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Reducing Alcohol Consumption in HIV Primary Care: A Randomised Controlled Trial of a Technology-Enhanced Intervention

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Summary

Background: Among HIV-infected individuals, heavy drinking poses serious health risks and can limit survival, but is often not addressed in busy HIV primary care clinics. We tested an intervention requiring minimal staff time to reduce heavy drinking among HIV primary care patients: brief Motivational Interviewing (MI) enhanced by 60-day patient involvement in “HealthCall”, automated telephone Interactive Voice Response (IVR) technology.

Methods: Urban HIV clinic patients reporting ≥ 4 U.S. drinks ≥ 1 day in the past month were randomised to parallel groups: educational control (n=88), MI-only (n=82), or MI+HealthCall (n=88). MI+HealthCall participants called HealthCall daily for 1-3 min to report alcohol and health behaviors; call data were summarized in monthly feedback graphs for patients. At 30 and 60 days, all patients were assessed and briefly discussed drinking. The nature of the treatment precluded masking. Primary outcomes measured at 30 and 60 days were mean drinks per drinking day and percent days abstinent.

Findings: Of randomised patients, 4 were withdrawn and 225 (88.6%) provided post-treatment data (control n=80, MI-only n=73, MI+HealthCall n=72). By 60 days, MI+HealthCall participants drank significantly fewer drinks per drinking day than those in MI-only (mean difference 292 drinks, 95% CI -74 -410, $p < 0.001$) or controls (mean difference 308, 95% CI 192 -424, $p < 0.001$). Groups did not differ on days abstinent.

Interpretation: MI+HealthCall patients reduced heavy drinking more than other groups, while requiring little additional staff time. IVR-based enhancements to brief interventions may offer clinical benefit in resource-limited HIV primary care settings.

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Panel: Research in Context

Systematic review: We searched PubMed (from inception to June 10, 2011) using the combination of search terms “HIV” AND “intervention” AND “alcohol”/“drinking” with “reduction”, “clinic”, or “primary care”. We found one randomised trial in an HIV clinic in Kenya with an alcohol abstinence goal, PMID: 21631622 (accessed June 8th), utilizing six 90-min sessions of CBT delivered by research staff. We found no randomised trials with a primary goal of alcohol reduction and designed to be sustainable in standard HIV treatment settings.

Interpretation: This study contributes substantially to current science as the first randomised trial of a brief alcohol reduction intervention in HIV primary care that can be practically administered by clinic staff as part of routine care. Post-treatment, we found significantly fewer drinks per drinking day in the technologically-enhanced motivational interview group than in the control or motivational interview-only group.

Alcohol is a substantial contributor to the global burden of disease and injury.¹ Among HIV-infected individuals, risks of heavy drinking are particularly high, including medication non-adherence, reduced immunity, accelerated HIV progression, and transmission risk.²⁻⁵ Further, among those infected with HIV, end-stage liver disease is now second only to AIDS as a cause of mortality and heavy drinking is especially harmful to the liver,⁶ even in the absence of hepatitis.⁷ In HIV treatment, little drinking-reduction support is available from frequently overextended medical providers,⁸ and clinic resources seldom provide for extended alcohol interventions. This situation suggests an urgent need for new approaches to address heavy drinking in HIV primary care patients.

In general primary care, brief motivational interviewing (MI) can reduce heavy drinking.^{14,15} However, we reasoned that disadvantaged minority HIV primary care patients, already ill and often experiencing many life complications, would require more than a single brief session to reduce heavy drinking. Emerging telephone-based technologies offer ways to improve health outcomes in resource-limited settings.^{9,10} One such technology is automated Interactive Voice Response (IVR), which has shown promise in helping patients manage chronic illness and medications¹¹ and has been used for alcohol screening and as an adjunct to standard care.^{12,13} This strategy seemed particularly appropriate for urban HIV primary care clinics, where limited staff time and resources make extended alcohol interventions unfeasible.⁸ If IVR enhancement of brief intervention were effective in reducing heavy drinking in this population, it could become a valuable and cost-effective clinical tool.

Accordingly, we designed an enhancement of brief MI consisting of daily, 1-3 minute patient engagement with “HealthCall”, an IVR-based system. Patients call HealthCall to report alcohol and related health behaviors. Call data are summarized for patients in monthly feedback graphs. Our goal was to extend the “dose” of a brief, evidence-based alcohol harm-reduction intervention without making unrealistic demands on staff. Previously, we showed that MI+HealthCall was acceptable to urban HIV primary care patients in an uncontrolled pilot study demonstrating significant drinking reduction over 60 days.¹⁶ Now, we report a randomised trial of MI+HealthCall to reduce heavy drinking in HIV primary care patients. Our primary outcomes were mean drinks per drinking day, consistent with our harm-reduction goal, and percent days abstinent from alcohol, a goal frequently of interest when treating alcoholism.

Method

Participants. Those eligible were HIV-positive English- or Spanish-speaking patients aged ≥ 18 years in a New York City hospital-affiliated HIV primary care clinic who consumed ≥ 4 U.S. drinks of alcohol at least once during the prior 30 days. Exclusion criteria included active psychosis, suicidality, or gross cognitive impairment (Halstead-Reitan Trails A).¹⁷ Participants provided written informed consent, and were compensated for assessments, but not for treatment or calling HealthCall. Study protocols were approved by institutional review boards at the hospital and New York State Psychiatric Institute. This trial is registered with ClinicalTrials.gov, NCT00371969.

Randomisation and Masking. Using a parallel, 3-arm individually-randomised design with 1:1:1 allocation ratio, participants were assigned to MI+HealthCall, MI-only, or attentional control. Computerized urn randomisation balanced treatment groups on current depression, illicit drug use, unstable housing, and hepatitis,¹⁸ all assessed with standardized measures. Patients and counselors were not masked to group allocation because of the interactions required for the interventions.

Procedures. Patients were referred by clinicians to one of two study clinic counselors for informed consent and assessment of eligibility and baseline characteristics, e.g., demographics, years since HIV diagnosis, current alcohol dependence.¹⁹ Measures were computerized and self-administered at the HIV clinic in patients' choice of English or Spanish. After assessment, counselors ran a web-based randomisation program and then immediately met with participants to administer the assigned treatment. Counselors were bilingual (English/Spanish), from the same race/ethnic groups as most of the patients, and had no prior experience in substance abuse counseling or MI. One had a MA in health education, and the other a BA in psychology. Counselors were trained (7 hours) by an experienced MI trainer, and supervised together (weekly, one hour) by an experienced licensed psychologist (EA). MI sessions were audiotaped and 10% randomly selected for standardized coding of MI fidelity;²⁰ both counselors performed MI adequately.

In the control arm, counselors informed patients that their drinking was greater than medically advisable. Patients then viewed a 30-minute educational DVD on HIV treatment and self-care without specific alcohol content. They then received a digital alarm watch (which they were told they could use as a medication reminder) and a pamphlet about drinking reduction techniques developed by the National Institute on Alcohol Abuse and Alcoholism.²¹ At 30 and 60 days, patients met with their counselor, who asked briefly about patients' drinking in the prior 30 days and further encouraged drinking reduction (~5 min).

In MI-only arm, counselors administered a 20-25 min MI at baseline, using standard MI techniques to motivate reduced drinking, e.g., dialogue about health consequences of heavy drinking, exploring ambivalence, barriers to change, developing a change plan. The change plan included a drinking-reduction goal if the patient was willing to set one. Patients then received the watch and pamphlet described above. At 30 and 60 days, counselor and patient met for 10-15 minutes, discussed the patient's drinking during the past 30 days, evaluated the drinking goal, and set a new goal if the patient wished.

In the MI+HealthCall arm, counselors conducted all activities described for the MI arm, and then briefly instructed patients in use of HealthCall, asking patients to call daily for the next 30 days. HealthCall uses a telephone Interactive Voice Response (IVR) platform to facilitate ongoing self-monitoring, awareness of drinking, and self-efficacy regarding drinking reduction.¹⁶ Patients access HealthCall via a toll-free number for daily 1-3 minute calls, answering pre-recorded questions about the previous day, including alcohol consumption (e.g., "How many beers did you drink yesterday?") and six yes/no questions about reasons for drinking or not drinking. All questions are asked about "yesterday" (morning, afternoon, evening) to ensure consistent reporting periods regardless of the hour called. Patients answered by pressing numbers on the telephone keypad. After instruction, patients immediately practiced using HealthCall and then completed their first call. Patient and counselor then identified an accessible telephone and convenient time for daily calls, and set the digital watch alarm to this time as a call reminder. During the 60 days, if patients failed to call HealthCall for 48 hours, counselors made brief reminder calls about the importance of regular calling.

HealthCall data were compiled into a database used to provide personalized feedback to patients via a computer-generated graph showing patients' daily drinking as reported to HealthCall over the previous 30 days. The graph displayed total drinks each day, days of missed calls, and summary statistics of average drinks/drinking day and reasons for drinking. The graphs also displayed patients' drinking goals. During the 30-day and 60-day meetings, counselors gave patients the graph, ensured that they understood it, and then used it as the

basis for 10-15 minute discussions, reinforcing success or problem-solving as applicable. If needed, the 30-day discussion also covered ways to call more regularly.

Outcomes

The pre-designated primary outcomes were mean drinks per drinking day, a harm-reduction goal reflecting the MI activities, and percent days abstinent, often of interest in treating alcohol dependence. Outcomes were assessed at baseline, 30, and 60 days, regardless of treatment arm. Alcohol consumption was measured with a computerized self-administered Time-Line Follow Back Interview (TLFB),²² which uses a calendar and memory aids to assist patients in reporting how many drinks they had each day over the past month. With these data, we created composite variables indicating mean drinks/drinking day and percent days abstinent over the prior 30 days. (HealthCall data were not analyzed as the primary outcome because these data were only available from the MI+HealthCall group). Breathalyzer analysis of blood alcohol concentration (BAC) was used at all assessment points to validate reports of abstinence. Only 12 patients at 30 days and 14 at 60 days evidenced BAC >0, with all values (0.001-0.002) suggesting non-beverage alcohol exposure (e.g., cologne) rather than drinking.

Statistical Analysis

Before starting the study, we estimated that N=270 would provide 80% power at $\alpha=0.05$ to detect a medium to small time-by-treatment interaction effect (approximate $d=0.4$ standard deviations), generally considered a clinically meaningful effect size. We stopped enrollment before reaching our target due to changes in hospital ownership.

Among patients who provided post-baseline TLFB data at 30 and/or 60 days, we modeled each continuous primary outcome as a function of time (baseline, 30 and 60 days) and treatment group using mixed-effects linear regression.²³ As a first step, we modeled main effects of two binary dummy variables representing time (30 days vs. other; 60 days vs. other), two binary treatment dummies (MI-only vs. other; MI+HealthCall vs. other), and the interaction of each time and treatment dummy, controlling for the main effects. We used Akaike's information criterion (AIC) to determine which interaction terms, if any, to retain in a final model. AIC indicates the goodness of fit of a statistical model; it utilizes the tradeoff between bias and variance, or accuracy and complexity, in model construction. Once a final best-fitting model was identified, we used contrasts to obtain specific between-group effect sizes and their significance levels. Effect sizes were represented by betas, indicating a unit difference (e.g., mean number of drinks/day; % of prior 30 days abstinent) adjusted for other variables in the model. In all cases, we estimated between-group contrasts at the study endpoint (60 days). When the model included significant time-by-treatment interactions (indicating that betas varied across time points), we additionally estimated between-group contrasts at 30 days. As planned, experiment-wise alpha was 0.05. Because contrasts were evaluated within a unified model, no further adjustment was required for multiple testing.

We conducted an exploratory analysis within the MI+HealthCall group to evaluate whether frequency of calls was related to change in primary outcomes. We computed baseline-to-60-day change scores for participants with complete data from the final study month (N=60 for abstinence data, N=49 for drink quantity data). Due to skewed distribution of percent calls made to HealthCall (skewness=-0.50, Shapiro-Wilk $W=0.96$, $p<0.01$), we dichotomized percent calls at the median value of 64%. The dichotomous calling variable and demographic covariates (age, sex, and ethnicity) were used as predictors in linear regression analyses of the change scores described above.

Role of the Funding Source

The funders had no role in study design, data collection, analysis, interpretation, write-up, or the decision to submit for publication. All authors had full access to study data; the corresponding author had final responsibility for the decision to submit.

Results

Of 295 patients referred from September 2007-May 2010 (Figure 1), 258 met inclusion criteria and were randomised and treated as follows: MI+HealthCall (N=88), MI-only (N=82), control (N=88). Four individuals were withdrawn: three withdrew consent and one developed psychosis.

Table 1 presents characteristics of the baseline sample (N=254). Of these, 22.4% were women, 48.8% were African American and 45.3% Hispanic. Of all patients, 20.9% were predominantly Spanish-speaking. About half completed high school; most were single and unemployed. Mean age was 45.7 years (range 22 -68); average time since HIV diagnosis was 8.2 years. On average, participants reported drinking 31.9% of the 30 days prior to baseline, with a mean of 7.1 drinks/drinking day; 48.8% of the sample met current DSM-IV alcohol dependence criteria. As shown, treatment groups did not differ significantly on any of these variables.

Of these 254 patients, 88.6% (n=225) returned for evaluation at 30 or 60 days post-baseline and were included in the analysis; those assigned to MI+HealthCall were analyzed in this group regardless of actual HealthCall use. Treatment groups did not differ on attrition ($\chi^2=1.17$, $df=2$, $p=0.56$). Participants with and without post-treatment data did not differ significantly on any characteristic in Table 1 ($p>0.10$). Thus, attrition is unlikely to bias our results.

Among those in the MI+HealthCall group, the median number of possible calls to HealthCall was 62.7% (s.d. 23.8). Frequent calling (>median) was associated with lower baseline abstinence (59.4 vs. 73.8% abstinent, $p<0.01$) but no other variable in Table 1 ($p>0.05$).

All groups decreased their mean drinks/drinking day over the 60 days (effect of time $p<0.001$; Figure 2). By the end of treatment, the MI+HealthCall group was the only arm whose mean drinks per drinking day was lower than the ≤ 4 drinks eligibility criterion for the study. The best-fitting regression model showed significant interactions between time and the MI+HealthCall group ($p<0.01$), reflecting a larger difference between MI+HealthCall and other groups at 60 days than at 30 days. Contrasts indicate that participants in the MI+HealthCall group had significantly fewer drinks/drinking day than those in the MI-only group at 30 days ($\beta=-2.19$, 95% CI -4.14 to -0.97, $p<0.001$) and at 60 days ($\beta=-2.92$, 95% CI -4.10 to -1.74, $p<0.001$). Similarly, the MI+HealthCall group drank significantly less per drinking day than the control group at 30 days ($\beta=-2.35$, 95% CI -3.55 to -1.15, $p<0.001$) and at 60 days ($\beta=-3.08$, 95% CI -4.24 to -1.92, $p<0.001$). The final model included no interactions of time with the MI-only or control groups. No significant difference was found between the MI-only and control group on number of drinks/drinking day ($\beta=-0.16$, 95% CI -1.10 to 0.78, $p=0.74$).

Percent of days abstinent increased over the 60 days in the entire sample ($p<0.001$; Figure 3). In the final model, there were no group by time interactions and no significant differences between groups on percent days abstinent at the study endpoint: MI+HealthCall vs. MI-only ($\beta=-3.20$, 95% CI -9.10 to 2.70, $p=0.29$), MI-only vs. control ($\beta=1.44$, 95% CI -4.36 to 7.24, $p=0.63$), MI+HealthCall vs. control ($\beta=-1.75$, 95% CI -7.55 to 4.05, $p=0.55$).

We dichotomized the MI+HealthCall group into frequent and infrequent callers at the median of % calls made, and compared them on baseline-to-60-day change scores. Frequent callers decreased drinks per drinking day by 4.6 drinks, and infrequent callers by 2.7 drinks ($t=-1.93$,

$p=0.06$); frequent callers increased % days abstinent by 21.4% and infrequent callers by 8.9% ($t=2.12$, $p=0.04$).

Discussion

Our results were consistent with the need for extended intervention to reduce heavy drinking in urban HIV primary care patients. While all groups decreased percent days abstinence and mean drinks/drinking day over time, by the end of treatment, only patients in the MI+HealthCall group decreased their mean drinks per drinking day below the eligibility level for the study (from about 7.5 to 3.5 drinks/drinking day). To our knowledge, this is the first randomised trial to demonstrate the efficacy of an intervention to reduce heavy drinking in U.S. HIV primary care. This drinking reduction was achieved through counseling totaling 30-40 minutes prior to the 60-day assessment (from counselors without previous substance abuse experience), and through interaction with an automated telephone IVR system designed to extend the intervention in a manner that would be practical for the time-pressured, often resource-strapped circumstances of many HIV clinics.

The finding of a significant effect for MI+HealthCall with regard to mean drinks/drinking day but not percent days abstinent is consistent with the theoretical basis of MI¹⁴ and how it was delivered by the counselors, i.e., a harm-reduction rather than abstinence-focused approach. The MI sessions attempted to increase patients' motivation to reduce drinking to safer levels, but not to change their attitudes about total abstinence, although an abstinence goal was welcomed among patients who chose it (31.7%, MI-only, 32.1% MI+HealthCall; $p=0.95$). Given that hazardous drinking is associated with liver fibrosis in HIV patients but moderate drinking is not,⁷ the harm-reduction goal was consistent with the patients' medical needs. Some clinicians or investigators may prefer an intervention with an abstinence goal in this patient population. A new study would be required to determine whether such an intervention would be successful.

Possible mechanisms of HealthCall's action may include self-monitoring, reminders of the MI session, improved self-efficacy or self-regulatory skills. Another possible explanation is simply the provision of more intervention time (i.e., higher dose) than the other arms. A fourth treatment arm testing daily IVR calls of the same length without alcohol content could clarify this issue. Such an arm did not seem warranted prior to testing whether MI+HealthCall was effective, but studies to understand HealthCall's mechanism could be considered in the future. These would not, however, change the unique aspect of HealthCall, which is that it can extend patient engagement in a brief intervention with little increase in clinic staff time.

We did not pay patients to call HealthCall because such payments are unlikely to be disseminable. While paying patients to call may have increased the percent of possible calls made (median, 64.4%), the study shows that urban minority HIV patients will use HealthCall, and that even with imperfect use (i.e., not every possible call made), participation in HealthCall appears to have a significant impact on health behavior.

As is always the case in studies of drinking reduction, the biological validators of alcohol use can only indicate drinking several hours before assessment. However, patient self-administration of the alcohol outcome measures precluded bias in these measures that would have occurred with counselor assessments, and provided patients with the privacy usually associated with valid reporting.

Shortly before completing this report, a randomised drinking-reduction trial was published that was conducted in Kenya HIV primary care patients. This intervention, while successful at

reducing drinking, required six 90-minute counseling sessions.²⁴ Although all efforts to reduce heavy drinking in this population are important, such an intervention is unlikely to be feasible in most HIV primary care settings. We know of no other randomized trials with a primary focus on drinking reduction in HIV primary care patients.

Our trial of MI+HealthCall was conducted in a U.S. urban treatment setting with a disadvantaged patient population; the minimal exclusion criteria and high proportion of participants with valid post-treatment data support generalisability of the results to similar populations. Counselors' background was similar to personnel often found in such clinics, enhancing prospects for dissemination. Further studies are needed to indicate utility in alternative settings and providers. However, the flexibility and low cost of HealthCall (our platform cost under US\$11,000), the ubiquity of telephone access across national and class boundaries,^{10,25} and our successful implementation by personnel without previous substance abuse treatment experience all suggest promise for MI+HealthCall in reducing excess drinking among individuals in treatment for HIV.

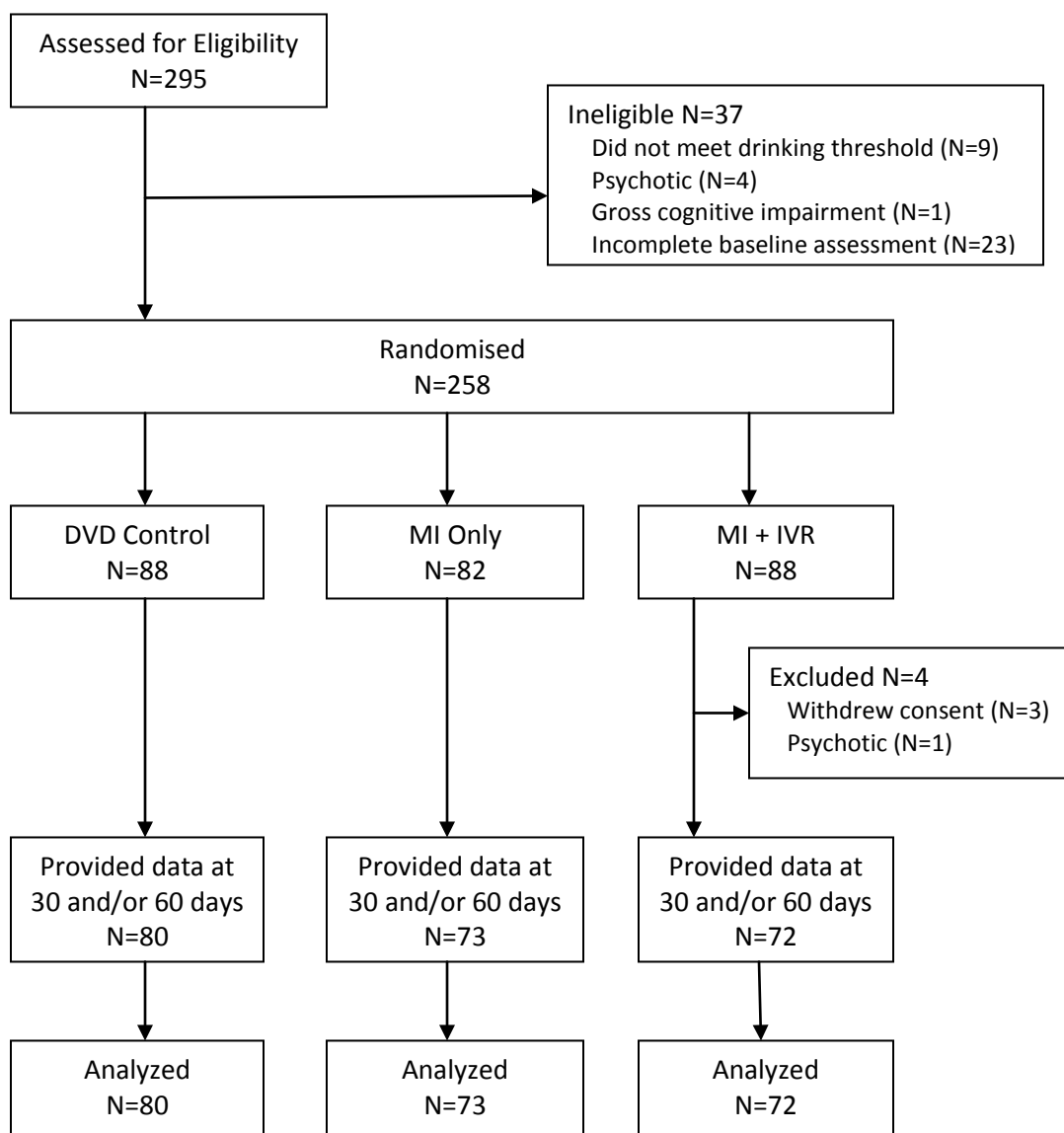
Figure 1: Flow of Study Participants

Table 1: Baseline Characteristics by Treatment Condition

	DVD Control (N=88)	MI Only (N=82)	MI+HealthCall (N=84)	Full Sample (N=254)	
	No. (%)				X² p
Female	17 (19.3)	20 (24.4)	20 (23.8)	57 (22.4)	0.68
Ethnicity					0.80
African American	40 (45.5)	43 (52.4)	41 (48.8)	124 (48.8)	---
Hispanic	44 (50.0)	34 (41.5)	37 (44.1)	115 (45.3)	---
Other	4 (4.6)	5 (6.1)	6 (7.2)	15 (5.9)	---
Spanish-speaking	23 (26.1)	15 (18.3)	15 (17.9)	53 (20.9)	0.82
High school education	55 (62.5)	49 (59.8)	44 (52.4)	148 (58.3)	0.38
Married / stable relationship	10 (11.4)	12 (14.6)	11 (13.1)	33 (13.0)	0.82
Employed	13 (14.8)	7 (8.5)	12 (14.3)	32 (12.6)	0.40
Current alcohol dependence	41 (46.6)	39 (47.6)	44 (52.4)	124 (48.8)	0.72
	Mean (sd, range)				ANOVA p
Age, years	44.5 (8.3, 22-60)	46.5 (7.9, 23-61)	46.1 (8.1, 24-68)	45.7 (8.1, 22-68)	0.22
Years since HIV diagnosis	13.0 (7.5, 0.3-30.4)	12.2 (7.5, 0.1-28.4)	13.1 (7.7, 0.1-30.4)	12.8 (7.6, 0.1-30.4)	0.70
Percent days drinking (past 30 days)	31.9 (25.1, 3.3-100)	30.2 (23.8, 3.3-100)	33.4 (24.2, 3.3-100)	31.9 (24.3, 3.3-100)	0.71
Drinks per drinking day (past 30 days)	6.8 (3.6, 2.1-20.0)	6.6 (3.9, 2.2-25.0)	7.8 (4.4, 1.9-25.0)	7.1 (4.0, 1.9-25.0)	0.13

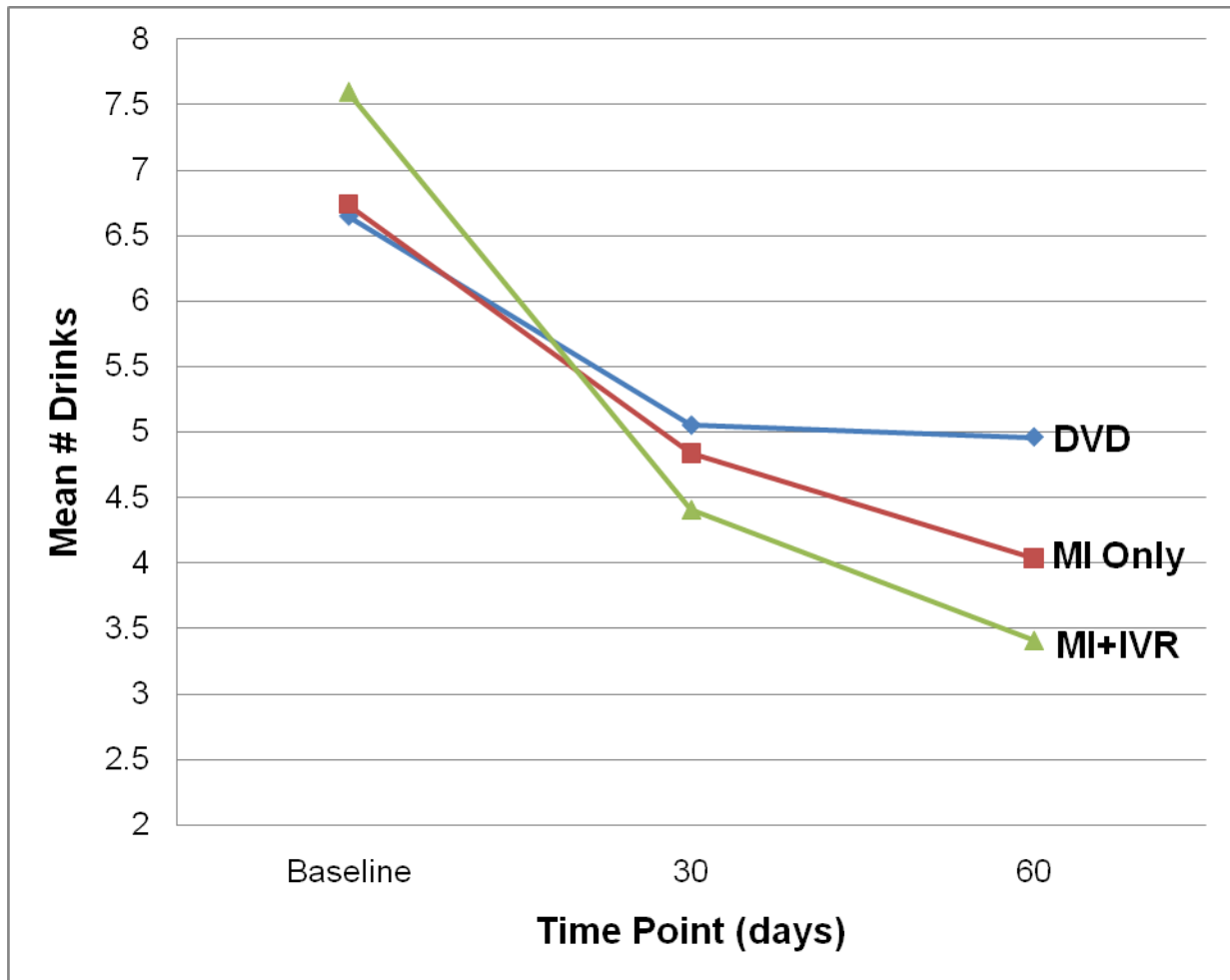
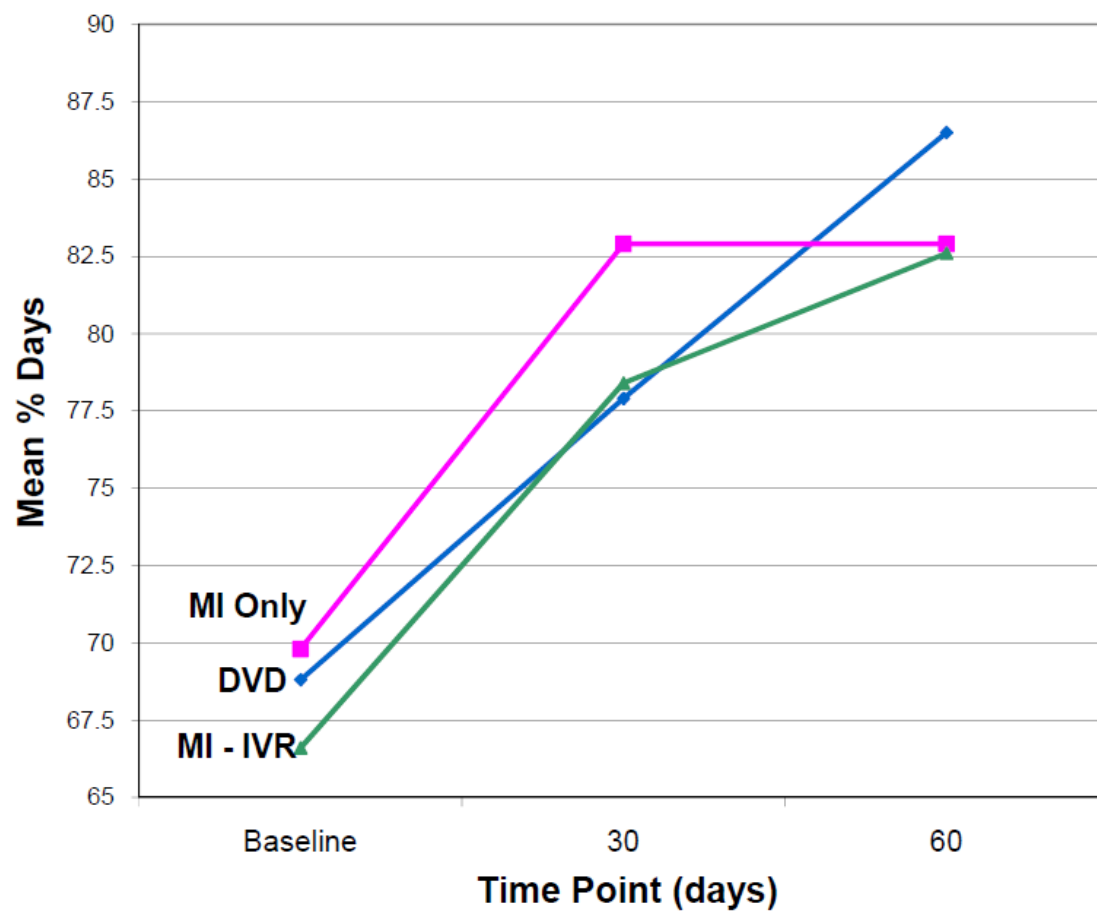
Figure 2: Mean Drinks per Drinking Day, by Treatment Group

Figure 3: Percent Days Abstinent, by Treatment Group

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