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Treatment outcomes of a stage I cognitive–behavioral trial to reduce alcohol use among human immunodeficiency virus-infected out-patients in western Kenya

Rebecca K. Papas[1], John E. Sidle[2,3], Benson N. Gakinya[2], Joyce B. Baliddawa[2], Steve Martino[4], Michael M. Mwaniki[5], Rogers Songole[2], Otieno E. Omolo[2], Allan M. Kamanda[5], David O. Ayuku[2], Claris Ojwang[6], Willis D. Owino-Ong'or[2], Magdalena Harrington[7], Kendall J. Bryant[8], Kathleen M. Carroll[4], Amy C. Justice[4], Joseph W. Hogan[1] & Stephen A. Maisto[9]

Alpert Medical School of Brown University, Providence, RI, USA,[1] Moi University School of Medicine, Eldoret, Kenya,[2] Indiana University School of Medicine, Indianapolis, IN, USA,[3] Yale University School of Medicine, New Haven, CT, USA,[4] Kenya Health Behavior Study, Eldoret, Kenya,[5] USAID–AMPATH partnership, Eldoret, Kenya,[6] Rhode Island Hospital, Providence, RI, USA,[7] National Institute of Alcohol Abuse and Alcoholism, Rockville, MD, USA[8] and Syracuse University, Syracuse, NY, USA[9]

ABSTRACT

Aims Dual epidemics of human immunodeficiency virus (HIV) and alcohol use disorders, and a dearth of professional resources for behavioral treatment in sub-Saharan Africa, suggest the need for development of culturally relevant and feasible interventions. The purpose of this study was to test the preliminary efficacy of a culturally adapted six-session gender-stratified group cognitive–behavioral therapy (CBT) intervention delivered by paraprofessionals to reduce alcohol use among HIV-infected out-patients in Eldoret, Kenya. **Design** Randomized clinical trial comparing CBT against a usual care assessment-only control. **Setting** A large HIV out-patient clinic in Eldoret, Kenya, part of the Academic Model for Providing Access to Healthcare collaboration. **Participants** Seventy-five HIV-infected out-patients who were antiretroviral (ARV)-initiated or ARV-eligible and who reported hazardous or binge drinking. **Measurements** Percentage of drinking days (PDD) and mean drinks per drinking days (DDD) measured continuously using the Time line Follow back method. **Findings** There were 299 ineligible and 102 eligible out-patients with 12 refusals. Effect sizes of the change in alcohol use since baseline between the two conditions at the 30-day follow-up were large [$d = 0.95$, $P = 0.0002$, mean difference = 24.93, 95% confidence interval (CI): 12.43, 37.43 PDD; $d = 0.76$, $P = 0.002$, mean difference = 2.88, 95% CI: 1.05, 4.70 DDD]. Randomized participants attended 93% of the six CBT sessions offered. Reported alcohol abstinence at the 90-day follow-up was 69% (CBT) and 38% (usual care). Paraprofessional counselors achieved independent ratings of adherence and competence equivalent to college-educated therapists in the United States. Treatment effect sizes were comparable to alcohol intervention studies conducted in the United States. **Conclusions** Cognitive–behavioral therapy can be adapted successfully to group paraprofessional delivery in Kenya and may be effective in reducing alcohol use among HIV-infected Kenyan out-patients.

Keywords Alcohol, cognitive-behavioral therapy, HIV, Kenya, randomized clinical trial.

Correspondence to: Rebecca K. Papas, Alpert Medical School of Brown University, Department of Psychiatry and Human Behavior, Providence, RI 02906, USA. E-mail: rebecca_papas@brown.edu
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INTRODUCTION

Approximately two-thirds of the world's 33.2 million individuals infected with the human immunodeficiency virus (HIV) virus live in sub-Saharan Africa. Several Africa-based studies have demonstrated a high rate of alcohol dependence [1–3], often involving the consumption of inexpensive local brew with high ethanol content

[4]. In Eldoret, Kenya, our work has also shown that an average *chang'aa* drink (locally made spirit) is equal to two US standard drinks [4], and prevalence of hazardous drinking was reported among HIV (53%) and general medicine (68%) out-patients [5]. Alcohol use displays a dose–response association with imperfect adherence to antiretrovirals (ARVs) [6], with comorbid medical diseases and acquired immune deficiency syndrome (AIDS)-defining conditions [7], and has been associated with increased risk of unprotected sex [8,9]. In Kenya, alcohol use correlates with HIV infection [10,11] and with risk of sexually transmitted infections [12,13]. There is growing evidence in both the United States and Africa that heavy drinking limits the success of HIV prevention efforts [14–16]. Hence, effective alcohol interventions are needed in sub-Saharan Africa.

In this report we describe a randomized clinical trial (RCT) of a culturally adapted cognitive–behavioral therapy (CBT) to reduce alcohol use among HIV-infected out-patients in Eldoret, Kenya. CBT is a highly structured, skills-based approach largely informed by social–cognitive theory [17,18], which construes the maintenance of addictive behaviors at least in part as learned behaviors to cope with stress and problems [19]. CBT was selected for this Kenyan adaptation because of its strong empirical support in both individual and group formats to reduce substance abuse [20–22], durability of treatment effects [23,24] and prior successful applications in sub-Saharan Africa to reduce risky sexual behaviors among HIV-infected Zambian couples [25] and to improve mood among Nigerian surgical patients [26]. Furthermore, because of its highly structured format, we felt that CBT was feasible for training paraprofessionals and for delivery to those with limited formal education. We first describe the methodology for the RCT, which we conceptualized as a stage 1 trial. The stage model of behavioral therapy research highlights the importance of developmental research (stage 1) to establish the feasibility and promise of novel behavioral therapies prior to large efficacy (stage 2) and transportability trials (stage 3) [27]. We then present treatment integrity and alcohol outcome results. We hypothesized that there would be a greater reduction in alcohol use [percentage of drinking days (PDD) and mean drinks per drinking day (DDD)] in the CBT condition relative to the usual care condition at the 30-day follow-up. We also conducted exploratory analyses to model the trajectory of alcohol use over time using repeated-measures regression.

METHODS

Setting

Kenya is a country in East Africa with 39 million citizens. Kiswahili is the national language. HIV prevalence was estimated to be 7.4% in 2007 [28]. There are few professional resources for treating alcohol use disorders; in 2005, there were 47 psychiatrists serving the entire country [29].

The Kenya Health Behavior Study

This trial was the first behavioral therapy study performed within the clinical services of the Academic Model Providing Access to Healthcare (AMPATH), a multi-national collaboration in western Kenya [30], which provides HIV care for more than 70 000 current HIV-infected out-patients in 25 clinics in western Kenya and utilizes an electronic medical records system [31]. The adaptation of CBT for use in this study and results of feasibility testing have been described in more detail elsewhere [4,32]. The study protocol was reviewed and approved by institutional review boards (IRBs) at all affiliated universities. The purpose of the project was to ascertain whether CBT, which has well-documented efficacy for reducing alcohol use in western settings, could be adapted to the Kenyan culture, language and group paraprofessional delivery. The team first adapted CBT and the research methods to the cultural context, then trained counselors according to methods described in our previous report [32].

Participants

Inclusion/exclusion criteria

Inclusion criteria were: age $\geq$ 18 years, enrollment as an AMPATH HIV out-patient attending the Eldoret clinic affiliated with Moi Teaching and Referral Hospital, hazardous or binge drinking criteria (score $\geq$ 3 on the Alcohol Use Disorders Identification Test (AUDIT-C) [33,34], or more than six drinks per occasion at least monthly), any alcohol use in the past 30 days, being ARV-eligible or ARV-initiated in the past 12 months (to capture a 'teachable moment' for quitting drinking and to enhance retention due to monthly clinic appointments to retrieve ARVs), spoken knowledge of Kiswahili, living within 1 hour's travelling distance from the clinic, no plans to move further away during the study period and being available during the weekly group time [see Consolidated Standards of Reporting Trials (CONSORT) diagram; Fig. 1]. Exclusion criteria included active psychosis or suicidality, attendance in the past year at an existing AMPATH alcohol peer support group or participation in the study's group CBT pre-pilot development.

Assessment of outcome

Alcohol use

Alcohol use was assessed for the past 30 days at baseline, then consecutively thereafter during weekly interviews

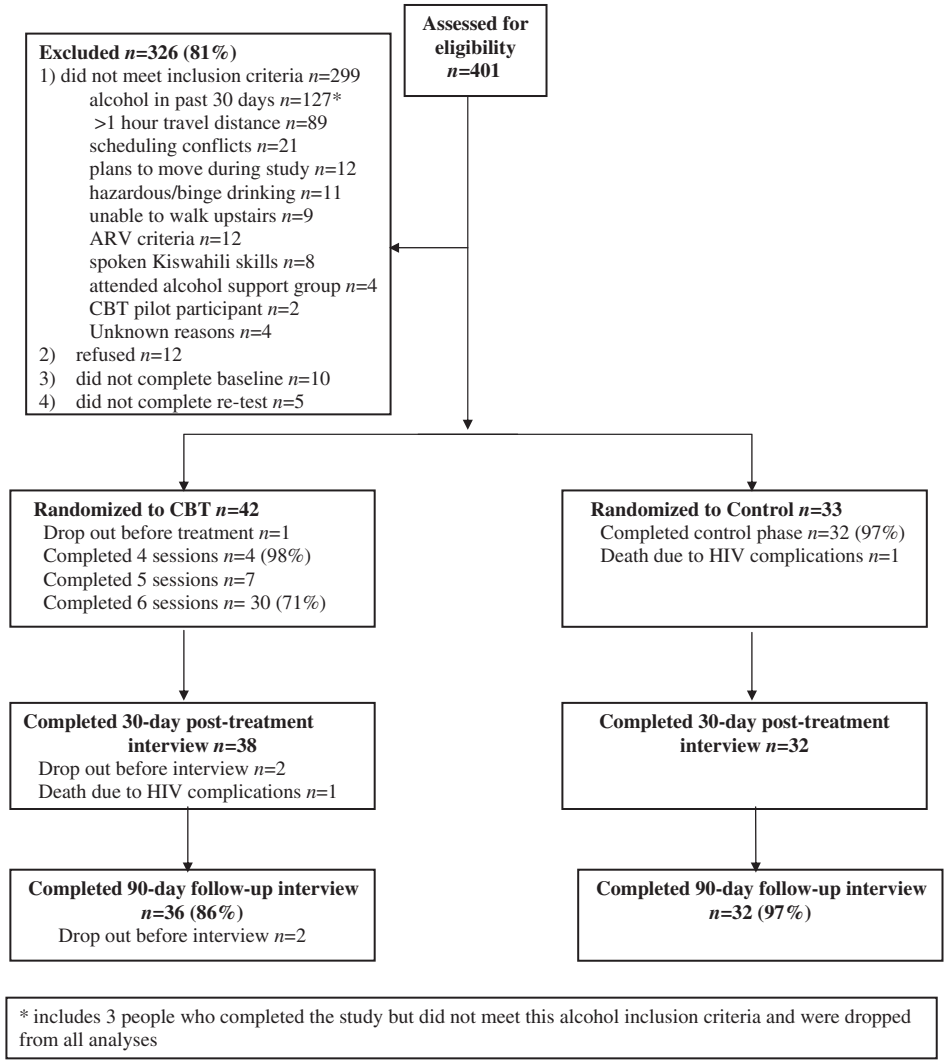

Figure 1 Consolidated Standards of Reporting Trials (CONSORT) diagram of eligibility, enrollment, randomization, treatment and follow-up rates. ARV: antiretroviral; CBT: cognitive–behavioral therapy; control: usual care condition

during the 6-week treatment phase, and at 30-, 60- and 90-day post-treatment interviews. If a participant missed a previous interview, the days since the last interview were assessed at the subsequent interview. Based on our previous work [4], we estimated use of local brew (*chang'aa*, spirit, and *busaa*, maize beer) by asking participants how much money they spent on personal consumption, and use of commercial drink by asking volume drunk for the respective time-periods. We used the adapted Time line Follow back (TLFB) method, a well-established, reliable and valid retrospective calendar-based measure employing memory cues to assess alcohol use [35–38]. Reported cost and volume were then converted into grams of ethanol and divided by 14 g to achieve equivalence to a US standard drink. The first 50% of each of the six cohorts ($n = 39$) were selected to complete a 7-day re-test of the survey. Seven-day re-test reliability using the adapted TLFB was 0.88 for PDD and 0.92 for DDD (Pearson's r, $P < 0.0001$ for both analyses). At every visit, we also assessed withdrawal symptoms using the validated Clinical Institute Withdrawal Assessment for Alcohol (CIWA-Ar) [39] and objective alcohol consumption using the Alco Screen® saliva tests donated by Chematics, Inc. (North Webster, IN, USA). This assay assesses alcohol consumed approximately in the last 1–6 hours at indications of 0.02, 0.04, 0.08 or 0.30% as reflected by swab color [40]. A positive saliva test precluded CBT participants from attending the CBT group due to the possibility of creating alcohol triggers for other participants. Additionally, usual care participants were not permitted to complete the interview with a positive test due to concerns for reporting validity. Participants whose score on the CIWA was 10 or more were provided with medical assessment and free medications, if needed. The CIWA-Ar and TLFB were adapted to the culture and Kiswahili language using World Health Organization (WHO)-modified methods [41].

Counselor CBT integrity

The Yale Adherence and Competence Scale (YACS), a reliable and valid therapist integrity rating system for several psychosocial addiction treatments [42,43], was modified for group delivery in Kenya. This scale, completed by independent raters, included 10 CBT-consistent items (e.g. focus on high-risk situations/triggers) and one item to capture any CBT-inconsistent categories (e.g. confronting participants). Each type of behavior was rated using a seven-point Likert-type scale on two dimensions: adherence (i.e. frequency and extensiveness; 1 = not present, 7 = extensively) and competence (i.e. skillfulness; 1 = very poor, 7 = excellent), for a total of 22 items.

Procedures

Recruitment

Eldoret HIV out-patients who had previously reported alcohol use during their first clinic visit were approached by same-sex research staff and asked for verbal consent for a brief interview to describe a health behavior study and to determine eligibility. Written informed consent was obtained from all eligible and interested participants. Recruitment of participants occurred over a 6-month period from February to July 2009, and follow-ups were completed in December 2009. As a pilot study, our sample size was intended to provide adequate treatment delivery experience for counselors, as well as provide an estimate of CBT treatment effect.

Randomization

A stratified simple randomization procedure was used to form gender-stratified cohorts. Within gender-based cohorts, participants were assigned randomly until a minimum was achieved of seven CBT and five usual care participants, thereby creating some waiting time. A group of seven was required for CBT to enhance participation, while fewer were required for the individual usual care condition to minimize waiting time before treatment initiation. Each participant was randomized after she or he drew from a jar a paper with the name of the condition. The papers were prepared by study administrators to conceal the name of the condition during the drawing, which was supervised by staff.

Interviews

All participant interviews were audio-taped and conducted by same-sex research staff in a private setting using a computer survey interface. Interviewers were trained for a minimum of 30 hours in survey administration followed by a minimum of two observed interviews with mock patients. For each interviewer, all surveys were reviewed for procedural adherence and typographical errors until four perfect administrations were demonstrated. Thereafter, one in four surveys was selected randomly for full review (with default to consecutive surveys if an error was observed). Performance feedback was given weekly for the first several months, and after that only if an error was noted. Non-blinded research assistants both recruited and interviewed participants; none delivered study interventions.

Counselor training, supervision and integrity

Treatment was delivered by two counselors with no prior CBT experience, one with a high school diploma and no counseling experience, and one with a 2-year post-high school counseling diploma and minimal counseling experience. They were trained as described in our previous report [32]. All CBT group sessions were videotaped and monitored weekly by R.P., with translational support provided as needed. Supervision was conducted via telephone during the latter stages of trial. Fifty per cent of sessions with men and women, respectively ($n = 18$ sessions) were selected randomly, translated into English, with random back-translational verification, and rated by two highly experienced YACS raters from the Yale Psychotherapy Development Center.

Data and safety monitoring

The study included a Data and Safety Monitoring Board with representatives from affiliated universities. Adverse events were monitored during the study and reported to R.P. by research staff.

Treatment conditions

CBT

The CBT condition consisted of six weekly 90-minute group sessions conducted in Kiswahili. As described in our previous report [32], the treatment protocol was highly structured and based on a manual, with a recommended alcohol quit date following the second session. Because of the adverse effects of alcohol among HIV-infected individuals [6,7], abstinence was described as the goal, and successive approximations to abstinence were reinforced. Groups were closed and gender-stratified due to issues of stigma and the consecutive building of knowledge across sessions (Table 1).

Usual care

The usual care condition consisted of routine medical care provided in the AMPATH clinic. While participants had the option to attend the onsite peer-led HIV support group, attendance to which was restricted in the

Table 1 Kenya Health Behavior Study cognitive–behavioral therapy (CBT) protocol.

CBT session content
Session 1
I. Welcome—5 minutes
II. Overview of treatment/expectations—15 minutes
III. Human immunodeficiency virus/alcohol education—20–30 minutes
IV. Group member introductions and introduction to CBT—40–50 minutes
Session 2
I. Check-in and practice exercises—20–30 minutes
II. Reasons for drinking and quitting drinking—30–40 minutes
III. Preparation for quitting—20–30 minutes
Quit day
Session 3
I. Check-in and practice exercises—20–30 minutes
II. CBT model—20–30 minutes
III. Analysis of behavior—35–45 minutes
Session 4
I. Check-in and practice exercises—45 minutes
II. Coping with triggers, urges and high-risk situations—45 minutes
Session 5
I. Check-in and practice exercises—20–30 minutes
II. Risky decisions leading to drinking—30–40 minutes
III. Problem-solving—30 minutes
Session 6
I. Check-in and practice exercises—20–30 minutes
II. Alcohol refusal skills—40 minutes
III. Develop a long-term plan; and wrap up—20–30 minutes

treatment condition, only one participant attended the group. All safety, monitoring and assessment procedures were identical across the two conditions.

Data analysis

Individuals assigned to the two treatment conditions were compared on demographic and other descriptive variables using independent *t*- or χ^2 tests. To test our hypotheses, we tested the change in alcohol use (PDD and DDD) from baseline to the 30-day follow-up between conditions using independent *t*-tests. Cohen's *d* effect sizes [44] were also calculated from the change in alcohol use between conditions from baseline to the 30-day follow-up, as well as at three additional study time-points: post-treatment, 60- and 90-day follow-ups. We also examined between-condition differences in the percentage reporting 100% abstinence at the four study time-points using χ^2 tests.

In order to understand more clearly the trajectories of reported alcohol use over time, we fitted repeated-measures regression models to mean PDD and DDD. The mean trajectories were characterized using three-piece linear trends, separately by treatment arm. This structure was selected to reflect rate of change during three key periods following baseline: an initial reactivity effect (lasting up to 2 weeks), an active treatment effect (between weeks 2 and 6, during which the intervention is being administered actively), and then a follow-up effect. The three-piece model was based on conceptual differences between initial reactivity, active treatment and follow-up periods, which can reflect different rates of change due to survey reactivity [45,46], variability in reinforcement rates and level of extra-session generalization of treatment [47,48].

We assumed a random-effects variance structure with random effects for intercept and each of the slopes; we also used robust standard errors to account for the possible mis-specification of the variance structure. This model is based on likelihood and therefore provides valid inferences under the missing-at-random assumption [49], as long as it is properly specified (6% missing observations). The fitted model was compared to observed time-specific (non-standardized) means.

RESULTS

Recruitment, retention and adverse events

A total of 401 individuals were screened for eligibility, 102 were eligible and 326 were excluded (Fig. 1), primarily because they did not drink alcohol in the past 30 days or lived more than 1 hour's travelling distance from the clinic. No participants were excluded from the study due to psychiatric criteria. Seventy-five participants were randomized, 42 to CBT and 33 to usual care. The number of participants in each cohort ranged from 12 to 15. Waiting time for initiation of the treatment phase was on average 23.26 days [standard deviation (SD) = 11.84] and did not vary according to participant gender ($P = 0.10$) or condition ($P = 0.69$). Six CBT groups were run (three for women). Of those randomized to CBT, participants attended 93% of the six sessions offered (mean = 5.6, SD = 0.66), excluding one dropout before treatment. Serious adverse events consisted of two deaths from HIV complications, one from each condition.

Participant baseline characteristics

Average age was 37.07 years (SD = 8.40) and highest mean year of education completed was 8.03 (SD = 4.15). Participants were diagnosed with HIV on average 1.35 years ago (SD = 1.51) and had a mean CD4 count of 284.09 (SD = 172.37), which is indicative of advanced immunosuppression according to WHO guidelines [50]. In the total sample in the past 30 days, number of drinking days ranged from 1 to 30 (mean = 9.99, SD = 7.89),

Table 2 Baseline demographic and clinical characteristics of participants by study condition.

	Total	*CBT*	*Control*	*Test statistic*
n (%)	75	42 (56.00)	33 (44.00)	
Age, mean (SD)	37.07 (8.40)	35.55 (7.57)	39.00 (9.11)	$t_{73} = -1.79$, $P = 0.08$
Education, highest year completed, mean (SD)	8.03 (4.15)	8.52 (3.93)	7.39 (4.38)	$t_{73} = 1.17$, $P = 0.24$
Married *n* (%)	43 (57.33)	22 (52.38)	21 (63.64)	$\chi^2_{(1)} = 0.96$, $P = 0.33$
ARV-initiated *n* (%)	46 (61.33)	23 (54.76)	23 (69.70)	$\chi^2_{(1)} = 1.74$, $P = 0.19$
Time since HIV diagnosis (years)	1.36 (1.51)	1.49 (1.72)	1.20 (1.20)	$t_{73} = 0.81$, $P = 0.42$
Drank *chang'aa* (spirit) past 30 days *n* (%)	57 (76.0)	31 (73.81)	26 (78.79)	$\chi^2_{(1)} = 0.25$, $P = 0.62$
Days of alcohol use past 30 days, mean (SD)	9.99 (7.89)	10.57 (7.72)	9.24 (8.17)	$t_{73} = 0.72$, $P = 0.47$
Drinks per drinking day (14 g *etoh*), mean (SD)	5.68 (4.01)	6.02 (4.48)	5.26 (3.33)	$t_{73} = 0.81$, $P = 0.42$
Tobacco use in past 30 days *n* (%)	21 (28.00)	15 (35.71)	6 (18.18)	$\chi^2_{(1)} = 2.82$, $P = 0.09$
Number of days smoked cigarettes in the past 30 day, mean (SD) ($n = 21$)	25.67 (8.91)	25.47 (9.05)	26.17 (9.39)	$t_{19} = -0.16$, $P = 0.88$
Number of cigarettes on days smoked, mean (SD)	4.95 (3.92)	4.80 (4.39)	5.33 (2.66)	$t_{19} = -0.28$, $P = 0.79$
Marijuana use in past 30 days *n* (%)	2 (2.68)	0	2 (6.06)	$\chi^2_{(1)} = 2.62$, $P = 0.11$
Khat (stimulant leaf) use in past 30 days *n* (%)	5 (6.76)	2 (4.88)	3 (9.09)	$\chi^2_{(1)} = 0.52$, $P = 0.47$

CBT: cognitive–behavioral therapy; ARV: antiretroviral; HIV: human immunodeficiency virus; SD: standard deviation.

mean number of drinks per drinking day ranged from 0.84 to 21.84 (mean = 5.68, SD = 4.01), with 76% of participants reporting drinking *chang'aa*. There were no significant differences between conditions on any outcome variables or covariates (Table 2).

CBT integrity

An initial sample of six tapes was rated by two independent raters and indicated a high level of inter-rater reliability (mean intraclass correlation coefficients) across both adherence (mean = 0.98) and competence (mean = 0.95) [51]. Mean ratings of 18 tapes suggested high levels of CBT adherence (mean = 5.26, SD = 0.95) and CBT competence (mean = 5.71, SD = 0.56). There was no skill rating of less than 4 (average skill) for any item. No CBT-inconsistent ratings were endorsed by raters, suggesting that treatment was highly focused on CBT delivery without the use of incompatible techniques. Adherence ($P = 0.39$) and competence ($P = 0.60$) scores did not differ significantly by gender of the treatment group. The most frequently seen interventions on the tapes reviewed were discussion of high-risk situations/triggers (mean = 6.67, SD = 0.77), reflective statements (mean = 5.78, SD = 1.83) and pros/cons/ambivalence about drinking (mean = 5.72, SD = 1.78), which is highly consistent with the treatment manual guidelines.

Alcohol use outcomes

Overall level of drinking was low in the trial, i.e. at the 90-day follow-up 69% of CBT participants reported abstinence and PDD was 5% (Table 3). There were six positive saliva tests, three in CBT and three in usual care; five occurred during the treatment phase. Three CBT participants and one baseline participant reported withdrawal symptoms requiring use of benzodiazepines. Results of *t*-tests showed that at 30 days post-treatment, reductions since baseline were significantly larger in the CBT condition compared to the usual care condition for both PDD ($P = 0.0002$) and DDD ($P = 0.002$). Cohen's *d* effect sizes of reductions since baseline compared between conditions at 30 days post-treatment were large ($d = 0.95$ PDD; $d = 0.76$ DDD) and at the 90-day follow-up were moderate ($d = 0.60$ PDD; $d = 0.56$ DDD). More CBT than control participants reported abstinence at all follow-ups (e.g. 30 days, 63% versus 25%, $\chi^2 = 10.19$, $P = 0.001$; 90 days, 69% versus 38%, $\chi^2 = 6.97$, $P = 0.008$).

Results of the repeated-measures regression models were similar for PDD and DDD. Scores indicated an initial reactivity effect (i.e. alcohol reduction) beginning after administration of the baseline survey and before treatment initiation across both conditions. During the treatment phase, CBT participants reported reducing alcohol use at a faster rate than control participants, as evidenced by the difference between slopes between conditions during the active treatment phase (−3.41, PDD; −0.36, DDD) (Table 4). During the follow-up phase, CBT participants maintained reductions while control participants continued to report gradual reductions over time. Review of the observed (non-standardized) mean scores showed a good fit to the data (Figs 2,3) [because of the small sample size and limited variability in drinking behavior at follow-up, we were unable to examine the possible effect of group membership on alcohol report (i.e. correlations between members of the same group when compared between groups)].

Table 3 Changes in post-baseline reported alcohol use data.

	CBT		*Control*		*Between-group difference*	
Study time-point	*Change from baseline*	*Point prevalence*	*Change from baseline*	*Point prevalence*	*Change from baseline*	*Cohens d effect size*
	Percentage of drinking days, mean (SD) or mean (95% CI)					
6-week treatment phase[a]	−23.26 (21.75)	10.57 (11.23)	−3.19 (21.57)	27.62 (26.71)	20.07 (9.97, 30.17)	0.93
30-day follow-up (past 30 days)[b]	−29.59 (23.37)	5.08 (9.74)	−4.66 (29.06)	27.01 (29.21)	24.93 (12.43, 37.43)	0.95
60-day follow-up (past 30 days)[b]	−27.71 (28.19)	6.95 (16.14)	−5.84 (27.58)	25.82 (28.37)	21.86 (8.50, 35.23)	0.78
90-day follow-up (past 30 days)[c]	−29.95 (27.81)	5.06 (13.18)	−13.03 (28.97)	18.64 (24.03)	16.93 (3.17, 30.68)	0.60
	Drinks per drinking day (14 g *etoh*), mean (SD) or mean (95% CI)					
6-week treatment phase[a]	−1.99 (3.46)	4.07 (4.06)	−0.95 (3.00)	4.30 (3.48)	1.04 (−0.48, 2.56)	0.32
30-day follow-up (past 30 days)[b]	−4.26 (4.43)	1.83 (3.35)	−1.38 (2.9)	3.93 (3.56)	2.88 (1.05, 4.70)	0.76
60-day follow-up (past 30 days)[b]	−4.71 (5.01)	1.38 (2.55)	−1.21 (3.71)	4.11 (4.14)	3.50 (1.37, 5.64)	0.78
90-day follow-up (past 30 days)[c]	−4.36 (5.04)	1.9 (3.87)	−1.85 (3.72)	3.46 (3.78)	2.51 (0.35, 4.68)	0.56

[a]Cognitive–behavioral therapy (CBT) $n = 41$, usual care (UC) $n = 33$. [b]CBT $n = 38$, UC $n = 32$. [c]CBT $n = 36$, UC $n = 32$. SD: standard deviation; CI: confidence interval.

DISCUSSION

To our knowledge, this is the first published randomized clinical trial of CBT to reduce alcohol use in sub-Saharan Africa. Results of this trial suggest that CBT can be adapted successfully to group paraprofessional delivery and may be effective in reducing alcohol use in this sample. Our hypothesis that CBT would be more effective than usual care in reducing reported alcohol use at the 30-day follow-up was supported for both primary outcomes (PDD and DDD). Large effects were sustained between CBT and usual care between baseline and the 30-day follow-up and moderate effects were sustained at the 90-day follow-up. These effect sizes are comparable to alcohol intervention studies conducted in the United States [52]. Repeated-measures regression analyses revealed a possible assessment reactivity effect [45,46], wherein participants across both conditions reported a reduction in alcohol use beginning after administration of the baseline survey. This transient effect is believed to be associated with self-monitoring and self-evaluation [53] and warrants further study. During the treatment phase, CBT participants reported more rapid reductions in alcohol use than control participants. During the follow-up phase CBT participants maintained reductions while control participants continued to report gradual reductions in use.

Because this design did not involve an outcome period beyond 90 days, it is not known whether differences between conditions increased or decreased beyond that period. Independent ratings of CBT integrity among paraprofessionals showed acceptable adherence and skill ratings, suggesting a successful treatment delivery approach. The group paraprofessional delivery model may provide a useful tool in settings with few professional resources by expanding available treatments for counteracting public health crises.

While our study results suggest a promise of efficacy for CBT in this setting, the study was exploratory and the sample was small. Hence, there was insufficient power to examine mediator and moderator analyses associated with behavior change (e.g. use/quality of CBT coping skills). From a qualitative standpoint, our treatment protocol provided education about biopsychosocial consequences of alcohol use, including the harmful effects of alcohol on HIV complications. Participants reported in debriefings that mitigation of these effects was a motivation for change. Further, our methods of assessing alcohol by money spent were also reported in debriefings to increase awareness of financial costs of drinking, and to act as a motivator for change, particularly for men. Because the adapted CBT manual was not compared to an active control condition, it did not control for increased attention. It is possible that increased attention

Table 4 Slopes of alcohol use using repeated measures regression at three study phases: initial reactivity (baseline-week 2), treatment (weeks 3–6) and follow-up (weeks 7–18).

Variable	*CBT (95% CI)*	*Control (95% CI)*	*Difference (95% CI)*
Percentage of drinking days			
Baseline mean	35.76 (27.68, 43.83)	29.56 (20.47, 38.65)	6.20 (−5.96, 18.35)
Slope 1	−11.18 (−14.89, −7.47)	−1.95 (−6.37, 2.47)	−9.23 (−15.00, −3.46)
Slope 2	−2.31 (−3.42, −1.20)	1.10 (−0.99, 3.19)	−3.41 (−5.77, −1.04)
Slope 3	0.19 (−0.17, 0.55)	−1.02 (−1.64, −0.39)	1.20 (0.49, 1.92)
Average number of drinks per drinking day (14 g *etoh*)			
Baseline mean	5.67 (4.40, 6.93)	4.97 (3.86, 6.09)	0.70 (−0.99, 2.38)
Slope 1	−1.67 (−2.24, −1.10)	−0.72 (−1.25, −0.19)	−0.95 (−1.73, −0.17)
Slope 2	−0.35 (−0.58, −0.12)	−0.01 (−0.27, 0.29)	−0.36 (−0.72, 0.002)
Slope 3	0.003 (−0.04, 0.05)	−0.08 (−0.16, 0.007)	0.08 (−0.02, 0.17)

CBT: cognitive–behavioral therapy; CI: confidence interval.

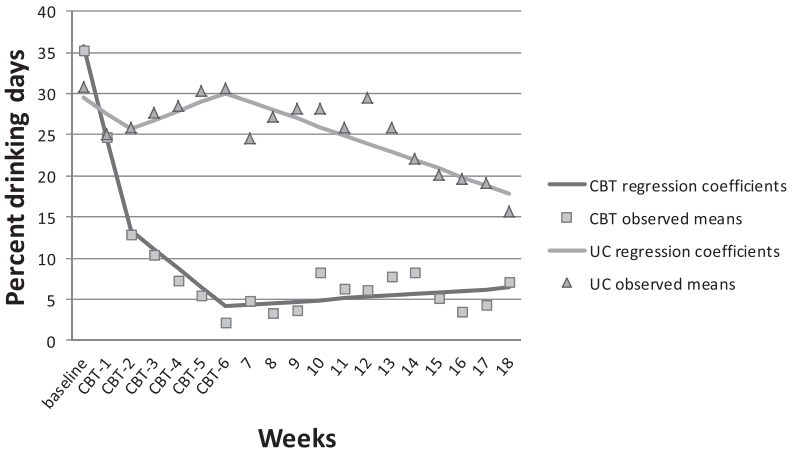

Figure 2 Repeated-measures regression coefficients and observed means of percentage of drinking days across three study phases: initial reactivity (baseline-week 2), treatment (weeks 3–6) and follow-up (weeks 7–18). CBT: cognitive–behavioral therapy; UC: usual care control. Note: baseline represents previous 30 days

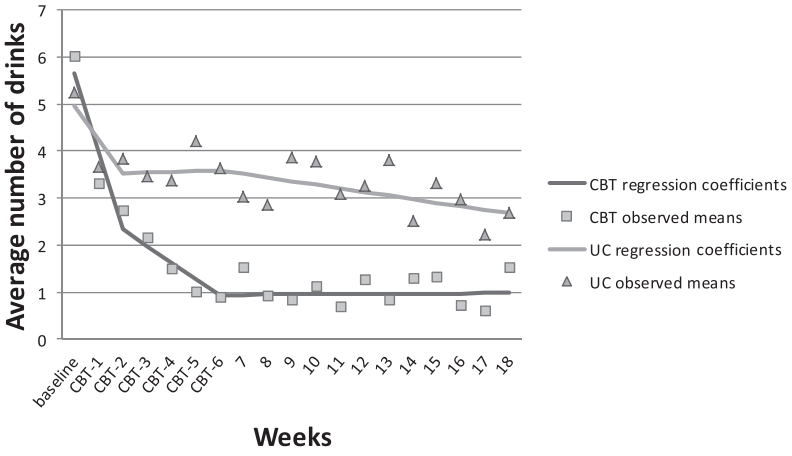

Figure 3 Repeated-measures regression coefficients and observed means of average drinks per drinking day across three study phases: initial reactivity (baseline-week 2), treatment (weeks 3–6) and follow-up (weeks 7–18). CBT: cognitive–behavioral therapy; UC; usual care control. Note: baseline represents previous 30 days

from counselors resulted in decreased report of use due to social desirability. It should be noted that alcohol use was assessed by research assistants rather than counselors. Our design also did not control for group factors such as cohesion and support, and so the impact of non-specific factors (i.e. those unrelated to CBT) cannot be ruled out as impacting reported use. These factors may have biased alcohol report and maximized group differences in favor of CBT.

This study represents a preliminary step to counteract the dual public health crises of alcohol use disorders and HIV transmission in sub-Saharan Africa. Consistent with

an emerging literature suggesting that heavy drinking limits the success of HIV prevention efforts [14–16], future research is needed to determine whether reduction of heavy drinking is a successful strategy for reducing sexual risk behaviors. Additionally, future research examining the efficacy of enhanced interventions that co-target both heavy drinking and sexual risk behaviors would be useful. Strengths of our study were the use of standardized protocols for treatment, training and integrity ratings; the feasibility of treatment delivery by paraprofessionals; and the systematic cultural adaptation of the intervention. Limitations of the study include the small sample size, reliance on self-report of alcohol use, a relatively brief follow-up, assessment by non-blinded research assistants and the lack of an active control group. Although we employed objective alcohol saliva tests for corroboration of self-reports of abstinence, the assay provides only a point-prevalence verification over the past 6 hours. Data on changes in sexual risk behaviors and other health outcomes were also not assessed. Because of these limitations, generalizability of study results awaits empirical demonstration. Future research employing an active control group and a longer follow-up period in a larger sample is needed to confirm efficacy, to examine the durability of this intervention over time on multiple risk behaviors, and to explore mediators of behavior change.

Clinical trial registration

Clinicaltrials.gov identifier: NCT00792519.

Declarations of interest

None.

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