# A Randomized Controlled Trial of a Brief Intervention to Reduce Alcohol Use Among Female Sex Workers in Mombasa, Kenya

*Kelly L. L'Engle, PhD,* Peter Mwarogo, MPH,† Nzioki Kingola, MPH,‡ William Sinkele, DMin,§ and Debra H. Weiner, MPH‖*

**Objective:** We assessed whether a brief alcohol intervention would lead to reduced alcohol use and sexually transmitted infection (STI)/HIV incidence and related sexual risk behaviors among moderate drinking female sex workers.

**Methods:** A randomized controlled intervention trial was conducted with 818 female sex workers affiliated with the AIDS, Population, Health, and Integrated Assistance II project in Mombasa, Kenya. Eligible women were hazardous or harmful drinkers who scored between 7 and 19 (full range, 1–40) on the Alcohol Use Disorders Identification Test. Intervention participants received 6 counseling sessions approximately monthly. The equal-attention control group received 6 nutrition sessions. Participants were followed for 6 and 12 months after the intervention, with at least 86% retention at both time points. We used general linear models in intention-to-treat analyses, adjusting for recruitment setting and HIV status at enrollment.

**Results:** There was a statistically significant reduction in alcohol use and binge drinking at 6 and 12 months, with intervention participants reporting less than one third of the odds of higher levels of drinking than the control group. The intervention did not impact laboratory-confirmed STI/HIV incidence, self-reported condom use, or sexual violence from nonpaying partners. However, the odds of reporting sexual violence from clients was significantly lower among intervention than control participants at both 6 and 12 months.

**Conclusions:** We found that a brief alcohol intervention can reduce self-reported alcohol consumption among a nondependent and non–treatment-seeking population most at risk for HIV. More attention is needed to understand the pathway from drinking to sexual behavior and STI/HIV acquisition.

**Key Words:** alcohol intervention, randomized controlled trial, female sex workers, HIV, Kenya

(*J Acquir Immune Defic Syndr* 2014;67:446–453)

## INTRODUCTION

Alcohol use is increasingly recognized as an important determinant of HIV acquisition and transmission and a potential factor that may undermine the impact of HIV prevention and treatment efforts. Female sex workers (FSW), defined as women who exchange sex for money or other goods, experience high HIV rates[1] and are a key population targeted by HIV prevention programs in both concentrated and generalized HIV epidemic settings, such as Kenya.[2,3] Evidence from many studies confirms the association between drinking and sexual risk behavior, showing that increased levels of alcohol use among FSW in low-income settings are associated with increased risk for HIV and other sexually transmitted infections (STIs), unprotected sex, and sexual violence.[4–8] Alcohol use in the context of commercial sex is prevalent and normative at multiple levels: in commercial sex venues, among sex workers, and among clients.[4,5,9] The causative pathway between alcohol intoxication and HIV acquisition is not well defined,[7,10] although gender imbalances and poverty that encourage drinking during sex work,[5,6,11] along with psychoactive effects on reasoning and judgment leading to behavioral disinhibition,[6,8,12] likely place women at increased risk of unsafe sexual practices and sexual coercion that lead to HIV acquisition.[4,7]

There is an urgent need to evaluate evidence-based alcohol reduction interventions that seek to reduce HIV infection among populations with high risk for acquiring HIV.[7,13] Brief interventions to reduce alcohol use among individuals in clinical and primary health care settings have successfully reduced alcohol use in nondependent non–treatment-seeking populations.[14–17] The brief intervention approach is well suited to implementation in a community setting with FSW[17,18] and importantly would provide the opportunity to address the nexus of alcohol-sex-HIV that is common in this population and can be feasibly and synergistically addressed through behavioral interventions for FSW.[10,13] Our study answers the call for rigorously testing brief alcohol interventions in developing

Received for publication April 4, 2014; accepted August 11, 2014.

From the *Social and Behavioral Health Sciences, FHI 360, Durham, NC; †FHI 360, Nairobi, Kenya; ‡International Center for Reproductive Health, Mombasa, Kenya; §Support for Addiction Prevention and Treatment in Africa (SAPTA), Nairobi, Kenya; and ‖Biostatistics, FHI 360, Durham, NC.

Supported by the Public Health Evaluation (PHE) component of the President's Emergency Plan for AIDS Relief (PEPFAR), PHE #KE09.0235. Funding was provided through the US Agency for International Development (USAID), under the terms of AID-623-A-11-00007.

The authors have no conflicts of interest to disclose.

The findings and conclusions in this paper are those of the authors and do not necessarily represent the official position of the funding agency.

Correspondence to: Kelly L. L'Engle, PhD, Social and Behavioral Health Sciences, FHI 360, 359 Blackwell Street Suite 200, Durham, NC 27701 (e-mail: klengle@fhi360.org).

Copyright © 2014 by Lippincott Williams & Wilkins



Copyright © Lippincott Williams & Wilkins. Unauthorized reproduction of this article is prohibited.

country settings to investigate impact on HIV/STIs and related sexual risk behaviors.[7,10,13,19]

Although interventions that explicitly address alcohol use in developing countries are increasing in number[6,20–23] and FSW have been targeted with a range of interventions to reduce HIV transmission,[2] few interventions have explicitly addressed alcohol use among FSW. In this randomized controlled trial in Kenya, we aimed to assess whether a brief intervention would lead to reduced alcohol use among moderate drinking FSW in a community-based setting, reduced STI and HIV incidence, reduced sexual violence, and increased condom use. In this article, we report the main findings of this trial at 6- and 12-month follow-ups.

## METHODS

### Participants

FSW were recruited from 3 AIDS, Population, Health, and Integrated Assistance (APHIA) II project locations, known as drop-in centers (DIC), in Mombasa, Kenya. Mombasa is a major port for East and Central Africa, and the presence of tourism and large manufacturing and service industries attract many sex workers from distant areas in East Africa. The DICs serve more than 15,000 FSW in Mombasa by providing peer education, condom distribution, and health services including HIV testing and counseling and STI diagnosis and treatment. The DICs also act as referral points for FSW to access other services, such as postexposure prophylaxis in the case of rape and enrollment into care and treatment for those who test HIV-positive.

Women eligible for study participation self-reported being an FSW (defined as having exchanged oral sex, anal sex, or vaginal sex for gifts or money in the past 6 months), were registered as an APHIA program participant, were at least 18 years old and lived in Mombasa and planned to reside there for the next 12 months. In addition, eligible women who were moderate risk drinkers defined as those who scored between 7 and 19 on the validated Alcohol Use Disorders Identification Test (AUDIT[24]), a 10-item, 40-point assessment (range, 1–40) designed to identify "harmful" (AUDIT score, 7–15) and "hazardous" (AUDIT score, 16–19) drinkers who may not yet be dependent on alcohol. Harmful alcohol use according to AUDIT criterion indicates alcohol use that produces or provokes health problems, and hazardous alcohol use indicates increased risk of physical, psychological, or social damage in the future. Finally, eligible women had a laboratory-confirmed negative result for gonorrhea, chlamydia, and trichomoniasis at enrollment. HIV status did not affect enrollment eligibility.

FSW provided verbal informed consent for screening before AUDIT administration. Women who scored $<7$ on the AUDIT had a brief counseling session and were provided with a written brochure about alcohol use, whereas women who scored $>19$ on the AUDIT were referred to an alcohol treatment and rehabilitation program in Mombasa. Written informed consent was obtained for full study participation. The study protocol was approved by Kenyatta National Hospital Ethical Research Committee and the FHI 360 Protection of Human Subjects Committee. This trial is registered with ClinicalTrials.gov, NCT01756469.

### Randomization and Masking

This study was an individually randomized, parallel, multisite, controlled trial. The random permuted blocks method was used to randomly assigned women to the brief intervention for alcohol use or an equal-attention nutrition intervention control group in a 1:1 ratio, separately for each DIC. A statistician not otherwise involved in the study generated the randomization sequences using the random function RANUNI in SAS [SAS Institute, Cary, NC] and produced written assignments sealed in individual tamper-evident opaque envelopes. The envelopes were fully protected until the site coordinator confirmed the prospective participant's eligibility, obtained written informed consent, and collected all baseline data. Given the nature of the intervention, study participants and site staff could not be masked to treatment allocation, but study investigators and analysts were masked until data handling and analysis decisions were finalized.

### Procedures

The study intervention consisted of 6 counseling sessions that took place monthly during the first 6 months of study participation. Nurse counselors were trained in motivational interviewing techniques and provided the intervention in one-on-one sessions lasting 20 minutes on average. The intervention was based on the WHO Brief Intervention for Alcohol Use[17] and contained elements from stages of change and social cognitive health behavior change theories. Motivational interviewing techniques, a focus on goal-setting and increasing self-efficacy for changing behavior, the provision of positive feedback and encouragement for change, and use of counseling notes and noting stage of change for alcohol reduction were essential intervention elements. To ensure cultural relevance for FSW in Kenya, focus groups to inform intervention adaptation were held with FSW. Intervention adaptations included incorporating a ladder image to assess motivation and readiness to change because the original ruler image was not understood by less literate FSW and development of visuals depicting real-life situations of FSW such as fighting while intoxicated and not drinking while pregnant. Focus group participants also were asked about drinking patterns of FSW and for suggestions they had to reduce risky drinking before engaging in sexual activity; these ideas were incorporated into the intervention visuals and mentioned by counselors as examples of methods FSW could use to reduce their drinking.

In the first counseling session that occurred at the enrollment visit, all participants were presented with their AUDIT screening results. Sessions for alcohol intervention participants then included identification and discussion of risks and consequences from drinking, soliciting participants' commitment to reduce drinking, identifying the goal of reduced drinking or abstinence, developing a habit-breaking plan, discussing high-risk situations and coping strategies, and providing feedback and encouragement. Nurse

© 2014 Lippincott Williams & Wilkins


Copyright © Lippincott Williams & Wilkins. Unauthorized reproduction of this article is prohibited.

counselors used a flipchart that included locally designed illustrations such as physiological consequences of alcohol use and depictions of risky situations relevant to FSW, and they recorded notes from each counseling session on a data, assessment, and plan form to track discussions across sessions and record the date for the next session. Quality assurance of intervention delivery was provided monthly by an alcohol intervention expert through direct observation of counseling sessions, meeting with the nurse counselors and presentation of cases, and review of data, assessment, and plan notes.

The nutrition control intervention, similarly delivered in monthly 20-minute sessions by the nurse counselors, was based on Kenyan National Guidelines on Nutrition and HIV/AIDS.[25] Sessions included assessment of women's nutritional status, addressed nutritional needs for women and their children and other key groups including people living with HIV and/or taking antiretroviral medication, and included development and monitoring of a nutrition care plan.

At enrollment, 6-month, and 12-month visits, participants were administered the AUDIT questionnaire and a behavioral interview, were tested and counseled for HIV if they were negative at previous study visits, received a gynecological examination that included laboratory testing for STIs, and were provided condoms and relevant referrals and treatment if indicated. The behavioral interview, which took 45 minutes on average to complete and was administered by a research assistant, covered demographics, STI risk behaviors, physical and sexual violence, alcohol use, food choices, and social norms related to these behaviors. HIV testing followed the Kenya Ministry of Public Health and Sanitation guidelines, which began with an HIV rapid test and involved confirmation testing using a different rapid test and/or enzyme-linked immunosorbent assay or Western Blot assay for an HIV-positive test result. Participants who tested positive for HIV at any study visit were not retested at subsequent visits. During the clinical examination, a vaginal swab was taken from each participant and used to conduct reverse transcriptase polymerase chain reaction testing for gonorrhea and chlamydia and the InPouch TV test to detect trichomoniasis. Six and 12-month visits were scheduled within an 8-week window around the target date up to 4 weeks before or after.

The apriori primary outcomes were self-reported frequency of alcohol use and binge drinking or a laboratory-confirmed STI (gonorrhea, chlamydia, and trichomoniasis), including HIV seroconversion. Although the AUDIT score, which has been used as an end point in other intervention research,[20,22,26] was the planned measure of drinking behavior, we found that it did not allow for adequate capture of changes in drinking during the study period. For example, some items referred to lifetime experiences and thus limited the ability to measure change in alcohol use or could not be easily or consistently answered by participants who had stopped drinking during the study period. Therefore, before unblinding, we replaced these end points with items from the behavioral interview asking about drinking behavior over the last 30 days that were answered by all participants regardless of current drinking status. These items were (1) frequency of drinking measured on a 4-point ordinal scale from no drinking to drinking every day[27] and (2) binge drinking, defined as 3 or more drinks on the same occasion,[12] using a 4-point scale ranging from "never" to "most of the time." We also assessed binge drinking before sex[12] and separately with paying clients and nonpaying partners, dichotomized to indicate whether this had occurred in the last 30 days.[8,28] The 3 STI infection types were selected as they are common among FSW in this area.[4,29] The analysis end point was defined as a positive laboratory result for any of the 3 STIs or a new HIV-positive test results at the given study visit.

Planned secondary outcomes included sexual violence victimization and condom use in the last 30 days. Because gender-based violence and condom behavior may vary by partner status,[20,23] we assessed these outcomes separately for clients vs. nonpaying sexual partners. Sexual violence was defined dichotomously as women reporting having been forced to have sex against her desire. Condom use, reported on a 5-point scale from "never" to "all of the time", was dichotomized for analysis as "all the time" vs. "less than all the time," within partner type.

## Statistical Analysis

We calculated that a sample of 600 would be required to detect a 30% reduction in binge drinking in the intervention arm (42%[4]–29%) with 80% power and a prespecified 0.10 level of significance (2-sided). We chose this level of significance because we felt that the risks associated with a type II error (failing to detect a meaningful effect when one truly exists) outweigh those of a type I error (incorrectly rejecting the null hypothesis of no effect), as the former could lead to abandoning a truly effective intervention that is recommended by WHO, evidence-based, logistically feasible to implement, and does not pose an increased risk of adverse health effects for participants. The sample size was increased to 800 to allow for up to 25% loss to follow-up.

Analysis of primary and secondary outcomes was by intention to treat. All participants who attended at least 1 scheduled visit were included in the analysis. All end point definitions and key data handling and analysis decisions were specified before unblinding.

Treatment groups were compared on change over time on study end points using generalized linear models (GEE) (SAS v9.3, Cary, NC; GENMOD procedure) with a link function (logit for binary data, cumulative logit for ordinal) and variance function (binomial for binary data, multinomial for ordinal) appropriate for the given end point. Models controlled for DIC and HIV status at enrollment, as planned, and contained a term for main-effects-by-visit interaction. All models of behavioral end points included responses from the enrollment visit to reduce within-subject variability (per protocol, all women were STI-negative at enrollment). Treatment effects were estimated, as planned, separately for the 6-month and 12-month visits to investigate effects immediately after the intervention and longer term impact through specific contrasts within the overall GEE model. Treatment effects are presented as the odds ratio (with, per-protocol, 90% confidence interval) for the odds of the intervention group vs. controls to have reported the dichotomous end point or, for ordinal variables, a higher level of the

 © 2014 Lippincott Williams & Wilkins

Copyright © Lippincott Williams & Wilkins. Unauthorized reproduction of this article is prohibited.

end point (eg, more frequent drinking). Odds ratio < 1.0 indicate a lower odds in the intervention group.

Contamination between treatment groups was assessed through qualitative comparison of reported alcohol use over time in the control group and nutrition behavior over time in the treatment group.

## RESULTS

During the 6-month recruitment period from March through October, 2011, we enrolled 818 participants (Fig. 1). Enrollment totals were comparable across DICs, and baseline characteristics were similar between intervention and control groups (Table 1). Although there was some between-group variation on baseline responses on some individual AUDIT items (data not shown), there was no obvious pattern. As expected, mean AUDIT scores were comparable (mean = 13.7, 13.4 for intervention and control groups, respectively), as were proportions considered "harmful" drinkers (39% vs. 32% for intervention and control groups, respectively). There were no allocation errors.

Six-month data collection was conducted from October 2011 through March 2012, and 12-month data collection occurred from March 2012 through October 2012. Completion rates were high (Fig. 1), with 752 participants (92%) completing at least 1 follow-up data collection visit and were comparable between groups. Only 18 of 1411 visits (1.3%) were more than 1 month from the target visit date. Nearly 3 quarters of participants completed all 5 postenrollment counseling sessions: 292 alcohol intervention participants (71.4%) and 296 nutrition control participants (72.5%). Very few participants did not complete any postenrollment counseling sessions (n = 21 [5.1%] in the alcohol intervention group and 17 [4.2%]) in the nutrition control group.

More participants in the alcohol intervention group than in the control group reported reduced drinking in the last 30 days at 6-month and 12-month follow-up visits (Table 2). This was the case for frequency of drinking alcohol, overall binge drinking, binge drinking with paying clients, and binge drinking with nonpaying partners. After adjusting for DIC and baseline HIV status, women in the intervention group had less than one third of the odds of reporting higher levels of drinking than women in the control group. We did not detect any between-group differences on laboratory-confirmed STIs including HIV. In terms of secondary outcomes (Table 3), the odds of self-reported sexual violence from clients was significantly lower among intervention than control participants at both 6 and 12 months. We found no between-group differences in sexual violence victimization by nonpaying partners or condom use with clients or nonpaying partners.

The intervention group's nutritional behavior did not change substantially over the course of the study. The control group's alcohol use, however, showed a marked decrease from enrollment to follow-up.

## DISCUSSION

This study shows that a brief intervention can reduce self-reported alcohol consumption among nondependent and non–treatment-seeking FSW in community-based settings. Contrary to expectations, women who received the brief intervention did not experience lower STI incidence or

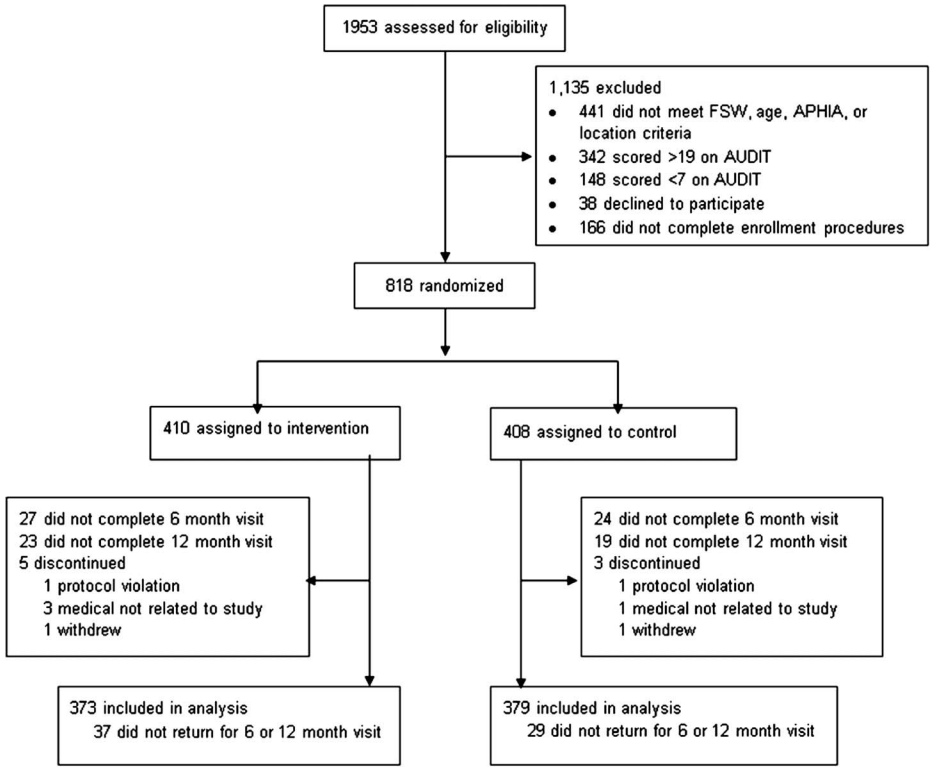


**FIGURE 1.** Trial profile.

© 2014 Lippincott Williams & Wilkins



Copyright © Lippincott Williams & Wilkins. Unauthorized reproduction of this article is prohibited.

**TABLE 1.** Participant Demographics and Baseline Characteristics

| | Intervention Group (n = 410)* | Control Group (n = 408) | Total (n = 818) |
|---|---|---|---|
| Age, yrs | 27.5 (6.8, 18–54) | 27.4 (6.4, 18–52) | 27.5 (6.6, 18–54) |
| Marital status, n (%) | N = 405 | N = 404 | N = 809 |
| Never married | 186 (46) | 191 (47) | 377 (47) |
| Separated or widowed or divorced | 205 (51) | 199 (49) | 404 (50) |
| Currently married | 14 (3) | 14 (3) | 28 (3) |
| Education, n (%) | | | |
| None | 12 (3) | 21 (5) | 33 (4) |
| Primary | 212 (52) | 204 (50) | 416 (51) |
| Secondary | 149 (36) | 146 (36) | 295 (36) |
| Postsecondary | 37 (9) | 37 (9) | 74 (9) |
| Religion†, n (%) | N = 410 | N = 406 | N = 816 |
| Christian | 295 (72) | 297 (73) | 592 (72) |
| Muslim | 115 (28) | 109 (27) | 224 (27) |
| No. partners in last 7 d | 2.3 (2.2, 0–21) | 2.7 (3.5, 0–35) | 2.5 (2.9, 0–35) |
| HIV-positive (%) | 82 (20) | 83 (20) | 165 (20) |
| AUDIT score‡ | 13.7 (3.6, 7–19) | 13.4 (3.6, 7–19) | 13.6 (3.6, 7–19) |
| AUDIT category, n (%) | | | |
| Hazardous (7–15) | 250 (61) | 278 (68) | 528 (65) |
| Harmful (16–19) | 160 (39) | 130 (32) | 290 (35) |
| DIC, n (%) | | | |
| Kisauni | 154 (38) | 152 (37) | 306 (37) |
| Chaani | 142 (35) | 143 (35) | 285 (35) |
| Likoni | 114 (28) | 113 (28) | 227 (28) |

*Column "n" reflects total number of participants randomized to treatment group; row "n" reflects the number answering the item if less than the full sample. Reported are mean (SD, range) or frequency and percentages. Percentages are based on the number of participants answering the item, which may be somewhat less than the full sample.

†Among those reporting religious affiliation.

‡By protocol, only women with AUDIT between 7 and 19, inclusive, were eligible for enrollment.

improvements in condom use, although they did report less sexual violence from clients. Strengths of our trial included good internal validity based on successful random assignment of participants and high response rates at both 6- and 12-month follow-up visits. The equal-attention nutrition control group further strengthened the study design and provided a rare opportunity to compare the brief alcohol intervention to a logistically equivalent control arm.

Findings that alcohol consumption decreased among all women enrolled in the study are in line with results from other alcohol research,[20–22,30] and evidence is converging across studies that screening for alcohol problems and participation in research may lead to reductions in drinking regardless of further intervention.[21,26,31] Reductions in drinking we observed among control group participants could be due to participant's reactivity to research, intervention contamination, social desirability bias if some control group participants realized they were in an alcohol-intervention study and chose to report in a more favorable manner, or general secular changes in alcohol consumption. All women enrolled in our trial completed the AUDIT and a lengthy behavioral interview at each visit, which may have led to self-monitoring and evaluation of alcohol use among all enrolled women regardless of treatment group.[31] Our evaluation of contamination across study arms, finding that nutrition behavior remained similar for intervention participants, whereas alcohol use decreased for the control group over the study period, suggests that other explanations besides sharing of health information across treatment groups likely account for decreases in drinking in the control group. A major study limitation was reliance on self-reports, although consistent findings across drinking frequency, binge drinking, and drinking before sex may suggest a degree of reliability in reporting by women in the sample. Although other means of assessing alcohol use were considered to complement self-reported behavior, the advantages of these methods did not outweigh their shortcomings. Even with the trend of reducing drinking in both treatment groups, we documented dramatically decreased self-reported alcohol use among intervention compared with control participants.

It is unclear why the study resulted in reduced alcohol consumption but this effect did not translate into observable differences in STI acquisition and condom use. Other alcohol reduction interventions among higher risk women have effectively reduced alcohol use[20,30,32] and condom use.[30] The absence of observed intervention effects on key STI and condom end points in the context of significant reductions in self-reported alcohol consumption observed in this trial does not negate the likely mediating role of alcohol use on HIV acquisition. It is possible that improved STI/HIV preventive behaviors might be witnessed during a longer follow-up period or that reducing alcohol use among the study sample was not a sufficient behavior change to impact sexual risk behaviors. Many FSW have sexual relationships with paying and nonpaying partners, and HIV risk may vary


© 2014 Lippincott Williams & Wilkins

Copyright © Lippincott Williams & Wilkins. Unauthorized reproduction of this article is prohibited.

**TABLE 2.** Primary End Points

| | Study Group | | | | | |
|---|---|---|---|---|---|---|
| | Intervention | | Control | | | |
| | n† | n (%) | n | n (%) | Adjusted* OR (90% CI) | *P* |
| Alcohol use over past 30 d | | | | | | |
| Drinking frequency | | | | | | |
| Baseline, n (%) | 373 | | 379 | | | |
| Never | | 5 (1.3) | | 3 (0.8) | | |
| <1/wk | | 17 (4.6) | | 20 (5.3) | | |
| At least 1/wk | | 307 (82.3) | | 301 (79.4) | | |
| Every day | | 44 (11.8) | | 55 (14.5) | | |
| 6 mo | 346 | | 355 | | 0.20 (0.15 to 0.27) | <0.0001 |
| Never | | 186 (53.8) | | 93 (26.2) | | |
| <1/wk | | 25 (7.2) | | 20 (5.6) | | |
| At least 1/wk | | 123 (35.5) | | 208 (58.6) | | |
| Every day | | 12 (3.5) | | 34 (9.6) | | |
| 12 mo | 350 | | 360 | | 0.25 (0.19 to 0.33) | <0.0001 |
| Never | | 232 (66.3) | | 142 (39.4) | | |
| <1/wk | | 29 (8.3) | | 27 (7.5) | | |
| At least 1/wk | | 82 (23.4) | | 163 (45.3) | | |
| Every day | | 7 (2.0) | | 28 (7.8) | | |
| Binge drinking, n (%) | | | | | | |
| Baseline | 373 | | 379 | | | |
| Never | | 4 (1.1) | | 8 (2.1) | | |
| Rarely | | 22 (5.9) | | 28 (7.4) | | |
| Sometimes | | 110 (29.5) | | 102 (26.9) | | |
| Most of the time | | 237 (63.5) | | 241 (63.6) | | |
| 6 mo | 346 | | 355 | | 0.13 (0.10 to 0.17) | <0.0001 |
| Never | | 255 (73.7) | | 118 (33.2) | | |
| Rarely | | 33 (9.5) | | 34 (9.6) | | |
| Sometimes | | 33 (9.5) | | 61 (17.2) | | |
| Most of the time | | 25 (7.2) | | 142 (40.0) | | |
| 12 mo | 350 | | 359 | | 0.18 (0.13 to 0.23) | <0.0001 |
| Never | | 276 (78.9) | | 171 (47.6) | | |
| Rarely | | 14 (4.0) | | 23 (6.4) | | |
| Sometimes | | 27 (7.7) | | 40 (11.1) | | |
| Most of the time | | 33 (9.4) | | 125 (34.8) | | |
| Binge drinking before sex with clients, n (%) | | | | | | |
| Baseline | 368 | 108 (29) | 377 | 134 (36) | | |
| 6 mo | 257 | 21 (8) | 309 | 76 (25) | 0.26 (0.17 to 0.40) | <0.0001 |
| 12 mo | 268 | 11 (4) | 305 | 52 (17) | 0.24 (0.14 to 0.41) | <0.0001 |
| Binge drinking before sex with nonpaying partners | | | | | | |
| Baseline | 284 | 75 (26) | 280 | 82 (29) | | |
| 6 mo | 208 | 9 (4) | 244 | 36 (15) | 0.28 (0.16 to 0.50) | 0.0003 |
| 12 mo | 233 | 10 (4) | 259 | 40 (15) | 0.26 (0.14 to 0.47) | 0.0002 |
| STI | | | | | | |
| Laboratory-confirmed STI at study visit | | | | | | |
| Baseline, n (%) | 373 | 0 | 379 | 0 | | |
| 6 mo | 338 | 33 (10) | 347 | 30 (9) | 1.18 (0.77 to 1.83) | 0.53 |
| 12 mo | 345 | 28 (8) | 352 | 32 (9) | 0.76 (0.44 to 1.33) | 0.42 |

*Adjusted for DIC and HIV status at enrollment.
†Number of participants contributing to analysis.

© 2014 Lippincott Williams & Wilkins



Copyright © Lippincott Williams & Wilkins. Unauthorized reproduction of this article is prohibited.

**TABLE 3.** Secondary End Points

| | Study Group | | | | | |
|---|---|---|---|---|---|---|
| | Intervention | | Comparison | | | |
| | n† | n (%) | n | n (%) | Adjusted* OR (90% CI) | *P* |
| Sexual violence over past 30 d | | | | | | |
| Sexual violence from clients, n (%) | | | | | | |
| Baseline | 368 | 130 (35) | 377 | 117 (31) | | |
| 6 mo | 258 | 44 (17) | 309 | 66 (21) | 0.60 (0.42 to 0.85) | 0.02 |
| 12 mo | 268 | 37 (14) | 304 | 59 (19) | 0.57 (0.39 to 0.84) | 0.02 |
| Sexual violence from nonpaying partners, n (%) | | | | | | |
| Baseline | 285 | 133 (47) | 280 | 120 (43) | | |
| 6 mo | 237 | 71 (30) | 261 | 75 (29) | 0.92 (0.66 to 1.29) | 0.69 |
| 12 mo | 233 | 54 (23) | 260 | 66 (25) | 0.76 (0.53 to 1.08) | 0.19 |
| Condom use over past 30 d | | | | | | |
| Always used condom with clients, n (%) | | | | | | |
| Baseline | 368 | 262 (71) | 376 | 261 (69) | | |
| 6 mo | 257 | 169 (66) | 308 | 212 (69) | 0.86 (0.64 to 1.14) | 0.38 |
| 12 mo | 268 | 134 (50) | 305 | 177 (58) | 0.74 (0.56 to 0.97) | 0.07 |
| Always used condom with nonpaying partners, n (%) | | | | | | |
| Baseline | 283 | 111 (39) | 280 | 119 (43) | | |
| 6 mo | 237 | 92 (39) | 259 | 115 (44) | 0.88 (0.66 to 1.17) | 0.46 |
| 12 mo | 232 | 87 (38) | 259 | 98 (38) | 0.97 (0.73 to 1.30) | 0.87 |

*Adjusted for DIC and HIV status at enrollment.
†Number of participants contributing to analysis.

by partner type.[33,34] The majority of the study sample had nonpaying partners, and these relationships are more complex and resistant to change, possibly diminishing the ability of the alcohol reduction intervention to effectively reduce STI/HIV incidence in this sample. Conceptual models are increasingly highlighting both proximal factors such as individuals' sexual partnerships and behaviors along with distal factors, such as HIV epidemic dynamics and access to health services, to explain the complicated relationship between alcohol use and HIV risk.[35,36] More research is needed to clarify these relationships.

Furthermore, study participants were enrolled in the APHIA II program, which provided ongoing education about condoms and HIV, easy access to condoms, and screening and treatment for STIs. It is possible that APHIA program participation ensured somewhat stable and elevated condom use and lower STI acquisition rates regardless of drinking frequency. For instance, we observed about 10% STI incidence among women in the control group, which is much lower than the 28% incidence we estimated apriori based on other research,[29] and we observed lower HIV incidence than was reported in a community-based sample of Mombasa FSW.[36] Another trial with FSW in a less-established health program might demonstrate positive results on these outcomes. Alternatively, community-based recruitment from bars, beaches, and other FSW venues might yield a sample with less information and access to services and therefore greater potential for intervention impact on STI and HIV outcomes. Randomization at the venue (cluster) level instead of the individual level also might help to reduce any contamination across study arms, although the assumption of nonmixing across venues would need to be verified. A more explicit focus on sexual risk reduction in the intervention sessions also might yield increased impact on sexual health outcomes, and this should be considered for future alcohol reduction interventions among FSW.[20,30] The observed impact on reduced sexual violence from clients is noteworthy, as very few studies from the region have targeted a reduction in interpersonal violence in commercial sex work.[23]

Our findings suggest that the brief intervention, adapted for delivery to FSW in the DIC setting, is a feasible approach for engaging women at risk and encouraging reduced alcohol consumption. We documented high participation rates that also have been seen in other 4-to-6 session alcohol reduction interventions delivered in community[20] and clinical[21] settings. Although it limits the generalizability of study results, we intentionally recruited women who were using the APHIA II services because they provide an efficient and effective means to reach higher risk women, and DICs are common programmatic approaches for reaching and engaging key populations in many countries. However, this brief intervention can be adapted for other settings with FSW and other vulnerable populations such as male sex workers[37] and people living with HIV[38] who are nonadherent to antiretroviral therapy.[39]

Despite many trials of brief interventions, the "active ingredients" that lead to successful reduction in alcohol consumption are not yet clear.[20,40] In addition to interpretation challenges arising from numerous randomized controlled studies showing significant reductions in drinking across study arms, questions about intervention duration and cadre of staff necessary for successful intervention delivery are particularly pressing. It also will be useful to explore how a group setting can be used to enhance or deliver the brief intervention


© 2014 Lippincott Williams & Wilkins

Copyright © Lippincott Williams & Wilkins. Unauthorized reproduction of this article is prohibited.

because peer and group education models are common in HIV prevention programs and group formats have numerous benefits.[40] More attention is needed to understand the impact of brief alcohol reduction interventions and specifically the pathway from drinking to sexual behavior and ultimately to STI/HIV acquisition.

## ACKNOWLEDGMENTS

*The authors thank all staff at the International Center for Reproductive Health in Mombasa and especially Agnes Rinyuru for coordinating the data collection and intervention delivery and Mary Thiongo for data management. The authors are grateful to Loice Magaria, Collins Odero, and Valentine Magero for study monitoring and clinical oversight; Samuel Field for statistical consultation; and Yanwu Zeng for analysis programming.*

## REFERENCES

1. Baral S, Beyrer C, Muessig K, et al. Burden of HIV among female sex workers in low-income and middle-income countries: a systematic review and meta-analysis. *Lancet Infect Dis.* 2012;12:538–549.
2. Chersich MF, Luchters S, Ntaganira I, et al. Priority interventions to reduce HIV transmission in sex work settings in sub-Saharan Africa and delivery of these services. *J Int AIDS Soc.* 2013;16:1–8.
3. World Health Organization. *Toolkit for Targeted HIV/AIDS Prevention and Care in Sex Work Settings*: Geneva, Switzerland: WHO; 2005.
4. Chersich MF, Luchters SM, Malonza IM, et al. Heavy episodic drinking among Kenyan female sex workers is associated with unsafe sex, sexual violence and sexually transmitted infections. *Int J STD AIDS.* 2007;18:764–769.
5. Li Q, Li X, Stanton B. Alcohol use among female sex workers and male clients: an integrative review of global literature. *Alcohol Alcohol.* 2010;45:188–199.
6. Kalichman SC, Simbayi LC, Kaufman M, et al. Alcohol use and sexual risks for HIV/AIDS in sub-Saharan Africa: systematic review of empirical findings. *Prev Sci.* 2007;8:141–151.
7. Shuper PA, Neuman M, Kanteres F, et al. Causal considerations on alcohol and HIV/AIDS–a systematic review. *Alcohol Alcohol.* 2010;45:159–166.
8. Zablotska IB, Gray RH, Serwadda D, et al. Alcohol use before sex and HIV acquisition: a longitudinal study in Rakai, Uganda. *AIDS.* 2006;20:1191–1196.
9. Chiao C, Morisky DE, Rosenberg R, et al. The relationship between HIV/sexually transmitted infection risk and alcohol use during commercial sex episodes: results from the study of female commercial sex workers in the Philippines. *Subst Use Misuse.* 2006;41:1509–1533.
10. Schneider M, Chersich M, Neuman M, et al. Alcohol consumption and HIV/AIDS: the neglected interface. *Addiction*. 2012;107:1369–1371.
11. Fritz K, Morojele N, Kalichman S. Alcohol: the forgotten drug in HIV/AIDS. *Lancet*. 2010;376:398–400.
12. Morojele NK, Kachieng'a MA, Mokoko E, et al. Alcohol use and sexual behaviour among risky drinkers and bar and shebeen patrons in Gauteng province, South Africa. *Soc Sci Med.* 2006;62:217–227.
13. Parry C, Ferreira-Borges C, Poznyak V, et al. The international study on alcohol and infectious diseases: three priorities for research. *Addiction*. 2013;108:1–2.
14. Kaner EF, Beyer F, Dickinson HO, et al. Effectiveness of brief alcohol interventions in primary care populations. *Cochrane Database Syst Rev.* 2007;2:CD004148.
15. A cross-national trial of brief interventions with heavy drinkers. WHO Brief Intervention Study Group. *Am J Public Health.* 1996;86:948–955.
16. Moyer A, Finney JW, Swearingen CE, et al. Brief interventions for alcohol problems: a meta-analytic review of controlled investigations in treatment-seeking and non-treatment-seeking populations. *Addiction*. 2002;97:279–292.
17. Babor TF, Higgins-Biddle JC. *Brief Intervention for Hazardous and Harmful Drinking. A Manual for Use in Primary Care*: Geneva, Switzerland: World Health Organization; 2001.
18. Room R, Babor T, Rehm J. Alcohol and public health. *Lancet*. 2005;365:519–530.
19. Nilsen P. Brief alcohol intervention–where to from here? Challenges remain for research and practice. *Addiction*. 2010;105:954–959.
20. Witte SS, Altantsetseg B, Aira T, et al. Reducing sexual HIV/STI risk and harmful alcohol use among female sex workers in Mongolia: a randomized clinical trial. *AIDS Behav.* 2011;15:1785–1794.
21. Papas RK, Sidle JE, Gakinya BN, et al. Treatment outcomes of a stage 1 cognitive-behavioral trial to reduce alcohol use among human immunodeficiency virus-infected out-patients in western Kenya. *Addiction*. 2011;106:2156–2166.
22. Rendall-Mkosi K, Morojele N, London L, et al. A randomized controlled trial of motivational interviewing to prevent risk for an alcohol-exposed pregnancy in the Western Cape, South Africa. *Addiction*. 2013;108:725–732.
23. Wechsberg WM, Luseno WK, Lam WK, et al. Substance use, sexual risk, and violence: HIV prevention intervention with sex workers in Pretoria. *AIDS Behav.* 2006;10:131–137.
24. Babor TF, Higgins-Biddle JC, Saunders JB, et al. *AUDIT: The Alcohol Use Disorders Identification Test. Guidelines for Use in Primary Care*: World Health Organization; 2001.
25. UNICEF Kenya, USAID Nairobi, FANTA. *Kenyan National Guidelines on Nutrition and HIV/AIDS.* Nairobi, Kenya: Ministry of Health, Government of Kenya; 2006.
26. Kaner E, Bland M, Cassidy P, et al. Effectiveness of screening and brief alcohol intervention in primary care (SIPS trial): pragmatic cluster randomised controlled trial. *BMJ*. 2013;346:e8501.
27. Piere S, Emukule G, Kitungulu B. *Behavioral Monitoring Survey*. Nairobi, Kenya: Family Health International; 2007.
28. Kalichman SC, Simbayi LC, Jooste S, et al. Frequency, quantity, and contextual use of alcohol among sexually transmitted infection clinic patients in Cape Town, South Africa. *Am J Drug Alcohol Abuse.* 2007;33:687–698.
29. Kaul R, Kimani J, Nagelkerke NJ, et al. Monthly antibiotic chemoprophylaxis and incidence of sexually transmitted infections and HIV-1 infection in Kenyan sex workers: a randomized controlled trial. *JAMA*. 2004;291:2555–2562.
30. Kalichman SC, Simbayi LC, Vermaak R, et al. HIV/AIDS risk reduction counseling for alcohol using sexually transmitted infections clinic patients in Cape Town, South Africa. *J Acquir Immune Defic Syndr.* 2007;44:594–600.
31. Clifford PR, Maisto SA. Subject reactivity effects and alcohol treatment outcome research. *J Stud Alcohol.* 2000;61:787–793.
32. Witte SS, Batsukh A, Chang M. Sexual risk behaviors, alcohol abuse, and intimate partner violence among sex workers in Mongolia: implications for HIV prevention intervention development. *J Prev Interv Community.* 2010;38:89–103.
33. Luchters S, Richter ML, Bosire W, et al. The contribution of emotional partners to sexual risk taking and violence among female sex workers in Mombasa, Kenya: a cohort study. *PLoS One.* 2013;8:e68855.
34. Voeten HA, Egesah OB, Varkevisser CM, et al. Female sex workers and unsafe sex in urban and rural Nyanza, Kenya: regular partners may contribute more to HIV transmission than clients. *Trop Med Int Health.* 2007;12:174–182.
35. Baral S, Logie CH, Grosso A, et al. Modified social ecological model: a tool to guide the assessment of the risks and risk contexts of HIV epidemics. *BMC Public Health.* 2013;13:482.
36. Chersich MF, Bosire W, Kingola N, et al. Effects of hazardous and harmful alcohol use on HIV incidence and sexual behavior: a cohort study of Kenyan female sex workers. *Global Health.* 2014;10:22.
37. Luchters S, Geibel S, Syengo M, et al. Use of AUDIT, and measures of drinking frequency and patterns to detect associations between alcohol and sexual behaviour in male sex workers in Kenya. *BMC Public Health.* 2011;11:384.
38. Scott-Sheldon LA, Carey MP, Carey KB, et al. Patterns of alcohol use and sexual behaviors among current drinkings in Cape Town, South Africa. *Addict Behav.* 2012;37:492–497.
39. Kalichman SC GT, Amaral CM, McNerney M, et al. Viral suppression and antiretroviral medication adherence among alcohol using HIV-positive adults. *Int J Behav Med.* 2014;21:811–820.
40. Connors GJ, Donovan DM, DiClemente CC. *Substance Abuse Treatment and the Stages of Change: Selecting and Planning Interventions*. New York, NY: Guilford Press; 2001.

© 2014 Lippincott Williams & Wilkins


Copyright © Lippincott Williams & Wilkins. Unauthorized reproduction of this article is prohibited.