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Motivational interviewing and problem-solving therapy intervention for patients on antiretroviral therapy for HIV in Tshwane, South Africa: A randomized controlled trial to assess the impact on alcohol consumption

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DECLARATION OF INTERESTS

None.

SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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Abstract

Background and Aims: Reduction of alcohol consumption is important for people undergoing treatment for HIV. We tested the efficacy of a brief intervention for reducing the average volume of alcohol consumed among patients on HIV antiretroviral therapy (ART).

Design, Setting and Participants: This study used a two-arm multi-centre randomized controlled trial with follow-up to 6 months. Recruitment occurred between May 2016 and October 2017 at six ART clinics at public hospitals in Tshwane, South Africa.

Participants were people living with HIV, mean age 40.8 years [standard deviation (SD) = 9.07], 57.5% female, and on average 6.9 years (SD = 3.62) on ART. At baseline (BL), the mean number of drinks consumed over the past 30 days was 25.2 (SD = 38.3). Of 756 eligible patients, 623 were enrolled.

Intervention: Participants were randomly assigned to a motivational interviewing (MI)/problem-solving therapy (PST) intervention arm (four modules of MI and PST delivered over two sessions by interventionists) or a treatment as usual (TAU) comparison arm. People assessing outcomes were masked to group assignment.

Measurements: The primary outcome was the number of standard drinks (15 ml pure alcohol) consumed during the past 30 days assessed at 6-month follow-up (6MFU).

Findings: Of the 305 participants randomized to MI/PST, 225 (74%) completed the intervention (all modules). At 6MFU, retention was 88% for the control and 83% for the intervention arm. In support of the hypothesis, an intention-to-treat-analysis for the primary outcome at 6MFU was −0.410 (95% confidence interval = −0.670 to −0.149) units lower on log scale in the intervention group than in the control group ($P = 0.002$), a 34% relative reduction in the number of drinks. Sensitivity analyses were undertaken for patients who had alcohol use disorders identification test (AUDIT) scores ≥ 8 at BL ($n = 299$). Findings were similar to those of the whole sample.

Conclusions: In South Africa, a motivational interviewing/problem-solving therapy intervention significantly reduced drinking levels in HIV-infected patients on antiretroviral therapy at 6-month follow-up.

Keywords

Alcohol; brief intervention; PLWHIV; problem-solving therapy; South Africa

INTRODUCTION

Several studies have shown that hazardous or heavy episodic drinking directly contributes to the acquisition and transmission of HIV, antiretroviral therapy (ART) non-adherence [1] and declines in CD4 counts, non-suppression of HIV viral load [2] and HIV disease severity [3]. South Africa has approximately 8.2 million people living with HIV (PLHIV) [4], approximately 70% of whom were receiving ART in 2019. Alcohol use is a major threat to South Africa's efforts to eliminate HIV. In this country, where a large proportion of PLHIV on ART are estimated to engage in heavy drinking [5], interventions to reduce alcohol consumption are especially needed to optimize ART adherence and HIV treatment outcomes.

Several randomized controlled trials (RCTs) have evaluated the efficacy of non-specialist health worker-delivered interventions to reduce alcohol use among PLHIV, with half conducted in Africa (see Supporting information, Table S1). These studies have demonstrated mainly positive findings, with eight showing significant reductions in current

or problem drinking, two only finding an intervention effect for subgroups and two studies not finding statistically significant intervention effects (Supporting information, Table S1). With the interventions in these trials varying in content, theoretical underpinnings, duration and dosage it is not surprising that there have been calls for more trials of psychological interventions for reducing alcohol consumption among PLHIV that disaggregate data by level of alcohol consumption, gender and age and include biomarkers of alcohol outcomes [6].

To address these gaps and help to resolve questions regarding the efficacy of brief alcohol-focused interventions for PLHIV, we aimed to test the efficacy of a brief psychological intervention delivered by non-specialist providers relative to treatment as usual (TAU) for reducing the average volume of alcohol consumed during the last 30 days (primary outcome) and on ART adherence and HIV disease progression (secondary outcomes). We hypothesized that participants who received the brief intervention would demonstrate greater reductions in the quantity of alcohol consumed and greater improvements in their ART adherence and viral load relative to participants who received TAU.

METHODS

Trial design

We used a two-arm parallel, individual, RCT with measures at baseline (BL) and 3- and 6-month post-randomization, the latter being the primary study end-point. A detailed description of the trial can be found in Parry et al. [7]. Supporting information, Table S2 describes modifications to the original protocol.

Participants

We recruited 626 patients from ART clinics in six hospitals in Tshwane, South Africa, between May 2016 and October 2017 (see sample size calculations below). Patients eligible for inclusion were on ART for at least 3 months, not being treated for tuberculosis, aged ≥ 18 years and who met criteria for current (past year) harmful/hazardous drinking [Alcohol Use Disorders Identification Test (AUDIT)-C score ≥ 4 for men and ≥ 3 for women] but not alcohol dependence (total AUDIT score < 23) [8, 9], resident in Tshwane, not enrolled in another trial and who did not have an extremely poor general health (Karnofsky clinical score > 50) [10]. At each clinic, research staff approached patients waiting for their ART appointment and described the study. Interested individuals were referred to a fieldworker who requested consent to screen them for study inclusion. Participants received grocery vouchers for completing study appointments [-South African Rand (ZAR) 80 for initial visit and ZAR 100 for follow-up assessments]. Transport expenses were reimbursed (ZAR 50 per visit). Ethical approval for the study was granted by the Research Ethics Committee of the South African Medical Research Council (ref. no. EC003–2/2014). The trial was registered in the Pan African Clinical Trials Register (PACTR201405000815100).

Interventions

Participants in the intervention arm were offered a psychological intervention that comprised four intervention modules, delivered over two individual contact sessions that were spaced a

week apart. The intervention combined motivational interviewing (MI) and problem-solving therapy (PST), a form of cognitive behavioural therapy (see Supporting information, Table S3). MI is effective for increasing motivation for alcohol behaviour change but the effects are often not durable, especially where alcohol is used as a strategy for coping with negative emotions and life problems [11]. We included PST to ensure that participants learned problem-focused and emotion-focused coping skills to sustain alcohol behaviour change [12].

This intervention has been used to address problem drinking and other mental health concerns in a range of patient populations in South Africa [13], including participants with HIV [12]. Findings from our formative work guided refinements to the intervention to enhance its acceptability and feasibility in this setting while retaining the core elements of MI and PST [14]. Each of the four 45-minute modules iteratively built on participants' readiness to change and the problem-solving and coping skills developed in the previous session and had a motivational, educational and practical component. All modules included opportunities to apply these skills through exercises and home-based activities. A patient handbook was provided that summarized the content. From enrolment, participants had 4 weeks to complete these modules.

Participants in the TAU arm received the standard package of care for PLHIV who drink at hazardous/harmful levels. Typically, PLHIV with adherence difficulties are referred for additional adherence counselling which varies in duration and content. If alcohol problems are suspected, patients are usually referred to on-site psychologists or social workers, if available, or off-site community mental health or alcohol services. Usually, only severe alcohol use disorders are detected.

Counselling sessions were provided by six female project staff. They received approximately 40 hours of intervention-specific training by psychologists who developed the intervention package (B.M., K.S.) and clinical supervision (C.K). The counsellors' qualifications varied, with three having psychology or social work backgrounds and all having prior training in generic counseling skills. Intervention sessions were audio-recorded, and a random selection of these audio-recordings were reviewed and discussed in weekly group supervision with the clinical supervisor. An independent assessor reviewed 10% of the recordings for fidelity to the intervention using a checklist employed previously [12]. Performance on each checklist item was rated on a 4-point scale (1, strongly disagree to 4, strongly agree), where higher scores indicated better fidelity. The superviser also supported counsellors to overcome the challenges to intervention delivery.

Measurements

BL measures—At BL, 50% of participants were randomly selected using computer-based randomly pre-selected participant identification numbers (PIDs) to provide a fingerprick blood sample to assess for phosphatidylethanol (PEth) [15], a biomarker of recent alcohol consumption. Nurses obtained venous blood from all participants to assess HIV viral load. The former analysis was undertaken by the United States Drug Testing Laboratories Inc. and the latter by the South African National Institute for Communicable Diseases. Demographic and outcome data were collected through interviewer-administered questionnaires available

in English and seTswana at BL and each follow-up. The questionnaires assessed patients' age, gender, income, education, employment status, housing status, relationship status, sources of income, food insecurity, duration of ART use as well as ART adherence and alcohol measures described in the outcome measures section. Participants assigned to the intervention arm were asked to return within 2 weeks to receive their first intervention session. All participants, irrespective of condition assignment, were asked to return at study assessment points for repeated data collection.

Primary outcome—The primary outcome was the number of standard drinks (15 ml pure alcohol) consumed over the past 30 days assessed by questions asked at 6-month follow-up 6MFU). This involved multiplying the number of standard drinks consumed on a typical drinking day with the number of drinking days on which alcohol was consumed in the past 30 days (see Supporting information, Appendix S1). As indicated in the trial protocol, we intended to include the number of standard drinks consumed over the past 30 days at BL and 3-month follow-up (3MFU), but this was changed to fully align the study with CONSORT (consolidated standards of reporting trials) [16]. A graphic was used to aid participants' estimation of the number of standard drinks consumed.

Secondary outcomes—The secondary outcomes included other alcohol consumption items, self-reported ART adherence and viral load. Secondary alcohol outcomes included the AUDIT score [8], the AUDIT-C score [9] and PEth ng/ml (obtained for 50% of the sample). The latter was due to the extremely high cost of conducting PEth testing. The reporting period of the AUDIT was changed from 12 months to 3 months at BL and each follow-up assessment to reflect the time since the previous data collection period.

Four adherence measures formed the basis of the secondary, self-reported ART adherence outcomes: (1) the AIDS Clinical Trials Group (ACTG) adherence questionnaire which assesses patients' current ART medications, dosing schedule and medication doses missed over the past 4 days (< 95% = poor adherence) [17]; (2) the Visual Analogue Scale (VAS), which assesses general levels of adherence over a 30-day time-frame (< 95% = poor adherence) [18]; (3) the Center for Adherence Support Evaluation (CASE) Adherence Index (< 11 = poor adherence) [19]; and (4) the Self-Rating Scale Item (SRSI) (poor/good adherence) [20].

These measures varied in aspects of adherence measured, recall periods and response tasks. For further details, see Parry et al. [7]. For the HIV viral load outcome, we assessed HIV viral load with 50 copies/ml as the cut-off for detectable viral load. All outcomes were assessed at BL and the two study end-points except for HIV viral load, which was assessed at BL and the primary end-point (6MFU) only.

Sample size

The required sample size per study arm at BL was 313 (see Parry et al. [7]), yielding a sample size of 626 for the overall study. We estimated the need to screen at least 750 patients at each of the initially planned four sites [7] to reach our target sample based on the expected prevalence of drinking. We had initially planned to recruit participants from all four district hospitals in the Tshwane Health District, but added two additional tertiary

hospitals to meet our targets. Sample size estimates were revised and based on the numbers of patients needed to detect differences between the intervention and comparison arms in the mean number of drinks per day over the past 30 days at each study end-point [7]. We assumed a small effect size of 0.2 (one-fifth of a standard drink per day) to be conservative. We calculated the sample size assuming a one-sided 5% hypothesis test at a power of 80%, with three time-points using a linear mixed model. An attrition rate of 15%, assumed to be the same for both study arms, was set for the end of the study (6 months).

Randomization and masking

Participants were assigned an ID number which was linked to a randomly selected code that determined the condition into which they would be placed. The random code was generated a priori by a computer-generated table by the statistician (S.M.). Randomization occurred within sites.

Treatment allocation was performed by site supervisers using pre-prepared and sealed opaque envelopes which were numbered consecutively and contained the randomly determined group assignment. Condition allocation only occurred after all BL procedures had been completed. The study staff who conducted the post-intervention outcome assessments were masked to the treatment allocation to ensure that the assessments remained unbiased and independent from the intervention sessions. Given the study's behavioural nature, the interventionists were not blinded to who was in the intervention arm.

Statistical analysis

Characteristics of participants at BL and study end-points were summarized by means and standard deviations (SD) for continuous variables and by frequencies and percentages with 95% confidence intervals (95% CI) for categorical variables. A two-sample test of proportions was used to compare rates of attrition between the two arms at 3MFU and 6MFU.

Missing data (n = 127, 67% females at 3MFU and n = 88, 69% females at 6MFU) were imputed using multiple imputation chained equations to impute outcomes at 3- and 6MFU separately. All participants who had at least non-missing BL assessments were included in the imputation for the primary and other outcomes. Using univariable logistic regression models, it was found that missingness was associated with group (study arm), gender, age and site across almost all outcomes of interest. Generally, the intervention arm, females and younger participants had more missing values in the outcomes at follow-up time-points. Two hospitals also had the most missing values. The imputation models were conditioned on the covariates group, gender, age and site, as well as the BL value of the outcome; therefore, we ensured that the missingness in our data are missing at random (MAR). The number of imputations was chosen to be 20 to ensure stability in the estimates combined from the imputations. The same generalized linear models (GLM) used to analyze each outcome were used to impute that outcome. Results based on imputations are reported for the models.

Intention-to-treat (ITT) outcome analyses were conducted using GLM. The following outcomes were modelled: discrete, average number of drinks consumed in the last 30

days (primary outcome); continuous, total AUDIT and AUDIT-C; and binary, PEth (≥ 50 ng/ml 'yes (unhealthy alcohol use)' versus 'no (no unhealthy use)'). We also examined the following categorical outcomes: detectable viral load, VAS, ACTG, CASE adherence and SRSI (poor/good adherence)

Negative binomial regression with log link was used to model the primary outcome. For binary outcomes, logistic regression was used using the logit link function. Continuous outcomes were modelled using the linear model. Two approaches were used to estimate treatment effects. In the first approach, model 1, the post-intervention outcome was modelled with a parameter for the treatment effect for each follow-up time-point separately. Hence, separate estimates are produced for 3MFU and 6MFU, with the comparison between drinking volume at BL and 6MFU being the primary outcome. The estimates are adjusted for the BL outcome. The treatment effect can be interpreted as the adjusted post-intervention difference between MI/PST and TAU arms. For the logistic and the negative binomial regression, exponentiated effects are reported which can be interpreted as the ratio of outcomes post-intervention for MI/PST relative to TAU. Results for model 1 are presented below, and results for model 2 are presented in the Supporting information, Appendix S1. All models were adjusted for gender, age, marital status, education and enrolment site. A fixed effect for site was included in the models as it was anticipated that the sites may be different with respect to the outcomes. However, the intervention effect for the primary outcome was not affected by site.

For the second approach, model 2, we modelled the outcomes longitudinally across all time points using generalized estimated equations (GEE). We assumed exchangeable correlation structure between time-points and robust standard errors were used. We fitted a parameter for the treatment arm, as well as a categorical time-effect and the interaction between the two. The interaction terms produced for both 3MFU and 6MFU can be interpreted as the difference in change from BL to post-intervention between the treatment and controls. In the case of the negative binomial and logistic models, the interaction terms are the ratios of the changes from BL to post-intervention.

As the use of the AUDIT-C to screen participants for eligibility yielded a final sample that included people with scores below 8 on the full AUDIT, we conducted a post-hoc sensitivity analysis to assess the impact of the intervention on the subgroup that had AUDIT ≥ 8 at BL; that is, PLHIV on ART with a higher level of alcohol risk behaviour.

This analysis was performed because, despite our initial screening process, our sample included a large proportion of relatively low-risk drinkers (the mean AUDIT score for the overall sample at BL was only 8.86). Stata version 16 [21] was used to analyze the data. Imputed and complete case results were compared, and did not differ meaningfully for the primary outcome. Statistical significance was taken at 5%.

RESULTS

Sample and follow-up

Trial results are reported according to CONSORT guidelines [22] (Supporting information, Appendix S2). In total, 756 PLHIV met eligibility criteria, 623 of whom were enrolled. Figure 1 describes participant flow and attrition at each step of the trial. A total of 318 participants were randomized to TAU and 305 to the intervention. The intervention completion rate was 73.8% (225/305). The combined retention rate was 80% at the 3MFU (TAU = 86%, MI/PST = 73%) and 86% at the 6MFU (TAU = 88%, MI/PST = 83%). Retention rates were significantly different at 3MFU ($P < 0.001$) but not at 6MFU ($P = 0.068$). The intervention was delivered with high fidelity, with counsellors scoring above three on all fidelity items. Four participants, all in the control arm, died from causes unrelated to the study.

Sample demographics and outcome variables at BL are presented in Table 1. The mean age of the participants was 40.8 years (SD = 9.07); 57.5% were female and 38.5% had completed high school or equivalent. More than three-quarters had been on ART for more than 4 years. The mean number of drinks consumed over the past 30 days was 25.2 overall (SD = 38.30) and 27.5 (SD = 44.14) and 22.8 (SD = 31.06) for participants in the TAU and intervention arms, respectively. The mean AUDIT score was 8.9 (range = 2–28). Forty-six per cent had PEth levels of 50 ng/ml and above. Mean scores on the VAS, ACTG, CASE adherence index and SRSI were 92.4%, 95%, 13.18 and 4.07, respectively, indicating high levels of adherence. Across both arms, 77% had an undetectable viral load (i.e. VL < 50 copies/ml). Overall, BL characteristics were balanced across the arms.

Study outcomes

Primary outcome—The mean (SD) average number of drinks consumed per month at BL, 3MFU and 6MFU for the MI-PST group are 22.8 (1.8), 14.1 (1.4) and 14.7 (1.7), respectively. The means and 95% CIs for this outcome at the three time-points and for both arms are presented in Fig. 2a. The average number of drinks consumed per month at 6MFU was 0.410 (95% CI = −0.670 to −0.149) units lower on the log scale, indicating a significant reduction from BL to 6MFU for intervention versus control ($P = 0.002$) (Table 2 and Fig. 2a). The risk ratio in the change from BL to 6MFU for intervention versus control was 0.65 [exp(−0.410)], which was significantly different ($P = 0.008$). This indicates that the intervention arm had a 34% greater relative reduction in average number of drinks consumed per month, compared with the relative reduction in the control arm. During the 6-month follow-up period, participants in the intervention arm ($n = 305$) reduced their consumption by an estimated total of 15 427 drinks (50.5 drinks per participant) compared with a reduction of 5629 drinks (17.7 drinks per participant) among control arm participants ($n = 318$).

Secondary outcomes (subgroup analyses)—The average number of drinks consumed per month at 3MFU was lower on the log scale, indicating a marginally significant reduction from BL to 3MFU for intervention versus control ($P = 0.075$) (Table 2 and Fig. 2b–i). For total AUDIT scores, the decrease from BL to follow-up for the treatment

arm was significantly greater than that of the control arm at both 3MFU and 6MFU ($P < 0.05$) (Table 2 and Fig. 2b). Participants in the intervention group also had lower adjusted log odds of having elevated PEth scores at 3MFU and 6MFU, respectively ($P < 0.05$) (Table 2 and Fig. 2c). The decrease in the AUDIT-C score was significantly greater at both time-points in the intervention arm (Table 2 and Fig. 2i). There were no statistically significant intervention effects for adherence to ART or viral load (Table 2).

Sensitivity analyses

Additional sensitivity analyses were undertaken for participants who had AUDIT scores ≥ 8 at BL ($n = 299$) (Table 3). Findings were very similar to those of the whole sample. For the primary outcome, the average number of drinks consumed per month at the 6MFU was 0.454 units on the log scale (95% CI = −0.797 to 0.0110) fewer, respectively, in the intervention group than in the control group ($P < 0.05$), adjusted for BL outcome and other covariates. With regard to secondary outcomes, the average number of drinks consumed per month at the 3MFU was significantly fewer in the intervention group than in the control group ($P < 0.05$), adjusted for BL outcome and other covariates. Significant differences in the change in log odds from BL for total AUDIT and AUDIT-C scores were found for the intervention arm, with the intervention arm having significantly greater decreases in total AUDIT and AUDIT-C scores at 3MFU and 6MFU ($P < 0.05$). There were no statistically significant intervention effects for the biomarker PEth or on adherence or viral load.

DISCUSSION

The brief alcohol-focused intervention was found to significantly reduce the average number of drinks consumed in the past 30 days at the 6MFU by more than a third in comparison with TAU. This drop, on average approximately nine fewer drinks per week, is likely to be substantial enough to impact upon the health of PLHIV on ART. Total AUDIT scores were also significantly lower in the intervention arm at 6MFU (compared with BL). However, contrary to expectations, the intervention arm did not demonstrate significantly greater improvements in ART adherence or rates of HIV viral suppression at the primary end-point compared with TAU. Similarly, the change in PEth scores was not significantly different between the intervention and control arm at 6MFU.

Our findings are in line with eight studies indicating that behavioural and psychological interventions targeting alcohol use among PLHIV significantly reduce alcohol consumption (see Supporting information, Table S2). Of these, five were conducted in Africa. In the two studies conducted in Kenya, six sessions of cognitive behavioural therapy significantly reduced alcohol use compared with TAU [23] or a healthy life-style alternative [24]. The third study was conducted in Zimbabwe [25] and comprised eight sessions of MI blended with brief cognitive behavioural therapy. The fourth study was conducted in Zambia and compared a single-session behavioural intervention with an enhanced intervention comprising six to 12 sessions of cognitive behavioural therapy [26]. The fifth study, conducted in the Western Cape province of South Africa, found that three to four sessions of MI and PST, delivered over a 6-week period, led to significant reductions in alcohol problem severity [12]. The current study used similar content to the study conducted in the

Western Cape, but the spacing of the modules was different, with two intervention modules being offered on a single contact occasion. This demonstrates that delivering the MI-PST content over two rather than three or four contact sessions can lead to alcohol behaviour change. Importantly, and unlike previous trials of MI-PST which did not examine changes in alcohol consumption, this study demonstrated significant reductions in number of drinks consumed as a result of the intervention. This trial also provided biomarker verification of the self-reported changes in alcohol use.

In contrast with Scott-Sheldon et al.'s systematic review and meta-analysis [27], which found that behavioural interventions targeting alcohol use among PLHIV reduced alcohol consumption and improved medication adherence relative to controls, the current study did not find an intervention effect for ART adherence. Our intervention did not directly address ART, but focused upon alcohol reduction specifically. Other South African studies have shown that HIV and ART health literacy is poor and that participants who drink alcohol find information clarifying alcohol's relationship to ART adherence valuable to support change and improvements to adherence [28]. Another factor could have been difficulties with adherence recall. We did not include objective measures of adherence; for example, through pill counts or biomarkers for ART adherence to validate self-reported adherence.

Furthermore, as study entry criteria did not focus upon levels of adherence or exclude those with high adherence levels, they yielded cohort characteristics that worked against demonstration of potential effectiveness of this intervention for improving adherence. ART adherence at BL was already high in both intervention and control arms. This risked ceiling effects that might have limited the ability to demonstrate a change in ART adherence outcomes. It should also be noted that a systematic review of interventions to improve adherence to ART found that multi-focal, rather than single, interventions, as occurred in this trial, showed generally superior effects [29].

The trial was not powered to detect changes in viral suppression, as more than three-quarters of participants had an undetectable viral load at BL. Given that Scott-Sheldon et al.'s systematic review and meta-analysis [27] found that behavioural interventions targeting alcohol use among PLHIV significantly reduced plasma viral load in intervention versus control participants, we expected that an intervention designed to reduce heavy drinking would reduce the proportion of participants in the intervention arm having a detectable viral load. However, this was not the case. As viral load is affected by many other factors, including gender [30] and nutrition [31], it is possible that one or more of these factors reduced the impact of the intervention.

While it took longer than expected to recruit participants into the trial, this is arguably due to the many eligibility criteria that they were required to meet for trial participation. Other studies have demonstrated that a high proportion of patients obtaining HIV care drink excessively and would probably benefit [5]. Furthermore, while strict COVID-19 restrictions on alcohol availability may have led to reductions in alcohol consumption levels, these changes were temporary. Liquor industry data [32] suggest that alcohol consumption now exceeds pre-pandemic levels. This intervention therefore continues to remain relevant for

HIV services in post-pandemic South Africa, should it be implemented as part of routine HIV care.

In terms of strengths, this trial recruited a large sample of PLHIV on ART, had an 86% retention rate across both arms at 6MFU and the intervention was conducted with a high degree of fidelity. However, some limitations should be borne in mind. First, the study was undertaken only in the Tshwane metropole of South Africa and might not necessarily be generalizable to HIV patients on ART elsewhere, although it is unlikely that geographic location would materially influence the findings. This was confirmed by research conducted in the Western Cape [12]. Secondly, the study was limited to only six hospitals further limiting generalizability. Thirdly, due to funding constraints, we were not able to follow-up patients for longer than 6 months, so the persistence of intervention effects beyond 6 months could not be determined. Fourthly, only 73% of participants in the intervention arm received the full dose of the intervention. Fifthly, the statistical evaluation of PEth was underpowered, as we only had a 50% sample due to funding constraints. Furthermore, as a large proportion of the sample had undetectable PEth levels, it was difficult to model this variable as a continuous variable, and this further reduced statistical power. Sixthly, many people in the final sample had full AUDIT scores below 8 due to the use of the AUDIT-C; thus, the study may have been underpowered to detect changes in heavy drinkers. Not having an objective measure of adherence might also have been a weakness of the study. An additional potential limitation is the absence of an equal attention control group following the removal of this arm due to funding constraints. This makes it difficult to determine if the reduction in the volume of alcohol consumed in the intervention arm was simply an artefact of the extra attention given to participants in this arm. A related limitation is that there was no tracking of the kind of usual care received by participants in the TAU arm and, in particular, what help they received to reduce their drinking. The findings may also have been limited by the use of imputation. However, the findings were not meaningfully different from complete case analysis of the primary outcome.

CONCLUSION

This trial has shown that this evidence-based brief intervention can have a significant and clinically meaningful impact on drinking volumes among PLHIV on ART. Additional research is needed to identify barriers to implement this intervention at scale in HIV care settings and to test strategies for overcoming such barriers. Extending the intervention to include an additional focus upon ART adherence might enhance its efficacy for increasing adherence and reducing viral load to undetectable levels.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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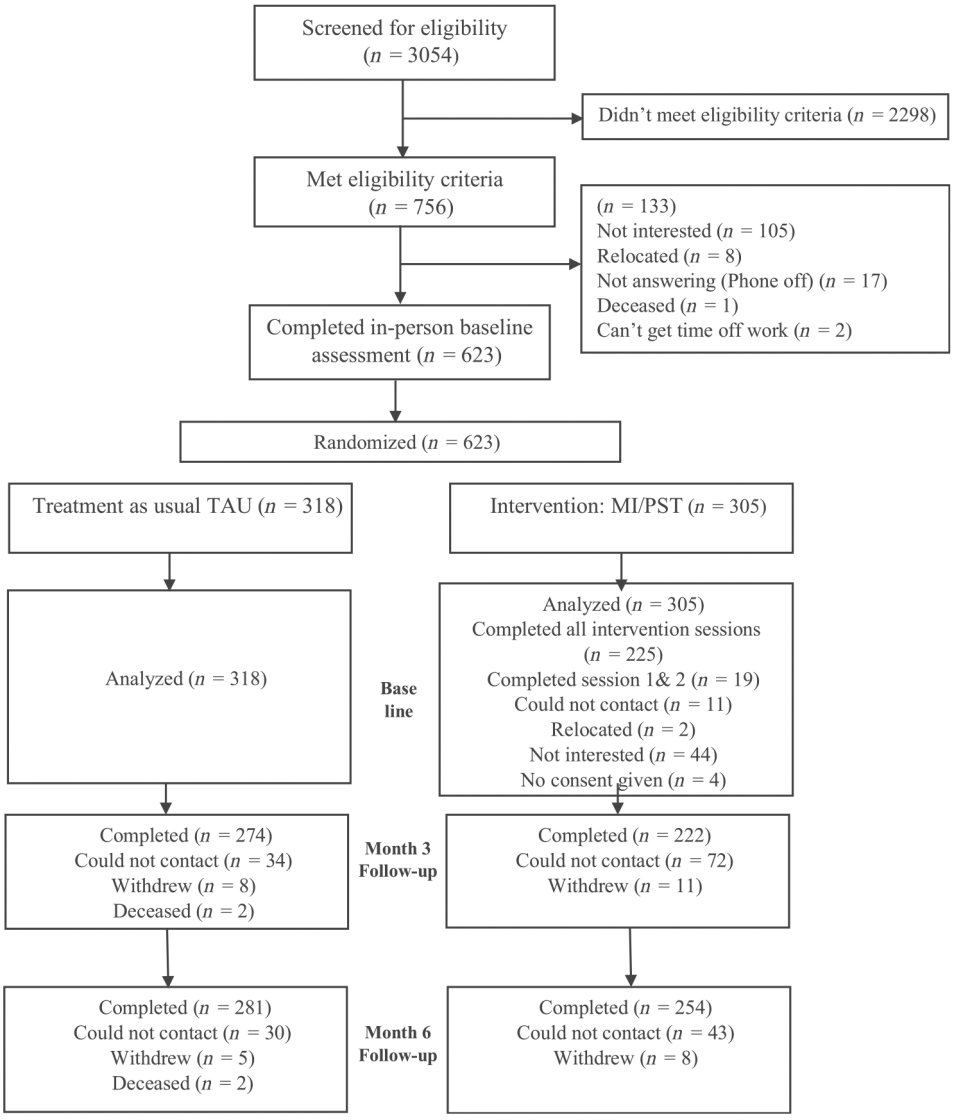

FIGURE 1.

Consolidated standards of reporting trials (CONSORT) flow diagram showing participant flow.

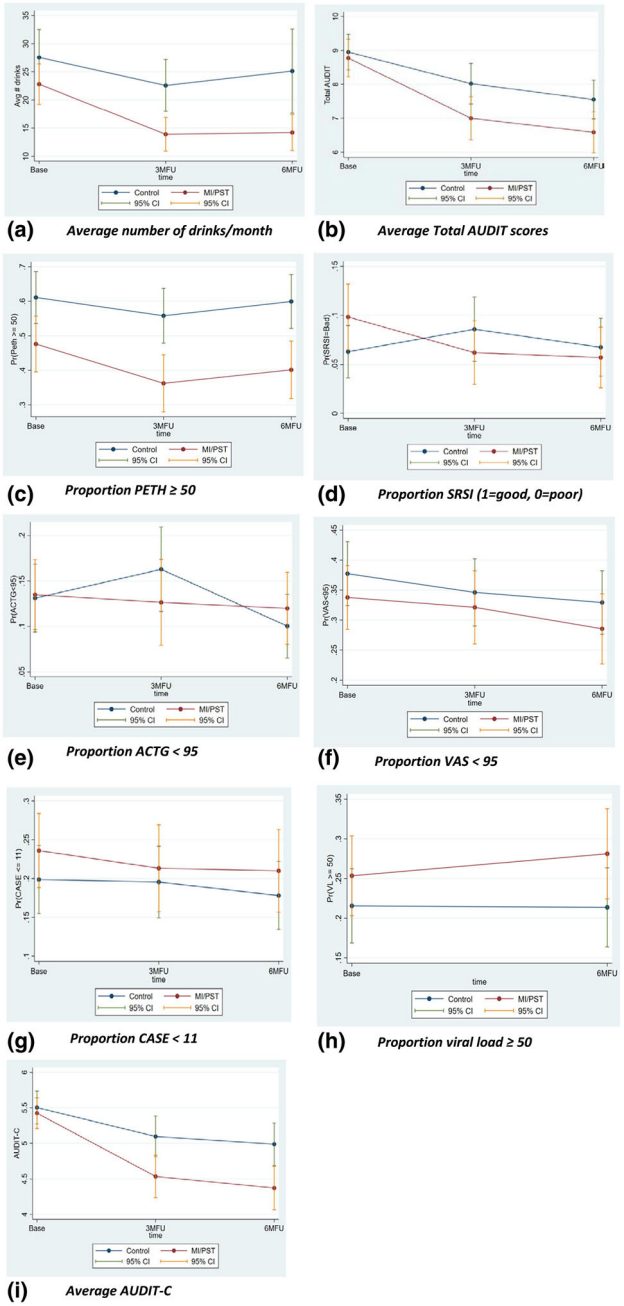

FIGURE 2.

(a–i) Primary and secondary outcomes at baseline, 3- and 6-month follow-up (imputed data).

TABLE 1

Sample demographic characteristics, years on ARVs, outcome variables (baseline, unadjusted).

Variable	Total (*n* = 623)	TAU (*n* = 318)	MI/PST (*n* = 305)
Age: mean (SD)	(40.78; 9.07)	(41.82; 9.14)	(39.70; 8.89)
Gender: *n* (%)			
Male	265 (42.5%)	150 (47.2%)	115 (37.7%)
Female	358 (57.5%)	168 (52.8%)	190 (62.3%)
Education: *n* (%)			
≤ Primary school	79 (12.7%)	43 (13.5%)	36 (11.8%)
Some high school	304 (48.8%)	154 (48.4%)	150 (49.2%)
High school or equivalent	159 (25.5%)	80 (15.2%)	79 (25.9%)
Some post-high school education	81 (13.0%)	41 (12.9%)	40 (13.1%)
Marital status: *n* (%)			
Married/living with someone	228 (36.6%)	113 (35.5%)	115 (37.7%)
Single, divorced, separated, widowed	395 (63.4%)	205 (64.5%)	190 (62.3%)
Employment status: *n* (%)			
Unemployed	264 (42.4%)	126 (39.6%)	138 (45.3%)
Employed part-time (formal sector)	110 (17.7%)	58 (18.2%)	52 (17.1%)
Employed full-time (formal sector)	185 (29.7%)	97 (30.5%)	88 (28.9%)
Self-employed	64 (10.3%)	37 (11.6%)	27 (8.9%)
Own income past 30 days: *n* (%)			
R0–R400	108 (17.3%)	53 (16.7%)	55 (18.0%)
R401–R1600	217 (34.8%)	106 (33.3%)	111 (36.4%)
R1600–R6400	245 (39.3%)	131 (41.2%)	114 (37.4%)
R6400 or more	53 (8.5%)	28 (8.8%)	25 (8.2%)
Years on ARVs: *n* (%)			
0 to ≤ 4	148 (24.0%)	69 (22.0%)	79 (26.1%)
4 to ≤ 7	175 (28.4%)	88 (28.1%)	87 (28.7%)
7 to ≤ 9	131 (21.3%)	68 (21.7%)	63 (20.8%)
9 or more	162 (26.3%)	88 (28.1%)	74 (24.4%)
Number of drinks consumed on a typical drinking day past 3 months: mean (SD)	7.10 (2.71)	7.19 (2.75)	7.01 (2.66)

Variable	Total (*n* = 623)	TAU (*n* = 318)	MI/PST (*n* = 305)
Number of drinks consumed on a typical drinking day past 3 months: *n* (%)			
1 or 2	31 (5.0%)	18 (5.7%)	13 (4.3%)
3 or 4	75 (12.0%)	37 (11.6%)	38 (12.5%)
5 or 6	243 (39.0%)	117 (36.8%)	126 (41.3%)
7 to 9	168 (27.0%)	89 (28.0%)	79 (25.9%)
10 or more	106 (17.0%)	57 (17.9%)	49 (16.1%)
Weekly or daily (almost daily) drinking of 6 or more drinks per occasion: *n* (%)	61 (10.3%)	33 (10.9%)	28 (9.6%)
AUDIT total score: mean (SD)	8.86 (4.74)	8.95 (4.67)	8.77 (4.82)
PEth scores (for 50% of participants)			
PEth ≥ 50 mg/ml: *n* (%)	142 (46.0%)	64 (39.5%)	78 (53.1%)
PEth < 50 mg/ml: *n* (%)	167 (54.1%)	98 (60.5%)	69 (46.9%)
Viral load: *n* (% < 50 copies/ml)	448 (76.6%)	233 (78.5%)	215 (74.7%)
Adherence measures			
Visual analog scale—overall: mean (SD)	(92.41; 13.49)	(92.14; 14.11)	(92.70; 12.82)
Total adherence ratio (ACTG): mean (SD)	(0.95; 0.15)	(0.95; 0.15)	(0.95; 0.14)
CASE adherence index: mean (SD)	(13.18; 2.93)	(13.22; 2.94)	(13.14; 2.93)
Self-rating scale item (SRSI): mean (SD)	(4.07; 1.05)	(4.08; 1.01)	(4.06; 1.09)

Abbreviations: ACTG = AIDS Clinical Trials Group; ART = antiretroviral therapy; AUDIT = Alcohol Use Disorders Identification Test; MI = motivational interviewing; PST = problem-solving therapy; TAU = treatment as usual; PEth = phosphatidylethanol; CASE = Center for Adherence Support Evaluation; SD = standard deviation.

TABLE 2

Comparison of intervention (MI/PST) to control (overall) for method 1 (adjusted for missingness).

	Method 1[a]					
	3-month follow-up versus baseline			6-month follow-up versus baseline		
Variable	**Estimate**	**95% CI**	***S*-value**	**Estimate**	**95% CI**	***P*-value**
Primary outcome						
Ave # drinks/month[b]				−0.410	−0.670; −0.149	0.002*
Secondary outcomes						
Ave # drinks/month[b]	−0.226	−0.475; 0.023	0.075			
Total AUDIT	−0.956	−1.703; −0.209	0.012*	−0.886	−1.622; −0.150	0.018*
PEth ≥ 50[c]	−0.894	−1.696; −0.091	0.029*	−0.661	−1.312; −0.01	0.047*
SRSI[d]	−0.726	−1.515; 0.064	0.072	−0.365	−1.147; 0.418	0.361
ACTG < 95	−0.411	−1.008; 0.185	0.177	0.086	−0.480; 0.651	0.767
VAS < 95	−0.067	−0.489; 0.354	0.755	−0.252	−0.674; 0.170	0.242
CASE < 11	−0.028	−0.527; 0.471	0.912	0.058	−0.416; 0.532	0.812
Viral load ≥ 50				0.356	−0.174; 0.886	0.188
AUDIT-C	−0.507	−0.877; −0.136	0.007*	−0.550	−0.956; −0.145	0.008*

Abbreviations: ACTG = AIDS Clinical Trials Group; AUDIT = Alcohol Use Disorders Identification Test; SRSI = Self-Rating Scale Item; VAS = Visual Analogue Scale; PEth = phosphatidylethanol; CI = confidence interval; MI/PST = motivational interviewing/problem-solving therapy; CASE = Center for Adherence Support Evaluation.

[a]Method 1: longitudinal models (generalized estimated equations) modelled across all time-points, with time × treatment interaction. Effect reported: interaction effect between time and treatment group at both follow-up points, essentially the difference in change from baseline to follow-up (on log scale for non-normal outcomes), adjusted for gender, age, marital status, education and site.

[b]Estimates are parameter estimates on log scale.

[c]50% of participants, assessed at baseline, 3 months and 6 months.

[d]Binary (poor = 1).

[e]Assessed at baseline and 6 months.

*P < 0.05.

TABLE 3

Comparison of intervention (MI/PST) to control (overall) (AUDIT≥ 8) for method 1 (adjusted for missingness).

	Method 1[a]					
	3-month follow-up versus baseline			**6-month follow-up versus baseline**		
Variable	**Estimate**[b]	**95% CI**	***P*-value**	**Estimate**[b]	**95% CI**	***P*-value**
Primary outcome						
Ave # drinks/month				−0.454	−0.797; −0.110	0.010 *
Secondary outcomes						
Ave # drinks/month	−0.333	−0.643; −0.023	0.035 *			
Total AUDIT	−1.344	−2.454; −0.235	0.018 *	−1.291	−2.414; −0.168	0.024 *
PEth > 50[c]	−0.500	−1.662; 0.662	0.399	−0.662	−1.685; 0.361	0.205
SRSI[d]	−0.99	−2.002; 0.023	0.055	−0.434	−1.492; 0.625	0.422
ACTG < 95	−0.325	−1.015; 0.365	0.355	0.044	−0.794; 0.0881	0.918
VAS < 95	0.012	−0.595; 0.618	0.970	0.081	−0.504; 0.665	0.787
CASE < 11	−0.096	−0.764; 0.571	−0.778	−0.271	−0.933; 0.390	0.422
Viral load ≥ 50				0.208	−0.556; 0.971	0.594
AUDIT-C	−0.826	−1.364; −0.289	0.003 *	−0.754	−1.341; −0.167 *	0.012 *

Abbreviations: ACTG = AIDS Clinical Trials Group; AUDIT = Alcohol Use Disorders Identification Test; PEth = phosphatidylethanol; SRSI = Self-Rating Scale item; VAS = Visual Analogue Scale; CASE = Center for Adherence Support Evaluation; MI/PST = motivational interviewing/problem-solving therapy; CI = confidence interval.

[a]Method 1: longitudinal models (generalized estimated equations) modelled across all time-points, with time × treatment interaction. Effect reported: interaction effect between time and treatment group at both follow-up points, essentially the difference in change from baseline to follow-up on log scale, adjusted for gender, age, marital status, education and site.

[b]Estimates are parameter estimates on log scale.

[c]50% of participants, assessed at baseline, 3 months and 6 months.

[d]Binary (poor = 1).

[e]Assessed at baseline and 6 months.

*$P < 0.05$.