A Qualitative Examination of the Indirect Effects of Modified Directly Observed Therapy on Health Behaviors Other Than Adherence

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Abstract

Modified directly observed therapy (mDOT), in which a portion of doses in a medication regimen are ingested under supervision, has had some demonstrated success in improving the high levels of adherence necessary to achieve maximum benefit from antiretroviral medications. Consistent with the Information-Motivation-Behavioral skills (IMB) model, mDOT's success is likely due to its direct impact on patients' knowledge, motivation, and behaviors related to adherence. However, mDOT's potential impact on patients' information, motivation, and behaviors related to health activities other than adherence to antiretroviral medications has not been explored. Data from participants enrolled in Project MOTIV8, a randomized controlled trial to test the efficacy of novel behavioral adherence interventions, were analyzed to explore the potential impact of mDOT on health behaviors other than adherence. Participants were recruited from local HIV clinics from 2004–2008. Thirty-four percent of those approached, agreed to participate in the study. Data from all participants randomized to the mDOT intervention arm thus far ($n = 50$, mean age 39.7 standard deviation [SD] = 9.0, 78% male 64% African American, and 86% infected via sexual transmission) were included. Overall, participants reported a high level of satisfaction with the mDOT intervention. Qualitative data revealed that mDOT had a positive impact on participants' adherence to nonantiretroviral medications as well as their involvement and communication with health care providers. In addition, participants reported that the daily mDOT visits had indirect effects on their daily functioning, including improvements in their daily living activities (e.g., earlier awakenings, getting dressed, and cleaning their homes) and an increased level of community involvement.

Introduction

ADHERENCE TO ANTIRETROVIRAL THERAPY (ART) has led to sustained viral suppression, decreases in morbidity and mortality, and an increased quality of life for many HIV positive individuals.^{1–6} Although ART has been demonstrated to be effective in suppressing the virus and increasing CD4 cell counts, patients must maintain high levels of adherence to benefit from therapy. Earlier, protease inhibitor (PI)-based regimens required near perfect (>95%) adherence to maintain clinical efficacy and avoid the development of resistance,⁷ however, research has demonstrated that newer, PI-boosted or non-nucleoside reverse transcriptase inhibitor (NNRTI) regimens may be more forgiving (from >54% to >75%–85%).^{8,9} Despite the varying thresholds, these moderate to high levels of adherence are often difficult to achieve and maintain,^{10,11} and several studies have documented less

than optimal adherence rates among patients ranging from 33% to 88%.^{12–16}

Given the levels of adherence required for ART to be effective (from >54% to >95%) and the barriers that patients face when taking ART,^{17,18} creative approaches for addressing nonadherence have been used. One such intervention is directly observed therapy (DOT), in which an individual ingests all doses of his or her medications under direct supervision.^{19,20} DOT was originally developed to treat individuals with tuberculosis (TB). As a pragmatic tool based on operant reinforcement principles,²¹ DOT has had some success in addressing the spread of TB.^{22,23}

As a result of its success with TB, clinicians and researchers have developed DOT protocols for HIV medication adherence which have demonstrated some success in controlled settings (e.g., prisons).^{24–26} However, DOT is often impractical in community-based HIV medication management, be-

cause it may require the direct observation of multiple doses of ART medications per day.²⁷ To address this problem, modified directly observed therapy (mDOT), in which a portion of doses in a medication regimen are ingested under supervision, was developed. mDOT has had some demonstrated efficacy^{24–26,28–31} and has proven to be feasible in a variety of community settings and populations.³² Despite these successes, some studies have demonstrated that mDOT may be an ineffective intervention for long-term adherence among individuals with comorbid disorders (e.g., active drug use and major depression).^{31,33}

The Information-Motivation-Behavioral skills (IMB) model has been posited as a way to understand the causal mechanisms of efficacious adherence interventions.^{34,35} Similar to other adherence interventions and consistent with the IMB model, mDOT's success is likely due to its direct and indirect impact on patients' knowledge, motivation, and behavioral skills in relation to adherence. Specifically, daily mDOT visits likely provide opportunities for patients to get answers to their adherence related questions as they arise (knowledge). The daily contact with a caring, supportive staff member also likely enhances patients' motivation to adhere (motivation). Finally, the daily access to mDOT staff likely provides ample opportunities to address barriers and develop problem solving skills for adherence (behavioral skills).

Beyond adherence behaviors, daily contact with an mDOT staff member is also likely to impact other health behaviors. For example, a patient who has daily contact with an mDOT staff person might seek answers to other health questions (knowledge), be inspired to improve his/her overall health (motivation), and may apply skills developed for ART adherence to other aspects of his/her life (behavioral skills). In their 2003 article, Mitty and colleagues³⁶ presented case studies of participants in an mDOT intervention and briefly mentioned that one patient's provider became aware of his depression due to his contact with an mDOT staff member. However, to our knowledge, this report contains the only mention of mDOT's potential impact on other health issues. The lack of published studies in this area encouraged us to develop this study to examine the potential for mDOT to impact other health behaviors.

Method

Participants

The present study focused on participants who received mDOT as part of their participation in Project MOTIV8. Project MOTIV8 is a three-arm randomized controlled trial to test the efficacy of novel behavioral interventions.³⁷ Participants were recruited from local HIV clinics between 2004 and 2008 and were eligible to participate if they were either starting a new ART regimen or had self-reported adherence problems. Thus far 34% of patients approached have been enrolled, 20% have refused participation and the remaining 46% are still in the process of completing consent procedures or were ultimately ruled ineligible. Patients who agreed to participate were randomly assigned to one of three groups: (1) a standard care (SC) group that received care as usual; (2) an enhanced counseling (EC) group that received adherence counseling utilizing motivational interviewing (MI) and cognitive behavioral therapy techniques (CBT); or (3) an en-

hanced counseling/observed therapy (EC/OT) group that received enhanced counseling identical to group 2, but also received mDOT. All participants in the study were followed for 48 weeks and agreed to: (1) keep one of their medications in an electronic monitoring device (MEMS), (2) meet regularly with project staff to download adherence data, and (3) complete four computer-assisted self-report evaluations. Participants randomized to either of the counseling interventions (EC or EC/OT) agreed to meet with a counselor 11 times over a 24-week period. Participants in the EC/OT arm agreed to meet with a staff member a total of 98 times over a period of 24-weeks to complete mDOT. Only participants randomized to the mDOT arm of Project MOTIV8 thus far were included in this study ($n = 50$).

Procedures

Participants received daily visits (Monday to Friday) from an mDOT staff member over a 24-week period (for a total of 98 possible visits for each participant). Most mDOT visits involved a staff member delivering one or more doses of ART, watching the participant ingest his/her medication, and collecting data on unobserved doses via a hand-held computer. In order to address real world challenges including newly available medication regimens (e.g., once daily regimens), varied dosing schedules (e.g., bedtime dosing instructions), and logistical limitations (e.g. participants who resided >25 miles from the city center), the mDOT protocol was adapted to meet participants' needs. For example, staff members delivered medications (16% of total mDOT contacts) to participants who were on once daily regimens with an evening dosing time and made contact via phone (10% of total mDOT contacts) for participants who lived more than 25 miles from the city center.

Measures

Satisfaction with mDOT. To evaluate participants' satisfaction with the mDOT intervention, data were collected using an audio Computer Assisted Structured Interview (aCASI) questionnaire based on Questionnaire Development System version 2.1 by Nova Research Co. (Bethesda, MD). Participants read and/or listened to a series of questions presented on a laptop computer and keyed in their responses. Satisfaction data reported were collected only from participants who had completed 24 weeks of mDOT ($n = 33$). Participants responded to five mDOT specific satisfaction questions as part of a larger assessment. All questions used a Likert-type response format. Two questions assessed mDOT's helpfulness with ART adherence (e.g., "Overall, how helpful were the mDOT visits in helping you adhere to your medications?") with responses ranging from 0 = "not at all helpful" to 4 = "extremely helpful." Two questions asked for participants' assessment of the convenience and burden of the mDOT visits (e.g., "How bothersome were the daily visits by the OT worker?") with responses ranging from 0 = "not bothersome at all" to 3 = "very bothersome." Finally, one question examined whether participants would recommend mDOT to their HIV positive friends or family members, with the response options, "yes" and "no."

Effects of mDOT on health-related behaviors. In order to ascertain whether mDOT had indirect effects on health be-

haviors other than adherence, qualitative data reported by participants and/or directly observed by mDOT staff members were collected. Participants' unsolicited feedback associated with mDOT was recorded in their study file during and subsequent to their engagement in the intervention. Additionally, observed health-related behavior changes that occurred during the course of the intervention were recorded when noted in participants' files. In order to put these observations into context, we provide case examples for several participants.

Results

Participant demographics

Demographic characteristics of participants are detailed in Table 1. Participants' ages ranged from 19 to 55 years ($M = 39.66 \pm 9.0$) and 72% had completed high school. The majority of the participants were male (78%) and 64% of the participants were African American. Eight-eight percent of mDOT participants reported that their most likely route of HIV infection was through sexual contact with an HIV-infected individual and over half (54%) reported a history of substance use, with 4% reporting current injection drug use. Forty-four percent of the participants reported little or no monthly income ($< \$500$). Seventy percent of mDOT participants had taken ART medications in the past and over half (56%) were on a boosted protease inhibitor (PI) highly active antiretroviral therapy (HAART) regimen (e.g., ritonavir, atazanavir, and tenofovir with emtricitabine).

Participant engagement in mDOT intervention

A total of 4359 mDOT visits were scheduled and 2891 (66%) of these visits were completed. Common reasons for missed mDOT visits were: (1) planned misses (12%), in which participants informed mDOT staff members in advance that they would not be able to meet on a given day, (2) patient no shows (12%), (3) discontinuation of involvement in MOTIV8 (7%), (4) staff misses (1%), (5) patient or provider initiated medication holidays (1%), (6) hospitalizations (1%), and (7) incarcerations (1%). Of the 50 participants randomized to mDOT, 33 had completed the full 24-week intervention, 11 were still actively engaged, but had not yet reached the 24-week point at the time of this study, and 6 discontinued their participation in the project.

Satisfaction with mDOT intervention

Questionnaires regarding overall satisfaction with mDOT were completed by the 33 participants who had completed the intervention at the time of this study. Satisfaction data from 6 participants who had dropped out of the study and 11 participants who had not yet reached the 24-week assessment point were unavailable. A significant number of participants (97%) reported that daily contact with the mDOT staff member was beneficial to their ART adherence, and also felt that daily mDOT visits would be helpful with other kinds of health conditions. The majority of the mDOT participants (94%) reported that they would recommend daily mDOT visits to their HIV positive friends and family members. In addition, several participants who had reached the end of mDOT reported being disappointed and wished that the daily contact could continue. Last, oth-

ers asked if they could reenroll in order to access additional mDOT visits.

mDOT's impact on other health related behaviors

The mDOT implemented in this study had an impact on several health behaviors not related to ART adherence. Figure 1 displays the results of the qualitative information gathered from participants on mDOT's impact on other health behaviors. Some of the additional benefits noted included: (1) an increase in participants' knowledge regarding medication dosing instructions, (2) an increase in participants' motivation to engage in activities of daily living, (3) an increase in participants' desire to become involved in their community, (4) participants' improved adherence to non-HIV medications, and (5) participants' development and use of adherence strategies for other medications.

In order to put our findings in context and to demonstrate

TABLE 1. mDOT PARTICIPANT DEMOGRAPHICS ($N = 50$)

	Mean $\pm$ SD or n and %
Age	39.7 $\pm$ 9.0
Gender	
Male	39 (78%)
Female	11 (22%)
Race/ethnicity	
African American	32 (64%)
Caucasian	13 (26%)
Hispanics	3 (6%)
More than one race	2 (4%)
Education	
Some high school	14 (28%)
High school degree/GED	16 (32%)
College or post-high school training	20 (40%)
Monthly income	
\$0–\$500	22 (44%)
\$501–\$2000	16 (32%)
More than \$2000	8 (16%)
Don't know/Declined to answer	4 (8%)
HIV risk factors	
Sex with an HIV+ man	33 (66%)
Sex with an HIV+ woman	10 (20%)
Shared needles with an HIV+ person	1 (2%)
Blood transfusion	3 (6%)
Don't know/other	3 (6%)
Substance use history	27 (54%)
Active IDU	2 (4%)
Housing status	
Homeless	2 (4%)
Temporary/Emergency housing	3 (6%)
Living with family/friends	11 (22%)
Rent/Own home	33 (67%)
ART naïve	11 (26%)
ART experienced	31 (74%)
Type of HAART regimen	
PI boosted	28 (56%)
PI with NRTI	2 (4%)
NRTI with NNRTI	20 (40%)

SD, standard deviation; IDU, injection drug use; ART, antiretroviral therapy; HAART, highly active antiretroviral therapy; PI, protease inhibitor; NRTI, nucleoside reverse transcriptase inhibitor; NNRTI, non-nucleoside reverse transcriptase inhibitor.

FIG. 1. An information-motivation-behavioral skills model of Motiv8 participant reports of the impact of modified directly observed therapy (mDOT) on health behaviors other than adherence to HIV medications.

how our findings are consistent with the IMB model, we have provided case examples of several participants below.

IMB—Information Example 1. Participant gains knowledge/information about detecting medication dosing errors. “A,” a 48-year-old African American male, reported gaining significant knowledge with regard to properly taking his non-HIV medications. After beginning mDOT, he reported being unsure and confused about some of the dosing instructions for his other medications and was afraid he was taking them incorrectly. During a routine visit with an mDOT staff member, he discussed his concerns. The mDOT interventionist reviewed the dosing instructions with “A,” assisted him in packaging his non-HIV medications in a weekly dosette, and suggested that he contact his primary health care provider to clarify his concerns. “A” reported contacting his health care provider, who addressed his concerns, and “A” subsequently began taking his medications correctly.

IMB—Motivation Examples 2 and 3. Participants become motivated to improve their daily quality of life. During a daily visit, “K,” a 43-year-old African American male, explained to an mDOT staff member how the intervention affected his motivation to wake up and get started with his day. “K” remarked, “I used to just sit around and be depressed. Some-

times I wouldn’t even get out of bed, but now I am getting up and getting dressed daily . . . I’m even cleaning my apartment now, because I know you’re coming.”

“L,” a 45-year-old African American female, who began taking ART for the first time, reported an increased desire to get out of the house and become more active in the community after engaging in the mDOT intervention. “L” stated, “Now I’m up and ready when my OT person comes, and after she leaves I get up and go for a walk around the neighborhood.”

IMB—Behavioral Skills and Behavior Examples 4 and 5. Participants reported increased adherence to non-ART medications. “S,” a 43-year-old African American male with previous ART experience, reported improved adherence to non-HIV medications as a result of the mDOT intervention and stated, “I remember to take my high blood pressure pills in the morning now with my HIV meds.”

“J,” a 55-year-old African American female with various health complications including cancer and heart disease, reported taking all of her medications at the same time. During the daily visits, the mDOT staff member not only observed her taking all of her morning medications together, but also packaging her evening heart disease medications in a pill box along with her HIV medications.

Discussion

Our findings demonstrate that mDOT can have a direct impact on health behaviors other than adherence to ART. mDOT's impact appears to come from the daily contact with caring professionals who assist participants in increasing their health-related information, motivation, and behavioral skills. Even in a community-based sample of individuals with multiple life stressors (e.g., limited income, substance use/abuse, and unstable housing), mDOT's impact on other health behaviors emerged. Past research has characterized DOT as labor-intensive, expensive, intrusive, and programmatically complex to initiate.³⁸ Our findings suggest that the challenges associated with implementing mDOT may be offset by the benefit of increased adherence to non-ART medications, a positive impact on other health related behaviors, and an enriched quality of life. Other studies have demonstrated the cost effectiveness of behavioral interventions for ART adherence³⁹ and future studies utilizing mDOT should build in a systematic assessment of all potential benefits, like those observed here, to evaluate the full impact of this intervention.

Although this study is one of the first to examine additional benefits of mDOT, it is not without its limitations. First, the sample size ($n = 50$) was relatively small and some of the participants had not yet completed their participation in the mDOT intervention. Despite the modest numbers and the fact that many participants had not completed the intervention, we were encouraged by the secondary benefits that emerged as a result of the mDOT intervention. Second, because participants receiving mDOT were concurrently involved in a counseling intervention, the impact of mDOT may have been confounded with counseling. Although counseling may have had an indirect impact on participants' adherence to non-HIV medications, it is important to note that the counseling intervention was specifically targeted to address HIV medication adherence and did not address other health behaviors. During the course of mDOT visits, we observed a direct link between daily mDOT visits and adherence with non HIV medications, such that the mDOT therapist served as a stimulus cue for behaviors other than adherence to HIV medications. The spread of effects to other health behaviors may not be unique to mDOT, it may be that increasing individuals' motivation to adhere to their HIV medications may motivate them to better care for themselves across a broad range of other health and social conditions. We hope to more fully explore this possibility at the conclusion of the trial when we will have sufficient numbers of participants who received counseling and mDOT vs. counseling alone to dismantle the differential impact of mDOT. Third, the overwhelmingly positive satisfaction data may have been impacted by the lack of feedback from the six participants who had dropped out of the study. Lastly, data from this study was not collected systematically from all participants; rather, over the course of the intervention, some participants revealed that mDOT impacted aspects of their lives other than adherence to ART medications. Our data would likely have been more robust if it had been collected from all participants from the inception of the study.

Despite these limitations, this study is novel in that it was the first to examine and document the benefits of mDOT on health behaviors other than adherence. Our findings support

the notion that mDOT is feasible in community settings, generally well received by participants, and has the potential to impact the physical, mental, and social well-being of HIV positive men and women.

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