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Efficacy of a single, brief alcohol reduction intervention among men and women living with HIV/AIDS and using alcohol in Kampala, Uganda; a randomized trial

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Abstract

Objective—We evaluated the efficacy of a brief motivational intervention (MI) counseling in reducing alcohol consumption among persons living with HIV/AIDS (PLWHA) in Kampala-Uganda.

Methods—PLWHA attending an outpatient HIV clinic with alcohol disorders identification test-Consumption component (AUDIT-C) score   3 points were randomized to either standardized positive prevention counseling alone or in combination with alcohol brief MI counseling. Mean change in AUDIT-C scores over 6 months were compared by treatment arm.

RESULTS—The mean (SD) AUDIT-C scores were 6.3(2.3) and 6.8(2.3), for control and MI arms (p=0.1) at baseline and change in mean AUDIT-C score was not statistically different between the treatment arms over the 6 months follow up time (P=0.8).

CONCLUSION—There was a non-differential reduction in alcohol consumption in both intervention and control arms. Standard positive prevention counseling should be provided to all PLWHA who use alcohol. Studies with more than one counseling session need to be evaluated.

Clinical trials.gov **trial identifier:** NCT01802736.

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INTRODUCTION

By end of 2014, nearly 37 million people were living with HIV/AIDS globally of which 25.8 million were in the Sub-Saharan Africa (SSA) region[1]. SSA countries have per capita alcohol consumption levels that are well above the global average of 6.2 liters of pure alcohol per year[2]. With the high prevalence of both HIV/AIDS and excessive alcohol consumption in SSA, it is not surprising that there is a high prevalence of alcohol use among PLWHA[3–5].

Alcohol use increases the risk for acquisition and transmission of HIV[6,7], while specifically in PLWHA, alcohol use is associated with delayed entry and poor retention in care[8,9], reduced adherence to antiretroviral therapy (ART)[10], increased risky sexual behaviors[11], impaired immunological and virological response to ART[12,13]. Therefore, interventions to reduce alcohol use among PLWHA could lead to improvement in HIV treatment outcomes and potential reduction in further HIV transmission risk[14].

Hazardous alcohol use, a pattern of drinking that increases the risk of harmful consequences[15], is traditionally treated with brief interventions (usually lasting less than 30 minutes a session) over 1 to 6 sessions to prevent development of harmful alcohol problems including alcohol dependence[16].

Several brief alcohol reduction interventions have been tested in PLWHA, however, most were done in high-income settings mainly in North America[17,18]. Findings from some trials show effective reduction in alcohol consumption, while others show no effect[19]. These findings may not be generalizable to SSA, where fewer studies have been done. A study conducted in Kenya showed that 6 sessions of cognitive behavioral therapy (CBT) resulted in significant reduction in percentage of alcohol drinking days among subjects in the CBT arm compared to the controls who received the standard usual care[20]. Another trial done among tuberculosis infected subjects in south Africa, of whom 54% where HIV infected showed that the information-motivation-behavioral skills intervention counseling was not more effective that an education leaflet given to participants[21]. With these few studies conducted, the effectiveness of brief alcohol reduction interventions among PLWHAs in SSA is not yet clearly known hence the need for additional studies among HIV infected alcohol drinkers[22–24].

Among the different brief alcohol reduction interventions, Motivation intervention(MI) is one of the most efficacious interventions for hazardous alcohol use[25]. MI is a form of directive client centered counseling approach that enhances the motivation to reduce alcohol use by helping the participants clarify and resolve their ambivalence about reducing alcohol use[26]. MI may be provided as a single session with a view that once subjects get motivated, they proceed to mobilize within themselves their own change resources without additional training in behavior change skills. The ability to deliver MI in a single session makes it particularly attractive in SSA which has a heavy workload in a setting of limited health care workers[27]. We evaluated the efficacy of a single brief Motivation Intervention (MI) counseling session on reduction of hazardous alcohol consumption among PLWHA not seeking alcohol-use care in Kampala Uganda.

METHODS

Study design, setting and population

This was a randomized trial (clinical trials.gov trial identifier NCT01802736) among HIV infected participants not seeking treatment for alcohol use. The study was conducted at the Adult Infectious Diseases Institute clinic (AIDC) located within the Mulago National referral and teaching hospital complex in Kampala Uganda. Details of the clinic population and services have been published previously[5]. This clinic has not had any prior alcohol intervention trials.

Enrollment procedures

To achieve a representative sample, every 15th patient returning for a clinic appointment was initially assessed for eligibility to participate in the screening for alcohol consumption. Participants were eligible for alcohol screening if they were; i) aged   18 years, ii) planning to continue receiving care or be followed up at the AIDC for the next 6 months and, iii) willing to provided written informed consent. Participants were excluded if they were very sick with Karnofsky clinical performance score <50 or if they were pregnant.

All participants fulfilling the initial screening were evaluated for alcohol consumption using the 10-item Alcohol Use Disorders Identification Tool (AUDIT) by a trained nurse-counselor, not involved in provision of routine care, in a private non-treatment/consultation room. The sum of the first 3 questions of the AUDIT questionnaire that capture alcohol consumption frequency, quantity and binge drinking, referred to as AUDIT-C, were used to screen for hazardous alcohol use[28,29]. The AUDIT-C tool has a minimum score of 0 and maximum score of 12 points. Participants with an AUDIT-C score of 3 and above were enrolled into the study.

In addition to the AUDIT interview, additional alcohol consumption evaluations were conducted on enrolled participants using alcohol Timeline Follow-back (TLFB) method to record days on which alcohol consumption occurred or did not occur within 30 days preceding the interview. The types and brand of alcohol consumed, on a typical drinking day was also collected. Information on socio-demographics, HIV treatment history, and alcohol consumption was also collected. Specifically data on participant age, sex, marital status, religion, highest educational level, employment status and income in the last month were collected. Participants were evaluated for depression using the 10-item Center for Epidemiology Studies on Depression tool (CESD-10). HIV clinical data including, HIV/ AIDS clinical stage, ART receipt status, and CD4 cell count were abstracted from clinic records. Self-reported adherence to medication in the last one month was assessed in both ART and non-ART receiving subjects using a visual analog scale ranging from 0–100 with 0 representing all prescribed treatment (ART or co-trimoxazole for those not yet on ART) not taken while 100% representing no missed medication.

Randomization and treatment allocation

Participants with an AUDIT-C score   3 were randomized to one of two study arms (standardized positive prevention counseling alone or standardized positive prevention

counseling plus MI counseling). The randomization was based on a computer generated random numbers using permuted blocks of 6, 8 and 10 for an overall total of 15 blocks and assigned to the 2 arms randomly in a 1:1 ratio. Participants were randomized using previously prepared, consecutively numbered, opaque, sealed envelopes. Inside the envelopes was a written paper marked with the treatment arm assignment. Treatment allocation was done by the study nurse who provided assessment interview by opening the next sequentially numbered sealed opaque envelope to reveal the participant's study arm. The participant was then taken to the respective counselor to receive their assigned counseling.

Study interventions

Both the control and intervention were designed with consultation of a psychologist and social scientist and were administered on the same day after the enrollment interview to subjects who had scored 3 points on the AUDIT-C. The goal of the treatments was to reduce alcohol use to as low as possible and to abstinence for participants who wished to subsequently abstain from it. The treatments were administered by different study personnel with two counselors dedicated exclusively to each treatment arm.

The intervention arm received the standardized "positive prevention" information and advice and in addition, received a single brief alcohol counseling session lasting between 20–30 minutes based on MI style. During the counseling sessions, the counselor reflectively listened to the participant elaborate their alcohol use, reaffirmed the issues surrounding the alcohol use, and inquired about the participants' plans to reduce alcohol use. The counselor strived to elicit, from the participant, the possible benefits and harms of not cutting down on their alcohol, what they have done along the way to try and cut down if any, what made them fail and what they are willing to do about those previous attempts to cut down. The counselor summarized the issues as presented by the participant, recognized and commended their efforts in trying to reduce their alcohol use, as well as corrected any misinformation that may have arisen. The participant then set a personal goal, of what they plan do for the next 6 months in reducing their alcohol use.

The active control arm received only a one on one set of standardized "positive prevention" information and advice lasting between 10–30 minutes delivered by a trained counselor. The "positive prevention" messages covered the following: how to prevent opportunistic infections, nutritional advice, supporting adherence to medications, encouraging HIV disclosure to sexual partners, safer sex practices including condom and contraceptive use, preventing sexually transmitted infections as well as avoiding alcohol and substance use. The counselor informed the participant the risks of alcohol use and encouraged them to reduce alcohol intake. After the counseling, participants were provided information on when they will be seen again and they proceeded to attend the other routine clinic procedures.

Follow up study assessments

At the follow-up visits, at 3 and 6 months post enrollment, participants' alcohol use that occurred since they were last seen was collected using the same methods as at baseline with modification of AUDIT to reflect a shorter inter-visit period of 3 months.

Implementation, training and support

The treatments were provided by minimum of bachelor's degree trained counselors and all had > 5 years clinical experience in HIV clinical counseling strategies but not alcohol counseling experience. Counselors received induction training and individual ongoing support. A training workshop specifically on treatment administration as well as receiving a treatment manual for the contents and mode of administration of counseling messages were done. There was role playing for potential participant presentations specifically for the MI arm and guidance how the counselor would proceed. During study implementation, there was one refresher training to emphasize adherence to treatment protocols. We carried out no formal assessment of treatment adherence and fidelity.

Statistical analysis

We aimed to test the hypothesis that the brief motivational intervention will result in greater reductions in AUDIT-C scores compared to the control arm. Results from a prior cross-sectional study showed the AUDIT-C standard deviation = 2.6[5]. In order to detect the minimum difference in mean AUDIT-C score of at least 1 point or more between study arms over 6 months and setting the power at 90 %, using a two sided test and an alpha level =0.05, and allowing for a 10% loss to follow up, 160 subjects were needed per study arm.

Data were collected on paper forms and double entered in a customized Microsoft access database (Microsoft Corp. Redmond WA). Statistical analyses were carried out using SAS V. 9.1.3 (SAS institute, Cary, NC) based on intention to treat principal, and a p-value < 0.05 was considered statistically significant.

Descriptive characteristics of the study population were summarized as means (Standard deviation, SD) and medians (interquartile range, IQR) for continuous variables and as percentages for categorical variables. Baseline characteristics were compared by treatment arm using chi-square test for categorical outcomes and t-tests or Wilcoxon test for continuous outcomes respectively. Baseline descriptive characteristics were compared by treatment arm using chi-square test for categorical outcomes and t-tests or Wilcoxon test for continuous outcomes respectively.

To assess study participation and attrition, the proportion of participants seen and those not seen at follow-up are calculated and reasons for missing are summarized. Because not all subjects returned for both follow-up visits, we tested for baseline factors associated with the probability of not having both follow-up visits (versus having two follow-up visits) using logistic regression methods.

Using known alcohol concentrations of both commercial and locally brewed alcoholic drinks taken on a typical drinking day[30], we calculated quantity of alcohol in grams (except for the communally served and shared drinks because an individual's approximate volume consumed couldn't be ascertained), consumed on typical day and converted them to United States equivalent standard drinks of ethanol by dividing by 14 grams.

The primary outcome, mean AUDIT-C score, was compared using the independent samples t-test by treatment arm at each study visit. Furthermore, the mean AUDIT-C score at 3 and 6

months within each treatment arm was compared with the mean baseline AUDIT-C using the dependent samples t-test. The difference in the AUDIT-C score between 6 months and the baseline were calculated for each subject and categorized as a reduction in alcohol use frequency and volume if the difference less than 0 or no reduction if the AUDIT-C difference was   0 points.

To assess the intervention effect over time, we used linear mixed effects model with the AUDIT-C score as the outcome, treatment arm by follow up time interaction, fixed effect of baseline AUDIT-C and follow-up time while the random component consisted of a random intercept for each subject and a random slope that allows the correlations between the repeated AUDIT-C measurements to vary over the follow-up time.

To examine gender differences in the intervention effects, we constructed separate linear mixed effects model in the strata created by gender.

A set of secondary outcomes, namely proportion of participants with full AUDIT score   8 points, median number of drinking days in the last one month, average number US equivalent standard drinks of alcohol consumed on a typical drinking day were compared between the treatment arms at the 3 and 6 months visit using chi-square, Wilcoxon rank sum, and student-t independent samples tests.

To examine the robustness of our primary findings to missing data or categorical outcome variable, a set of two sensitivity analyses were conducted. The primary linear mixed model was rerun after multiple imputation of missing data. Because we had non-monotone missingness, we used the Markov Chain Monte Carlo method to create 20 imputed datasets that were further analysed as the primary outcome analysis and their results combined using the *proc MIanalyse* function in SAS.

Ethics statement

The study was approved by the scientific review committee of the Infectious Diseases Institute, the Makerere University School of Public Health Research and Ethics Committee and the Uganda National Council of Science and Technology. The trial was registered on the United States clinical trials registry trial identifier NCT01802736. All subjects provided individual written informed consent and received no monetary compensation for participation.

RESULTS

Descriptive characteristics

Between August 2013 and April 2014, 1,253 subjects were approached, of whom 982 (78.4 %) fulfilled the initial eligibility criteria and were screened for alcohol use. Of these, 342 (34.8%) subjects scored 3 or more points on the AUDIT-C test of which 337 accepted and were randomized to the two study arms (Figure 1).

The median (interquartile range, [IQR]) age of the enrolled participants was 39 (32–46) years, 221 (65.6%) were males, 303 (89.9%) were employed and 258 (76.6%) were

receiving ART. Baseline characteristics were similar in the two arms (table 1), except the median CD4 cell count which was higher in intervention arm 424(288–567) compared to the control arm 363 (264–480) cells/µl, p < 0.001. The mean AUDIT-C score at baseline were comparable in the treatment arms, (6.4 SD 2.2 in the control and 6.8 SD 2.3) in the intervention arms respectively, p= 0.099).

The mean AUDIT-C score at baseline were comparable in the treatment arms, i.e 6.4 (standard deviation [SD] 2.2) in the control and 6.8 (SD 2.3) in the intervention arms respectively, p= 0.099.

A total of 286/337 (84.9 %%) participants returned for the 3-month visit and 321 (95.3%) returned for the 6-month visit (fig. 1). Overall, 304 (90.2%) returned for at least one follow-up visit while 280 (83.1%) returned for both follow-up visits. There was a statistical trend for subjects with baseline full AUDIT scores above 8, not completing both follow up visits, (OR= 1.9, 95% CI 0.96–3.75, p=0.06). The odds of not completing both follow up visits were 14% higher for every one point increase in baseline AUDIT-C scores. The odds of not completing both follow-up visits did not differ by treatment arm, subject characteristics, CD4 level or adherence level.

Change in alcohol consumption over time

There was an overall reduction in the mean AUDIT-C score in the 6 months of follow up (from 6.4 to 3.4 [p< 0.0001] in the control arm and 6.8 to 3.9 (p= 0.001) in the intervention arm).

The decline in both arms was greatest in the first 3 months after the counseling (table 3). The mean AUDIT-C score at 3 months was significantly lower in the control arm compared to the interventional arm (control group 3.5 [SD 3.0] versus 4.3 [SD 3.0] in the interventional group p=0.034) (table 2), however, the mean scores were not different between groups at 6 months (control group 3.4 [SD 3.0] versus 3.9 [SD 3.0] in the interventional group p=0.141).

There was no significant difference in mean AUDIT-C change over the 6 months follow-up time between the intervention and the control arms, mean AUDIT-C difference of the differences = −0.07, 95% CI −0.70 – 0.56, p= 0.8266 (table 3).

The proportion of participants with mean AUDIT-C scores   3 was significantly lower in the control group compared to the interventional arm at 3 months (58.5% in control group versus 71.5% in interventional group p=0.019) and at 6 months (57.2% in control group versus 70.2% in interventional group p=0.024).

Overall, 354/610 (58%) of the person-visits had reduction in AUDIT-C scores, with no differential AUDIT-C reduction by arm, that is 180/304 (59.2%) persons-visits in the intervention arm and 174/306(56.9%) in the control arm (p=0.56). The majority, 22/354(62.7%) of the reductions occurred in the first 3 months, with the remaining 132/354(37.3%) occurring between the 3 and 6 months visit. There was no statistically significant difference in the proportion of participants who had a reduction in AUDIT-C score between the baseline and month six visit in intervention arm 128/157(81.5%) versus control 121/157 (77.1%) arm, (p= 0.3296).

Gender stratified mixed effects model showed that mean difference in AUDIT-C change over time was not different by treatment arm among males (0.38, 95%CI –0.41–1.17, p= 0.3493) while among females, the MI arm had greater AUDIT-C reductions compared to control arm (–1.10, 95% CI –2.19 – –0.02, p=0.0457).

Although the median drinking days were not different between arms at baseline, (6.0 in control versus 7.0 in intervention group), the drinking days were significantly lower in the control group compared to the interventional group (3.0 in control versus 4.0 in intervention group). However, no difference was observed in median drinking days between the two arms at 6 months of follow up. A similar trend was observed in the mean number of drinks consumed (table 2).

DISCUSSION

Identifying an efficacious single session brief alcohol intervention would greatly reduce the consequences of hazardous alcohol consumption among PLWHA in SSA. Brief alcohol interventions, especially those limited to a single session that can be integrated into routine care, are advantageous for resource-limited settings[31]. In this trial we observed significant reductions in alcohol consumption after a single brief counseling session among HIV infected men and women consuming alcohol at hazardous levels and not seeking treatment for alcohol use in Kampala, Uganda. The greatest reductions in alcohol use were in the first 3 months after the intervention. There were minimal reductions observed between the 3 and 6 months interval. The proportion of participants with reduction in AUDIT-C scores was higher but the difference was not statistically significant in the intervention arm compared to the active control arm. Similarly there was no statistically significant difference in mean change in AUDIT-C scores 6 months following the intervention and control treatment counseling. The trial shows that MI counseling did not result in greater reductions in alcohol consumption over and above the standard of care positive prevention counseling among HIV infected persons with hazardous alcohol use.

Our study is one of the few studies in SSA that has attempted to reduce alcohol consumption among PLWHA not seeking care for their alcohol use and increases our understanding of alcohol use interventions in this setting. Moreover our use of random allocation of treatment and a single MI session is in line with the *mesa grande* recommendations[25].

Despite evidence from systematic reviews demonstrating support for the use of brief alcohol interventions and motivational interviewing in primary care settings to reduce both alcohol use and related behaviors[32,33] we did not observe similar results among PLWHA in Uganda. The difference in the findings is that the studies included in the reviews used participants whose HIV status was either unknown, or HIV un-infected and were from settings of low HIV prevalence while this study was exclusively among HIV positive participants enrolled in clinical care. In the few trials conducted among PLWHA, similar findings of no effect of the intervention were observed by Samet *et al* in 151 PLWHA in Boston,[34] and two other trials, one by Gilbert *et al* using the "Video doctor" and by Parsons *et al* using cognitive behavioral and skills training demonstrated no difference in alcohol consumption in the interventional group compared to standard of care after 6 months[19,35].

In fact, a synthesis of interventions among only PLWHA by Brown and colleagues concludes that the reviewed studies provided mixed results on reduction in both alcohol frequency and quantity between the intervention and comparison conditions with six of the studies demonstrating significant reductions in alcohol frequency and quantity between the intervention and comparison conditions and the other six showing no significant interventions effects.[36] Among the studies with efficacious intervention effects, is one study done in a typical SSA large outpatient HIV clinic in western Kenya, recruited HIV infected hazardous/binge drinkers, using 6 sessions of cognitive behavioral therapy, delivered by para-professionals resulted in greater alcohol reductions in the intervention compared to a standard of care control[20]. Another trial by Velasquez et al, among HIV infected men who have sex with men, participants randomized to 4 session of motivational interview counseling significantly reduced their number of drinks as well as heavy drinking in the last 30 days compared to the controls who received educational material only[37]. The difference between this trial and our trial is that the intervention was provided in more than one session and effects were assessed after a short time interval of 30 days. Indeed, our trial shows that the reductions in alcohol consumption are realized within the first few months closest to the intervention(s)[37]. A more recent trial among only HIV infected women showed that 2 sessions of brief intervention resulted in a 58% reduction in the 90-days alcohol consumption frequency over 12 months in the intervention arm[38].

The marked but non differential reductions in alcohol consumption as measured by AUDIT-C suggests that both the intervention and control had equally "partially effective components"[39] because our "active" control arm also received one on one counseling messages unlike other studies that use patient leaflets in the control arm.

Prior research has shown that participation and answering alcohol assessment questions may lead in reduced reporting of drinking behavior, mainly due to self-reflection and/or assessment reactivity to alcohol related questions[40]. These effects therefore may have distorted the measured intervention effects and could account for the lack of effect noted in our study. However, it is not possible to determine whether these effects occurred and whether any such effects were differential by treatment arm.

We observed differential intervention effects by gender, with a statistically significant effect of MI only among female participants. This suggests a possible gender interaction effects, although our study was not powered to test the significance of this interaction. It is possible that the men were not satisfied with the one on one counseling style as has been previously proposed in a study conducted in south Africa[41]. Additional studies are required to confirm this apparent beneficial effect of MI among only women.

These results need to be interpreted in the context of the following limitations. We used self-reported measures of alcohol consumption which may be prone to recall and social desirability response biases. The best way to validate the self-report would be to use alcohol biomarkers; however this was not feasible at the time the study commenced and we believe that our use of the timeline follow-back method aided in alcohol use recall[42]. Although we conducted baseline alcohol assessment interviews prior to randomization, we are not able to ascertain whether there was any differential bias in reporting alcohol use by study arm

during the follow-up period. Biomarkers have revealed differing drinking results as compared to self-report (*Hahn et al in press*), therefore future studies in this setting should consider their use.

Although we did not provide an objective assessment to fidelity of the intervention, we provided pre-implementation training, study treatment manuals and continuous implementation support to ensure that the interventions were provided as per the protocol. The duration of follow-up may have been short to comprehensively ascertain the effects of the counseling programs and therefore we may have recorded only the short term efficacy of the counseling programs. We did not expect a longer effect with a single counseling. We observed most of the reductions in the first 3 months, probably an indicator that a single counseling session effects may not be maintained over a longer duration. Therefore, future studies may need to consider addition of booster counseling sessions.

Our findings are from a single HIV clinic thus may not be generalizable; however, this clinic has a patient population that is similar to a typical patient population of PLHWA in SSA[43].

Based our findings and from literature on interventions for alcohol use among PLWHA, a single session of MI may not result in significantly greater reduction in alcohol use frequency and quantity over six months as compared to general positive prevention counseling in HIV clinics. Therefore, strengthening and standardizing the current positive prevention messages to always include alcohol reduction information to is a feasible and should be taken up in current HIV clinical practice. These counseling messages are easily administered by trained routine care provider (rather than a specialist counselor) and are brief allowing for incorporation into routine clinical care.

It is possible that more interventional effects may be demonstrated with repeated MI sessions in PLWHA with hazardous alcohol use more so among female subjects. Therefore, a larger trial, designed to address the apparent gender interaction, providing additional counseling sessions and longer follow-up evaluations possibly supported with innovative interactive telephony and technology support and objectively assess alcohol consumption using biomarkers is needed. In addition, identification of determinants and mediators of treatment response and the best measures of motivation to reduce alcohol use and how these measurements should be assessed in subsequent studies and practice on the treatment of alcohol use among PLWHA in SSA

Acknowledgments

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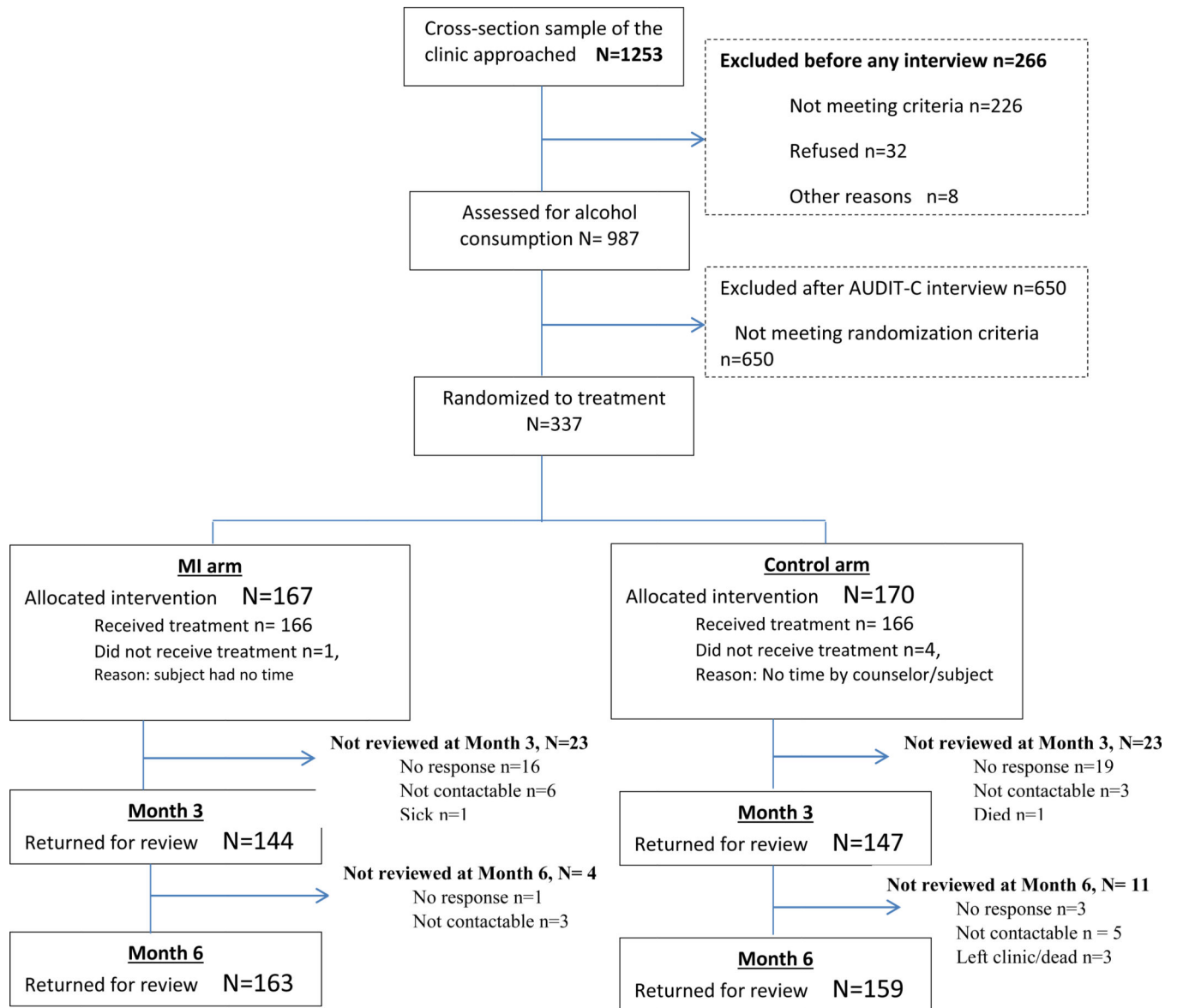
Figure 1.
Trial profile of PLWHA enrolled in the Alcohol intervention trial at the Infectious Diseases institute, Kampala Uganda.

Table 1

Baseline Characteristics of PLWHA by treatment allocation group, enrolled in the ASK trial, Kampala Uganda

Characteristic	All subjects N (%) 337	Control arm N (%) 170(50.5)	Intervention arm N (%) 167(49.5)
Median Age (years, IQR)	39(32–46)	40(32–45)	39(31–46)
Gender			
Male	221(65.6)	113(66.5)	108(64.7)
Female	116(34.4)	57(33.5)	59(35.3)
Education Level			
Primary or less	167(49.6)	74(43.5)	73(55.7)
Secondary level	129(38.3)	73(42.9)	56(33.5)
Tertiary / diploma	41(12.2)	23(13.5)	18(10.8)
Religion ~			
Roman Catholic	152(45.4)	65(38.5)	87(52.4)
Anglican	152(45.4)	85(50.3)	67(40.4)
others: Pentecostal/Muslim	31(9.2)	19(11.2)	12(7.2)
Income in last Month			
< 20 USD	55(16.3)	27(15.9)	28(16.8)
20–400 USD	254(75.4)	130(76.5)	124(74.3)
> 400 USD	24(7.1)	11(6.5)	13(7.8)
Declined	4(1.2)	2(1.2)	2(1.2)
Paid employment			
Yes	303(90.2)	154(91.1)	149(89.2)
No[1]	33(9.8)	15(8.9)	18(10.8)
Marital status			
Single/Never Married	36(10.8)	14(8.4)	22(13.2)
Married/Cohabiting	185(55.4)	90(53.9)	95(56.9)
Single/Separated//Widowed	113(33.8)	63(37.7)	50(29.9)
HIV/AIDS Clinical Stage			
I & II	145(44.3)	71(42.8)	74(46.0)
III & IV	182(55.7)	95(57.2)	87(54.0)
CD4 Cell count *Median (IQR) cells/mm3*	382(276–509)	363(264–480)	424(288–567)
Receiving ART			
Yes	258(76.6)	134(78.8)	124(74.3)
No	79(23.4)	36(21.2)	43(25.8)
Adherence to Medication&			
< 95%	115(34.2)	59(34.7)	56(33.5)
95%	222(65.9)	111(65.3)	111(66.5)
CESD-10 score			

Characteristic	All subjects N (%) 337	Control arm N (%) 170(50.5)	Intervention arm N (%) 167(49.5)
< 10 points	247(73.3)	125(73.5)	122(73.1)
10 points	90(26.7)	45(26.5)	45(27.0)
Baseline AUDIT-C score *Mean (standard deviation)*	6.6(2.3)	6.3(2.3)	6.8(2.3)
Median (IQR)	6.0 (5.0–8.0)	6.0(5.0–8.0)	6.0(5.0–8.0)
Mean (standard deviation) baseline full AUDIT Score	11.3(6.2)	11.1(6.2)	11.4(6.2)
Full AUDIT score category			
< 8	106(31.4)	56(32.9)	50(29.9)
8	231(68.5)	114(67.1)	117(70.1)
Mean (standard deviation) Number of drinking days in last one month	9.1(8.9)	8.5(8.4)	9.8(9.3)
Median (IQR) Number of US standard drinks taken on typical drinking day	4.8(4.0 – 7.0)	4.8(4.2–7.0)	4.8(4.0–6.4)

Table 2

Baseline, 3 and 6 months visits' alcohol consumption outcomes of PLWHA enrolled in the alcohol trial, Kampala Uganda.

Outcome	variable	N	Control arm	N	Intervention arm	p-value
Mean AUDIT-C score	Baseline	170	6.4(2.2)	167	6.8(2.3)	0.0989
	3 months	147	3.5(3.0)	144	4.3(3.0)	0.0339
	6 months	159	3.4(3.0)	161	3.9(3.0)	0.1407
Proportion of subjects with AUDIT-C ≥3	Baseline	170	170(100)	167	167(100)	1.000
	3 months	147	86(58.5)	144	103(71.5)	0.0199
	6 months	159	91(57.2)	161	113(70.2)	0.0244
Mean (STTDEV) US standard drinks taken on a typical drinking day in the preceding 3 months (standard drink=14g)	Baseline	153	6.0(3.0)	151	5.8(2.7)	0.5688
	3 months	105	5.2(2.4)	117	6.0(3.4)	0.0309
	6 months	127	5.7(3.2)	134	6.0(2.8)	0.3597
Median drinking days in last one month(Median IQR)	Baseline	170	6.0(2.0–11.0)	167	7.0(2.0–13.0)	0.2934
	3 months	147	3.0(0.0–7.0)	144	4.0(1.0–9.0)	0.0508
	6 months	159	3.0(0.0–10.0)	163	5.0(0.0–10.0)	0.2503
Mean (SD)Full AUDIT Score	Baseline	170	11.1(6.2)	167	11.4(6.2)	0.6259
	3 months	147	6.5(5.6)	144	7.6(5.4)	0.0906
	6 months	159	7.5(5.6)	163	7.7(5.2)	0.7514
Proportion of subjects scoring ≥8 on the full AUDIT	Baseline	170	114(67.1)	167	117(70.1)	0.5530
	3 months	147	47(32.0)	144	62(43.1)	0.0508
	6 months	159	66(41.5)	163	69(42.3)	0.8812

Table 3

Results of Linear mixed model of Alcohol use disorders identification test-Consumption (AUDIT-C) scores by arm and over time in Kampala Uganda.

Outcome classification		Mean AUDIT-C change	95% CI	p-value
Intervention effect of MI (versus SPP) at 6 months	Complete case analysis	−0.07	−0.70 – 0.56	0.8266
Intervention effect of MI (versus SPP) at 6 months	Multiple imputation	0.01	−0.32–0.34	0.9440
Intervention effect of MI (versus SPP) at 6 months	Males only complete cases	0.38	−0.41–1.17	0.3493
Intervention effect of MI (versus SPP) at 6 months	Females only complete case analysis	−1.10	−2.19 – −0.02	0.0457

All models are linear mixed effects adjusting for follow up visit, and baseline AUDIT-C score, random intercept and random slope for follow-up visit.