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The Feasibility of Modified Directly Observed Therapy for HIV-Seropositive African American Substance Users

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ABSTRACT
Recently, modified directly observed therapy (MDOT) has emerged as a promising intervention to address nonadherence for hard-to-reach populations infected with HIV. To date, there are no existing data on MDOT focusing exclusively on African Americans. The present study sought to determine the feasibility of MDOT among 31 HIV-seropositive African American substance users in the South. An outreach worker observed the participants’ medication intake 5 days per week (once per day) for a period of 3 months (intensive phase). This phase was followed by a transition phase of 3 months during which the frequency of MDOT was gradually tapered from 5 days to once weekly. Assessments to gather demographic information, HIV risk behaviors, substance use, depression, and medication adherence were conducted at baseline, 3 months, and 6 months. Results indicated that more participants adhered to their medication regimen and had viral loads of less than 400 copies per milliliter at 3 and 6 months compared to baseline. Participants reported significantly less depressive symptoms at the 6-month assessment compared to baseline and 3 months. With regard to acceptability, 95% of participants indicated they liked having the outreach visits, 100% reported MDOT helped them take their medications, and only 5% felt MDOT was a violation of privacy. These results suggest MDOT is feasible among African American substance users in the South and a larger controlled study of MDOT with this population is warranted.

INTRODUCTION

African Americans are disproportionately impacted by the HIV/AIDS epidemic. In 2005, approximately 49% of all HIV/AIDS cases were African Americans.1 African Americans with AIDS have a higher mortality rate compared to other racial and ethnic groups.2 Despite the advent of highly active antiretroviral therapies (HAART), AIDS is the leading cause of death among African American women aged 25–34.3 Substance abuse has been cited along with other barriers (e.g., socioeconomic issues, access to care, delay in diagnosis) as a factor that impacts treatment success among African Americans.1,4 Poor adherence to HIV medication regimens has been widely associated with drug abuse.5–7 In a study of African American

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women, crack and other drug users were significantly less likely to adhere to their antiretroviral medication regimen as prescribed compared to nonusers. While the average rate of adherence to HAART is 71%, a study of African American drug users reported complete adherence with zidovudine was less than 32%.

Recently, modified directly observed therapy (MDOT) has emerged as a promising tool in the efforts to improve adherence to HAART regimens. MDOT involves ingesting a portion of the total doses of HAART regimen under supervision. MDOT has been successfully applied to marginalized HIV patients who demonstrate significant barriers to medication adherence. Feasibility of observed therapy was demonstrated in community based programs and among drug users. Emergent literature has also reported high rates of virologic suppression and positive clinical outcomes resulting from observed therapy. For example, in a study of patients seeking treatment at methadone clinics, 56% of the patients enrolled in directly administered antiretroviral therapy achieved an HIV RNA level less than 400 copies per milliliter relative to 32% in a comparison group.

The challenges of implementing MDOT for HIV medication adherence include the duration of treatment, frequency of medication dosing, timing of MDOT initiation, and the development of drug resistance. In a simulation model using Markov assumptions with Monte Carlo uncertainty analysis, Kagay and colleagues reported MDOT may increase the risk of drug resistance. However, the analysis also revealed that MDOT can improve the risk of virologic failure, development of opportunistic infections, and death. Although concerns over MDOT in HIV remain and need to be addressed in future research, much of the literature on MDOT suggests it can have a significant impact on improving medication adherence among hard-to-reach populations.

To date, there is no existing study focusing exclusively on the use of MDOT among African Americans. Cultural barriers to antiretroviral treatment for African Americans include lack of access to health care and support services, cultural differences between patients and providers, HIV-related stigma, denial, mistrust, and myths associated with HIV/AIDS. A belief held by some American Africans that HIV/AIDS is a form of genocide has been documented in the literature. In a national phone survey of 500 African Americans, 53% held the belief, “There is a cure for AIDS, but it is being withheld from the poor,” and 48% endorsed, “HIV is a man-made virus.” This “conspiracy theory” has resulted in mistrust of the government and medical institutions, posing significant barrier to HIV prevention and care. In light of these cultural barriers, evaluating the feasibility of MDOT among African Americans is warranted.

In addition to a lack of literature on African Americans, current studies on MDOT have not examined the feasibility of observed therapy in the southern United States. Compared to the rest of the nation, the South has the greatest number of AIDS cases, AIDS deaths, and new AIDS diagnoses. Furthermore, the impact of HIV/AIDS among African Americans is particularly salient in the South. For example, in Mississippi, African Americans accounted for over 70% of HIV/AIDS cases in 2005. The Southern states are culturally distinct from the rest of the country. This region of the United States is characterized by political conservatism, poverty, lack of insurance, inadequate health infrastructures, poor access to health care and social services, and an insufficient number of HIV providers. Thus, the acceptability of MDOT in the South warrants investigation. In this study, we report the results of a pilot study to determine the feasibility of MDOT among HIV seropositive African American substance users living in rural and urban areas in the southern United States.

MATERIALS AND METHODS

Participants

Patients receiving treatment at primary care clinics and a university based infectious disease clinic were referred to the study by their health care providers. Eligibility criteria for enrollment were: (1) age older than 18, (2) African American, (3) currently on HAART, (4) missed
at least 10% of the prescribed HAART doses over a 4-day period, and (5) history of substance use. The substance use history was defined as meeting one or more of the following: (1) used cocaine/crack or heroin in the past 6 months, (2) used marijuana more than 4 times per week in the past 6 months, and (3) used alcohol in the past 30 days [and endorsed at least one of four CAGE questions (Cutting down, Annoyance by criticism, Guilty feeling, and Eye-openers)\textsuperscript{33} and consumed more than 14 drinks/week (male) or consumed more than 7 drinks per week (female), or (c) consumed more than 4 drinks at one time (male) or consumed more than 3 at one time (female)]. Of the 49 patients screened for the study, 18 were excluded because they did not meet the non-adherence and/or substance use eligibility criteria. The remaining 31 participants were invited to participate in the study. Participants signed the appropriate informed consent and release of medical information forms. The study was conducted in accordance with the US Department of Health and Human Services and University Institutional Review Board (IRB) guidelines for human experimentation.

Assessment

Assessments were made at baseline, 3 months, and 6 months. Laboratory work for viral load determination was completed by the participants’ health care providers during routine medical visits every three months. Study enrollment was timed to correspond within a week of the regularly scheduled blood work for viral load. The subsequent assessments were conducted at the same time as the routine medical visits and viral load data were extracted from the participants’ medical records at 3 and 6 months.

Face-to-face interviews were conducted to collect psychosocial and behavioral data. The interviews were administered by research associates not involved with the outreach visits to minimize social desirability bias. The assessment package included surveys of demographic information, HIV risk behaviors, substance use, depression using the Beck Depression Inventory-II (BDI-II)\textsuperscript{34} and adherence to HIV medication. Nonadherence was assessed using self-report and determined by dividing the number of missed doses by the number of total prescribed doses over a 4 day period. At 3 and 6 months, the interviews also included questions to determine intervention acceptability and feasibility. Participants were provided an honorarium of $20 for each of the first two assessments and $25 for the final assessment.

Intervention

The intervention consisted of a 3-month intensive phase and a 3-month transition phase. During the intensive phase, an outreach worker met with the participants 5 days per week. The direct observation was made once per day with the morning dose. The evening and weekend doses were self-administered by the participants. All initial visits with participants were made by two research associates in an effort to enhance the safety of the staff. The location and time of subsequent outreach visits were determined jointly by the participant and the outreach worker. At the initial visit, a list of places and phone numbers where the participant might be located or contacted was obtained along with a follow-up plan in the event that the participant was not at the designated meeting place. During this visit, the outreach worker also addressed possible concerns regarding the daily visits, such as fear of disclosure.

The outreach visits lasted approximately 15 minutes. At each visit, the outreach worker observed the participants take their medication. Symptoms of side effects, medical concerns, and adherence to self-administered doses were assessed and recorded daily. As necessary, the outreach worker served as a liaison to the participants’ medical clinic (i.e., communicated with health care providers on medication side effects and medical concerns, reminded participants of clinic appointments), facilitated medication refills, and provided referrals and linkages to care.

During the 3-month transition phase, outreach visits were tapered gradually from 5 days to 1 day per week. The tapering schedule was as follows: (1) week 13–15, 4 days per week, (2) week 16–18, 3 days per week, (3) week 19–21,
2 days per week, and (4) week 22–24, 1 day per week.

The team of interviewers and outreach workers comprised African American women from the community who had experience working in a research setting. Each team member attended a 2-day HIV workshop conducted by the American Red Cross. The research team also received training on antiretroviral medication from the second author, a pharmacist specializing in HIV medication, and crisis management from the first author, a licensed psychologist.

RESULTS

Thirty-one African Americans participated in the study. The demographic characteristics of the study sample are illustrated in Table 1. The mean age of the participants was 41 ± 8. The majority of participants were unemployed. Of the 61% who indicated they had medical insurance, all reported they had Medicaid. Ninety percent of the study sample indicated using the state program to pay for HIV medication. All participants reported using alcohol or other illegal drugs in the past 6 months and 90% indicated drug use in the past 3 months. The median viral load at baseline was 3898 copies per milliliter (range, < 50 to > 750,000 copies per milliliter).

Twenty-four participants completed the intensive phase at 3 months (77% retention) and 21 completed the transition phase at 6 months (68% retention). Among those who exited the study early, 50% (n = 5) were participant initiated and 50% (n=5) were administrative drops (initiated by the research team). Reasons for participant initiated termination included no longer being interested (n = 3), change in life circumstances (n = 1), and desiring financial compensation for participation (n = 1). Factors for the administrative drops were participant non-responsiveness (n = 2), inability to track the participant due to homelessness (n = 1), the participant being verbally abusive to the outreach worker (n = 1), and a participant being on “medication holiday” (n = 1).

For the current study, adherence was viewed as a dichotomous variable. Although 10% non-adherence was used as the study inclusion criteria to identify any potentially nonadherent individuals, participants were dichotomized into either an adherent or nonadherent group for the analyses using the criterion of 80% adherence. Participants taking less than 80% of their prescribed doses over a 4-day period were considered non-adherent to their medication regimen. At baseline, none of the participants met the 80% criterion for adherence to their HAART regimen. At the 3-month assessment, 75% of the participants met the 80% criterion for adherence to their regimen, and at 6 months, 67% met the 80% criterion for adherence.

Positive changes in viral load were also observed, as 39% of participants (11/29) had viral loads of less than 400 copies per milliliter at

| Table 1. Baseline Characteristics of Thirty-One Participants |
|-----------------|-----------------|
| Gender          | Value ( % of participants) |
| Male            | 45%              |
| Female          | 55%              |
| Unemployment    | 97%              |
| Monthly household income | |
| $0–$500         | 45%              |
| $501–$1000      | 29%              |
| $1000           | 26%              |
| Monthly household income | |
| Own home/apartment | 39% | |
| Parent’s home/apartment | 36% | |
| Someone else’s home/apartment | 13% | |
| Rooming/halfway house | 7% | |
| Homeless        | 3%               |
| History of incarceration | 61% | |
| Drug use        |                  |
| Alcohol         | 56%              |
| Cocaine/crack   | 48%              |
| Marijuana       | 36%              |
| Heroin          | 0%               |
| Antiretroviral regimen type | |
| NNRTI-based     | 29%              |
| PI-based        | 42%              |
| Boosted PI      | 10%              |
| Fusion inhibitor-based | 3% | |
| Triple/Quad NRTI | 16%           |
| Antiretroviral dosing frequency | |
| Once-daily      | 19%              |
| Twice-daily     | 81%              |
| HIV plasma viral load | |
| < 400 copies/mL | 38%              |
| 400–100,000 copies/mL | 31% | |
| > 100,000 copies/mL | 31% | |

aData from 29 participants.
baseline. This figure increased to 55% at 3 months (11/20) and 67% at 6 months (8/12). Viral load data were missing for 2 participants at baseline. Of the participants remaining in the program at 3 and 6 months, viral load data were missing for 4 participants at 3 months and 9 participants at 6 months. The missing data were due to participants missing their regular scheduled medical appointments, viral load results not being available in medical charts, hospitalization, and incarceration.

In addition to medication adherence and viral load, changes were also observed in urgent care and drug use. At baseline, 23% of the participants reported visits to the emergency room in the past month. The rate was reduced to 4% at 3 months but increased to 29% at 6 months. The reported drug use in the past 3 months was 90% at baseline, 75% at 3 months, and 67% at 6 months.

A repeated measures analysis of variance was used to examine the BDI-II scores at baseline, 3 months, and 6 months. The results indicated significant differences among the 3 time points, $F(2,40) = 4.78, p < 0.05$. Follow-up analyses revealed significant differences between baseline and 6 months, $t(20) = 2.42, p < 0.05$, means 18.24 and 9.81, respectively. A significant difference was also observed between 3 months and 6 months, $t(20) = 2.41, p < 0.05$, means 17.71 and 9.81, respectively.

Participants evaluated the outreach program at 3 and 6 months. Findings from both assessments were similar hence only results from the 6 months assessment are reported. Ninety-five percent indicted they enjoyed the outreach visits, 100% reported the MDOT visits helped them take their medication, 95% stated the MDOT program helped them keep their clinic appointment, and 5% felt MDOT was a violation of privacy. When asked what they had gained most from the MDOT program, the most commonly endorsed response was the positive relationship with their outreach worker (37%). This was followed by “more able to take my medications regularly” (32%) and “someone comes and helps me” (16%). All participants endorsed home as the most comfortable place to meet the outreach worker. Having “something come up” was the primary reason for missing an MDOT visit. Table 2 shows participants’ responses to a list of benefits and concerns regarding the MDOT program.

### TABLE 2. BENEFITS AND CONCERNS REGARDING MDOT

<table>
<thead>
<tr>
<th>Benefits and concerns</th>
<th>Value (% of participants)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Better overall health care</td>
<td>84%</td>
</tr>
<tr>
<td>More healthy in general</td>
<td>79%</td>
</tr>
<tr>
<td>Better understanding of HIV illness/medication</td>
<td>74%</td>
</tr>
<tr>
<td>Confidence in ability to care for self</td>
<td>74%</td>
</tr>
<tr>
<td>Better relationship with provider</td>
<td>63%</td>
</tr>
<tr>
<td>More proactive about HIV illness</td>
<td>37%</td>
</tr>
<tr>
<td>Prevented crisis involving HIV illness</td>
<td>32%</td>
</tr>
<tr>
<td>Linkage to social services</td>
<td>21%</td>
</tr>
<tr>
<td>Interrupts my day</td>
<td>11%</td>
</tr>
</tbody>
</table>

MDOT, modified directly observed therapy.

DISCUSSION

Taken together with other MDOT studies from various settings (e.g., prison, methadone clinic) that have included a disproportionate number of African American substance users, the present findings further suggest MDOT may have potential clinical benefits and is feasible among African American substance users. Consistent with previous literature, improvements in adherence and viral load suppression were observed at the 3- and 6-month assessments. Although substance abuse treatment was not a target of this study, fewer participants reported drug use at 3 and 6 months compared to baseline. This is consistent with findings from Macalino and colleagues. In that study, fewer participants reported using crack cocaine or injecting heroin after 3 months of MDOT. Additionally, im-
Improvement in depressed mood was observed among our participants at the completion of the MDOT program.

The MDOT program was viewed favorably by participants. Although HIV is a highly stigmatized disease, all the patients who met study eligibility criteria elected to participate in the program and no participant dropped out of the study due to fear of disclosure. Participants whose household members were unaware of their HIV status met the outreach worker outside their home or disguised the true nature of the visits. Only one participant felt MDOT was a violation of privacy. Most of the participants who remained in the program rated MDOT positively. All the participants reported MDOT helped them take their medication and most enjoyed the outreach visits. The aspect of the program that participants found most valuable was the positive relationship they had established with their outreach worker. Many participants were apprehensive at the initiation of the outreach visits. However, rapport with the outreach worker was quickly established and participants viewed the outreach worker as a positive force in their lives.

The retention rate for the presently described community-based MDOT program for African American substance users was 77% at 3 months and 68% at 6 months. Studies of community-based MDOT that do not focus exclusively on substance users have reported retention rates of 81% at 3 months,13 and 79%37 and 87%11 at 6 months. Our retention rates are lower than these programs. This may be the result of the barriers posed by drug abuse. Among substance abusers, an observed therapy program in a community setting yielded a retention rate of 45% at 6 months.12

Table 3 provides a list of the variables that are instrumental to a successful MDOT program among African American substance users in the South. Because most of those factors have been discussed in previous literature on observed therapy,14,15 the present discussion will focus on cultural sensitivity, the most notable aspect of the current study. The National Minority AIDS Education and Training Center (NMAETC) recognized the importance of culturally appropriate healthcare for African Americans infected with HIV/AIDS. To that end, the NMAETC developed a model for cultural competency in the management of HIV. The model consists of six core elements: barriers to health care, ethics in cultural competency, sensitivity of the provider, assessment appropriate to a cultural determination, facts related to ethnocentric physiologic differences, and encounters (BESAFE).38 Guided by the BESAFE model, the interviewers and outreach workers in the current study were African American women who were knowledgeable and sensitive to the complex cultural and situational barriers face by our participants. Among African American substance users, there is a heightened level of mistrust toward law enforcement, social services, and healthcare establishments. Cultural competency is critical to engage and retain this population. Initially, suspicion of the MDOT study was present among some participants who thought the program was law enforcement or social services in disguise. They feared imprisonment for illegal drug activities or removal of a social benefit. Our culturally sensitivity team successfully eliminated those barriers to establish trust and rapport.

Cultural competency also extends to understanding the habits and behaviors of African American substance users, their community, and their physical environment. For example, in this study, crack users were harder to track compared to those who smoked marijuana and used alcohol. In addition, there was a tendency for crack users to disappear on a drug binge after receiving their monthly income check. Intimate knowledge of the community enabled our research team to track the hard-to-reach participants.

Table 3. Key factors for a successful MDOT program for African American substance users in a community setting

| Staff the outreach team with culturally competent individuals |
| Flexib l work schedule for outreach workers |
| Gather extensive tracking information |
| Provide referral to social service programs |
| Set clear boundaries between outreach workers and participants |
| Establish relationship with participant’s health care providers |
| Integrate MDOT into health care clinics |

MDOT, modified directly observed therapy.
Participants in the current study received education on HAART provided by their healthcare team. However, despite that education, most participants had minimal understanding of their HIV therapy. A successful MDOT program with African American substance users should include a health education component (e.g., HIV, HAART, adherence). The education should be delivered in culturally appropriate terms to enhance comprehension.

There are several limitations to this study. The foremost limitations are the small sample size and the absence of a control group. Viral load data for this study were collected from the participants’ medical charts. This method of data collection relied on the participants to keep their medical appointments, have their blood drawn, and the viral load results be available in the medical charts. Due to these barriers, viral load data were unavailable for some participants. In this study, we were unable to determine if there were any effects of MDOT on the development of resistant HIV, in particular at 6 months when there was lower adherence. Despite the limitations, results of the current pilot study indicate that MDOT is feasible and can be effectively delivered to African American substance users in the Southern United States. Overall, participants viewed the program favorably. Preliminary data also suggest the potential of MDOT to improve medication adherence and viral load suppression. When delivered with cultural competence, MDOT may eliminate some cultural barriers associated with effective treatment for African Americans infected with HIV. Randomized trails of this approach are warranted.

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REFERENCES


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