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Enhancing HIV Medication Adherence in India

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Abstract

Background—This pilot study evaluated an intervention designed to enhance adherence among those new to antiretroviral therapy.

Methods—Participants (n = 80) were recruited from a hospital clinic in Chandigarh, India, and randomized to a 3-month group intervention or individual enhanced standard of care followed by crossover of condition and assessed over 6 months. Adherence was measured by prescription refill, pill count, and self-report.

Results—At baseline, 56% of group condition (immediate intervention) and 54% of individual condition (delayed intervention) participants were nonadherent by pill count and 23% of group and 26% of individual condition participants self-reported skipping medication at least once over the last 3 months. From the postintervention to long-term follow-up, adherence in the group condition (immediate intervention) improved in comparison with adherence in the individual condition (delayed intervention; $\chi^2 = 5.67$, $P = .02$).

Conclusions—Results support the use of interventions early in treatment to provide information and social support to establish long-term healthy adherence behaviors.

Keywords

India; adherence; intervention; assessment; behavior

Despite an estimated HIV/AIDS incidence[1] of 0.3%, the Indian subcontinent has the third largest HIV/AIDS population worldwide.[2] With a population of nearly 2 billion,[3] India is the home of approximately 2.4 million people living with HIV/AIDS.[4] HIV in India is primarily HIV clade C, and no-cost first-line anti-retroviral therapy (ART) has been provided by the government of India, since 2004. More recently, subsidized medication

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programs have been “partially decentralized” to expand the availability of medication to a wider catchment area.[5-7] Successful highly active antiretroviral therapy/antiretroviral adherence is essential to optimizing reductions in morbidity and mortality associated with HIV,[8] as well as decreasing transmission[9] and the prevention of drug-resistant strains of virus.[10] Due to the very high levels of medication adherence required to achieve virologic suppression, that is, 95% or greater,[11] medication adherence has become a critical component in maximizing both treatment and prevention outcomes.[12] Today, although ARV medications may initially be associated with unpleasant side effects, adherence is essential if patients are to achieve viral suppression and a reduction in HIV-related symptoms.

Although this health care delivery model provides HIV services at secondary-level Community Health Centers, limited access to care and ARV nonadherence may result from the reliance on district hospitals as the primary providers of HIV care and ART medications.[13] Patients may be required to travel long distances for their monthly ART supply—instead of receiving care at local community health centers—and face significant challenges obtaining medication refills and maintaining optimal levels of adherence.[13] The costs associated with obtaining medication continue to be a barrier to optimal medication adherence in resource-limited settings.[14] In fact, while ART has transformed the prognosis of HIV-infected patients, only an estimated 158 000 people are receiving ART in India.[2] Equally important, long-term follow-up with regular monitoring, promotion of adherence to treatment, and involvement of family caregiver/caregivers[15] may also be restricted by geographical isolation and play a critical role in inadequate HIV care.[14]

While a significant limitation to access to care, stigma associated with receiving HIV care at local public health centers may actually be secondary to the barriers associated with travelling to district hospitals for care and prescription refills, especially for symptomatic patients with limited mobility (lack of social support, transportation, and money for travel). Other factors may also influence treatment response[16]; individuals factors such as physical illness,[13] psychological distress, and the emotional burden of HIV,[5,17] stigma,[18,19] and time on ARV[15] medications may be implicated in poor adherence. Treatment responses have been observed to be enhanced among patients linked to community health resources providing individualized sociomedical care,[15] which may influence positive general health perceptions[5] and an overall commitment to prioritizing medication adherence.

Accurate assessment of adherence is essential in HIV management and in resource-limited settings where funding for virologic testing to monitor and interpret treatment response is not available, there is a greater need for accurate provider evaluation.[20] Patient self-reported rates of adherence are often unreliable for the interpretation of treatment outcomes and are frequently contradicted by objective measures of adherence,[15] such as CD4 and viral load, or physician evaluation.[20] To date, there is no gold standard for nonbiological measurement of adherence, and none of the establish methods of assessment, for example, patient self-report, patients keeping appointments at clinic visits, pill counts, pharmacy records, measurement of drug levels, biologic surrogate markers, and a medication event monitoring system are completely accurate or reliable.[10] In addition, while biased self-reported adherence is common,[10] little research has addressed its reliability or utility for evaluating adherence interventions among the Indian population.

This pilot study sought to evaluate the barriers and facilitators associated with adherence and the impact of a group-based intervention designed to enhance adherence in comparison with an individual enhanced standard of care. The intervention utilized information and social support to motivate patient–provider communication and treatment adherence and enhance positive beliefs and behaviors related to ARV medication. The study utilized a crossover design to examine the impact of an immediate- versus delayed-onset intervention to evaluate the impact of establishing adherence behaviors early on in the use of ARV medications. It was hypothesized that participants in the immediate-onset group intervention would be more adherent than those in the delayed onset condition.

Methods

Prior to study onset, Institutional Review Board (IRB) approval was obtained from the University of Miami IRB, and Ethical Review Committee approval was obtained from the Postgraduate Institution for Medical Education & Research (PGIMER), the Indian Council of Medical Research, and the National AIDS Control Organization.

Recruitment and Eligibility

Eighty participants were recruited over a 2-year period from the PGIMER Immunodeficiency Clinic in Chandigarh, India. Interested candidates were screened to determine eligibility. No clinic employees were study personnel, and the study offices were not located at the clinic site to reduce the potential for perceived coercion or the influence of association with the clinic.

Inclusion/Exclusion Criteria

Eligible participants were at least 18 years of age, HIV seropositive, and new to ARV medication use (3-12 months of ARV medication use without a past prescription verified by pharmacy records). Women who had previously taken nevirapine (NVP) associated with pregnancy, persons with active alcohol or drug dependence, and persons who were inpatient hospital patients, under hospice care, or deemed unable to attend appointments or sessions due to extreme illness or mental disability were not eligible for this study. No participants were excluded on the basis of literacy as all materials for assessments and interventions were read by trained assessors.

This pilot study was a randomized controlled clinical trial in which participants were randomly assigned to condition, that is, group (immediate-onset medication adherence intervention [MAI]) or individual (enhanced standard of care) and followed for 6 months. At the end of the first 3 months, participants in both conditions crossed over to the alternate condition for the following 3 months (ie, group to individual and individual to group); participants randomized to the individual condition were thus considered a delayed-onset group. The crossover design was utilized due to ethical considerations associated with the anticipated benefit of the intervention among this vulnerable population. Participants completed psychosocial, behavioral, and biological assessments at baseline, 3 months, and 6 months, and adherence was assessed monthly.

Intervention Content: Group Condition

Participants attending the MAI condition completed regular provider visits plus 3 monthly facilitator-led 1-hour sessions addressing HIV and ARV medications, adherence, and HIV-related coping and social support within a manualized framework. Sessions utilized an interactive group (n = 10 per group) format to maximize the number of participants reached and the impact of facilitator and peer support and included an adherence assessment. Facilitators were master's level psychologists trained in administration of the intervention.

Intervention Content: Individual Condition

Participants in the individual, enhanced standard of care condition attended regular provider visits plus monthly time-matched sessions with study staff consisting of an adherence assessment and HIV educational videos on healthy living (eg, nutrition, exercise, and relaxation).

Assessments

Participants were individually assessed at baseline, 3 months, and 6 months by study staff; interviews included sociodemographic data (eg, education, income, living situation, marital status, spouse/partner HIV serostatus, time since HIV diagnosis, and time on ARV medications) and psychosocial data (eg, total barriers to care and HIV-related impact on social functioning). Adherence was assessed monthly by assessor pill count, pharmacy fill record, and current self-reported adherence and skipped doses. Pill count adherence was calculated as the absolute value of the number of pills the patient took divided by the number of pills that should have been taken since the last pharmacy refill. Higher adherence scores indicated poorer adherence. A cut score ≤4 pills above or below the correct amount to be taken was considered adherent for the purposes of this study and used to create a dichotomous score of *adherent* (1) and *nonadherent* (0). Adherence was determined by the maximum amount of pills to be taken in 1 daily dose (2 or 4 pills for all participants), accounting for the time of day the participants were assessed, acknowledging that at the time of assessment, they may not have yet taken all their pills for the day. The amount taken (and the correct amount to be taken) were assessed by pill count and corroborated with pharmacy refill records. Adherence change was dichotomized as either improved adherence or decreased/same level of adherence. A tolerance was not included in this measure—participants either improved or did not improve. This information was included in the section on Postintervention. Biological assessment consisted of CD4 count and viral load.

Statistical Analyses

Data analyses were conducted using chi-square tests of independence, *t* tests to assess group differences, and logistic regression at a 2-tailed significance level of .05 to assess the ability of associated psychosocial measures to predict improvement in adherence. Missing data were excluded via pairwise deletion. All tests were performed using IBM Statistical Package for the Social Sciences (SPSS) version 19.0.

Results

Characteristics

Participants (n = 80) were predominantly male (70%) with mean age of 38.1 ± 8.6 years. Nearly half (50%) reported at most 9 years of education and most had a monthly income ≤3000 INR (Indian rupees). In all, 62% reported living in a rural area, 78% were married, and nearly half (49%) of spouses were HIV positive. The mean time since HIV diagnosis was 18.2 ± 24.6 months, and the mean time on ARV medications was 6.9 ± 3.0 months. Time on ARV medications (r = .16, P = .17), distance from clinic (r = −.07, P = .54), income (r = .06, P = .73), and having an HIV-positive spouse (χ^2 =.45, P = .51) were not associated with the pill count adherence. Outliers (±2 standard deviations from the mean, n = 2) were removed for analysis of baseline adherence scores. All participants were included in follow-up analyses; there was no difference in outcomes obtained when including or excluding outliers identified at baseline. At baseline, 56% of group condition and 54% of individual condition participants were nonadherent by pill count, and 23% of group and 26% of individual condition participants self-reported skipping their medication at least once over the last 3 months; pill count and self-reports were not associated (r = −.16, P = .15). There were no differences between group and individual condition participants among demographic variables or baseline adherence values (Table 1).

Postintervention

Table 2 presents the impact of the intervention on adherence over time. Results illustrate that the mean adherence scores in both conditions improved by postintervention, but that improvements in the individual condition (delayed onset) were not maintained in the long-term follow-up.

Results indicated a significant difference in the degree of variability between conditions in the pill count adherence values. Thus, the assumption of underlying homogeneity of variance between conditions was violated and a traditional analysis of variance was precluded. Therefore, in order to evaluate the impact of the intervention on adherence, change scores were calculated by subtracting baseline from postintervention adherence scores and postintervention from long-term follow-up scores. Scores were dichotomized as either improved adherence (postto preintervention <0) or unchanged/decreased adherence (postto preintervention ≥0). Postintervention adherence in both conditions improved (Fisher exact test, P < .001), and there was no difference in pill count adherence between conditions (χ^2 = .07, P = .79). In addition, self-reported missed doses did not significantly improve (Fisher exact test, P = .456).

Long-Term Follow-Up

From postintervention to 6-month postbaseline, adherence in the group condition (immediate onset) continued to improve (χ^2 = 5.67, P = .02) but not among those in the individual condition (delayed onset; Table 3). Using the dichotomized scores, over the course of the entire study, participants in both conditions improved (Fisher exact test, P < .001), and there was no difference between conditions in the number of participants who

improved (χ^2 = .54, P = .46). Self-reported missed doses did not improve (Fisher exact test, P = .288).

Associations With Psychosocial and Biological Factors

Only 25% of participants had detectable viral load (>50 copies/mL) and only 5% had viral load ≥1000 copies/mL. Viral load was $\log_{10}$ transformed; however, likely due to the limited variability, viral load was not associated with adherence (r = .05, P = .63). To determine the influence of psychosocial factors on the change in adherence, predictor change scores were calculated by subtracting baseline from postintervention scores and postintervention from follow-up scores. Scores were then dichotomized as either improved or unchanged/decreased. A change in patient–provider communication from baseline to follow-up was associated with pill count adherence (χ^2 = 4.7, P = .04). Self-reported missed doses were associated with a change in beliefs about medication from baseline to follow-up (χ^2 = 5.1, P = .004) and with changes in commitment to adherence (Fisher exact test, P = .004) and social support (Fisher exact test, P = .009) from postintervention to follow-up.

Prediction of Pill Count Adherence

To determine the role of psychosocial factors in the prediction of adherence, a stepwise logistic regression was conducted with psychosocial change scores. The model (χ^2 = 20.6, P < .001) included 2 psychosocial predictors, change in perceived barriers to medication adherence, and change in social functioning, as well as condition (Table 4). As a whole, the model correctly classified 89.7% of cases and explained between 23% (Cox and Snell R^2) and 45% (Nagelkerke R^2) of the variance in change in adherence.

Discussion

This pilot study sought to evaluate barriers and facilitators associated with adherence and the impact of a group-based intervention designed to enhance adherence in comparison with an individual, enhanced standard of care. Patient–provider communication, commitment to adherence, social functioning and social support, and reduced perceived barriers to medication adherence were associated with adherence at long-term follow-up. Additional comparisons between the impact of an immediate- versus delayed-onset intervention demonstrated the impact of establishing adherence behaviors early on in the use of ARV medications. It was hypothesized that participants in the immediate group intervention would be more adherent than those in the delayed-onset condition and that both interventions would be superior to the enhanced standard of care. Participants in the immediate-onset group condition improved medication adherence over the course of the study, in comparison with the delayed-onset group participants. Participants in the individual enhanced standard of care condition showed improved adherence but did not maintain these gains through the long-term follow-up.

Elements of the intervention associated with adherence included change in patient–provider communication, social support, and commitment to adherence, in keeping with existing studies.[21,22] Of interest is the lack of association between measures of adherence, suggesting that participants may be motivated to provide investigators and providers with desirable

responses to queries regarding adherence or treatment compliance. In resource-limited settings, which rely entirely on patient self-report or provider intuition, results support the implementation of interventions enhancing patient–provider communication, and more importantly, accurate assessment of adherence. A strategy for rapid pill count may be a useful adjunct for accurate adherence appraisal in the clinical setting. Outcomes also support the potential utility of a group intervention as a strategy. Future studies should explore the impact of peer support on adherence and treatment engagement.

The individual enhanced standard of care included a monthly pill count and physician visit. Results suggest that counting pills may have influenced adherence behavior in the short term; however, patients in the delayed intervention onset group did not develop and maintain adherence behaviors. This may have been due to the lack of an early intervention serving as the foundation for improved health behavior. The majority of participants had been on ARV medications between 6 and 9 months and diagnosed with HIV between 1½ and 2 years. In contrast with previous literature reporting that less than 24 months of medication use is associated with adherence,[5] length of time on medication was not associated with adherence in the current study.

Participants were predominantly middle-aged men, most were married and about half had less than a high school education. Interestingly, while about half had a positive spouse/primary partner, adherence was not associated with spousal serostatus. In addition, although more than half of the samples lived in a rural setting and almost all reported very low income, adherence was not associated with travel distance from health clinics or monthly income, consistent with the findings from previous studies.[10] Results support recent studies on high levels of adherence among public hospital patients,[7] and the majority of participants were adherent by self-report and pill count. However, similar to previous studies by Anuradha and colleagues (2012), one quarter of participants reported skipping medication within the last 3 months.

This pilot study was primarily limited by its sample size and the use of the crossover design, which precluded the assessment of longer term outcomes and examination of subsamples within the study conditions. Overall adherence scores may have been impacted by a small number of nonadherent participants. In addition, the majority of participants were adherent, which limited variability and statistical analyses. Finally, the lack of reliable CD4 and viral load data did not provide the gold standard for evaluation of adherence and prediction of treatment outcomes. Subsequent studies should consider the use of targeted recruitment designed to identify low-adhering participants. In addition, the importance of accurate and reliable biological assessment should be addressed in resource-limited settings.

Conclusions

This study of adherence in northern India identified high levels of adherence by self-report and a lack of concurrence with more objective measurement. Plans to reduce HIV transmission by test and treat methods must include recognition of the potential for continued transmission to occur among low-adhering members of largely adhering patient populations. The need for targeted interventions for nonadhering patients cannot be

overemphasized, and maintaining long-term adherence may require an early intervention strategy, making communication and problem-solving strategies a key component for successful adherence to “lifelong” medication.

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Table 1
Characteristics of Participants by Condition Assignment (n = 80)

Characteristics	Individual, N = 46	Group, N = 34	OR	95% CI (OR)
Gender				
Male	35	21	0.51	0.19-1.3
Female	11	12	1.7	0.65-4.6
Hijra (transvestite)	0	1	–	–
Age				
18-35	17	11	0.74	0.29-1.9
36-50	28	18	0.72	0.30-1.8
51-60	0	5	–	–
Years of education				
0-3 years	4	2	0.66	0.11-3.8
4-9 years	2	18	1.2	0.51-3.0
At least 10 years	11	10	1.3	0.49-3.6
College level	9	4	0.55	0.15-2.0
Living area				
Urban	20	10	0.54	0.21-1.4
Rural	26	24	1.8	0.72-4.7
Monthly income (Indian rupees)				
<5000 INR (∼$98)	34	20	0.66	0.11-3.8
5001-9999 (∼$197)	9	5	1.2	0.51-3.0
1000-1999 (∼$395)	3	8	1.3	0.49-3.6
2000 or more	0	1	0.55	0.15-2.0
Marital status				
Married	37	26	0.90	0.31-2.6
Single/separated/divorced	6	1	0.20	0.02-1.8
Widowed	3.7	7	3	0.88-15.6
HIV serostatus of spouse				
Positive	23	16	0.89	0.37-2.2
Do not know	3	1	0.43	0.04-4.4
Self-reported skipping				
Recently skipped medication	12	8	0.80	0.41-3.2
Did not recently skip	34	26	0.87	0.31-2.4
	mean ± SD	mean ± SD	*t* (*df*)	*P*
Time since HIV dx, months	16.5 ± 21.4	20.6 ± 28.6	−0.72 (78)	.47
Time on ARV drugs, months	6.8 ± 2.8	7.1 ± 3.2	−0.42 (78)	.68
Adherence value (pill count)	6.9 ± 6.7	8.0 ± 7.9	−0.63 (76)	.53

Abbreviations: OR, odds ratio; CI, confidence interval; ARV, antiretroviral; SD, standard deviation; *df*, degrees of freedom.

Table 2

Impact of Intervention on Pill Count Adherence

Time Period	Individual, N	mean ± SD	Group, N	mean ± SD	*t* (*df*)	*P*
Baseline	45	6.9 ± 6.7	34	8.0 ± 7.9	−0.62 (76)	.53
Postintervention	44	4.3 ± 11.3	34	3.1 ± 7.4	0.50 (77)	.62
Long-term follow-up	44	7.7 ± 18.2	31	1.4 ± 1.7	2.2 (46)	.03

Abbreviations: SD, standard deviation; *df*, degrees of freedom.

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Table 3
Impact of Intervention on Dichotomized Change in Pill Count Adherence

Time Point/Period	Individual, N	Percentage	Group, N	Percentage
Baseline[a]				
Adherent	21	45.7	15	44.1
Nonadherent	25	54.3	19	55.9
Baseline to Postintervention[b]				
Improvement	33	73.3	24	70.6
No improvement	12	26.7	10	29.4
Postintervention to Long-term Follow-up[c]				
Improvement	7	15.2	13	39.4
No improvement	38	82.6	20	58.8
Baseline to long-term Follow-up[d]				
Improvement	33	73.3	25	80.6
No improvement	12	26.7	6	19.4

[a] Between conditions: Fisher exact test, $P = .70$.

[b] Within conditions: Fisher exact test, $P < .001$, between conditions: $\chi^2 =. 07$, $P =.79$.

[c] Within conditions: $\chi^2 = 1.7$, $P = .20$, between conditions: $\chi^2 = 5.67$, $P = .02$.

[d] Within conditions: Fisher exact test, $P < .001$, between conditions: $\chi^2 = .54$, $P = 46$.

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Table 4

Logistic Regression Predicting Adherence

	β (SE)	Wald (*df*)	*P*	OR (95% CI)
Total barriers	.05 (0.03)	4.4 (1)	.04	1.1 (1.0, 1.1)
Social functioning	1.1 (0.69)	4.4 (1)	.04	4.3 (1.1, 16.7)
Condition	2.2 (1.2)	3.2 (1)	.07	9.1 (0.81, 102.6)

Abbreviations: SE, standard error; *df*, degrees of freedom; CI, confidence interval.