



# Decreased Alcohol Consumption in an Implementation Study of Computerized Brief Intervention among HIV Patients in Clinical Care

Mary E. McCaul<sup>1</sup> · Heidi E. Hutton<sup>1</sup> · Karen L. Cropsey<sup>2</sup> · Heidi M. Crane<sup>3</sup> · Catherine R. Lesko<sup>4</sup> · Geetanjali Chander<sup>5</sup> · Michael J. Mugavero<sup>6</sup> · Mari M. Kitahata<sup>3</sup> · Bryan Lau<sup>4</sup> · Michael S. Saag<sup>6</sup>

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## Abstract

This prospective, nonrandomized implementation study evaluated a computerized brief intervention (CBI) for persons with HIV (PWH) and heavy/hazardous alcohol use. CBI was integrated into two HIV primary care clinics. Eligible patients were engaged in care,  $\geq 18$  years old, English speaking, endorsed heavy/hazardous alcohol use on the Alcohol Use Disorders Identification Test-C (AUDIT-C). Two 20-min computerized sessions using cognitive behavioral techniques were delivered by a 3-D avatar on touch screen tablets. Of 816 eligible AUDIT-C scores, 537 (66%) resulted in CBI invitation, 226 (42%) of invited patients enrolled, and 176 (78%) of enrolled patients watched at least one session. CBI enrollment was associated with a significant average reduction of 9.1 drinks/week (95% CI – 14.5, – 3.6) 4–12 months post-enrollment. Among those who participated in one or both sessions, average reduction in drinks/week was 11.7 drinks/week (95% CI – 18.8, – 4.6). There was corresponding improvement in AUDIT-C scores. Overall patients reported high levels of intervention satisfaction, particularly among older and Black patients. These promising results point to a practical intervention for alcohol reduction in this vulnerable patient population with elevated rates of heavy/hazardous drinking. Future research should examine strategies to increase initial engagement, strengthen intervention effects to increase the number of patients who achieve non-hazardous drinking, and examine the duration of therapeutic effects.

**Keywords** HIV · Heavy alcohol use · Binge drinking · Brief alcohol intervention · HIV viral load

## Introduction

Heavy/hazardous drinking (i.e., drinking above National Institute on Alcohol Abuse and Alcoholism (NIAAA) guidelines for daily or weekly alcohol consumption/engaging in binge drinking) is a major contributor to morbidity and mortality in the United States [1]. Yet only about 10% of affected persons receive specialized alcohol treatment in any given year [2]. Brief alcohol interventions (BI) address this gap in care by extending identification of and intervention with heavy drinkers to medical and community settings. Meta-analyses support moderate effects of alcohol screening and BI for decreasing alcohol use among persons drinking above NIAAA-recommended guidelines [3], and routine BI implementation is endorsed by a variety of medical groups (e.g., American Medical Association, the American Society of Addiction Medicine and the U.S. Preventive Services Task Force [4]). In practice, however, multiple barriers have slowed BI implementation, including lack of provider training, time, and confidence to intervene [5].

✉ Mary E. McCaul  
mmccaul1@jhmi.edu

<sup>1</sup> Department of Psychiatry and Behavioral Sciences, Johns Hopkins University School of Medicine, 550 N Broadway, Suite 115, Baltimore, MD 21205, USA

<sup>2</sup> Department of Psychiatry and Behavioral Neurobiology, University of Alabama At Birmingham, Birmingham, AL, USA

<sup>3</sup> Department of Medicine, University of Washington, Seattle, WA, USA

<sup>4</sup> Department of Epidemiology, Johns Hopkins Bloomberg School of Public Health, Baltimore, MD, USA

<sup>5</sup> Department of Medicine, Johns Hopkins University School of Medicine, Baltimore, MD, USA

<sup>6</sup> Department of Medicine, University of Alabama at Birmingham, Birmingham, AL, USA

Importantly, heavy alcohol use is more prevalent among persons with HIV (PWH) than the general population [6], and has been associated with a variety of harmful effects, including increased risk for HIV transmission [7, 8], poorer engagement and retention in the HIV care continuum [9], and decreased ART uptake, adherence, and viral suppression [10–12]. Thus alcohol interventions that can be implemented successfully in HIV care settings are of high clinical and public health importance. Although most HIV care providers report assessing alcohol use and associated problems, few have received alcohol-specific training, and, as a consequence, few report having the knowledge and confidence to intervene with patients drinking at unhealthy levels [13]. Because HIV care is typically provided in a medical home model with recurrent visits, integration of alcohol interventions in the HIV clinic has the potential to maximize availability and uptake.

There is robust evidence that person-delivered behavioral interventions are effective in reducing alcohol consumption among PWH [14]. In a randomized clinical trial with women enrolled in HIV care, Chander and colleagues [15] reported significant reductions in drinking frequency among women who received a two-session BI intervention + standard care compared with women receiving standard care alone. Similarly, at six-month and one-year follow-up, a motivational interviewing intervention, including an in-person motivational intervention (MI) session, two brief phone calls and a booster session, compared with treatment as usual significantly reduced drinks per week and number of heavy drinking days among HIV-infected men who have sex with men [16].

Digitally-delivered or enhanced BI using computer (CBI), mobile devices and other digital technology is being studied to address patients' common reluctance or inability to seek help and the practical barriers to alcohol treatment delivery within busy health care settings. Much of the initial research was conducted with college-enrolled, young adults; however, investigators are now expanding target populations and settings. Among pregnant women who screened positive for alcohol risk at an urban prenatal care clinic, CBI was associated with medium-sized intervention effects for 90-day alcohol abstinence and improvement in birth outcomes [17]. A recent large-scale study among primary care patients examined the comparative effectiveness of counselor- versus computer-delivered BI. Assessment only and no assessment comparator groups were included in the study design to control for the well-established decrease in drinking associated with comprehensive evaluation of alcohol use. This study reported comparable decreases in alcohol use for counselor- and computer-delivered BI, with both being more effective than the two assessment comparator conditions [18]. Among persons with unhealthy alcohol use enrolled in HIV primary care, Hasin and colleagues [19] reported

a significant reduction in drinks per drinking day in persons randomized to in-person MI with Health Call (a daily interactive voice response technology call during which patients self-reported their drinking and received personalized feedback) compared to an advice/education control. A recent meta-analysis of in-person versus computer-delivered interventions reported no differences in alcohol outcomes over short-term follow-up periods ( $\leq 4$  months) [20]. As a whole, these findings suggest that computer-delivered BI is as effective as person-delivered BI, while reducing many of the barriers typically associated with provider-delivered care. Notably, self-report of stigmatized, socially undesirable behaviors such as drug and alcohol use appears to be higher during computerized assessment relative to paper or face-to-face provider interactions [21], potentially improving identification and intervention.

The present study evaluated the effects of a 2-session CBI for PWH with heavy/hazardous alcohol use delivered in two HIV care clinics. Using a motivational interviewing style, the CBI intervention incorporated well-established alcohol-specific BI strategies, including personalized feedback, pros and cons of drinking, managing drinking triggers and goal setting. Using the REAIM evaluation framework [22], this paper focuses on patient-level effectiveness and satisfaction; intervention reach was examined in an earlier paper [23]. Implementation processes including facilitators and barriers were assessed in anticipation of future sustainability research. We predicted that patients who received the intervention would reduce their short-term alcohol use compared with patients who did not receive the intervention, and that there would be high levels of intervention satisfaction.

## Methods

### Participants

The Center for AIDS Research Network of Integrated Clinical Systems (CNICS) is a prospective HIV clinical cohort consisting of 8 sites and over 30,000 PWH across the United States [24]. The present study was integrated into routine care at two CNICS clinics (University of Alabama, Birmingham 1917 HIV clinic, and University of Washington, Seattle Madison HIV clinic) between June 18, 2013 and August 31, 2015. Eligible patients had to be actively engaged in care (defined as having attended at least two clinic visits),  $\geq 18$  years old, English speaking, endorse heavy/hazardous alcohol use (defined by Alcohol Use Disorders Identification Test-C ([25]; AUDIT-C) score  $\geq 3$  for women and  $\geq 4$  for men) and had completed the MINI International Neuropsychiatric Interview Alcohol Use Disorders ([26]; MINI AUD) during the past 12 months. Pregnant women were excluded and referred to clinic social workers for more

intensive care. Targeted study enrollment was 100 participants/clinic based on estimated effects size (ranging from 6 to 12 drinks per week) and intraclass correlation (ranging from 0.05 to 0.20).

## Procedures

CNICS data include baseline patient demographics, including likely route of HIV acquisition, laboratory measurements, diagnoses, and prescribed medications. Approximately every 4–6 months at scheduled HIV clinic visits, PWH complete a clinical assessment of patient-reported measures and outcomes (PROs) by Computer-Assisted Self-Interview Software (CASI) tools [27]. PRO measures include past 3-month drug use collected using the modified Alcohol, Smoking and Substance Involvement Screening Test (ASSIST [28]) and past 2-week panic and depressive symptoms using the Patient Health Questionnaire (Panic Disorder PHQ-PD [29] and Depression PHQ-9 [30] modules. Laboratory data are linked to PROs using the most proximal values during the window from 6 months before to 1 month after PRO completion.

The PROs include two sets of alcohol-related questions: the Alcohol Use Disorders Identification Test ([31]; AUDIT) for detecting risk of heavy/hazardous drinking; and the Mini-International Neuropsychiatric Interview [26] for Alcohol Abuse/Dependence (AUD MINI) diagnosis. Patients complete the AUDIT-C as part of every PRO assessment, and they complete the additional items of the full AUDIT annually if reporting at-risk drinking on the AUDIT-C. The AUD MINI is collected once per year for patients whose AUDIT-C score indicates current heavy/hazardous drinking. Patients were classified as having alcohol dependence if they answered “yes” to the MINI screening item (Have you had  $\geq 3$  alcoholic drinks within a 3-h period on  $\geq 3$  occasions in the past 12 months?) and “yes” to at least 3 of 8 DSM-IV alcohol dependence symptoms. Patients who answered “yes” to fewer than 3 dependence symptoms but who endorsed any of 4 MINI questions about problems related to their alcohol use were classified as having alcohol abuse. The MINI is 89% sensitive and 90% specific for detecting alcohol dependence as validated by a structured clinical interview [26].

Based on PRO responses, site Research Coordinators were paged by the PRO platform in real time to approach eligible patients, provide a brief study description and obtain informed consent from patients interested in intervention participation. Coordinators attempted to engage missed patients at subsequent visits over a 12-month period. Whenever possible, CBI was delivered promptly following informed consent. When this was not possible due to clinic scheduling or patient unavailability, the Research Coordinators continued to offer CBI to consented patients at subsequent visits over a 12-month period. All eligible patients

could access standard of care services for unhealthy alcohol use, which typically included social work referral to outside alcohol treatment services. There were no incentives offered for PRO completion or study participation, including CBI completion. All procedures were approved by the local Institutional Review Board.

## CBI Intervention

Our CBIs used well-established, empirically validated cognitive behavioral techniques, including personalized feedback, pros/cons of drinking, and goal setting for reduction/cessation of alcohol use. Content was tailored to drinking severity and adapted to include HIV-specific content by study team members (HEH, MEMc). The two 20-min sessions were delivered in motivational interviewing style by a 3-D avatar named Peedy the Parrot using a touch screen tablet with previously tested Computer Intervention Authoring Software (CIAS; Steven Ondersma, Ph.D., Detroit, Michigan).

Four CBI sessions were tailored based on session number (1 vs. 2) and drinking severity. In session 1, *Peedy Prime* was delivered to PWH who reported heavy/hazardous drinking on the AUDIT-C but did not meet MINI abuse/dependence criteria. It provided education about standard drink sizes and what constitutes lower-risk drinking versus drinking that exceeds daily (hazardous/binge) and weekly (heavy) drinking limits. Prime also reviewed the pros/cons of alcohol use through a Decisional Balance exercise, and the impact of alcohol on HIV, HCV, other comorbid medical conditions and medication adherence. Patients were trained on a strategy (3 D's: Delay, Discuss, and Do Something Else) for coping with their personal triggers, and then had the opportunity to set drinking goals. PWH who met MINI alcohol abuse/dependence criteria at session 1 received *Peedy Pharma*, which included *Peedy Prime* content and provided an overview of alcohol pharmacotherapy (APT) options and a brief description of how these medications may help meet drinking reduction goals.

At their next regular clinic visit that occurred within four to twelve months following session 1, patients were invited to participate in a second CBI session selected based on interim alcohol consumption measured on AUDIT-C. Patients who reduced drinking below hazardous levels received *Peedy Prize* with affirming messages. Patients who continued hazardous drinking viewed *Peedy Problem*, reinforcing alcohol pharmacotherapy and identifying and addressing medication adherence barriers.

## Outcome Assessment

The primary outcome of interest was change in number of drinks/week, calculated from responses on the PRO AUDIT-C. Secondary alcohol outcomes included changes

in: drinking frequency (days/week); quantity (drinks/drinking day); AUDIT-C score; prevalence of hazardous/binge drinking (defined as  $\geq 4$  drinks on one occasion for women or  $\geq 5$  drinks on one occasion for men); and prevalence of heavy drinking, based on sex-specific NIAAA guidelines for weekly alcohol consumption (defined as  $> 7$  drinks/week for women and  $> 14$  drinks/week for men). Typically, the AUDIT-C uses response option ranges (e.g., 2–3 times/week for drinking frequency) to query patients on quantity and frequency of drinking and binge drinking. We expanded response options on the CNICS PRO to collect specific values (e.g., 2 times/week or 3 times/week), enabling us to determine specific drinking days/week and drinks/drinking day as well as calculate drinks/week by multiplying the two numbers together.

All PROs were completed as part of routine HIV care using CASI format, minimizing social desirability bias in self-reported alcohol use. Because patients routinely complete PROs as part of their clinic visit, the availability of these outcome data was not conditional on study consent or CBI participation. The baseline PRO was defined as the PRO that immediately preceded an approach for study participation or, for those patients who were not approached for participation, established their study eligibility. Of 545 patients invited to CBI participate, 507 or 93% were asked on the same day as the baseline PRO; 38 patients were asked a median of 44 days later. The follow-up PRO was completed during a 4–12 month window following baseline. If there was more than one PRO in the outcome window, we used the PRO that was most proximal to the 8-month anniversary of baseline.

We were interested in HIV viral load as a secondary outcome, based on the hypothesis that, if the intervention reduced hazardous alcohol use and hazardous alcohol use decreases the probability of having a suppressed viral load, the intervention might increase the probability of having a suppressed viral load at follow-up. We analyzed HIV viral loads measured in a 4–12 month window following baseline. If there was more than one viral load in the outcome window, we used the viral load most proximal to the 8-month anniversary of baseline. We classified viral loads  $< 200$  copies/mL as suppressed.

Finally, we surveyed patients' satisfaction with the CBI. The survey was developed for use with CIAS and adapted here to assess satisfaction with an alcohol intervention [32]; psychometric properties including internal consistency have not been examined. Immediately following each CBI session, PWH were invited to rate their satisfaction on a 10-item scale assessing ease of use, amount and type of information provided (e.g., I learned new information from the video, The video helped me think about making changes in my drinking), length of video, willingness to watch another video in the future, and overall video liking (e.g., Overall

I liked watching the video, I liked Peedy the Parrot as my guide). Patients rated each item on a 5-point Likert scale (1 = "Not at all" and 5 = "Very much").

## Statistical Analysis

To account for unmeasured confounders (e.g., motivation to change, current mood/health, alcohol treatment availability), we conducted an instrumental variable analysis [33], treating the Study Coordinator approach as the instrument. For each outcome, we report: (1) the effect of the invitation to participate; (2) the complier average treatment effect of CBI enrollment (i.e., consent to participate); and (3) the complier average treatment effect of completing  $\geq 1$  CBI session(s). To assess (1) we fit linear regression models, conditional on receiving an invitation to participate in the CBI. We fit the models using GEE with an exchangeable correlation structure to account for correlated outcomes within patients who contributed  $> 1$  PRO. To get (2) and (3), we used a two-stage least squares regression, first predicting the probability of enrolling in CBI (2) or completing  $\geq 1$  CBI sessions (3), and then fitting a linear or generalized linear regression model for the outcomes, conditional on the predicted probabilities from the first model.

To handle missing outcome data (for patients who did not return for a clinic visit or who did not complete a PRO during a clinic visit during the 4–12 month post-baseline outcome window or who did not have a viral load measured during the 4–12 month post-baseline outcome window), we imputed the missing data [34]. We generated 40 complete datasets using multiple imputation with chained equations, conducted analyses in each of the 40 datasets, and combined the results using Rubin's rules. As is recommended, the imputation models leveraged all covariates in Table 1 and quantity, frequency, and binge frequency outcomes.

Because men and women differ in expectancies, effects and consequences of alcohol use [35], we estimated the association between CBI invitation and each of the drinking outcomes separately in men and in women. We also estimated associations between CBI invitation and drinking outcomes separately in patients who met criteria for alcohol dependence, alcohol abuse, or neither, based on baseline MINI responses.

Finally, a summary satisfaction score was calculated by combining each patient's rating (1 to 5) on the 10-item satisfaction survey. We compared satisfaction scores by sex, race, and age. We also examined whether patient ratings on session 1 predicted whether they would participate in session 2 and whether their drinking would decrease below hazardous levels (i.e., they would be eligible for Peedy Prize on session 2). Because scores were highly left skewed, non-parametric methods were used for all comparisons.

**Table 1** Participant characteristics for 1) all eligible Person-Patient reported outcomes (PROs), 2) approached vs not approached among eligible Person-PROs study participation, 3) enrolled vs. not enrolled among approached Person-PROs, and 4) participated vs did not participate in CBI among enrolled Person-PROs

	Total	ARCH approached		Enrolled		Participated in $\geq 1$ sessions	
		No	Yes	No	Yes	No	Yes
Total	816	279	537	311	226	50	176
Male (N,%)	671 (82)	233 (84)	438 (82)	256 (82)	182 (81)	37 (74)	145 (82)
Age (M, IQR*)	45 (33, 51)	45 (33, 51)	45 (33, 51)	45 (33, 51)	44 (33, 51)	44 (29, 53)	44 (35, 51)
Race/Ethnicity							
White	347 (43)	111 (40)	236 (44)	140 (45)	96 (43)	22 (44)	74 (42)
Black	382 (47)	126 (45)	256 (48)	142 (46)	114 (51)	25 (50)	89 (51)
Hispanic	65 (8)	38 (14)	27 (5)	18 (6)	9 (4)	2 (4)	7 (4)
Other	20 (2)	4 (1)	16 (3)	10 (3)	6 (3)	1 (2)	5 (3)
Missing	2	0	2	1	1	0	1
HIV risk factor							
MSM**	560 (69)	196 (70)	364 (68)	204 (66)	160 (71)	34 (68)	126 (72)
IDU***	139 (17)	48 (17)	91 (17)	50 (16)	41 (18)	7 (14)	34 (19)
CD4 cells/ $\mu$ L	515 (339, 725)	518 (323, 720)	515 (346, 735)	535 (345, 737)	495 (349, 713)	476 (330, 671)	503 (350, 735)
Missing	70	29	41	28	13	4	9
Detectable viral load (N,%)	138 (17)	49 (18)	89 (17)	49 (16)	40 (18)	10 (21)	30 (17)
Missing	19	11	8	4	4	2	2
AUDIT-C score****	6 (5, 7)	5 (4, 7)	6 (5, 8)	6 (5, 8)	6 (5, 7)	6 (5, 8)	6 (5, 7)
Drinking days/week	2.5 (1, 4.5)	2.5 (1, 4.5)	2.5 (1, 4.5)	2.5 (1, 4.5)	2.5 (1, 4.5)	2.5 (1, 4.5)	2.5 (1, 4.5)
Drinks/drinking day	3 (3, 5)	3 (2, 4)	4 (3, 5)	4 (3, 5)	4 (3, 6)	4 (3, 6)	4 (3, 5)
Drinks/week	9 (5, 13.5)	7.5 (4, 13)	10 (5, 18)	10 (5, 15)	10 (5, 18)	10 (5, 19.5)	10 (5, 18)
AUD MINI diagnosis*****							
Alcohol dependence	149 (18)	42 (15)	107 (20)	53 (17)	54 (24)	10 (20)	44 (25)
Alcohol abuse	157 (19)	52 (19)	105 (20)	56 (18)	49 (22)	9 (18)	40 (23)
Illicit opioids							
Current	37 (5)	16 (6)	21 (4)	12 (4)	9 (4)	2 (4)	7 (4)
Past	128 (17)	40 (16)	88 (17)	45 (15)	43 (20)	11 (23)	32 (19)
Missing	44	22	22	12	10	3	7
Cocaine/crack							
Current	130 (16)	42 (16)	88 (17)	48 (15)	40 (18)	6 (12)	34 (20)
Past	299 (38)	97 (38)	202 (38)	115 (37)	87 (40)	22 (45)	65 (38)
Missing	28	21	7	1	6	1	5
Methamphetamine							
Current	63 (8)	21 (8)	42 (8)	25 (8)	17 (8)	3 (6)	14 (8)
Past	196 (25)	66 (26)	130 (25)	67 (22)	63 (28)	15 (30)	48 (28)
Missing	34	21	13	9	4	0	4
Smoking							
Current	379 (47)	121 (45)	258 (48)	144 (46)	114 (51)	24 (48)	90 (51)
Past	197 (25)	73 (27)	124 (23)	77 (25)	47 (21)	9 (18)	38 (22)
Missing	14	12	2	1	1	0	1
Anxiety							
Panic disorder	128 (16)	44 (16)	84 (16)	41 (13)	43 (19)	10 (20)	33 (19)
Panic symptoms	138 (17)	42 (16)	96 (18)	55 (18)	41 (18)	9 (18)	32 (18)
Missing	17	9	8	5	3	0	3
Depressive symptoms							
Severe	117 (14)	35 (13)	82 (15)	41 (13)	41 (18)	13 (26)	28 (16)
Moderate	110 (14)	37 (14)	73 (14)	34 (11)	39 (17)	10 (20)	29 (17)
Mild	197 (24)	73 (27)	124 (23)	70 (23)	54 (24)	9 (18)	45 (26)

**Table 1** (continued)

	Total	ARCH approached		Enrolled		Participated in $\geq 1$ sessions	
		No	Yes	No	Yes	No	Yes
Missing	6	5	1	0	1	0	1

## Results

### Participant Characteristics

During the study period, 9,710 PROs were completed at the two intervention sites. Of those, 2265 (23%) indicated heavy/hazardous drinking on the AUDIT-C and 1382 (14%) also had a MINI completed within the prior 12 months. There were 816 PROs that were eligible for a CBI invitation (i.e., hazardous drinking, recent MINI, and not previously invited to study participation) contributed by 677 unique individuals. Two-thirds of the eligible PROs resulted in a CBI invitation; 226 (42% of those invited) led to the patient enrolling in CBI; and 176 (78% of those enrolled) patients participated in at least one session associated with the CBI and 99 (44%) completed both sessions. Common reasons for missed invitations included staff already working with another study participant, patient already in exam room for clinical visit, and patient sent to lab or other service provider. Among eligible PROs, 62% (N = 503) had a PRO completed and 86% (N = 702) had a viral load measured within the 4–12 month follow-up window. These proportions were similar for PROs that did and did not result in an invitation to participate in the CBI.

Most eligible PROs were contributed by male patients (82%) with median age of 45 years who had good control of their HIV disease; median CD4 cell count was 515 cells/ $\mu$ L and 83% had undetectable viral load. White and

Black patients were roughly evenly represented. Prevalence of alcohol abuse and dependence was high (19% and 18%, respectively) as was prevalence of illicit substance use and mental health symptoms (Table 1). Patient characteristics were balanced among PROs that led to a CBI invitation and those that did not.

One hundred-seventy six persons who completed session 1 provided a PRO during the follow-up period (median time from baseline to follow-up was 7.3 months (IQR:6, 9). Of those, 136 (77%) viewed Peedy Prime and 40 (23%) saw Peedy Pharma. Among those who viewed Peedy Prime, 91 (67%) participated in session 2; 20 (22%) reduced their drinking below hazardous levels and viewed Peedy Prize and 71 (78%) were still drinking at hazardous levels and viewed Peedy Problem. Among those who viewed Peedy Pharma at session 1 and provided a follow-up PRO, 12 (30%) completed session 2; 4 viewed Peedy Prize and 8 viewed Peedy Problem.

### Drinking Reductions Across Conditions

Table 2 presents engagement and treatment effects on drinking related outcomes. In crude analysis, an invitation to participate in CBI (including those who did and did not consent to enrollment) was associated with a reduction of 3.9 drinks per week (95% Confidence Interval [CI] – 6.1, – 1.8) compared to persons who were not approached. This was a combination of a reduction in the number of drinking days per week (– 0.5; 95% CI – 0.9, – 0.1) and a reduction in

**Table 2** Associations and complier average treatment effect estimates for levels of engagement with a Computerized Brief Intervention for alcohol consumption offered to persons with HIV engaged in continuity care who screened positive for hazardous alcohol use

	ATE CBI Invitation	CATE* CBI Enrollment	$\geq 1$ video
Change in drinks/week	– 3.9 (– 6.1, – 1.8)	– 9.1 (– 14.5, – 3.6)	– 11.7 (– 18.8, – 4.6)
Change in drinking days/week	– 0.5 (– 0.9, – 0.1)	– 1.2 (– 2.2, – 0.2)	– 1.6 (– 2.9, – 0.3)
Change in drinks/drinking day	– 0.5 (– 1.2, 0.2)	– 1.2 (– 2.8, 0.5)	– 1.5 (– 3.7, 0.6)
Change in AUDIT-C score	– 0.8 (– 1.6, – 0.1)	– 2.2 (– 3.9, – 0.4)	– 2.7 (– 4.9, – 0.5)

The reference group is person-PROs where there was not an approach (N = 279). The first column is observed data (unadjusted associations). The last 2 columns are adjusted for covariates and are best estimates of the effect of enrolling in the intervention and viewing at least one video among engagers

ART antiretroviral therapy, AUDIT-C Alcohol Use Disorders Identification Test, IDU injection drug use, MSM men who have sex with men

\*Adjusted for age, sex, race/ethnicity, MSM, IDU, CD4, detectable viral load, history of ART initiation, current cocaine/crack/illicit opioid/methamphetamine use, panic disorders/symptoms, depression (severe/moderate/mild/none) and current smoking; age and CD4 were modeled with restricted quadratic splines with knots at the 5<sup>th</sup>, 35<sup>th</sup>, 65<sup>th</sup>, and 95<sup>th</sup> percentiles of their distributions

the number of drinks per drinking day ( $-0.5$ ; 95% CI  $-1.2, 0.2$ ) (although the latter association was not statistically significant at  $\alpha=0.05$ ), resulting in a reduction in AUDIT-C score of almost one point at follow-up ( $-0.8$ ; 95% CI  $-1.6, -0.1$ ).

Among patients who consented to participation when invited (enrollers, including those who did and did not watch a session), CBI enrollment was associated with a reduction of 9.1 drinks per week (95% CI  $-14.5, -3.6$ ) compared to persons who were not approached. Among patients who participated in one or more sessions (engagers), CBI engagement was associated with a reduction of 11.7 drinks per week (95% CI  $-18.8, -4.6$ ) compared to persons who were not approached. CBI enrollment and engagement were associated with both a reduction in the number of drinking days per week and in the number of drinks per drinking day. Enrollment and engagement also were associated with a reduction in AUDIT-C score of  $-2.2$  (95% CI  $-3.9, -0.4$ ) and  $-2.7$  (95% CI  $-4.9, -0.5$ ), respectively. There were no clinically or statistically meaningful differences in the association between invitation to participate in the CBI and changes in the quantity or frequency of alcohol use, nor in the prevalence of hazardous/binge drinking at follow-up, among men versus women nor among patients with/without alcohol abuse or dependence.

### Effects on Viral Load

Prevalence of unsuppressed viral load was 17% at the index PRO (Table 1) and there were no differences across study conditions at baseline. (93% of persons had initiated ART prior to their baseline PRO.) Prevalence remained unchanged at 16% at 4–12 months after the intervention. There were no differences in the prevalence of detectable viral load associated with engagement with the CBI.

### Satisfaction Survey Findings

Surveys were completed by a total of 167 PWH, including 104 and 101 PWH following visit 1 and 2, respectively. Satisfaction scores ranged from 17 to 50, and were highly left skewed with a mean of 42.5 (S.D. = 8.1) and median of 45. Almost 40% of patients rated their satisfaction at the maximum score of 50. For visit 1, ratings were higher among older vs younger (age  $\geq 45$ ) (Median (IQR) = 48 (42, 50) vs 45 (33, 49);  $p=0.019$ ), and Black vs other race/ethnicity patients (Median (IQR) = 49 (47, 50) vs 40 (33, 46);  $p=0.001$ ). There was no significant difference for female vs male patients (Median (IQR) = 48 (44, 50) vs 45 (35, 50);  $p=0.218$ ).

Higher ratings at visit 1 were associated with an increased likelihood of completing visit 2. Specifically, median visit 1 satisfaction scores were significantly higher among patients

who completed visit 2 ( $N=37$ ) compared with those who did not complete visit 2 ( $N=67$ ) (Median (IQR) = 49 (43, 50) vs 44 (33, 49);  $p=0.003$ ). For Visit 2, there was no difference in satisfaction ratings between patients who had decreased their drinking below heavy/hazardous levels and were eligible for Peedy Prize versus those who were continuing to drink at heavy/hazardous levels (Median (IQR) = 45 (35, 50) vs 45 (39, 49); ns).

## Discussion

Using the REAIM evaluation framework, this study demonstrated the acceptability and effectiveness of CBI enrollment and engagement for hazardous drinking patients in HIV care. CBI enrollment (comparing those who consented but did not participate in the CBI intervention versus persons who were not approached) was associated with a significant reduction of 9.1 drinks per week reported 4–12 months post-enrollment. CBI engagement (comparing those who watched one or both sessions to persons who were not approached) was associated with a decrease of 11.7 drinks per week, including reductions in quantity and frequency of alcohol consumption. There was a corresponding improvement in AUDIT-C scores in both enrollers and engagers. Importantly, no differences in drinking outcomes were observed between women and men or as a function of alcohol diagnosis, suggesting that enrollment and engagement with the intervention was effective between sexes and across alcohol severity levels.

Importantly, the current study focused on implementation and outcomes of CBI in two busy HIV care clinics, thus patients were not randomized into a traditional clinical trial. To address this, we used a novel instrumental variable analysis to compensate for the potential of confounding by unidentified factors (e.g., patient's motivation to change, current mood and health, and availability of other alcohol treatment resources) in the absence of randomization. Our instrument was the invitation to participate in CBI, which was dependent only upon availability of the study coordinator and or characteristics of overall clinic activity (e.g., volume, pace), and not on patient characteristics. For an instrumental variable analysis to be unbiased, the instrument must: 1) be causally associated with the intervention; 2) not affect the outcome except through the intervention (called the "exclusion restriction"); and 3) not share any causes with the outcome [33]. In the present study, patients could participate in CBI only if they were invited by the study coordinator. To examine whether the CBI invitation did not share causes with subsequent alcohol use, we compared measured patient characteristics for those who were versus were not approached for CBI invitation and found

no significant differences. Thus, our analytic approach and resulting outcomes are well-supported.

Drinking outcomes were examined as a function of three CBI-related events—invitation, enrollment and engagement. The association between the instrument (invitation) and the outcome can be thought of as an intent-to-treat effect (assuming the criteria for the instrument outlined above are met). There was a slight reduction of 3.9 drinks per week among those who were invited to participate in CBI compared to those who were not invited. Almost half (42%) of invited clinic patients consented to CBI participation (enrollers); this is notable since patients were attending a routine clinic visit, not seeking alcohol treatment and not incentivized for study participation. Our enrollment rate is in line with those reported in other alcohol intervention trials (53% [36], 38% [37], 47% [38] in health care settings. In a prior paper, we examined the characteristics of enrollers; on average, they had heavier alcohol use and higher prevalence of mental health and alcohol use disorder symptoms compared to those who did not enroll [23]. When analyses were narrowed to include only those who consented to participate (a more traditional intent-to-treat approach), we observed a significant reduction of 9.1 drinks per week among enrollers compared to those who were not approached. It is unlikely that this result reflects assessment reactivity since ongoing alcohol measurement was a routine part of clinical care. However, accepting the intervention invitation may have reflected greater readiness to change among more severely affected individuals, which has been conceptualized as the first step in the change process [39]. This interpretation is supported by the absence of external incentives for study participation. Finally, when analyses compared those who participated in at least one session (engagers) to those who were not approached, drinking was reduced on average by almost 12 drinks per week, demonstrating an impact of the intervention itself. Overall, enrollment and engagement with a brief computerized intervention was effective in achieving a clinically significant reduction in weekly drinking and a corresponding improvement in AUDIT-C score among hazardous drinkers engaged in HIV care.

Although there was no difference between patients with and without an alcohol use disorder in the likelihood of enrolling in the study and engaging in the first Peedy session, we did observe a difference in the likelihood of watching the second Peedy session as a function of drinking severity. Specifically, two-thirds of patients who initially watched Peedy Prime subsequently participated in a second Peedy session. In contrast, 30% of patients who watched Peedy Pharma participated in a second Peedy session. This difference probably reflects the difference in drinking severity and AUD symptoms between the two groups. Despite the clinically impactful reduction in weekly drinking among patients who enrolled and engaged in the intervention, three-quarters of

the patients were still drinking above NIAAA recommended levels following the intervention. Importantly, alcohol research has identified benefits of drinking reductions that may not achieve abstinence or low risk consumption [40]. This has led to the recommendation to incorporate reduction in heavy/hazardous drinking as a clinically significant indicator of treatment response [41].

The REAIM framework supports examination of five core components of implementation research: Reach, Effectiveness, Adoption, Implementation and Maintenance [22]. While the present report focuses primarily on effectiveness, our results point to several key findings of relevance to implementation and maintenance of the intervention: 1) the importance of seamless integration of the intervention into routine clinic care – because informed consent was required, we missed approximately one-third of eligible participants; 2) the challenge of engaging patients in the intervention during their busy clinical visit highlighted the importance of development of a mobile platform – this has become particularly important with the move to telehealth during the pandemic; 3) the need to further step up care for persons who are still drinking hazardously following the initial intervention session including enhanced integration of an AUD medication such as naltrexone (oral or injectable extended-release) that has been shown to decrease alcohol use and improve viral suppression [42]. Further, based on prior brief intervention research, it is expected that there would be a diminishing effect over time, suggesting the need for booster intervention sessions.

To date, relatively few studies have examined the effectiveness of specific alcohol interventions for PWH in the United States, although research is starting to inform care options. As described in the introduction, most studies have used person-delivered interventions, limiting their utility in busy HIV care practices. Some have sought to boost in-person intervention effectiveness with technology-delivered services. The current study results suggest that a computer-delivered alcohol intervention can yield clinically meaningful changes in drinking behavior among PWH. These findings are supported by research on the use of technology-delivered clinical interventions for other mental health disorders. A recent meta-analysis of randomized clinical trials of smartphone-supported psychological interventions found significantly greater reductions in anxiety symptoms among intervention compared with control conditions [43]. Similarly, a meta-analysis of web-delivered CBT for major depression, panic disorder, social anxiety disorder and generalized anxiety disorder demonstrated clinical improvement for all four disorders, with good acceptability as measured by patient adherence and satisfaction [44]. It should be noted that we took several steps to increase intervention impact and satisfaction including offering two sessions, tailoring scripts for



alcohol use severity, providing a selection of menu driven counseling options and adopting an avatar that was generally well liked and perceived as supportive and empathetic.

Overall ratings of the initial session were quite high; ratings were particularly favorable among Black and older PWH. These findings are in line with the satisfaction ratings of a computerized alcohol brief intervention in other clinical populations [45, 46]. Ratings remained high at Session 2 suggesting that CBI is acceptable to be delivered over time across multiple sessions. Importantly, persons who rated session 1 higher were more likely to watch session 2, but were not necessarily more likely to reduce their drinking between sessions 1 and 2. These overall strong ratings align with the broader literature on computer-delivered assessments and interventions.

This study has several notable strengths. Perhaps most importantly, we evaluated an intervention that could be integrated into routine clinical care with relatively minimal investments of clinic resources. Second, because the intervention is computerized, it is replicable across sites and not subject to intervention “fatigue.” Third, quantity and frequency of alcohol consumption at both baseline and follow-up were obtained as part of ongoing routine clinical care regardless of whether or not persons chose to enroll in CBI; these reports should be less subject to bias and reactivity than the time and person intensive assessments to quantify alcohol consumption and associated problems traditionally used in alcohol treatment trials. Fourth, unlike many clinical research studies that pay patients based on their participation, there were no financial incentives for patients to engage in this study. Finally, generalization of our findings to other HIV care clinics was enhanced by: 1) the study sample was not restricted by narrow inclusion or exclusion criteria; 2) the impact of the intervention was not mixed with observer effects; and 3) the intervention was implemented in two clinics with very different patient demographic characteristics and staffing patterns.

The current study also has several limitations that need to be acknowledged. First, there was a relatively small sample size that limited subgroup analyses. Second, because data were collected during routine clinic visits, we had limited data on changes in VL or AUD medication treatment as a function of the intervention. We did examine pharmacotherapy use in the clinics as a whole and found that prevalence of naltrexone use for AUD treatment was quite low. Clearly this will be an important area for future research. Third, although most of our CBI content used well-established, empirically validated cognitive-behavioral techniques, the current intervention was tailored specifically for PWH. This tailored intervention had not been examined in a randomized efficacy study prior to use in our implementation study.

## Conclusions

We found good rates of patient enrollment, clinically meaningful levels of change, and high patient satisfaction with a two session, computerized brief alcohol intervention tailored for PWH receiving HIV continuity care. These promising results point to a practical intervention for alcohol reduction in this vulnerable patient population with elevated rates of heavy/hazardous drinking. It will be important in future research to replicate the present findings and to explore additional strategies to increase patient enrollment and engagement and to intensify treatment services for patients who were unable to reduce their drinking below hazardous levels following brief intervention. Based on implementation lessons learned in the current study, our ongoing research is examining the use of a mobile platform that allows patients to complete the intervention on their own and integration of an AUD treatment algorithm to intensify treatment in a stepped-care approach.

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## Declarations

**Conflict of interest** HC has received grant funding from ViiV. Other authors have no relevant financial or non-financial interests to disclose. The other authors have no conflicts of interest to declare that are relevant to the content of this article. All authors certify that they have no affiliations with or involvement in any organization or entity with any financial interest or non-financial interest in the subject matter or materials discussed in this manuscript. The authors have no financial or proprietary interests in any material discussed in this article.

**Ethical Approval** This research was approved by the Institutional Review Board at the participating sites – The University of Alabama at Birmingham and the University of Washington, Seattle. The study was performed in accordance with the ethical standards as laid down in the 1964 Declaration of Helsinki and its later amendments.

**Informed Consent** Informed consent was obtained from all PWH included in the study.

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