

## A low-cost, sustainable intervention for drinking reduction in the HIV primary care setting

E. AHARONOVICH<sup>1,4</sup>, M. L. HATZENBUEHLER<sup>4</sup>, B. JOHNSTON<sup>2</sup>, A. O'LEARY<sup>3</sup>, J. MORGENSTERN<sup>1</sup>, M. L. WAINBERG<sup>4</sup>, P. YAO<sup>4</sup>, J. E. HELZER<sup>5</sup>, & D. S. HASIN<sup>1,4</sup>

<sup>1</sup>Columbia University, New York, <sup>2</sup>St. Vincent's Hospital, New York, <sup>3</sup>Centers for Disease Control and Prevention, Atlanta, Georgia, <sup>4</sup>New York State Psychiatric Institute, and <sup>5</sup>University of Vermont, New York, New York

### Abstract

Excess drinking poses multiple substantial health risks to HIV-infected individuals. However, no published intervention studies have focused on drinking reduction as the main outcome in HIV primary care patients. An intervention in this setting must place minimal demands on pressured staff and resources. This pilot study tested such an intervention, which consisted of brief Motivational Interviewing (MI) and HealthCall, an automated daily telephone self-monitoring system based on Interactive Voice Response (IVR), designed to extend and enhance the effects of brief MI. Thirty-one patients entered the study, received a 30-minute MI and were instructed in daily use of the IVR system. They received graphical feedback on their daily drinking from the HealthCall database after 30 days. A statistically significant decrease in drinking was found over time, both as reported in daily IVR calls ( $\beta = -0.01$ , se 0.01,  $p = .03$ ) and in follow-up interviews ( $\beta = -0.04$ , se 0.12,  $p = .02$ ) at 60 days. The proportion of daily calls made supported the feasibility of the intervention. The results indicate that HealthCall is acceptable to a disadvantaged HIV patient population, and preliminary data support the efficacy of this intervention in reducing harmful drinking among HIV primary care patients.

### Introduction

End-stage liver disease is now a leading cause of death among HIV-infected individuals (García-Samaniego et al., 2002; Cohen et al., 2002; Selik et al., 2002). Drinking poses substantial risks to individuals with liver damage or disease. Excess drinking is associated with HIV disease progression, hepatic comorbidity, anemia and thrombocytopenia (Conigliaro et al., 2003, 2004; Pol et al., 2004), and with rapid progression of liver fibrosis among individuals with HIV/HCV (Mariné-Barjoan et al., 2004). Further, excess drinking predicts liver toxicity (Núñez et al., 2001; Sulkowski et al., 2000; Kresina et al., 2002) and poor treatment response (Miguez et al., 2003; Samet et al., 2003; Prakash et al., 2001) among those treated with antiretroviral medication (ARV). Heavy drinking is also associated with both increased sexual transmission risk behaviour (Marks et al., 1998; Robins et al., 1997; Lauchli et al., 1996; McKirnan et al., 2001) and poor adherence to ARV (Chesney et al., 2000; Palepu et al., 2004; Samet et al., 2004), which may in turn lead to higher viral load and increased infectivity, as well as hasten the development of drug-resistant strains of the virus.

Despite these findings, alcohol remains frequently underestimated and overlooked in HIV treatment (Powderly, 2004).

The site of HIV care is often the HIV primary care clinic. In this setting, which is often pressured for staff time and resources, standard alcoholism treatment is not feasible and is unwarranted for patients drinking at unsafe levels who are not alcohol dependent. While primary care has been suggested as an advantageous setting for brief drinking-reduction interventions (Babor, 1990), brief drinking interventions that require administration by physicians are not sustainable (Spandorfer et al., 1999; Friedmann et al., 2000; Schermer et al., 2003; Orleans et al., 1985; Emmons & Rollnick, 2001; Weller et al., 1992). Thus, drinking reduction interventions for HIV primary care must be effective when administered by non-physicians, while making minimal time demands. To date, no studies have been published specifically focused on drinking-reduction interventions designed to be sustainable in HIV settings.

To address this, we designed such an intervention, which consisted of two elements.

*(1) Motivational Interviewing (MI)*

MI is a brief evidence-based intervention for reduction of excessive drinking and other conditions (Miller & Rollnick, 2002) that assumes ambivalence about ostensibly desirable behaviour change. MI includes techniques to develop awareness of the discrepancy between desires to engage and not to engage in the target behaviour, resolving ambivalence about the behaviours, eliciting talk about change, gaining a commitment to change by goal-setting, and feedback (Emmons & Rollnick, 2001). After training, non-physician counsellors are often the personnel who administer MI. Randomized trials show that MI reduces drinking across many settings and populations (Dunn et al., 2001; Burke et al., 2002, 2003). Working closely with HIV primary care clinic staff, we tailored a 30-minute single-session MI to these patients and setting. The brief MI session was designed to focus mainly on patients' drinking in relation to their HIV status, as well as to hepatitis and medication. At the end of the session, counsellors worked with patients who were willing to establish a reduced-drinking goal for the next 30 days. More complex goals were not attempted in such a brief intervention.

*(2) HealthCall*

MI, especially in its briefest form, may not be enough to sustain behaviour change among difficult populations (Stein et al., 2002; Baker et al., 2002). The problem is how to extend the 'dose' among a disadvantaged HIV patient population without extending demands on HIV staff time. We designed HealthCall to address this problem. In practical terms, HealthCall is an automated daily telephone self-monitoring system for drinking based on Interactive Voice Response (IVR). Generically, IVR is a telephone-based procedure allowing individuals to interact with recorded questions and statements. When an IVR is called, the caller hears scripted questions and inputs brief answers using the telephone touchpad or voice response. The sequence of questions is determined by individual responses as they fit the decision tree programmed into the IVR system. Answers can be collected in a database. Based on previous studies using IVR as a longitudinal data-collection tool on drinking (Helzer et al., 2002; Mundt et al., 1995a, 1995b; Searles et al., 1995, 2000, 2002), we designed HealthCall to administer 1–3 minutes of questions on alcohol and related behaviours in a friendly, pre-recorded voice in English or Spanish via a toll-free number. Patients responded through the telephone touchpad.

There were several reasons to choose IVR as an intervention aid. First, IVR is cognitively non-

demanding, broadening the base of patients who may benefit (Copenhaver et al., 2003). Second, for those uninterested in psychological exploration or self-disclosure, IVR may be more neutral and less personal. Third, research has demonstrated that when combined with another intervention, methods like IVR that increase self-monitoring can reduce drinking behaviours (Mullen et al., 1997). Fourth, IVR avoids the inconvenience of written self-monitoring aids that are often given to patients in many drinking-reduction interventions (e.g., Fleming et al., 1997; NIAAA, 1995, 2002). Fifth, an important element in behaviour change is feedback. HealthCall allows a unique form of personalized feedback through generating a printed bar-graph display of the daily information collected via the IVR. In the study described below, we presented this visual feedback to patients at 30-day intervals in brief meetings with their MI counsellors.

The goals for this pilot study were two-fold: (1) to determine if low SES, largely minority HIV primary care patients would make regular calls to the IVR; and (2) to obtain preliminary evidence on whether participation appeared to reduce drinking.

**Methods***Sample*

Thirty-one patients entered the study. Of these, 80.7% were male; the mean age was 40.3 (range 27–55). Ethnically, 51.6% were Hispanic, 38.7% African-American, 6.5% white and 3.2% other. About a fifth (20.7%) lived in shelters or other temporary housing, and 29.0% did not have their own phone. Concerning health, 41.4% had Hepatitis B and/or C, 44.8% reported feeling ill or very ill in the week prior to entering the study, 35.5% reported that their mood was low or very low during the same period, and 54.8% were taking antiretroviral medication. Drug use was reported by 35.5%. All patients had 4+ drinks at least once in the last 30 days; 54.9% reported 5+ drinks at least once in the past week and 87.1% reported 5+ drinks at least once in the past month.

*Procedure*

Subjects were recruited via staff referrals from a large, hospital-based outpatient HIV primary care clinic in New York City. Eligibility to participate in the study was determined by having 4 or more drinks per occasion at least once in the prior 30 days. Exclusion criteria included: patient was currently psychotic, suicidal or homicidal; patient had definite plans to leave the greater New York metropolitan area within the study period; and patient did not

speak English or Spanish or had a hearing impairment that precluded use of the telephone. IRB approval was received both by the hospital clinic and by New York State Psychiatric Institute.

Two bilingual health counsellors (a research nurse and a health educator) from the HIV clinic were trained in MI by a certified MI trainer. During the study, a licensed clinical psychologist (EA) supervised the counsellors in weekly meetings. These covered how the study procedures were working, MI techniques, and patient reactions to the study.

During the first meeting, the patient gave informed consent and was assessed with a structured questionnaire. The MI counsellor administered the brief MI and trained the patient to use the IVR. The patient then made his/her first call to the IVR with the MI counsellor present. The patient received a wallet-sized reminder card with IVR calling instructions and date of the return visit.

The IVR 'script' began with an initial greeting, and then included three questions about alcohol consumption covering the number of drinks of beer, wine and liquor consumed in the previous 24 hours. For those who drank, nine questions covered reasons for drinking (e.g. 'to relax', or 'to be sociable'); for those who did not drink, nine questions covered reasons for not drinking (e.g. 'felt guilty' or 'I made a commitment to myself not to drink'). The number of questions was equal for drinkers and non-drinkers so that the telephone participation time would be the same. The IVR then asked 7 questions about other experiences in the prior 24 hours, including medication adherence, stress, mood (ranging from good to bad), feelings of health/illness, and current feeling of intoxication. The IVR ended by thanking the patient for participation.

At the end of the 30-day calling period, the MI counsellor met with the patient again and showed the bar graph representing his/her IVR-reported drinking. The counsellor then evaluated the patient for all outcome measures, including patient reactions to the intervention. The MI counsellor placed a reminder call to the patient after two consecutive missed calls. Due to counsellor caseload, the need for a second or third reminder call was determined on a case-by-case basis.

Originally, we planned to offer the intervention only for 30 days, with the more limited goal of determining calling feasibility. However, many patients wished to continue after their MI counsellor showed them their bar graph. Thus, we extended the intervention to determine how long patients would call and the duration that seemed most helpful in drinking reduction. Among the 31 patients entering the study, 28 patients returned for a 30-day interview and began an additional 30 days of participation. Of these, 24 returned for a 60-day interview

when a final 30 days were offered; 18 patients began the final 90 days, and 15 returned for the 90-day interview. Patients were paid \$40 per interview with the MI counsellor. They were not paid for calling the IVR because we wished to know if the intervention showed promise of being sustainable, and HIV clinics are unlikely to pay patients for participating in treatment.

### *Measures*

In the first meeting and at the end of each 30-day calling period, the MI counsellor conducted a brief structured interview with the patient. The structured interview included three sections: (1) frequency (days) and quantity (drinks) of alcohol consumed in the past week and month; (2) drug use (days/week), mood, physical health and medication adherence in the past week; and (3) additional questions covering qualitative patient reactions to different aspects of the intervention. Questions on alcohol consumption were derived from the AUDADIS (Grant & Hasin, 1992; Grant et al., 1995; Hasin et al., 1997; Grant et al., 2003), which covers standard drinks defined to respondents, including beer, wine and liquor. The AUDADIS has been shown to be reliable and valid in substance abuse, psychiatric and medical patients, as well as general population samples, both in the US and internationally (Grant et al., 1995; Hasin et al., 1996, 1997; Cottler et al., 1997; Pull et al., 1997; Chatterji et al., 1997; Ustun et al., 1997; Canino et al., 1999). Questions on mood were derived from the Schedule for Affective Disorders and Schizophrenia (Endicott & Spitzer, 1978).

### *Analysis*

We examined two main outcomes: calling levels and drinking levels. Calling was defined as a binary variable, while drinking level was indicated by number of drinks per day. We investigated drinking level from two sources of data: the IVR data that patients called in, and their reports on drinking in the past 7 days in the baseline, 30- and 60-day interviews. The IVR data requires only short-term (24-hour) recall, is made privately and is likely to be most accurate. However, missed calls lead to missing data. Drinking over the prior 7 days reported in baseline, 30- and 60-day interviews requires longer recall, but is complete among interviewed patients and is the type of data that would be used in a randomized trial comparing the efficacy of IVR as a drinking reduction to another intervention. In analysing the IVR drinking data, we addressed missing data by imputing the highest drinking value reported in the previous three days. At the point that patients

stopped calling completely, the IVR data were no longer available and were handled as missing.

Each outcome was analysed for within-subject change over time with repeated measures analysis with generalized linear models (GLM). Generalized estimating equations (GEE) were applied using SAS to estimate model parameters. GEE takes into account within-subject correlations of the repeated measures, uses all available data, and allows covariate analysis. A binary or linear model was used, depending on the form of the outcome variable. Covariates included: gender, age, race/ethnicity, hepatitis, MI counsellor (to examine counsellor effect), language preference, living in shelter/temporary housing, and baseline (last 7 days) drinking level, cocaine use, feeling ill, and low mood.

**Results**

*Calling results*

Of all calls made to the IVR, 23.1% were from pay phones. Thus, lack of phones was not a barrier to participation, and some patients made a surprising effort to participate. During the first 30 days, 715, or 76.9% of the 930 possible IVR calls (31 × 30) were made. The median number of calls per patient was 25. During the second 30 days (days 31–60), the 28 patients who continued made 548 (65.2%) of the possible calls. The median number of calls made during this time was 23. Twenty-four patients returned for a 60-day interview (77.4% of the original sample). During the final 30 days (days 61–90), the 18 patients who wished to continue made 382 (70.7%) of the possible calls, and 15 (48% of the original sample) returned for a 90-day interview. Thus, while patients who wished to continue

after 60 days did well in maintaining consistent calling, a 60-day intervention appeared to optimize participation relative to improvement in drinking (see below). We thus present remaining results mainly for the 60-day time.

Repeated measures analysis of within-subject change in call likelihood over time indicated that there was no significant change in call likelihood over the first 30 days. Consistent with the descriptive results showing that some patients did not continue, the GEE analysis using a logistic regression model showed a decline in calls over 60 days ( $\beta = -0.03$ , se 0.01,  $p < .0001$ ). Variables associated with increased calling likelihood over time at 60 days were use of cocaine at baseline ( $\beta = 1.91$ , se 0.33,  $p < .00001$ ), having a home and/or cell phone ( $\beta = 1.02$ , se 0.40,  $p = .01$ ), speaking Spanish ( $\beta = 0.86$ , se 0.40,  $p = .03$ ), and feeling ill at baseline ( $\beta = 2.00$ , se 0.39,  $p < .0001$ ). Importantly, higher drinking at baseline (largest drinks in the past 7 days) was also associated with greater call likelihood at 60 days ( $\beta = 0.07$ , se 0.02,  $p < .01$ ).

As noted, we had planned to place reminder calls to patients after they missed two consecutive days, up to three times for any patient. The highest number of such calls would have been 176 over the full 90 days. In fact, fewer reminder calls were placed (the actual number was unavailable) due to counsellor absence and workload.

*Drinking results*

Figure 1 shows the mean IVR-reported number of drinks per day, per patient, over 60 days. With some day-to-day variation, the graph clearly shows a downward trend.

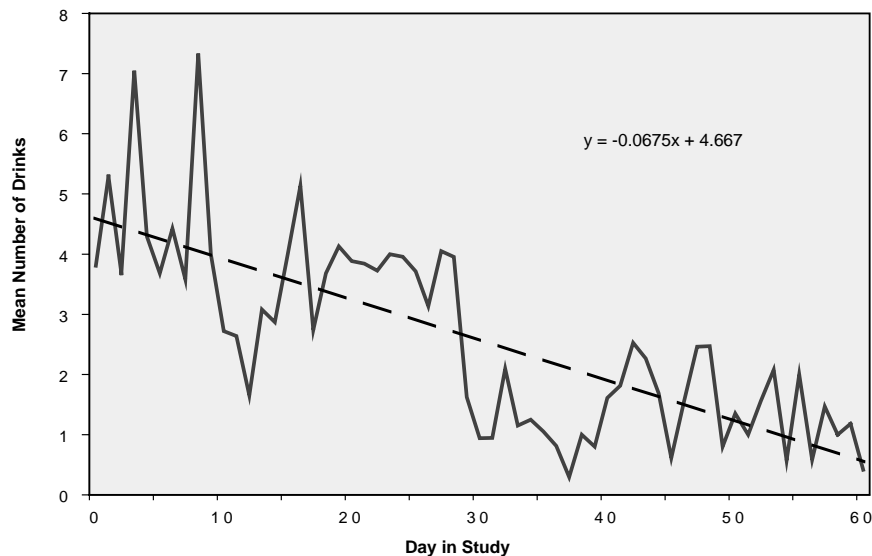


Figure 1. Mean Number of Drinks, by Day in Study.

Within-subject analysis of change in drinking level over time was first conducted using IVR-reported drinking. Drinking reduction was not statistically significant at 30 days ( $\beta = -0.01$ , se 0.01,  $p = .31$ ), but at 60 days, the decline in drinking had become significant ( $\beta = -0.01$ , se 0.005,  $p = .03$ ). (Results were also significant,  $p = .005$ , among patients remaining for 90 days). In terms of characteristics associated with change in drinking level at 60 days, patients with a home/cell phone decreased their drinking more ( $\beta = -1.08$ , se 0.45,  $p = .02$ ), while patients not feeling ill in the week prior to baseline showed a trend towards greater decrease ( $\beta = -1.08$ , se 0.57,  $p = .05$ ).

To analyse within-subject change in drinking level over time using the interview data, we created three drinking variables based on the 7-day drinking data collected in the interviews. These included highest number of drinks in a single day, mean drinks per day across the seven days, and total number of drinks in the seven days. The mean highest drinks per day was 8.4 (se 1.5) at baseline, 4.1 (se 1.1) at 30 days and 3.8 (se 1.3) at 60 days. Mean drinks per day was 3.2 (se 0.5) at baseline, 1.7 (se 0.5) at 30 days and 1.2 (se 0.4) at 60 days. The mean total drinks in the last 7 days was 22.3 (se 3.7) at baseline, 12.0 (se 3.4) at 30 days and 8.6 (se 3.1) at 60 days. These all suggest decreased drinking over time.

Using repeated measures GLM with a linear regression model, results were very similar regardless of the drinking variable, so we present highest number of drinks/day in the prior 7 days. Drinking level decreased significantly over the three time points of baseline, 30 and 60 days ( $\beta = -0.49$ , se 0.17,  $p = .003$ ). Patients feeling healthy at baseline decreased their drinking more ( $\beta = -0.62$ , se 0.19,  $p = .001$ ) as did those with better baseline mood ( $\beta = -0.92$ , se 0.24,  $p < .01$ ).

To address whether patients with milder drinking problems were more likely to return for follow-up at 60 days, largest numbers of drinks in the 7 days prior to baseline was compared between patients who did not return at 60 days ( $n = 7$ , median number of drinks 6.0) were compared with those who did return ( $n = 24$ , median number of drinks 6.5). A non-parametric exact test indicated that this was not a statistically significant difference ( $p = .51$ ).

We did not intervene directly on cocaine use in either the MI or the IVR. However, cocaine use as assessed in the brief interviews declined significantly at 60 days using the same method of analysis ( $\beta = -0.70$ , se 0.36,  $p < .05$ ).

#### *Patient feedback on the intervention*

All patients reported that the IVR calls increased awareness of their drinking levels. Patients also

reported positive reactions to the calls ('making the calls makes me feel good about myself'; 'the calls helped my self-control; I get pride to keep up with my goal'). No patient who received a reminder call to keep calling reported a negative reaction to the reminders; a few said such calls showed that someone cared how they were doing.

Many patients reacted with surprise to the graph, either because their drinking was greater than they realized ('... It was hard to see how much I was really drinking'), or because they did not realize they were doing so well ('I'm surprised I was able to make my goal. I'm happy'). Either way, the graph made a strong, useful impact ('... helped me be honest with myself'; '... inspirational to continue on my goal', '... made me feel good I could cut down'). Of the 17 patients on antiretroviral medication at baseline (as indicated by their charts), 6 (35.3%) stated they improved medication adherence through the intervention; improvement in medication adherence was seen in both the IVR and interview reports but did not reach statistical significance. Of drug users at baseline, 11 of the 13 felt their drug use decreased as a result of the intervention. About 2/3 of the patients found the calls interesting or neutral as long as they continued to call. Others found the calls interesting initially but somewhat repetitious later, especially in the final 30 days.

#### **Discussion**

In terms of our first goal for this pilot study, we determined that among this low-income HIV primary care patient population, a high proportion of patients drinking excessively who participated in a brief MI interview and IVR instruction were willing to make near-daily calls to the IVR for extended periods of time. There was no significant decline in calling over the first 30 days. While some decline occurred by the 60- and 90-day points, the patients who remained in the study continued to make most of their calls. Importantly, higher drinking at baseline was actually associated with better (higher) call likelihood at 60 days, suggesting that self-selection for drinking was not responsible for the results. Because patients were paid for the interview but not for making their calls, it is unlikely that the remuneration was responsible for the patients' impressive calling record, supporting feasibility and sustainability of IVR as a component of drinking-reduction intervention.

We initially intended to offer the intervention for only 30 days. However, we extended the trial when some patients said they wished to continue, utilizing the pilot phase to indicate an optimal duration to achieve drinking improvement relative to continued participation. From this, a 60-day period appeared

best, suggesting that this period be used in a randomized trial of the intervention compared to a control condition. Qualitative feedback from the patients as well as input from the MI counsellors suggested that after the first 30 days, continued calling would be enhanced by some variation in the outgoing greeting (e.g. acknowledgment of entering the 2nd 30 days, a comment that the day of the call falls on a holiday), an element that can be easily incorporated.

In terms of our second goal based on a within-subjects change analysis, a significant and substantial drop in drinking levels occurred at the 60- and 90-day points. Qualitative comments from the debriefing interviews re-affirmed that a number of the patients found the intervention helpful, including the initial interview, the daily calling, and viewing their drinking in the bar graph presentation. We also saw increases in medication adherence that did not reach significance in this small group, and less use of drugs that reached statistical significance ( $p < .05$ ) by 60 days. This suggests that drinking reduction was not achieved via replacement of alcohol by other substances. These results are encouraging, and support the need for more rigorous scrutiny of a randomized controlled trial to understand their efficacy better. In particular, the design of such a trial should allow determination of whether Health-Call offers significant improvement over a control condition, or participation in the initial MI interview only.

Limitations to the study are noted. (1) This was a preliminary 'test-of-concept' trial, so the target  $N$  was initially 30 patients, and no controlled comparison group was included. A future controlled trial with a larger  $N$  is clearly warranted. (2) Refusals were not recorded systematically enough to report an accurate response rate. Anecdotal reports from the counsellors indicated few refusals, but this is clearly important to track in a future study. (3) While we used alcohol measures whose psychometric properties have been extensively demonstrated in English and Spanish-speaking substance abuse, psychiatric and medical patients, blood alcohol content (BAC) indicators of recent alcohol consumption were not obtained at follow-up. BAC cannot substitute for number of drinks, and thus could not be used for the analyses in this or a larger study. Further, sufficient alcohol consumption was reported at follow-up that we have no reason to suspect wide-scale denial of drinking. However, BAC data would be helpful as a validity check to include in a future trial. (4) Although drinking was reduced at 30 days as shown on Figure 1, the results at this point were not yet significant given the small  $N$ . Response to the intervention was stronger and significant by 60 days. A larger trial that includes a post-intervention

follow-up will provide more information about the overall response to the intervention at the 30-day and 60 day point as well as subsequently.

The two clinic counsellors who administered the intervention were interested and enthusiastic about what they did. Having non-physician clinic staff rather than physicians or specialized researchers administer the intervention is promising for later dissemination of the results.

Antiretroviral medications reduce mortality from HIV/AIDS, but bring serious, chronic health issues to the fore. Thus, the development of sustainable, effective drinking-reduction interventions among HIV primary care patients is important. To our knowledge, no published interventions focused on drinking reduction as the primary outcome among patients in HIV clinics have been developed or tested. Extensive evidence supports brief motivational interviewing (MI) as an effective drinking-reduction intervention in many treatment settings, including primary care. However, risk reduction interventions often produce initial or short-term behavioural changes that erode over time, and very brief MI may require enhancement to be effective. This preliminary study shows that rather than an erosion of the effects of brief MI over time, the opposite occurred, with drinking continuing to diminish over 60 days. Thus, IVR plus periodic graphical feedback may be a way to enhance brief MI without extensive demands on clinic staff. The next step is a rigorous controlled trial that will provide more information on efficacy and mechanisms of effect. If efficacy is supported in a larger trial, then the efficacy of this intervention can also be tested in other types of patient groups where drinking reduction is important.

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