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HealthCall: Technology-based extension of Motivational Interviewing to reduce noninjection drug use in HIV primary care patients: a pilot study

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Abstract

<u>Background</u>. To reduce non-injection drug use (NIDU) among HIV primary care patients, more than single brief interventions may be needed, but clinic resources are often too limited for extended interventions. To extend brief Motivational Interviewing (MI) to reduce NIDU, we designed and conducted a pilot study of "HealthCall", consisting of brief (1-3 min) daily patient calls reporting NIDU and health behaviors to a telephone-based Interactive Voice Response system, which provided data for subsequent personalized feedback.

<u>Method.</u> Urban HIV adult clinic patients reporting≥4 days of NIDU in the past month were randomized to two groups: MI-only (n=20), or MI+HealthCall (n=20). At 30 and 60 days, patients were assessed and briefly discussed their NIDU behaviors with counselors. The outcome was days used primary drug. Medical marijuana issues precluded HealthCall with patients whose primary substance was marijuana (n=7); excluding these, 28 patients (MI-only n=17; MI+HealthCall n=11) provided post-treatment data for analysis.

<u>Results</u>. Time significantly predicted reduction in days used (p<.0001). At 60 days, betweengroup differences approached trend level, with an effect size of 0.62 favoring the MI+HealthCall arm.

<u>Conclusions</u>. This pilot study suggests that HealthCall is feasible and acceptable to patients in resource-limited HIV primary care settings, and can extend patient involvement in brief intervention with little additional staff time. A larger efficacy trial of HealthCall for NIDU-reduction in such settings is warranted.

In the past, injection drug use has been a principal means of HIV transmission, but HIV is now equally prevalent among injection- and non-injection drug users, and increasingly occurs through heterosexual risk behaviors while under the influence of non-injected drugs (Mitchell and Latimer, 2009; Des Jarlais et al., 2007). In addition, non-injection drug use (NIDU) is associated with poor adherence to antiretroviral therapy (ART), leading to drug-resistant strains of HIV and increased mortality (Mausbach et al., 2007; Woody, 2009). Reducing NIDU in HIVinfected individuals is therefore an important health priority. Evidence-based behavioral treatment can reduce substance abuse (e.g., McKee et al., 2007; Carroll et al., 1994; Meade et al., 2010), but these interventions require between 6 and 15 60-90 min sessions in which counselors administer complex manualized treatment. Brief interventions such as motivational interviewing (MI) have also been proposed (Burke et al., 2001; Miller and Rollnick, 2002); Rollnick and Miller, 1995), but among patients with complex problems, evidence suggests that more extensive intervention is required for efficacy (Emmons and Rollnick, 2001). Many HIVinfected individuals are treated in HIV primary care clinics, where resources limit the time and training for staff to focus on NIDU reduction. In such settings, innovative solutions are needed to extend the "dose" of NIDU-reduction intervention without placing unrealistic demands on clinic staff.

One potential way to extend intervention is through emerging telephone-based technologies, which offer ways to improve health outcomes in resource-limited settings, for example, automated Interactive Voice Response (IVR). IVR is a flexible, telephone-based technology that has shown promise in helping patients to manage chronic illness and medications (Oake et al., 2009; Kaplan 2006; Lester et al., 2010; Reid et al., 2007). IVR has been used for alcohol screening and as an adjunct to standard care (Helzer et al., 2008; Rose et al., 2010). This strategy seemed particularly appropriate for urban HIV primary care clinics, where limited staff time and resources make extended interventions for substance abuse unfeasible (Strauss et al., 2009).

Accordingly, we designed an enhancement of brief Motivational Interviewing consisting of 1-3 minute patient calls to "HealthCall", utilizing a telephone Interactive Voice Response (IVR) platform. Originally targeting heavy drinking, we designed HealthCall to facilitate ongoing self-monitoring, awareness of use, and self-efficacy regarding reduction. Patients call HealthCall daily via a toll-free number to report on the targeted health behavior and potentially related moods, behaviors and situations occurring in the prior 24 hours. Call data are summarized for patients in monthly personalized feedback graphs. We previously showed that MI+HealthCall to reduce heavy drinking was acceptable to disadvantaged minority HIV primary care patients (Aharonovich et al., 2006). A subsequent large randomized trial in this population showed significantly greater drinking reduction for participants in MI+HealthCall compared to MI-only or an educational control condition (Hasin et al., under review). The intervention was implemented over a 60-day period, which the earlier study showed was the optimal duration based on reduction in substance use relative to continued participation (Aharonovich et al., 2006).

Given patients' positive responses to HealthCall for heavy drinking and at the urging of clinic medical staff, we adapted MI+HealthCall to focus on reduction in NIDU as the outcome. We report on a proof-of-concept pilot study consisting of a small randomized trial comparing MI+HealthCall to MI-only to reduce NIDU in urban HIV primary care patients. Our primary outcome was number of days the patient used his/her primary drug in the prior 30 days.

Method

<u>Participants</u>. Inclusion criteria consisted of: being HIV-positive, English- or Spanish-speaking, aged ≥18 years, enrolled in a New York City hospital-affiliated HIV primary care clinic, using drugs four or more days during the prior 30 days (including illicit non-injection drugs or licit drugs taken without prescription or more than prescribed). Exclusion criteria included active psychosis, suicidality, gross cognitive impairment (Halstead-Reitan Trails A; Reitan and Wolfson, 1992), injection drugs use in the last 30 days, or alcohol as primary substance. Participants provided written informed consent, and were compensated for assessments, but not for treatment or calling HealthCall. The study protocol was approved by the hospital institutional review board.

<u>Procedures</u>. Patients were referred to study counselors for written informed consent and assessment of eligibility. Of 43 patients screened for the study (Figure 2), 40 met inclusion criteria and were randomized to treatment as follows: MI-only (N=20) and MI+HealthCall (N=20). The randomization was done via 10-block standard ABAB design. After receiving the treatment condition, patients returned at 30 and 60 days for assessments and brief meetings (10-15 min) with a counselor. Patients received \$20 gift certificates for each assessment. Calling HealthCall was not compensated as HIV clinics are unlikely to pay patients to participate in treatment and we wanted to test a potentially sustainable intervention.

<u>Counselors</u>. Counselors were bilingual (English/Spanish) and from the same race/ethnic groups as most of the patients. One had a MA in health education, and the other a BA in psychology. Both were trained in the delivery of brief MI and HealthCall for drinking reduction (Hasin et al., under review) but neither had previous experience in substance abuse counseling. Counselors were supervised weekly by a licensed psychologist (EA). MI sessions were audiotaped and 10% were randomly selected for fidelity ratings, which indicated acceptable MI performance using a standardized coding system (MITI; Moyers et al., 2005).

Treatments

<u>MI-only</u>. In MI-only arm, counselors administered a 20-25 min MI at baseline, using standard MI techniques, e.g., dialogue about health consequences of NIDU, exploring ambivalence, barriers to change, developing a change plan, including (for those who chose) a specific NIDU-reduction goal (reflected in \$ amounts) for the next 30 days. Patients then received a digital alarm watch which they were told they could use as a medication reminder. At 30 and 60 days, counselor and patient met for 10-15 minutes to review overall drug use and set or re-set a drug reduction goal for the next 30 days.

<u>MI+HealthCall</u>. In the MI+HealthCall arm, counselors conducted all baseline activities described in the MI arm. They then instructed patients in the use of HealthCall and asked patients to call daily for the next 30 days. Patients then completed a practice call to HealthCall. The HealthCall menu for NIDU included a short set of pre-recorded questions about the previous day covering use of primary drug, dollar amount of the drug used, use of other drugs, HIV medication adherence and feelings of wellness, stress and overall quality of the day. All HealthCall questions are asked about "yesterday" (morning, afternoon, evening) to ensure a consistent reporting period regardless of the hour called. Patients responded by pressing numbers on the telephone keypad. After the practice call, counselors helped patients identify an accessible telephone and convenient time for daily calls, and set the watch alarm to this time as a reminder to call. HealthCall data were automatically uploaded to a database and used to provide personalized feedback to patients about their drug use in form that contained a computer-generated graph (Figure 1) during 30-day and 60-day meetings. The form displayed the number of days using primary drug in the prior 30 days, total reported amount of drug for each day, summary statistic of average amount per day and reasons for using. Days patients did not call HealthCall were shown as missing. Among patients who set a personal NIDU reduction goal, the goal was displayed on the graph. If patients went longer than 48 hours without calling, counselors made a brief reminder call about the importance of regular calling. If needed, the 30-day meeting included discussion of ways to improve calling frequency.

<u>Assessment</u>. Patients were assessed using a self-administered audio computer-assisted interview (A-CASI) for baseline variables such as demographics, years since HIV diagnosis, current primary drug and history of drug use. All measures were administered at the HIV clinic in the patient's choice of English or Spanish. The primary study outcome, days using primary drug, was assessed at baseline, 30 days and 60 days in both arms with the Time-Line Follow Back Interview (TLFB),²¹ which uses a calendar and memory aids to reconstruct estimates of drug use levels. We used these data to create composite variables indicating mean days using primary drug. We did not analyze HealthCall data as the primary outcome because these data were available only from the MI+HealthCall group. Patient feedback was elicited at 60 days (end of treatment) with structured questions and unstructured comments.

<u>Statistical Analysis</u>. We analyzed change among participants with data from the 30-and/or 60day assessments. The primary outcome, days used primary drug in last 30 days, was transformed (log+1) to better meet normality assumptions and then analyzed with repeated measures analysis using generalized linear models (GLM). Generalized estimating equations (GEE) were applied to estimate model parameters. GEE takes into account within-subject correlations of the repeated measures, uses all available data, and allows incorporation of covariates, which included gender, age, race and log of days used at baseline.

Results

<u>Retention</u>. Of 40 participants, seven whose primary drug was marijuana were excluded from further consideration due to complications arising from medical marijuana issues. Of the remaining 33 patients, retention to 30 days was 84.8% and to 60 days, 78.8%. Patients not retained in the study either had known relocations outside New York City (n=3) or simply did not return to the HIV clinic at all (n=2). Treatment groups did not differ on attrition (p>0.10) and thus attrition is not likely to be a source of bias in our results.

<u>Baseline Characteristics</u>. Table 1 presents the demographic and drug use characteristics of the baseline sample (N=33). Of all participants, 75.8% were male, 63.6% were African American, 21.2% were Hispanic and the rest Caucasian. Over a third (36.4%) lived in shelters or other unstable housing, 48.5% had hepatitis, and the mean age was in the mid-40s. Cocaine/crack was the predominant primary substance (75.8%), with rest heroin (15.2%) and methamphetamine (9.1%) abusers.

<u>Call Data</u>. Calls to HealthCall lasted a mean of 1 minute, 59 seconds. Among those in the MI+HealthCall group, the mean and median number of possible calls to HealthCall (excluding days incarcerated or hospitalized) was 58% and 56%. Analyses showed that age, sex, race, primary drug, and counselor were unrelated to call response (p>.05).

<u>Reduction in Days of Primary Drug Use</u>, Figure 3 shows a clear downward trend in mean days used primary drug for both groups, with a greater decline for the MI+HealthCall group. The GEE model showed a significant effect of time (p<00001) for both treatment groups over the 60-day period. Group differences at 30 day and 60 day time points were not significant but approached trend level at 60 days (p=0.13), with an effect size of 0.62 (Cohen's *d*) indicating that the log-transformed means of the two groups are separated by 0.62 times their pooled standard deviation, typically understood as a moderate effect (Cohen, 1988, p. 77-81).

Patient Feedback. Using the patient feedback from the end-of-treatment (60-day) assessment, all patients said calls were easy and increased awareness of their drug use. Many (69.2%) said the calls helped them reduce drug use; 57% said that they would continue calling if possible. Patients commented that using HealthCall was "exciting and provided positive reinforcement" and helped "become more alert" and "maintain focus." Patients responded positively to the accessibility and interactive quality, saying that "it is like having to answer to someone every day," "gave... attention never received from doctors." A few patients who found HealthCall helpful nonetheless said making the calls was "hard to remember" or "annoying." Seeing the personalized graphs gave patients a sense of accountability (the graphs allowed seeing "the peaks of when I went beyond my goal" "make me think about the money I'm spending," "it was depressing to see how much I used") or accomplishment ("show that I can do it"). Patient reactions to counselor reminder calls were generally favorable; one patient said "they are really on top of me and would like me to maintain awareness of my usage." Participants also made suggestions to improve HealthCall, e.g., that we add questions about their drinking.

Discussion

This is the first study using IVR technology to extend brief MI aimed at reducing NIDU among HIV primary care patients. HealthCall was designed to be acceptable to patients yet not place unrealistic demands on staff time. In this proof-of-concept study, participants were largely members of disadvantaged minority groups, many with multiple problems including unstable housing. Retention in the study was excellent, and the patients made many of the possible daily calls to HealthCall. For both treatment arms (MI-only and MI+HealthCall), patients significantly decreased their number of days using their primary drug from baseline to 60 days. As predicted, participants in the MI+HealthCall group showed greater reduction, moving from an average of 9.2 to 2 days of NIDU per month, with a moderate effect size. Although we did not expect a significant difference between the groups due to the small sample size, the p-value for a group difference 60 days approached trend level, and the effect size was well within the range supporting the value of a larger study. Results supported potential value of HealthCall as an extension to MI that would result in greater reduction of days used among patients whose primary drug was cocaine/crack, heroin or methamphetamine, and consequently further investigation of MI enhanced by HealthCall in a larger randomized trial.

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. At present, HealthCall's mechanism of action is unknown, but exploration of mechanisms in a larger trial would be useful.

Given that this was a pilot phase of investigation, we wished to explore whether MI+HealthCall could be helpful to patients whose primary drug was marijuana, despite knowledge of potential complications due to the wish of some patients to use marijuana for medical purposes. Although all patients whose primary drug was marijuana met DSM-IV criteria for abuse or dependence,

agreed to participate in the study, and did not differ significantly from others in the sample on any of the demographic variables measured, this group proved reluctant to reduce what was, in several cases, daily marijuana use for purposes such as stimulating appetite. This contrasted sharply from the users of other drugs, who did not see medical benefits to their substance use. Thus, study results indicate that the screening and MI+HealthCall procedures in their current form are not optimal for HIV primary care patients whose primary substance is marijuana. Future studies could include further adaptations to be suitable for this group.

Study limitations are noted. (1) This was a pilot study with a target N of 40. A larger randomized study with enough power to detect significant differences is warranted. (2) Given the scope of the study, we considered only reduction in days used NIDU as the primary outcome. Other indicators of drug use and other outcomes (ART adherence; sexual risk behaviors) would provide a better understanding of the direct and indirect benefits of HealthCall. (3) Patients whose primary or only drug was marijuana differed from primary users of other drugs on motives for use. Patients spoke of health benefits (e.g. stimulating appetite) of marijuana and wished to continue, in contrast to primary users of other drugs who saw their use as mostly harmful and clearly perceived the need to reduce. Different screening and/or intervention procedures might overcome the challenge of differentiating between medical and other marijuana users, which would require formative developmental work and a new pilot study.

Patients made suggestions to us on how to improve HealthCall, and we have incorporated these suggestions, as well as increasing the interactivity of HealthCall, which patients appear to value. We are currently preparing to conduct a larger randomized trial that will provide information about this version, as well as information on a much broader range of measures and post-treatment follow-up data on whether benefits extend past the end of treatment.

Our sample was drawn from a urban treatment setting with a disadvantaged patient population, and our minimal exclusion criteria and high retention rate support generalizeability to similar populations. The study shows that IVR technology could be implemented by non-physician staff with few additional demands on clinic resources. Further studies are needed to demonstrate utility with alternative settings and providers (e.g., case managers, peer counselors). The flexibility and low cost of HealthCall (the platform cost ~\$11,000 U.S), the ubiquity of telephone access across national and class boundaries (Lester et al., 2010; Shacham et al., 2009) and our successful implementation are all promising indicators of the dissemination of our strategy.

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Figure 1: Sample Graph Showing Days and Amount of Primary Drug Use





Table 1: Baseline Characteristics	by Treatment Condition
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	MI+IVR N=15	MI Only N=18	
	%	%	
Female	26.7	22.2	
Ethnicity			
African American	60.0	66.7	
Hispanic	26.7	16.7	
Caucasian	6.7	5.6	
Spanish-speaking	6.7	0.0	
Unstable housing	53.3	22.2	
Hepatitis	60.0	38.9	
HIV meds prescribed	46.7	77.8	
Primary drug			
Cocaine/Crack	80.0	72.2	
Heroin	20.0	11.1	
Methamphetamine	0.0	16.7	
	Mean (sd)	Mean (sd)	
Age, years	46.3(5.7)	44.8(7.3)	
Mean Number of Days Used Out of Last 30 days (SD)	9.2(7.0)	10.2(6.9)	

		30	60	60 days
Mean	Baseline	days	days	Effect Size*
Days used				
primary drug				
MI-only	10.2	6.2	4.1	
MI+HealthCall	9.2	3.4	2.0	0.62
*log transformed				

Table 2: Results, NIDU prior 30 days, N=33

Figure 3: Days Used (log-transformed, by Group and Time Point)

