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Lessons Learned from an HIV Adherence Pilot Study in the Deep South

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Abstract

Objective—Adherence to treatment for chronic illnesses, including HIV disease, is a complex process, and needs practical interventions in poorly-resourced clinic settings.

Methods—This study tested the feasibility of an adherence intervention in 73 HIV-infected individuals in a Deep South public clinic based on Fisher & Fisher's Information-Motivation-Behavioral Skills Model.

Results—There was high baseline adherence and unexpectedly high clinic attrition, and 27% of the intervention group received less than one-quarter of the planned intervention contacts. Refill rate was the adherence measure that correlated best with HIV viral load and CD4 count, and there was poor use of electronic adherence monitoring (MEMS). Interviewed individuals expressed positive feelings about audio-supported computer-assisted survey instruments (ACASI) and the intervention support.

Conclusions—This process evaluation showed feasible study components in this population and setting. Lessons learned included: 1) clinic retention is an important part of adherence; 2) telephone interventions may need to add additional technology and flexibility to maximize dose; 3) ongoing fidelity monitoring is important with motivational interviewing; 4) refill rate was the most accurate adherence assessment; 5) MEMS was not well-accepted; 6) ACASI was easily used in this population; and 7) individuals appreciated adherence support from a consistent caring individual.

Keywords

adherence; HIV; feasibility; Deep South; IMB

1. Introduction

1.1. Medication adherence in HIV disease

In the current age of fully suppressive antiretroviral therapy (ART) for HIV disease, strict adherence to the medication regimen is critical for long-term positive health outcomes(1–5). Experimental adherence intervention studies have shown limited results and/or used labor-intensive and expensive interventions (6).

Another limitation of the existing literature is that adherence studies have been conducted primarily in major urban centers on the West Coast or the Northeast (7–9). In the last decade, a shift in the HIV epidemic to the rural South has been noted (10); yet few ART adherence interventions have been studied in this region. A disproportionately high rate of HIV infection is concentrated in the region known as the Deep South, which consists of the six states of Alabama, Georgia, Louisiana, Mississippi, North Carolina, and South Carolina. The number of newly reported AIDS cases increased 38% in the Deep South from 2000 to 2005, while it increased only 17% nationally (excluding the Deep South states) (11).

Besides a few studies done in urban settings in the South (12,13), there is a gap in adherence studies of representation by HIV-positive patients in the Deep South. Cultural characteristics that are unique to the Deep South may influence adherence to both care and medications: the widespread nature of rural poverty, historical racism, lower education and literacy levels, and the poor overall health status seen in other chronic diseases such as diabetes and cardiovascular disease. In addition, HIV-infected individuals in the Deep South are likely to be members of minority groups that are more likely to be isolated and stigmatized (10,14).

This paper reports a process evaluation to assess the feasibility of this intervention and identifies the particular components considered valuable to the participants. An outcome evaluation of the intervention, which includes an in-depth description of the instruments and statistical outcomes, will be reported in another paper. In this study, feasibility was assessed based on: recruitment/retention, the ability to conduct intervention contacts, the impact of intervention fidelity, reliability/validity of the adherence measures used in this population, the feasibility/acceptability of electronic adherence measurement in this population, and acceptability and perceived value of the intervention components.

2. Methods

2.1. Setting

This study was conducted in a public Infectious Diseases clinic in the Deep South. Approval to conduct the study was received from the institutional review board at the university medical center.

2.2. Recruitment/randomization

Participants whose clinic provider reported that the patient was starting ART for the first time or was restarting ART after at least six months off medications were considered for inclusion. Recruitment started by prescreening those individuals with upcoming clinic appointments using electronic medical records. This identified those patients with a detectable viral load and a CD4 count of 350 or below at the previous clinic visit, indicating patients who may not be on ART and may be starting medications at this clinic visit.

Research staff asked the provider immediately after the prescreened clinic visit about whether ART was initiated and if the patient was willing and able to discuss participation in a research

study. If the patient agreed to enroll, baseline data collection was begun. Randomization occurred at the next clinic visit (V-1) when baseline adherence was measured.

2.3. Intervention

Participants in the intervention group were scheduled for the first face-to-face intervention session with the interventionist (IN) one week after randomization. The intervention consisted of two one-on-one sessions with the IN at weeks 1 and 2 after the next clinic visit; and six telephone calls on a tapering schedule (approximately weeks 3, 4, 6, 10, 16, 24). Elements important to the Information-Motivation-Behavioral Skills model were utilized in the intervention: education about HIV, ART, and the importance of adherence; a video of peers discussing their adherence issues to address social motivation, and motivational interviewing (MI) to address personal motivation; and adherence-enhancing devices (pillbox and an alarm watch) and training in communication skills to use with the clinical provider to address behavioral skills. Participants were given a small amount of money to help defray transportation to the clinic. No incentives were given for telephone call. See Table 1 for a listing of components of the intervention and when they were addressed.

2.4. Data collection

Data collection was anticipated at the three clinic visits after enrollment, which were anticipated to be at approximately one month after enrollment (V-1), three months later (V-2), and three months after that (V-3). During V-1, V-2, and V-3, data were collected using an audio-supported computer-assisted survey instrument (ACASI) in the exam room before or after the participant saw his or her provider. The Life Windows Information-Motivation-Behavioral Skill Adherence Assessment Questionnaire (LW-IMB-AAQ) (15) was administered using a software package created for the University of Connecticut's LifeWindows experimental research study and included a virtual guide. Assessments in that section of the ACASI included demographic information, the Short Form-8 (SF-8) Health Survey (16), assessment of information, motivation, and behavioral skills associated with ART adherence, and self-report adherence measures.

The other section of the ACASI assessment was developed using MediaLab v.2006 (MediaLab, 2006), a user-friendly software package that translates pen-and-pencil questionnaires to the ACASI format. This format was used to administer the Center for Epidemiology – Depression Scale (CES-D) (17). Each question and all the response options were supported by audio content.

2.5. Process evaluation variables of interest

2.5.1. Retention rates—Retention was measured by the number of scheduled clinic visits within the research period that were attended. Individuals received a reminder call, if reachable, one week prior to each scheduled research visit, and again two days before the scheduled visit.

2.5.2. Intervention contacts—Data were collected on completion of intervention sessions, as well as the number of minutes for each session. Updated participant contact information was collected at each data collection visit and through regular monthly update calls. Each participant was asked to provide three telephone numbers where they could be reached or where they could receive a message, as well as their current address. For each unsuccessful contact, 2–3 attempts were made to the primary telephone number, and then other numbers were called and messages left if possible. Finally, a letter was sent to the participant requesting that he or she contact the IN using a toll-free telephone number.

2.5.3. Intervention fidelity—The IN received training in motivational interviewing (MI) from an expert trained as a Motivational Interviewing Network of Trainers (MINT) trainer,

involving 18 hours of training and practice. Fidelity to motivational interviewing (MI) was measured by sending a random selection of audio-recordings of all the face-to-face intervention sessions to a different expert in MI who coded them using the Motivational Interviewing Treatment Integrity 2.0 (MITI) instrument (18,19). This instrument was used to count and assess the elements of MI that are considered to be essential (global therapist rating, reflection to question ratio, percent open questions, percent complex reflections, and MI-adherent comments) against a standard for beginner, competent, and proficient use of MI.

2.5.4. Reliability/validity of instruments—Two measures of self-reported medication adherence were used. One was a 3-day recall based on an adherence measure used by the Adult AIDS Clinical Trials Group (AACTG) (20). The other self-reported adherence measure asked individuals to indicate on a line visual analogue scale (VAS) the percent of HIV medications they took “in the last three to four weeks.”

An objective adherence measure was refill rate. The refill rate was calculated by dividing the number of refills in the study period by the number of months during the same time period, as all prescriptions were written on a monthly basis. At each study contact, the participant was asked to provide updated pharmacy information. These three adherence measures were compared with each other and with clinical outcomes (viral load and change in CD4), to determine their value and feasibility.

2.5.5. Feasibility of electronic adherence measurement—The first 20 participants, whether randomized to intervention or control groups, were given electronic medication bottle caps (Medication Event Monitoring System, MEMS[®]) to assess adherence by monitoring the openings of one of their pill bottles for a month before each of the three data collection visits. While MEMS has long been considered the gold standard for medication adherence measurement, the acceptability of this cap by individuals has not been fully explored in this Deep South population.

Participants were given a MEMS cap and pill bottle at enrollment with instructions on how to use it as well as a log for documenting times when more than one dose of the medication was removed from the bottle at one time. The MEMS caps were to be returned at V-1. The MEMS cap, bottle, and log were mailed to each MEMS participant approximately one month prior to V-2 and V-3 with instructions to use them and return them at V-2 or V-3.

2.5.6. Acceptability and value of the intervention—Individuals who completed the intervention arm (n = 22) were asked at V-3 if they would consent to an hour-long interview to assist the research team in evaluating the intervention. Interview questions addressed their feelings about the study as a whole and an evaluation of components of the data collection and the intervention.

3. Results

3.1. Sample

Seventy-three participants enrolled in this study from July 2005 – March, 2006; however, only 56 were randomized as 17 participants did not return after enrollment. Study participants reflected the demographics of the clinic population: 37% female, 89% African American, 64% below the federal poverty scale, and half with high school education or below. Study participants had a baseline self-reported adherence of 82%, with no significant difference between groups.

3.2. Recruitment/retention

There was an attrition rate of 51% from the time of enrollment; 17% of enrollees did not attend another clinic visit after being prescribed ART and therefore had no baseline adherence data. Of those who dropped out, 38% did so because of a complete loss to clinic follow-up; another 38% had a gap in their care of longer than 4–6 months, putting them outside the research protocol. These drop-outs occurred despite two reminders before each clinic visit. Attrition rate was not significantly different between groups. See Figure 1 for recruitment/retention flow.

Demographic characteristics, literacy level, IMB subscale scores, severity of HIV disease, and group assignment were unrelated to completion of the study except for a weak positive association with depressive symptoms ($p = 0.06$).

3.3. Intervention contacts

Of the 33 participants who were randomized to the intervention group, 18 (55%) completed 7–8 of the 8 planned intervention contacts, six (18%) completed 3–6 contacts, four (12%) completed 1–2 contacts, and five (15%) did not complete any intervention contacts. In the process of making these contacts, 74% of face-to-face contacts and 57% of telephone contacts were made with no unsuccessful attempts, with others needing up to 9 attempts before making contact or sending a letter. Comments by two of the individuals who had limited telephone contact indicated that they would have preferred to come to clinic for the contacts due to lack of consistent telephone access. See Table 2 for a description of the number of intervention contacts performed for each participant, the time lapse between these contacts, and the length of time spent for each.

3.4. Intervention training and fidelity

The PI, who was a nurse practitioner with more than 10 years experience working in the HIV field, served as the interventionist (IN) and trained for approximately 18 hours with an MI expert using discussion, readings, and role-playing. Coding of eight randomly-selected tapes of face-to-face intervention sessions revealed that the IN had beginning proficiency in MI, but did not advance beyond that level throughout the year of intervention delivery. Moyers, Miller, and Hendrickson (21), when studying the aspects of MI that are most associated with client engagement in counseling, found that the counselor's interpersonal skills, such as the spirit of MI and empathy/understanding, were more important than the specific MI-adherent or MI-non-adherent behaviors. The randomly-selected tapes showed a neutral level of these interpersonal skills at the outset (rated as 4 on a scale of 1 to 7), and increased to 5 or 6 in each category as the intervention period progressed.

3.5. Reliability of Adherence Assessment

3.5.1. Adherence assessment measures—Self-reported adherence by 3-day recall or by 3–4 week VAS was consistently higher than the electronic measurement. At V-1 ($n = 11$) adherence by electronic measurement was 74.8%, 84.9% by 3-day recall and 90.3% by 3–4 week VAS. At V-2 ($n = 3$) and V-3 ($n = 4$) self-reported adherence was consistently 100%; the electronic measurement showed adherence rates ranging from 75–100% (V-2) and 60–86% (V-3). There was a significant correlation at V-1 between MEMS and other methods of measurement, with $r = .611$ with 3-day recall ($p = .046$) and $r = .793$ with VAS measurement ($p = .004$).

The refill rate was the measure most closely associated with clinical indicators drawn at each data collection visit. In particular, the refill rate at V-3, where the average time lapse from baseline was 5.78 months ($SD = 1.34$), had a statistically significant correlation with change

in viral load ($r_s = -.34$, $p = .045$). At the same time, the correlation for 3-day adherence recall was $r_s = -0.33$ ($p = .06$) and for 3–4 week VAS recall was $r_s = -0.12$ ($p = .30$).

Because self-reported adherence was conducted at data collection visits, there was significantly more missing data for this than for refill rate, which was obtained by research staff calling the reported pharmacy **until the participant was considered lost to follow-up**. Using 90% as the definition of adherence, 44 self-reported adherence by VAS **using the method of last observation carried forward**, but only 23 were considered adherent by refills per month. **When using intent-to-treat analysis, where those lost to follow-up were considered nonadherent, 31 self-reported at least 90% adherence by VAS, still with greater frequency than the 23 considered adherent by refill rate.** Using the Mann-Whitney test because of marked skewness of the dependent variable, at least 90% adherence by refill rate was significantly associated with greater change in CD4 ($p = 0.001$) and lower HIV viral load ($p = 0.02$) than non-adherence, both measured at last visit, whereas there were no significant differences identified by self-reported VAS.

3.5.2. Electronic adherence measurement—There was limited use of MEMS caps for electronic monitoring of adherence. One individual refused to take the cap at V-1 because of privacy concerns. Eleven of the 19 participants (58%) who were initially given caps returned them at V-1; that rate dropped to three caps out of 13 (23%) sent before V-2 and four caps out of nine (44%) sent before V-3. There was no difference between experimental or control groups in return rate.

3.6. Value of intervention

Individuals were uniformly positive about the study as a whole, the ACASI data collection, and about the intervention contacts. One woman stated,

Yes, it has [been helpful]. And the reason that I say that was because coming in and talking about this [was helpful], cause I don't talk very much at home about it, cause there's nobody to really talk to ... [The interventionist] gave me a lot of encouragement, and she would comfort you with it by the way she would talk with you, you know, and then most of the time she just let me talk and she would just listen, and that helped me out a lot, that I had somebody to talk to.

This comment addresses the supportive aspects of MI, which assisted the participant to feel encouraged and supported when the participant did not feel comfortable seeking social support from his/her family/friends. One of the important components of MI, the patient-centered directiveness of focusing on specific change in a particular behavior, was not commented on by participants.

The participants said that they became increasingly comfortable with the face-to-face sessions and telephone calls and found them beneficial. As one man stated, "I enjoyed being a part of the [research study], for the simple reason that it, it helped me with my confidence to do better, taking medicine and things, it also gives ... a reason for people to talk to me more about my situation, [makes me] educated about it more if something springs up."

Most participants found the video to be helpful. Many stated that they used one of the reminder devices; a few said they used neither, as they believed that they had a good reminder system already in place.

All individuals stated that they liked the ACASI format at least as well as a paper-and-pencil questionnaire. There was little difficulty with self-completion of questionnaires, though two of the 56 participants required the reading of response options and assistance with the mouse due to complete lack of literacy and comprehension of computer usage. The informants also

commented that another benefit to the ACASI format was the improved sense of privacy when responding to sensitive questions.

4. Discussion and conclusion

Because of factors associated with the Deep South population such as high rates of poverty and illiteracy, there were concerns about the feasibility of the recruitment plan, the ability to retain vulnerable clients over the length of the intervention period, the ability to conduct the intervention, the ability to manage fidelity to the intervention protocols by an individual trained but not expert in MI, reliability/validity of the data collection instruments in this population, the feasibility/acceptability of electronic adherence measurement in this population, and acceptability and perceived value of the intervention components. The following lessons learned will assist in the implementation of further research in this and similar clinic settings.

4.1. Discussion

This study is one of the first published reports using the IMB model in an adherence intervention in a Deep South population. This gap in the literature suggested the need for a pilot study to determine its feasibility in a clinic setting with this population. The lessons learned include:

1. the recruitment technique of prescreening laboratory values of expected patients for potential eligibility, and being present in clinic at those prescreened appointment times was feasible;
2. adherence to clinic visits in retention in a clinical trial would have been an important factor to address;
3. more thorough training of MI would be helpful, and consistent feedback to the interventionist to maximize fidelity and continue training was valuable;
4. ACASI was very acceptable in this population, and participants preferred ACASI over interview or paper-and-pencil questionnaires;
5. refill rate appeared to be the most accurate measure of adherence, as determined by its positive correlation with clinical indicators, while the MEMS was not well-accepted; and
6. the intervention was perceived as valuable by the participants, particularly in the consistent presence of a caring individual who was focusing communication on the patient and his/her issues

4.1.1. Retention—Recruitment occurred in the clinic setting, and did not require the patient to make the initial contact with the research center, as is often the case in research settings. Thus, recruitment occurred fairly quickly. Also, data collection was conducted in the clinic setting during scheduled clinical care, making the study accessible for this clinic population. Enrollment into the study reflected the wide range of patients seen in clinical practice who might otherwise not participate in research if they had to take the initiative to enroll or make extra visits.

Despite these factors, an aspect of adherence that profoundly affected the power of this study was clinic attendance. Two-thirds of those who did not complete the study did so because of complete or temporary loss to care. Further research will need to include clinic attendance as another aspect of adherence that could benefit from intervention.

4.1.2. Intervention contacts—Because of the difficulty with consistent telephone contact in this transient, low-income population, interventions may be better maintained by giving

patients a choice about face-to-face or telephone contacts. In addition, in order to minimize intervention drop-out, the participants may benefit from small incentives for telephone contact in addition to the face-to-face sessions. The use of cellular telephones may help overcome the difficulty of consistent telephone contact and incorrect telephone numbers, though this would make the intervention less translatable to the clinic setting because clinics are less able to provide clients with cellular telephones for contact.

4.1.3. Intervention fidelity—Ongoing fidelity monitoring by an expert in MI, using the Motivational Interviewing Treatment Integrity (MITI) Code proved to be essential in preventing drift from the spirit and skills of MI, and to provide continuing education for the interventionist. Using randomly-selected tapes throughout the course of the intervention period allowed for learning based on positive comments and suggestions for changes.

4.1.4. Reliability of adherence assessment instruments—Refill rate was the adherence measure that demonstrated the strongest association with change in viral load. This suggests that it should be used as a method to assess adherence in this population.

4.1.5. Acceptability of electronic measurement—Participants had difficulty using the MEMS cap. They expressed privacy concerns, as well as lack of forethought regarding the use of the cap and/or its return to the next clinic visit, despite being reminded one week and two days prior to their appointment. An incentive for the return of the MEMS cap may increase the likelihood of return. Other possible approaches for assessing ART adherence recently reported in the literature are a random telephone pill count (22) or a rating scale of the last month's adherence (23).

4.1.6. Value of Intervention—The interviews clearly demonstrated that the participants valued the intervention and the patient-centered nature of the MI contact. Many participants indicated that they appreciated the regular contact with a consistent caring individual. Therefore, having the same individual provide the contact and intervention is an important aspect of the intervention. Motivational Interviewing's characteristic patient-centered focus on behavior change was not commented on by participants, which may mean that the empathic spirit of MI was the most salient component to them, or that the IN was not sufficiently directive.

4.2. Conclusions

Limitations in this study included the small sample size, the beginner competency level of the IN and the high attrition rate. The individuals who dropped out of care for at least a temporary basis, and thus dropped out of the study, may have had a very different experience of the intervention and study protocols.

According to the exit interviews, participants considered this intervention to be valuable and they viewed the intervention positively. The high attrition rate of both experimental and control group participants, the difficulty in reaching participants consistently for intervention contacts, and/or the level of MI proficiency of the IN, may have impacted the efficacy of the intervention. The lessons learned in conducting this pilot study will be beneficial in pursuing further research in this and other interventions in this clinic population.

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Figure 1.
Recruitment and retention patterns of study participants (7/11/05 – 3/10/06)

Table 1

Components of intervention

Element of intervention	1 (face-to-face)	2 (face-to-face)	3 (phone)	4 (phone)	5 (phone)	6 (phone)	7 (phone)	8 (phone)
Information on HIV and the importance of adherence	X	X	X	X	X	X	X	X
Social motivation – video of peers talking about how they overcame adherence obstacles	X							
Personal motivation - motivational interviewing	X	X	X	X	X	X	X	X
Behavioral skills – reminder watch and pill box								
Behavioral Skills – communication with provider		X		X				X
Behavioral Skills – problem-solving			X	X	X	X	X	X

Table 2

Implementation of Intervention contacts

Intervention	Mean	SD	n	Range
Number of intervention contacts before visit 2	4.4	2.0	27	0 – 7
Number of intervention contacts by end of study	7.5	1.0	21	0 – 8
Days between 2 face-to-face sessions	9.4	6.4	26	0 – 28
Days between 2 nd session and 1 st telephone call	7.5	2.8	24	4 – 17
Days between 1 st and 2 nd call	9.4	4.3	24	5 – 24
Days between 2 nd and 3 rd call	16.2	21.6	23	2 – 112
Days between 3 rd and 4 th call	29.3	7.9	19	13 – 49
Days between 4 th and 5 th call	36.2	12.6	17	14 – 62
Days between 5 th and 6 th call	50.1	17.0	15	18 – 75
Minutes of 1 st face-to-face contact	53.1	9.8	21	34 – 70
Minutes of 2 nd face-to-face contact	33.8	8.7	24	10 – 48
Minutes of telephone contacts	8.7	3.8	25	2 – 33