



Computer delivered intervention for alcohol and sexual risk reduction among women attending an urban sexually transmitted infection clinic: A randomized controlled trial[☆]

Geetanjali Chander^{a,1,*}, Heidi E. Hutton^{b,1}, Xiaoqiang Xu^b, Chelsea E. Canan^c, Jennifer Gaver^a, Joseph Finkelstein^d, Catherine R. Lesko^c, Mary E. McCaul^b, Bryan Lau^c

^a Johns Hopkins University School of Medicine, Department of Medicine, 1830 E. Monument Street, Baltimore, MD 21287, United States

^b Johns Hopkins University School of Medicine, Department of Psychiatry and Behavioral Sciences, 550 N. Broadway, Baltimore, MD 21205, United States

^c Johns Hopkins University Bloomberg School of Public Health, Department of Epidemiology, 615 N Wolfe Street, Baltimore, MD 21287, United States

^d Icahn School of Medicine at Mount Sinai, 1425 Madison Ave, New York, NY 10029, United States

ARTICLE INFO

Keywords:

Unhealthy alcohol use
Computer delivered brief alcohol intervention
Randomized controlled trial
Women
HIV
Alcohol use disorder

ABSTRACT

Objective: We sought to determine if a computer delivered brief alcohol intervention (CBI) with or without interactive voice response counseling and text messages (CBI-IVR-TM), reduced alcohol use and sexual risk behaviors compared to attention control.

Methods: We conducted a 3-arm RCT among women (n = 439) recruited from Baltimore City Sexually Transmitted Infection (STI) Clinics. Eligibility included: 1) consumption of >7 drinks per week or 2) ≥2 episodes of heavy episodic drinking or ≥2 episodes of sex under the influence of alcohol in the prior three months. Research assessments conducted at baseline, 3, 6 and 12 months included a 30-day Timeline Followback querying daily alcohol use, drug use, and sexual activity. We used the MINI International Neuropsychiatric Interview-DSM-IV to ascertain drinking severity. Primary alcohol outcomes included: drinking days, heavy drinking days, drinks per drinking day. Secondary sexual risk outcomes included number of sexual partners, days of condomless sex, and days of condomless sex under the influence of drugs and alcohol.

Results: Median age was 31 (IQR 25–44 years), 88% were African American, 65% reported current recreational drug use, and 26% endorsed depressive symptoms. On the MINI 66% met criteria for alcohol use disorder (49% alcohol dependence, 18% abuse). At follow-up, all three groups reduced drinking days, heavy drinking days, drinks per drinking day and drinks per week with no significant differences between study arms. There was no difference in sexual risk outcomes among the groups.

Conclusions: Among women attending an urban STI clinic single session CBI with or without IVR and text message boosters was insufficient to reduce unhealthy alcohol use or sexual risk behaviors beyond control. The high severity of alcohol use and the prevalence of mental health symptoms and other substance use comorbidity underscores the importance of developing programs that address not only alcohol use but other determinants of STI risk among women.

1. Introduction

Unhealthy alcohol use, the spectrum of consumption that includes hazardous use, heavy episodic (binge) drinking (HED), and alcohol use disorder (AUD) (Saitz, 2005); is prevalent among women receiving care in sexually transmitted infection (STI) clinics with 69% reporting past

year alcohol use and 24% reporting symptoms of an AUD (Cook et al., 2006). In this clinical setting, unhealthy alcohol use among women is a particularly strong contributor to HIV and other STI risk behaviors (Carey, Senn, Walsh, Scott-Sheldon, & Carey, 2016; Hutton, McCaul, Santora, & Erbeling, 2008; Jenness et al., 2011; Norris et al., 2009; Scott-Sheldon et al., 2009, 2013). Furthermore, although women at STI

[☆] Presented at the 2018 Research Society of Alcoholism Meeting, San Diego, California.

* Corresponding author at: 1830 E. Monument Street, Baltimore, MD 21287, United States.

E-mail address: Gchande1@jhmi.edu (G. Chander).

¹ Co First Author.

<https://doi.org/10.1016/j.abrep.2021.100367>

Received 11 February 2021; Received in revised form 9 June 2021; Accepted 28 June 2021

Available online 6 July 2021

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clinics report less alcohol use than men, their alcohol use is more likely to be associated with number of sex partners and condomless sex with non-primary sex partners compared with men (Carey et al., 2016). HED in particular is associated with condomless vaginal and receptive anal sex among women (Hutton et al., 2008; Jenness et al., 2011). In an urban STI clinic, women with HED were three times more likely to report anal sex compared to women without alcohol use (33% vs. 11%) and more than twice as likely to report anal sex compared to women who drank alcohol but without binge use. In this same sample, gonorrhea was 5 times higher among women with HED compared to women who abstained (10.6% vs. 2.2%; $p < 0.05$); there was no association among men (Hutton et al., 2008). Given the prevalence of unhealthy alcohol use among women attending STI clinics, and the associated sexual risk behaviors, STI clinics are an important setting to deliver behavioral alcohol reduction interventions as a component of STI prevention for women.

Brief alcohol interventions (BI) range from a brief single behavioral intervention to multi-contact interventions, and can consist of personalized feedback with comparison to norms, elements of cognitive behavioral therapy and/or motivational interviewing, problem solving and include goal setting (Curry et al., 2018). BI can be effective in reducing drinks per week and heavy drinking days among women of childbearing age in primary care settings (Manwell, Fleming, Mundt, Stauffacher, & Barry, 2000) and both drinking days and heavy drinking days among women in HIV clinical settings (Chander, Hutton, Lau, Xu, & McCaul, 2015). Single session interventions can also decrease sexual risk behaviors. A meta-analysis of brief, single session interventions for sexual risk reduction demonstrates a small, but significant reduction in sexual risk taking, defined as increasing condom use and decreasing unprotected sex (Sagherian, Huedo-Medina, Pellowski, Eaton, & Johnson, 2016).

Despite the potential benefits for BI, implementation can be challenging due to lack of provider time, knowledge or resources and competing provider demands (Johnson, Jackson, Guillaume, Meier, & Goyder, 2011). Computer delivered brief alcohol interventions (CBI) can address many of these implementation barriers, thus increasing access BI access while maintaining intervention fidelity and allowing for tailoring to specific clinical populations and health needs (Portnoy, Scott-Sheldon, Johnson, & Carey, 2008). Augmenting clinic-based CBI with other technologies such as text messaging and interactive voice response allows for extension of the intervention beyond the clinic visit, reinforcing behavioral content and potentially enhancing CBI effectiveness (Hasin et al., 2013; Tofighi, Abrantes, & Stein, 2018). This may be particularly important in settings where single visits are the norm, such as STI clinics, as data from in-person delivered brief interventions indicate that multi-session brief interventions may be more effective than a single session (Mdege et al., 2013; O'Connor et al., 2018).

Despite the promise of CBI for alcohol and sexual risk behavior delivered in STI clinics, their effectiveness is currently not known. In a randomized controlled trial (RCT) we sought to determine if a CBI with or without supplemental interactive voice response (IVR) counseling and text messages can reduce alcohol use (primary outcome) and sexual transmission behaviors (secondary outcome) among women with hazardous alcohol use receiving care in two urban STI clinics. We hypothesized that both CBI only and CBI + IVR/Text messages would lead to greater reduction in drinking days, heavy drinking days, drinks per drinking day and drinks per week, compared to the control condition of a computer-delivered oral health intervention. Furthermore, we secondarily hypothesized that CBI only and CBI + IVR/Text messages would lead to greater reduction in days of condomless sex and days of condomless sex under the influence of alcohol.

2. Methods

2.1. Study design

We conducted a three arm, parallel-group randomized trial of CBI

with or without IVR and text messages compared to attention control among women with hazardous alcohol use attending 2 urban STI clinics. The Johns Hopkins School of Medicine Institutional Review Board and the Baltimore City Health Department Public Health Review approved this study and this study was registered at clinical trials.gov (NCT01125371).

2.2. Setting and participants

Participants were recruited between June 2012-May 2015 from 2 public STI clinics in Baltimore City. We used several methods of recruitment including provider referral, clinic flyers advertising a study for women, and a waiting room recruitment table. Women were eligible for participation if they met the following criteria: ≥ 18 years old and presenting to STI clinic for clinical services; sexually active with men in the prior 90 days; and if they met one of the following 3 criteria: 1) consumed > 7 standard drinks per week (determined by the Quick Drinking Screen (QDS) (Roy et al., 2008) or 2) > 3 drinks per occasion at least twice in the prior three months (QDS) or 3) had sex under the influence of any alcohol at least two times in prior 3 months. We excluded women if they were 1) non-English speaking (CBI was in English only), 2) pregnant, 3) currently receiving alcohol treatment, 4) actively psychotic, 5) unable to understand the informed consent (determined by standard questions administered at the end of consent), 6) did not have a cell phone, 7) did not use text messaging, 8) were planning to move out of the area within the following 12 months.

2.3. Randomization

We randomized women after their baseline assessment (allocation [1:1:1]). Randomization was centralized, with group assignment delivered to the study coordinator via REDCap (Harris et al., 2009). An independent data manager generated and uploaded the randomization sequence onto the REDCap server. We used block randomization, with random block sizes of 3, 6 and 9. Randomization was stratified by the presence or absence of active recreational drug use. Outcomes assessors and investigators were blinded to group assignments; however, due to the nature of the intervention, neither the study coordinator nor participants were blinded.

2.4. Study conditions

Women randomized to the CBI and control conditions received the intervention on the same day as their baseline assessment in a private office. Participants in all three arms received usual care provided by the STI clinics, including STI screening and treatment, and referral for HIV testing. In addition, participants received a pamphlet of local resources that included a comprehensive list of federally qualified health centers in Baltimore City and local resources for free dental care, psychiatric care, primary medical care, substance abuse treatment programs (including tobacco), Alcoholics Anonymous and Narcotics Anonymous meetings, and domestic violence resources.

2.5. Computer delivered brief alcohol intervention (CBI)

The CBI was based on an informational, motivational and behavioral skills model (Fisher et al., 1994, 2006). Using the Motivational Enhancement System (MES) Platform (Interva,inc), this interactive 20-minute intervention was delivered in a motivational interviewing style (Miller & Rollnick, 2013) by a 3 dimensional avatar, Peedy the Parrot (Ondersma et al., 2005, 2007). The intervention included core components of brief alcohol intervention, including decisional balance, triggers, identifying risky mood and situations and if desired goal setting to cut down/quit alcohol use and increase condom use and increase condom use when drinking. The intervention provided personalized feedback on level of alcohol related risk compared to other women. In

addition, the CBI had multiple branching points where feedback was provided depending on women's responses to the avatar's questions, e. g. pros and cons of alcohol use. More specific tailoring occurred at two key points: 1) When women selected a drinking trigger from a list of 15 types of moods or situations they were presented with a variety of skills relevant to their trigger. 2) Women also received tailored feedback in the optional goal setting module. Women who chose not to set a goal branched into feedback querying about what would have to happen and when would they know to set a goal. For women who selected that they would like to reduce their drinking but chose a goal still above 'safer' drinking limits, the avatar provided feedback on safer and riskier drinking with an option to keep their goal as is or reset a new one. The intervention was enhanced with content addressing sex-related alcohol expectancies. Using decisional balance, the intervention explored women's expectations about the effect of alcohol on sexual desire and sexual risk behaviors and the consequences of alcohol use before or during sex (Hutton et al., 2015; Lewis, Hutton, Agee, McCaul, & Chander, 2015). This added content, along with cultural tailoring, was informed by formative work derived from in-depth interviews with women drawn from the same STI clinic sites as participated in the study (Hutton et al., 2015; Lewis et al., 2015).

2.6. Computer delivered brief alcohol intervention plus IVR counseling and text messages

Women randomized to this arm received the CBI as described above, enhanced with 3 automated booster counseling calls using interactive voice response technology (IVR) and text messages. The booster calls, occurring at 2, 4 and 6 weeks after the CBI reinforced the intervention content, and queried participants drinking and sexual risk behaviors and goals. The telecommunications system used computer telephony to carry out automated telephone conversations with participants. The system was programmed with branching logic that responded to the respondents answer to whether they met their goals they set with Peedy for safer alcohol use and/or safer sex (defined as condom use and condom use when drinking alcohol). Based on their response, they were branched into different counseling algorithms. If they had not set a goal during the intervention, then they were asked if they would like to set one at this time. Text messages were delivered 3 times per week for 6 weeks on Fridays, Saturdays, Mondays or Tuesdays based on participant preference. The messages reinforced behavioral skills such as handling risky moods or situations and included motivational statements.

2.7. Control

The control arm received a computer-delivered informational intervention on oral health, including appropriate brushing and flossing techniques and educational information on gum disease. The content was selected to address a local public health need, with the length of this session approximating that of the CBI for alcohol. We used the same platform to deliver both the control condition and the CBI.

2.8. Assessment visits

All study participants completed the same in-person research assessments at baseline, 3, 6 and 12 months. Assessments were conducted by research assistants blinded to participants' study condition. Participants were compensated for their time and travel at baseline (\$30) and at their 3-month (\$35); 6-month (\$40) and 12-month (\$50) follow up assessments, with a \$20 bonus for completing all three follow-up assessments after baseline. The baseline assessment was on average two hours (maximum assessment time 3 h) and follow up visits lasted approximately 60 to 90 min. Per our study protocol, if a woman became pregnant during the course of the study, we referred her to more extensive treatment at that time, given the risk of alcohol exposed pregnancy. As such, no further study visits after the visit where

pregnancy was disclosed were conducted.

2.9. Outcomes

Our primary and secondary outcomes were ascertained via a 30 day Time Line Follow Back (TLFB) interview, which quantified alcohol use, other drug use, and sexual risk behaviors on each day over the prior 30 days (Carey, Carey, Maisto, Gordon, & Weinhardt, 2001; Robinson, Sobell, Sobell, & Leo, 2014; Weinhardt et al., 1998). Using structured interview prompts, the TLFB collects detailed quantity/frequency data including type of alcohol consumed, number of standard drinks/drinking day, and number of drinking days. As we were interested in specifying effect of alcohol quantity on outcomes, our TLFB protocol included a thorough analysis of the alcohol by volume composition of each daily drink. We derived four a priori drinking outcomes: 1) number of heavy drinking days, defined as > 3 drinks per occasion (primary); 2) number of drinking days, 3) the average number of drinks per week; and 4) number of drinks per drinking day.

The TLFB interview also assessed each encounter of sexual activity over the prior 30 days, by partner (main, casual or unknown partner), type of sexual activity (oral, anal, or vaginal), condom use, and whether the episode was under the influence alcohol or drugs (Carey et al., 2001; Weinhardt et al., 1998). As secondary outcomes, we analyzed three outcomes related to sexual behavior: 1) number of sexual partners; 2) number of days with condomless vaginal or anal sex; and 3) number of days with vaginal or anal sex while under the influence of alcohol or drugs.

For women who reported one or more days in a controlled environment during the TLFB due to a hospitalization, incarceration, or inpatient rehabilitation treatment, the outcomes were calculated based on the number of days that the woman was not in the controlled environment, and then standardized to a 30-day period.

On a subset of women (N = 43) presenting to their final visit we obtained dried blood spot for the direct alcohol biomarker phosphatidyl ethanol (PEth) (USDTL, Des Plaines, IL) for comparison with self-reported recent alcohol use (Hahn et al., 2012; Schrock, Wurst, Thon, & Weinmann, 2017; Wurst et al., 2015). PEth can detect unhealthy alcohol use for up to three weeks (Wurst et al., 2015). This was added to the study protocol during the final year of the study. Participants were paid an additional \$5 for the blood spot.

2.10. Independent variables

Women self-reported demographic information, alcohol-related symptoms and behaviors, and mental health symptoms, via an automated computer-assisted self-interview (ACASI). The Alcohol Use Disorders Identification Test (AUDIT) (Saunders, Aasland, Babor, de la Fuente, & Grant, 1993) provided information on alcohol problem severity, using cut-offs of < 7, 7–12, and ≥ 13 (Rubinsky, Kivlahan, Volk, Maynard, & Bradley, 2010). The MINI-International Neuropsychiatric Interview (M.I.N.I.) DSM-IV (Sheehan et al., 1998) was used to classify individuals as having an alcohol use disorder (AUD) if they scored one or more on the alcohol abuse items and/or three or more on the dependence items. Four screening measures were used to assess the presence of mental health symptoms. Depressive symptoms were measured continuously using the PHQ-8 (Kroenke et al., 2009). Generalized anxiety (GAD) was measured using the GAD-7, with symptoms categorized as mild, moderate or severe based on cut points of 5, 10, and 15 (Spitzer, Kroenke, Williams, & Lowe, 2006). Panic and PTSD symptoms were dichotomized as present or absent as indicated by a positive response to the first question on the PHQ-P (Wittkamp, Baas, van Weert, Lucassen, & Schene, 2011) and a score of ≥ 3 on the Primary Care PTSD (PC-PTSD) screen (Ouimette, Wade, Prins, & Schohn, 2008; Prins et al., 2003; van Dam, Ehring, Vedel, & Emmelkamp, 2010); respectively. Daily use of the following illicit substances was assessed using the 30-day timeline follow-back: marijuana, cocaine, heroin, and non-medical

use of prescription drugs (Robinson et al., 2014).

2.11. Sample size

Based on prior literature on the effectiveness of brief alcohol interventions and computer-delivered intervention on reduction in heavy drinking days, drinking days and drinks per week, we set our target sample size to detect a small to medium effect size (Cohen's $d = 0.30-0.35$) (Manwell et al., 2000; Ondersma, Svikis, & Schuster, 2007). Calculations assumed a repeated measures analysis (baseline and three follow-up periods), a balanced design, rho of 0.50 or within-person correlation between measurements, and an alpha level of 0.0167 (0.05 experiment-wise error rate Bonferroni type adjustment (Bland & Altman, 1995) for three pair-wise hypothesis comparisons at 6 months with earlier and later treatment effects tested at an unadjusted alpha of 0.05) (Cohen, 1988; Diggle, Liang, & Zeger, 2004; Sas & Programs, 2006). For our primary outcomes, a sample size of 450 provided 0.87 power to detect an effect size d of 0.35.

2.12. Statistical methods

We calculated the median and interquartile range (IQR) for the four outcomes at each visit using an intention-to-treat treatment assignment to stratify the treatment groups. To assess changes in the four drinking behaviors by treatment group, we fit adjusted generalized estimating equation (GEE) models with a binomial distribution for number of drinking days and number of binge drinking days, which had an upper bound of 30, or a log normal distribution for drinks per drinking day and standard drinks per week, which were unbounded. All models were fit with categorical indicators for assigned treatment group, baseline MINI category (dependence, abuse, neither). Models were adjusted for the baseline values of all four outcomes of interest for the given model to improve precision (Colantuoni & Rosenblum, 2015; Steingrimsson, Hanley, & Rosenblum, 2017), continuous age, education, depressive, GAD and panic symptoms, PTSD, and number of days in the past 30 of use of the following: marijuana, cocaine, heroin, and prescription drugs for non-medical use.

For each outcome, we fit the respective regression model to obtain the coefficients for all covariates. We then predicted the outcome for each woman in the study sample 3 times: first, as if all women were in the control group, and second, as if each woman was in the CBI only group, and finally under the assumption that each woman was in the CBI + IVR/TEST group (Robins, 1986; Snowden, Rose, & Mortimer, 2011). We created 1000 bootstrap samples by resampling with replacement from the study sample and ran the regression models on all 1000 resamples. We calculated the point estimates as the median point estimate of the 1000 bootstrapped samples and calculated 95% confidence intervals as the 2.5th and 97.5th percentiles of the bootstrapped estimates (Steingrimsson et al., 2017). For the CBI + IVR/text and CBI only treatment groups, we calculated the difference between the estimated outcomes under the treatment group compared to the control group.

We identified statistically significant differences by assessing whether the 95% confidence interval of the difference (i.e. the 2.5th and 97.5th percentile of the differences from all bootstrap samples) contained zero.

To account for missing visits, we weighted all models by the inverse probability of missing a given visit (Cain & Cole, 2009; Seaman & White, 2013; Sun et al., 2018). Inverse probability weighting is an alternative to account for missing data and one may prefer this approach over multiple imputation when an entire visit is missed by a study participant (Seaman & White, 2013). The inverse probability weights were calculated using a logistic regression model with 'missing' modeled as a function of whether the participant missed a prior visit, treatment group, the four baseline drinking measures, age, education, baseline MINI category (dependence, abuse, neither), depressive symptoms, anxiety symptoms,

panic symptoms, and PTSD. The model covariates were chosen based on data exploration to determine factors associated with both treatment group and missing visits. To further investigate the variation of the drinking measures at different response levels, we fit the drinking measures using quantile mixed effect models. The dependent and independent variables were the same as in the GEE models described above. The same weights obtained from the missing visit models were also applied. The generated weights were included to allow participants to be up or down weighted based upon the probability of missing a visit.

2.13. Secondary analyses

2.13.1. Sexual risk behavior

We fit GEE models to test intervention effects on sexual behaviors among treatment groups. The outcomes were the number of sexual partners, number of days with condomless sex, and number of days of condomless sex under the influence of alcohol. For each treatment group we estimated the values of our outcome measures at each visit and their change from baseline at each follow up visit. We tested the change from baseline between the CBI group against control group, and the CBI + IVR group against control group.

3. Results

We recruited participants between June 2012 and May 2015 with final follow up in June 2016. Recruitment ended when targeted sample size was achieved. Fig. 1 shows the CONSORT flow diagram. A total of 608 women were screened and 439 were randomized, of whom 146 were assigned to the CBI + IVR/Text group, 145 to the CBI only group, and 148 to the control group. Fourteen women did not complete any follow up visits (3.1%). At 3, 6, and 12 months, participant follow-up ranged from 82 to 86% in the CBI + IVR/Text group, 89–92% in the CBI arm, and 87–91% in the control arm.

Table 1 describes the characteristics of the study sample by treatment arm. The median age was 31 years (IQR: 25–44 years) and the majority of women (88%) were African American. Illicit drug use was common, with 65% of women reporting current illicit drug use. On both the MINI and AUDIT alcohol assessments, severity of alcohol use was high. On the MINI assessment, 49% ($n = 217$) of all women met dependence criteria and an additional 18% ($n = 81$) met criteria for alcohol abuse. On the AUDIT assessment, 44% of women scored ≥ 13 in the harmful range and 29% in the hazardous range between 7 and 12, and the remaining 25% scored in the low risk range < 7 . Mental health symptoms were also prevalent at baseline, with 37% of women reporting trauma symptoms, and 49% reporting any generalized anxiety symptoms (20% with moderate to severe symptoms). The median score on the PHQ for depression was 7, with 26% scoring 10 or greater, indicating moderate to severe depressive symptoms.

3.1. Intervention effects on heavy drinking days, drinking days, drinks per drinking day and drinks per week

Tables 2 provides unadjusted estimates of our drinking outcomes by study condition. Participants in all three study arms significantly reduced their heavy drinking days, drinking days, drinks per drinking day and drinks per week over the follow up period with no statistically significant difference between study arms.

Table 3 provides the estimated number of heavy drinking days, drinking days, drinks per drinking day, and drinks per week. Models were adjusted and weighted to account for missing data (Colantuoni & Rosenblum, 2015). Similar to the unadjusted data, estimated drinking outcomes decreased in all three study arms without significant differences between the study arms.

Analyses stratified by the presence or absence of an alcohol use disorder (see supplemental table) also demonstrated reduction in alcohol use across all study arms, without significant differences

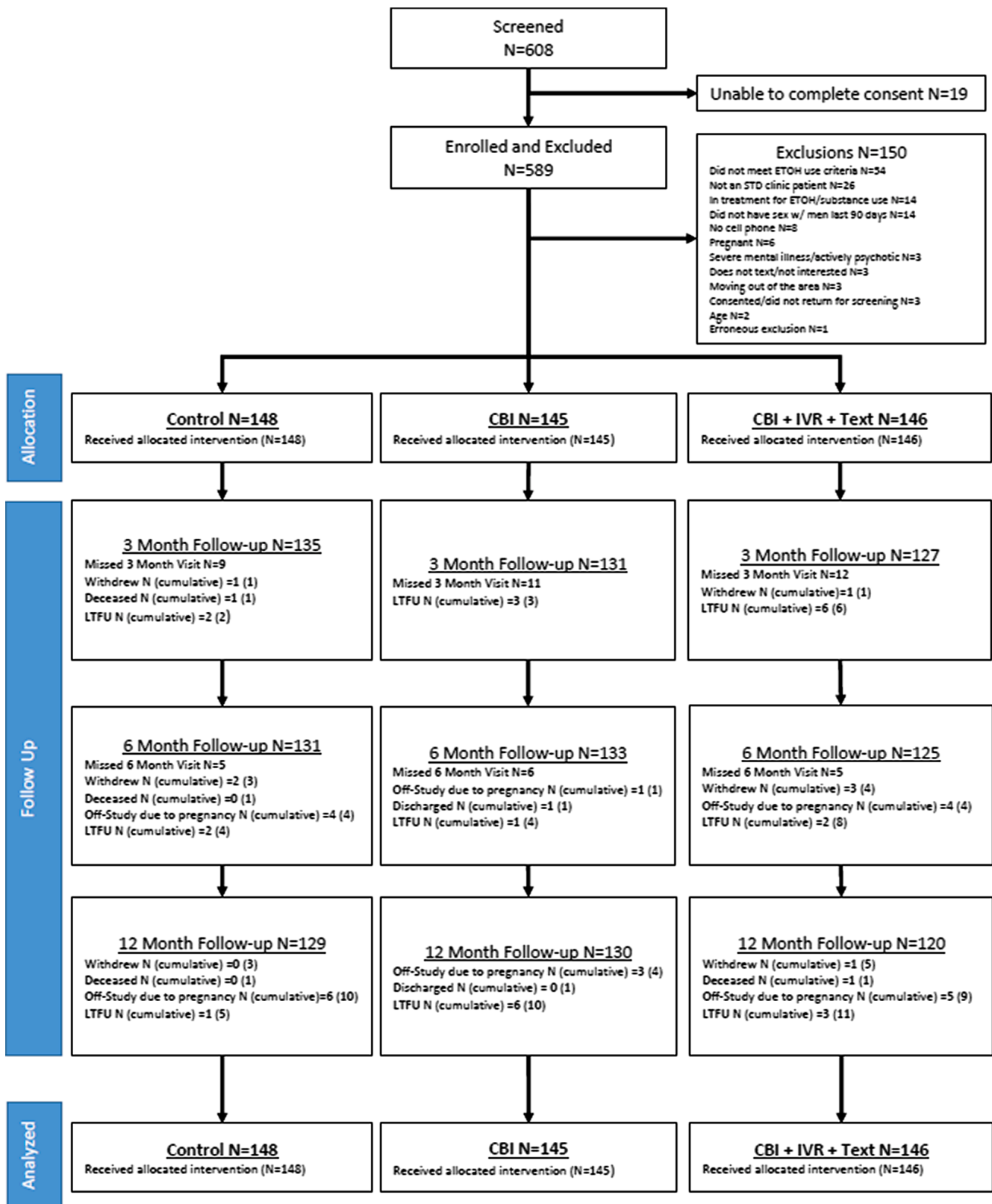


Fig. 1. CONSORT diagram. *LTFU = Lost to follow-up.

between study arms. Finally, we examined differences in intervention effect using quantile regression, and there was no significant differences in the distribution between the three arms across alcohol treatment outcomes.

3.2. Sexual risk behavior

Table 4 displays sexual risk outcomes by treatment assignment. The three individuals excluded from the alcohol analysis were added back into the sample. There were no significant differences in the number of

Table 1

Baseline characteristics of study participants (n = 439). *P values are from 1-way ANOVA test, Wilcoxon rank sum test, chi-square test, or Fisher's exact test.

| | CBI + IVR/ text (N = 146) | CBI only (N = 145) | Control (N = 148) | Cross- group P* |
|----------------------------------------------------|---------------------------------|-----------------------|----------------------|-----------------------|
| Age, median (IQR) | 32 (25, 43) | 31 (25, 45) | 31 (24, 45) | 0.891 |
| Race, N (%) | | | | 0.601 |
| African American | 131 (89.7) | 125 (86.2) | 132 (89.2) | |
| Other | 15 (10.3) | 20 (13.8) | 16 (10.8) | |
| Education, N (%) | | | | 0.524 |
| < Grade 12 | 42(28.8) | 41 (28.3) | 50 (33.8) | |
| GED or higher | 104 (71.2) | 104 (71.7) | 98 (66.2) | |
| Income, N (%) | | | | 0.428 |
| \$0 ~ \$5,000 | 77 (53.5) | 63 (43.4) | 75 (50.7) | |
| \$5,001 ~ \$10,000 | 23 (16.0) | 35 (24.1) | 25 (16.9) | |
| \$10,001 ~ \$15,000 | 18 (13.0) | 24 (16.6) | 22 (14.9) | |
| \$15,001 or more | 26 (19.0) | 23 (15.9) | 26 (17.6) | |
| HIV status, N (%) | | | | 0.480 |
| No | 132 (90.4) | 129 (89.00) | 140 (63.3) | |
| Yes | 8 (5.5) | 10 (7.0) | 4 (18.2) | |
| Unsure | 6 (4.1) | 6 (4.2) | 4 (18.2) | |
| Illicit drug use, N (%) | | | | 0.968 |
| Yes | 95 (65.1) | 93 (64.1) | 97 (65.5) | |
| Marijuana, N (%) | | | | 0.389 |
| Yes | 78 (53.4) | 72 (49.7) | 71 (48.0) | |
| Cocaine, N (%) | | | | 0.902 |
| Yes | 21 (14.4) | 21 (14.6) | 20 (13.5) | |
| Heroin, N (%) | | | | 0.335 |
| Yes | 16 (11.0) | 9 (6.2) | 7 (4.7) | |
| Injection drug, N (%) | | | | 0.362 |
| Yes | 3 (2.1) | 2 (1.4) | 1 (0.7) | |
| Non-medical use of prescription drugs, N (%) | | | | 0.660 |
| Yes | 9 (6.2) | 16 (11.0) | 12 (8.1) | |
| PHQ Depressive Symptoms, median (IQR) | 6 (3, 10) | 7 (3, 12) | 7.5 (4, 12) | 0.510 |
| PHQ Panic Symptoms, N (%) | | | | 0.083 |
| Yes | 35 (24.0) | 52 (35.9) | 43 (29.1) | |
| PTSD, N (%) | | | | 0.174 |
| Yes | 46 (31.5) | 61 (42.1) | 54 (36.5) | |
| Generalized Anxiety Symptoms, N (%) | | | | 0.488 |
| None | 81 (55.5) | 63 (43.4) | 72 (48.6) | |
| Mild | 39 (26.7) | 45 (31.0) | 43 (29.1) | |
| Moderate | 15 (10.3) | 20 (13.8) | 20 (13.5) | |
| Severe | 10 (7.0) | 17 (11.7) | 13 (8.8) | |
| Missing | 1 (0.7) | 0 (0) | 0 (0) | |
| MINI Assessment, N (%) | | | | 0.452 |
| Neither | 54 (37.0) | 42 (29.0) | 45 (30.4) | |
| Abuse | 23 (15.8) | 32 (22.1) | 26 (17.6) | |
| Dependence | 69 (47.3) | 71 (49.0) | 77 (52.0) | |
| Audit Score, N (%) | | | | 0.287 |
| <7 | 40 (27.4) | 35 (24.1) | 43 (29.1) | |
| 7-12 | 34 (23.3) | 47 (32.4) | 47 (31.8) | |
| ≥13 | 72 (49.3) | 63 (43.4) | 58 (39.2) | |

sexual partners, number of days with condomless sex, and number of days of condomless sex under the influence of alcohol across the treatment arms.

3.3. Self-reported alcohol and PETH

During the final year of the study, we performed PETH testing on a subset of participants at their visit 4 (n = 43), to assess if self-report of recent alcohol use as measured on the TLFB was consistent with the alcohol biomarker. Six tests had insufficient quantity to test. Among the remaining 37 samples, there was a moderate correlation between PETH values (range 0.504) and drinking outcomes for number of heavy drinking days (Spearman: 0.48, P < 0.01), drinks per drinking day (0.47, p < 0.01), and drinks per week (0.44, p < 0.01). A weak positive

Table 2

The four unadjusted primary alcohol outcomes by treatment arm as quantified by TLFB for the past 30 days.

| | Number of heavy drinking days, median (IQR) | | | |
|-------------------|------------------------------------------------|-----------------------|-----------------------|------------------------|
| | Baseline (N = 439) | 3 months (N = 390) | 6 months (N = 389) | 12 months (N = 378) |
| CBI + IVR/text | 6 (2, 13) | 3 (1, 7) | 3 (0, 7) | 2 (0, 6) |
| CBI only | 6 (3, 11) | 3 (1, 8) | 4 (1, 8) | 2 (0, 6) |
| Control | 6 (2, 11) | 3 (0, 8) | 2 (0, 8) | 3 (1, 6) |
| | Number of drinking days, median (IQR) | | | |
| | Baseline (N = 439) | 3 months (N = 390) | 6 months (N = 389) | 12 months (N = 378) |
| CBI + IVR/text | 9 (5, 15) | 6.4 (3, 10) | 6 (2, 11) | 6 (2, 11) |
| CBI only | 9 (6, 14) | 7 (4, 12) | 7 (2, 12) | 6 (2, 11) |
| Control | 8.5 (5.8, 15) | 6 (2.1, 11) | 5 (2, 11) | 6 (2, 10) |
| | Standard Drinks per drinking day, median (IQR) | | | |
| | Baseline (N = 439) | 3 months (N = 390) | 6 months (N = 389) | 12 months (N = 378) |
| CBI + IVR/text | 5.6 (3.2, 8.8) | 3.7 (2.2, 6.2) | 3.8 (1.4, 6.4) | 3 (1.5, 5.7) |
| CBI only | 5.6 (3.3, 9.3) | 4.2 (2.3, 6.4) | 4.4 (2.1, 6.8) | 3.4 (1.4, 5.6) |
| Control | 6.1 (3.7, 7.8) | 4.1 (2, 6.5) | 3.8 (1.7, 6.2) | 3.8 (1.4, 6.5) |
| | Standard drinks/week, median (IQR) | | | |
| | Baseline (N = 439) | 3 months (N = 390) | 6 months (N = 389) | 12 months (N = 378) |
| CBI + IVR/text | 12.0 (4.7, 28.7) | 6.5 (2.1, 13.6) | 5.6 (1.1, 13.1) | 4.3 (1.0, 11.5) |
| CBI only | 12.4 (5.8, 25.5) | 7.0 (2.9, 15.4) | 6.8 (1.4, 15.7) | 5.3 (1.0, 12.4) |
| Control | 12.0 (5.3, 25.3) | 6.4 (1.6, 16.1) | 4.4 (0.9, 15.7) | 5.4 (1.4, 11.2) |

correlation was observed between PETH score and number of drinking days (0.30, p < 0.01) (see supplemental table 5).

4. Discussion

In this study, a CBI with or without IVR and text messages did not result in greater reduction in alcohol use or sexual risk behaviors compared to attention control. Alcohol use severity was significantly higher than expected with nearly 68% of women meeting criteria for AUD. Comorbid drug use was common, with 50% reporting marijuana use and 15% reporting cocaine use. Mental health symptoms were prevalent; 37% of women reported PTSD symptoms, 30% panic symptoms, 26% depressive symptoms, 22% GAD symptoms. Clearly, these urban STI clinics serve a population with high severity of alcohol use, and concurrent mental health and other substance use comorbidity. It is well established that brief interventions have limited effectiveness among persons with AUD (Saitz, 2010). The overlapping drug and mental health comorbidities that are themselves risk factors for unhealthy alcohol use, may have further limited the effectiveness of our brief alcohol reduction intervention. Thus single session computer delivered intervention, even with the addition of text messaging and IVR may not have been sufficient to decrease alcohol use compared with the attentional control.

Studies of alcohol reduction interventions in STI and reproductive health clinical settings provide mixed results. Crawford and colleagues tested a multi-step program, comprised of clinician delivered brief advice (2-3 min) followed by a longer (30 min) appointment with an Alcohol Health Worker (AWH), compared to control (Crawford et al., 2015). Though nearly all randomized to the treatment arm received the brief advice, uptake of the AWH was lower, with 20% receiving both brief advice and AWH counseling. At 6 months follow up, there was no

Table 3

(N = 439) The expected adjusted estimate of the primary alcohol outcomes by treatment arm and the intervention treatment effect between the CBI and CBI + IVR treatment arms as compared to the control arm.

| Predicted number of heavy drinking days | | | | | |
|-----------------------------------------|--------------------|--------------------|-------------------|---------------------|-----------------------|
| | Control | CBI only | CBI + IVR | CBI - Control | (CBI + IVR) - Control |
| 3 months | 4.90 (4.04, 5.84) | 4.60 (3.77, 5.46) | 3.90 (3.14, 4.82) | -0.32 (-1.60, 0.87) | -1.02 (-2.14, 0.20) |
| 6 months | 4.90 (3.96, 5.80) | 4.61 (3.79, 5.44) | 4.08 (3.24, 5.06) | -0.34 (-1.38, 0.88) | -0.82 (-2.03, 0.45) |
| 12 months | 4.83 (3.86, 5.81) | 4.53 (3.69, 5.31) | 3.82 (3.04, 4.70) | -0.31 (-1.51, 0.89) | -1.00 (-2.26, 0.15) |
| Predicted number of drinking days | | | | | |
| | Control | CBI only | CBI + IVR | CBI - Control | (CBI + IVR) - Control |
| 3 months | 7.67 (6.69, 8.75) | 7.45 (6.47, 8.47) | 7.23 (6.21, 8.36) | -0.21 (-1.55, 1.15) | -0.43 (-1.82, 1.03) |
| 6 months | 7.74 (6.72, 8.81) | 7.45 (6.53, 8.55) | 7.26 (6.29, 8.46) | -0.32 (-1.70, 1.13) | -0.45 (-1.81, 1.02) |
| 12 months | 7.65 (6.61, 8.81) | 7.27 (6.26, 8.30) | 7.11 (6.17, 8.19) | -0.39 (-1.74, 0.99) | -0.55 (-1.99, 0.89) |
| Predicted drinks per drinking day | | | | | |
| | Control | CBI only | CBI + IVR | CBI - Control | (CBI + IVR) - Control |
| 3 months | 5.32 (3.92, 6.73) | 5.16 (4.14, 5.95) | 4.95 (4.15, 5.89) | -0.23 (-2.05, 1.30) | -0.37 (-2.10, 1.30) |
| 6 months | 6.22 (3.43, 7.76) | 5.61 (4.78, 6.32) | 5.73 (4.52, 7.11) | -0.61 (-2.31, 2.16) | -0.40 (-2.32, 2.59) |
| 12 months | 3.92 (-0.2, 8.77) | 4.53 (3.70, 5.53) | 5.08 (3.79, 9.62) | 0.67 (-4.25, 4.83) | 1.18 (-3.82, 6.99) |
| Predicted number of drinks per week | | | | | |
| | Control | CBI only | CBI + IVR | CBI - Control | (CBI + IVR) - Control |
| 3 months | 9.52 (7.69, 13.75) | 8.96 (7.60, 10.54) | 8.2 (6.79, 10.76) | -0.56 (-4.76, 1.87) | -1.28 (-5.34, 2.00) |
| 6 months | 9.53 (7.64, 14.03) | 9.10 (7.62, 10.63) | 8.8 (6.94, 12.03) | -0.53 (-5.15, 1.88) | -0.92 (-5.35, 3.13) |
| 12 months | 9.59 (7.58, 14.03) | 8.95 (7.53, 10.46) | 8.2 (6.66, 10.47) | -0.70 (-5.47, 1.64) | -1.51 (-5.93, 1.60) |

All models were fit with categorical indicators for assigned treatment group, baseline MINI category (dependence, abuse, neither). Models were adjusted for the baseline values of all the four outcomes of interest, continuous age, education, depressive, GAD and panic symptoms, PTSD, and number of days with illicit drug use over the past 30 days for the following substances: marijuana, cocaine, heroin, prescription drugs.

Table 4

(N = 439) The expected adjusted estimate of sexual risk outcomes by treatment arm and the intervention treatment effect between the CBI and CBI + IVR treatment arms as compared to the control arm.

| | Control | CBI only | CBI + IVR | CBI - Control | (CBI + IVR) - Control |
|--------------------------------------------------------------------------|----------------|----------------|----------------|----------------------|-----------------------|
| Estimated number of sexual partners | | | | | |
| Baseline | 1.9 (1.4, 2.4) | 1.7 (1.5, 2.0) | 1.6 (1.4, 1.9) | -0.15 (-0.72, 0.42) | -0.24 (-0.81, 0.32) |
| 3 Months | 1.4 (1.2, 1.7) | 1.3 (1.1, 1.4) | 1.3 (1.0, 1.5) | -0.14 (-0.43, 0.16) | -0.14 (-0.49, 0.21) |
| 6 Months | 1.2 (1.1, 1.4) | 1.1 (0.9, 1.4) | 1.2 (1.0, 1.3) | -0.06 (-0.35, 0.22) | -0.05 (-0.29, 0.19) |
| 12 Months | 1.1 (1.0, 1.2) | 1.1 (0.9, 1.3) | 1.0 (0.9, 1.2) | 0.03 (-0.22, 0.28) | -0.04 (-0.24, 0.17) |
| Estimated days of condomless sex | | | | | |
| Baseline | 4.3 (3.6, 5.1) | 3.9 (3.1, 4.6) | 3.7 (3.0, 4.4) | -0.48 (-1.55, 0.60) | -0.61 (-1.65, 0.44) |
| 3 Months | 3.6 (2.9, 4.3) | 3.8 (2.9, 4.6) | 3.4 (2.5, 4.3) | 0.18 (-0.94, 1.30) | -0.12 (-1.27, 1.02) |
| 6 Months | 4.2 (3.3, 5.1) | 2.9 (2.2, 3.6) | 3.6 (2.7, 4.4) | -1.28 (-2.42, -0.14) | -0.63 (-1.81, 0.56) |
| 12 Months | 3.2 (2.5, 4.0) | 3.4 (2.6, 4.2) | 3.0 (2.3, 3.7) | 0.15 (-0.92, 1.21) | -0.28 (-1.28, 0.71) |
| Estimated days of condomless sex under the influence of alcohol or drugs | | | | | |
| Baseline | 3.5 (2.7, 4.2) | 3.2 (2.6, 3.8) | 3.7 (3.1, 4.4) | -0.26 (-1.23, 0.70) | 0.29 (-0.66, 1.24) |
| 3 Months | 2.6 (2.0, 3.1) | 2.5 (1.8, 3.1) | 2.7 (2.1, 3.4) | -0.09 (-0.95, 0.77) | 0.17 (-0.68, 1.02) |
| 6 Months | 2.4 (1.8, 3.1) | 2.2 (1.5, 2.8) | 2.4 (1.8, 3.0) | -0.26 (-1.17, 0.66) | -0.05 (-0.91, 0.81) |
| 12 Months | 2.2 (1.6, 2.8) | 2.1 (1.5, 2.6) | 2.0 (1.5, 2.5) | -0.18 (-1.00, 0.65) | -0.25 (-1.03, 0.53) |

significant difference in neither drinks per week nor unprotected sex between the study arms. Though our CBI was longer than the brief advice provided by Crawford et al, and we used intervention extenders for 6 weeks, our intervention similarly did not demonstrate a difference between intervention and control. In a recent exploratory trial, Carey et al tested brief intervention (<60 min) combined with 12 weeks text messages and a curated website compared to control (Carey et al., 2020). The study included 48 women, between the ages of 18–29 years, receiving care in a reproductive health clinic. At the three month follow-up, both the intervention and control reduced drinks per week, heavy drinking days and number of sexual partners, without significant differences between the groups; however, they did note a larger reduction in the number of drinks before having sex and the maximum number of drinks per day in the intervention compared to the control groups. These more promising findings using a longer brief intervention and greater duration of text messaging support the need for more intensive services in these health care settings.

As noted above, alcohol reduction occurred across all three arms in our study. Assessment reactivity may account in part for this reduction among participants (Clifford, Maisto, & Davis, 2007; Meier, Miller, Lombardi, & Leffingwell, 2017). Assessment frequency, comprehensiveness, length, and mode of administration have been associated with reductions in alcohol use (Clifford et al., 2007). In our study the time line follow back interview was conducted in person, on four occasions and lasted a minimum of 60 min, with some greater than two hours. Detailed collection of not only daily alcohol use, but also sexual risk behaviors and drug use may have been a more potent intervention than a 15–20 min computer-delivered counseling session, especially given that the TLFB was repeated over time. Thus any potential intervention effect may have been obscured by the effects of the assessment itself. This is consistent with Hester and colleagues who evaluated the effectiveness of a computer delivered intervention among college students and found reductions in alcohol use and alcohol related problems in both the intervention and assessment only control groups, also noting that

control participants described increased awareness of how much they were drinking (Hester, Delaney, & Campbell, 2012). They subsequently designed a second trial with a delayed assessment and noted a greater intervention effect size. In addition to assessment reactivity, regression to the mean may also account in part for drinking reduction across all three groups. That alcohol use did decline in all groups – likely in part secondary to repeated review of drinking behaviors in TLFB- suggests that repeated contacts over time may be instrumental in alcohol reduction.

Our study has strengths and limitations. This was a rigorous RCT that met enrollment and retention targets. However, our sample consisted of urban women, attending an STI clinic with a high level of comorbidity. Our sample characteristics may limit the generalizability of our findings. In addition, the use of self-reported outcomes can be subject to both recall and social desirability bias. While PEth results were consistent with self-report, only a subset of women were tested, and all at their final study visit. Finally, while prior to intervention implementation we tested all components of the intervention to receive feedback on the content, ease of use and usability, mode of delivery and the virtual guide/avatar, we did not conduct post-intervention interviews thus limiting our ability to comment on the broader acceptability among clinical trial participants.

In summary, a single session computer delivered brief alcohol intervention with or without text messages and interactive voice response boosters was insufficient to meaningfully reduce unhealthy alcohol use or sexual risk behaviors beyond an attention control among women receiving care in an urban STI clinic. The high severity of alcohol use in addition to the prevalence of mental health and other substance use comorbidity in this sample underscores the importance of developing programs that can address not only alcohol use but other determinants of HIV and STI risk among women. Our trial has important implications for the design of alcohol and sexual risk reduction interventions in women with multiple overlapping comorbidities. Indeed, targeting alcohol use only, when other risk factors for both alcohol consumption and sexual risk behaviors are present may not result in clinically meaningful, or sustainable behavior change. Multiple computer-delivered sessions with greater tailoring to increase personalization of the intervention's health message, along with greater human interaction, may be necessary to increase CBI effectiveness (Hawkins, Kreuter, Resnicow, Fishbein, & Dijkstra, 2008; Noar, Harrington, & Aldrich, 2016). In addition, partnering with the local community to develop culturally and contextually relevant multi-level interventions that address alcohol use in combination with other mental health and substance use comorbidities will be required to implement effective alcohol and HIV risk sexual risk reduction interventions for women.

Funding

National Institute of Alcohol Abuse and Alcoholism R01AA018632.

CRedit authorship contribution statement

Geetanjali Chander: Conceptualization, Methodology, Funding acquisition, Supervision, Project administration, Resources, Writing – original draft. **Heidi E. Hutton:** Conceptualization, Methodology, Funding acquisition, Supervision, Writing – review & editing. **Xiao-qiang Xu:** Visualization, Formal analysis, Data curation. **Chelsea E. Canan:** Formal analysis, Writing – review & editing. **Jennifer Gaver:** Project administration, Data curation, Writing – review & editing. **Catherine R. Lesko:** Methodology, Visualization, Formal analysis. **Mary E. McCaul:** Supervision, Writing – review & editing. **Bryan Lau:** Funding acquisition, Methodology, Formal analysis, Supervision, Writing – review & editing.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Acknowledgements

This study was supported by the National Institute of Alcohol Abuse and Alcoholism (NIAAA). The funders had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.

Appendix A. Supplementary material

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.abrep.2021.100367>.

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