventionists will carefully monitor participants' reactions to feedback and encourage participants to reflect on each piece of feedback provided. Interventionists will inquire about the participant's interest in making changes to his alcohol consumption. For participants who are receptive to changing their drinking, interventionists will work with them to set a drinking goal. The focus of the session will then shift to increasing self-efficacy for changing drinking and problem-solving potential impediments to change. For participants who express interested in mandating their current pattern of drinking, interventionists will further explore potential motivations for changing in the future.

<u>Follow-up sessions</u>. Follow-up session(s) begin with a brief summary of the previous session and discussion of the participants' current drinking behavior. Interventionists will discuss with participants their progress towards meeting drinking goals and obstacles faced when attempting to meet original goals. Interventionists will highlight a wide range of potential benefits of reducing drinking (e.g., saving money, improving health). At the final MI session (session 2 for those not in EI and session 5 for those in EI), interventionists will initiate a brief discussion of strategies for maintaining changes in drinking in the future.

2.6.6. Extended intervention (EI)

Given previous clinical research suggesting that much of the change in drinking behavior occurs after two interventions sessions [10,12], we set the minimum number of sessions for all participants to two sessions. The EI condition will continue the intervention through 9 months, which will allow us to determine its total effect relative to no EI at 12 months. EI will entail extending any intervention a participant is receiving: BI or MI and ITM. Tests of interactions between EI and both BI vs. MI and no ITM vs. ITM will tell us whether EI is more or less important for each of these intervention approaches.

2.6.7. Interactive text messaging (ITM)

The ITM program was developed based on existing technology-based intervention in HIV care [15] and results of focus groups and pilot testing with the target audience. During the first 30 days of the program all participants randomized into the ITM condition receive daily texts that ask them to report (1) the number of drinks they consumed the previous day; (2) what aspects of the previous day's drinking they disliked (e.g. having a hangover today); (3) whether they plan to drink on the current day; and (4) how much they plan to drink on the current day. Customized messages will be used to reinforce abstinence/moderate drinking and individual drinking goals. Every seven days the system provides the participant with feedback on the number of drinks the participant consumed during the week with a tailored message based on whether they consumed under 15 drinks, avoided heavy drinking, or reduced drinking relative to baseline. The results of the ITM assessments of drinking also provide data that the interventionists can present to participants to reinforce positive changes in drinking, remind participants about the drawbacks of their drinking, and address potential barriers to changing drinking.

At the end of each week, the ITM system will ask participants how many doses of ART they missed during the prior week. Based on their answer, a responding text message will either (a) congratulate the participant for not missing any doses or (b) state the importance of taking every dose of ART regardless of alcohol use on that day. Twice each week, the system will also send a message randomly selected from a bank of affirming messages and quotes on health and well-being. Additionally, a message offering tips for reducing drinking will be sent once weekly.

Participants assigned to EI will continue to receive ITM beyond the initial 30 days, but at a reduced frequency. Drinking assessments will shift from daily to weekly assessments of number of days drinking alcohol, number of drinks consumed, and heavy drinking episodes (i.e. days on which the participant consumed 5 + standard alcoholic drinks). Positive affirming messages will be sent twice weekly throughout EI, and

tips for changing drinking will be sent once weekly.

2.7. Timeline

Recruitment began in August 2016 and will continue until approximately March of 2020 with the final follow-ups completed 12 months later.

2.8. Sample size calculations

Sample size needs were determined by conducting a power analysis for the primary aims based on the desire to have power of .80 to detect a significant effect of a given experimental factor on alcohol use. A twosided significance (alpha) of 0.05 was used throughout. A recent metaanalysis indicated that trials examining behavioral interventions to reduce drinking in people with HIV have yielded effects sizes on reduced drinking in the range of d = 0.11 to 0.24 [72]. However, the two trials reviewed that had a sole intervention focus on alcohol use yielded effects sizes in the medium range (d = 0.56). In our recent trial of MI in MSM with HIV, we found effect sizes ranging from 0.33 to 0.50 [10] with an assessment-only control. Based on these results, we decided to power the trial to detect a small to medium effect size ($\sim d = 0.35$) for any of the three experimental factors in the factorial design. Given that baseline drinking accounts for about 20% of the variance in drinking at follow-ups and will be included in the model, power analyses revealed that a sample size of 204 would be needed to detect effects of d = 0.35 at any one follow-up with power of .80. Given our expected follow-up rates of at least 90%, an initial sample of 224 would be adequate to achieve the desired power to test main effects. Consistent with recommendations for optimization trials, we did not power the study specifically to test interactions among conditions but will examine cell means to determine which combinations of interventions appear to produce the largest effect relative to their intensity and complexity of delivery [73,74].

2.9. Analysis plan

Analyses will be conducted using generalized linear models (GLMs) to test the main and interactive effects of each of the three factors in the study design. Specifically we will use a negative binomial distribution to examine (a) the number of drinks consumed and (b) the number of heavy drinking days in the past 30 days at 6 and 12 months. In our prior trial [10], it was not necessary to adjust analyses for zero-inflation, but zero-inflated models will be conducted if necessary in the present trial. We will also include a random effect for interventionist, if we see evidence of outcomes differing by interventionist. Terms for BI vs. MI, no ITM vs. ITM, and no EI vs. EI will be effects coded (i.e., orthogonally) so they can be evaluated concurrently with the three 2-way interactions and one 3-way interaction among these factors. We do not have primary hypotheses regarding interactions, but rather the interaction terms will inform us whether there is meaningful non-additivity. For example, a negative 3-way interaction could indicate that using three of the more intensive interventions does not provide as large a total effect as would be expected based on each main effect and is therefore less efficient than using any two interventions [73,74]. Analyses will control for the baseline value of the dependent variable and recruitment site. Following intention-to-treat principles, analyses will be conducted on all participants who were randomized to an intervention condition regardless of the number of sessions of intervention they complete. We will conduct our primary analyses using all available data. We will also use multiple imputation for missing outcome data and re-run analyses with imputed data as a sensitivity analysis. We will test interactions between treatment conditions and site but do not expect to find any such interaction effects since all interventions will be delivered by personnel at Brown. As a secondary analysis, we will examine the time by EI condition interaction to determine the relative improvement in outcome associated with EI at 12 months compared to at 6 months.

Additionally, we will use GLMs with appropriate link functions to test the main and interactive effects of the three study factors on multiple variable at 6 and 12 months. These include (a) number of days engaging in condomless sex with a non-steady partner, (b) percent of days adherent to ART, and (c) viral suppression (<20 copies/ml). Analyses will control for the baseline value of the dependent variable and recruitment site. We also will conduct causal modeling to determine whether there is a significant natural indirect effect of treatment on each of these DVs through its effect on heavy drinking, implementing the approach of Valeri and VanderWeele [75].

3. Discussion

Multiple randomized controlled trials have provided evidence for the efficacy of behavioral interventions for reducing alcohol use in people living with HIV [72], with some evidence that interventions with a primary focus on alcohol use—as opposed to alcohol use being one of a number of intervention targets—have particularly strong effects [11,12, 76,77]. In our recent trial, MI with personalized feedback showed robust effects on reducing drinking when compared to an assessment-only HIV treatment as usual control [10]. However, more work is needed to refine behavioral intervention approaches to maximize their efficiency and effectiveness, hence the purpose of the current study.

Consistent with a Multiphase Optimization Strategy (MOST) [73,74], the present study utilizes a factorial randomized controlled trial design to address multiple questions regarding the most efficient and effective methods to address heavy drinking in MSM with HIV. First, the study will compare MI with personalized feedback to a BI that follows clinical guidelines for best-practice interventions in primary care settings; both conditions will also include detailed research assessments of alcohol use, which also may impact drinking. By comparing MI to a credible active comparison condition, we will be able to address whether MI outperforms BI significantly in MSM with HIV and thus warrants the more extensive clinical training and longer session length needed to deliver MI. A recent trial in HIV primary care found that MI did not outperform HIV care as usual, which included screening and brief intervention [78]. However, results did show a relative advantage of MI compared to brief intervention among those with low perceived importance of changing drinking and those who used other drugs. The present study will contribute additional data on the potential benefits of MI, including when MI is delivered as part of a telehealth intervention package.

Second, this study will test whether randomizing participants to an ITM program focused on alcohol use—and secondarily on ART adherence—can lead to additional reductions in drinking when added to either BI or MI. ITM is a particularly attractive intervention component because it requires little human oversight and can provide patients frequent prompts in real time to monitor their drinking and their progress in changing drinking. Automated text messaging interventions have shown promise for reducing alcohol and other drug use [79,80], as well as increasing ART adherence and improving viral and CD4 outcomes [81–83]. However, ITM has not yet been evaluated in the context of behavioral interventions to reduce drinking in people with HIV.

Third, this study will examine the duration of intervention needed to produce optimal effects. Outside of studies that have tested telephonebased continuing care for patients receiving addictions treatment [84–89], few behavioral alcohol interventions have based the number of sessions and the duration of the intervention on empirical data, relying instead on clinical judgement, precedent, or pilot testing to set these intervention parameters. The present study is novel in its inclusion of intervention quantity/duration as an experimental factor in an alcohol intervention among people with HIV. Specifically, we will test whether extending intervention to five sessions over 9 months provides additional benefits beyond those obtained conducting two sessions over 1 month. These results can inform the field about the most efficient allocation of clinical resources to address heavy drinking in HIV care. Continuing contact with patients over time can allow patients to consider changes, implement change efforts, and adjust goals and strategies for reducing drinking as they experience successes, challenges, and consequences of their efforts. If patients struggle to change their drinking with brief counseling, continued clinical contacts provide repeated opportunities to connect patients to additional addictions treatment, similar to a stepped care approach [90,91]. This approach to behavioral interventions may increase the efficacy of and reduce the costs associated with alcohol use treatment [92,93].

Finally, the present study is novel in its use of communication technologies to deliver alcohol interventions. Efforts to disseminate MI at HIV care settings may be hampered by the need to have MI-trained staff on-site. Although a range of provider types can be trained to provide MI, proficient use of MI principles and techniques requires ongoing practice and coaching with feedback [94,95]. Telehealth provides a potential solution to this challenge, allowing a small number of counselors in a centralized location to provide services to many patients. Telephone-delivered alcohol interventions have shown promising results [96-99], and we have incorporated telephone-delivered MI in prior trials [10,100]. However, telephone delivery of MI is constrained in that body language and facial expression cannot be used to gauge engagement and motivational state [101]. Recent evidence suggests that videoconferencing can be used to deliver evidence-based behavioral counseling at home [102-105], with preliminary results suggesting promise for home-based interventions [106,107]. In a pilot study, we found that we were able to deliver MI with high fidelity using videoconferencing [108]. We believe that using a combination of both videoconferencing and telephone counseling-which allows for easy scheduling of sessions that maximizes patient convenience-may be especially practical and effective. Therefore, in the present study both BI and MI will be delivered by videoconferencing and telephone with rigorous evaluation of intervention fidelity when using these modalities. If we observe similar effect sizes using telehealth when benchmarked against in-person interventions, this would argue for greater use of telehealth to address alcohol use in HIV care settings.

The present trial's 2 (BI vs. MI with personalized feedback) \times 2 (ITM vs. no ITM) \times 2 (1-month intervention vs. extended 9-month intervention) factorial design will allow us to evaluate the main effects of each experimental factor with adequate statistical power, addressing three hypotheses in one experiment. The design also will allow us to test in an exploratory fashion potential 2-way and 3-way interactions among the factors. Consistent with recommendations for MOST trials [73,74,109], we will use trial results to select an optimized intervention package that retains those components that have a significant main effect or are involved in a synergistic interaction with at least one factor with a significant main effect [110]. Considerations of effect sizes and resources needed to deliver each component also will inform selection of an optimized intervention package. For example, if MI provides only minimal benefit relative to BI when combined with both ITM and EI, the most efficient intervention package would be BI + ITM + EI because MI requires more time to deliver and requires greater training and ongoing supervision than BI.

Once identified, the optimized intervention package can be employed in large-scale implementation studies in multiple HIV clinical care sites with rigorous evaluation of cost effectiveness and implementation outcomes. Thus, the present study has the potential to contribute crucial empirical evidence for implementing effective and efficient behavioral interventions to address heavy alcohol use among MSM in HIV care, which may have multiple positive impacts across the HIV care continuum.

Declaration of competing interest

The authors have no conflicts of interest to declare.

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