ORIGINAL ARTICLE

Adherence counseling and reminder text messages improve uptake of antiretroviral therapy in a tertiary hospital in Nigeria

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Abstract

Context: Human Immunodeficiency Virus/Acquired Immunodeficiency Syndrome (HIV/AIDS) is one of the world's most challenging pandemics. For treatment with Highly Active Anti-Retroviral Therapy (HAART) to be effective, high rate of adherence is essential.

Aim: To demonstrate the effect of adherence counseling and text message reminders in improving patients' adherence to HAART.

Settings and Design: A randomized control trial among non-adherents was carried out in a tertiary hospital in Nigeria between March and July, 2011.

Materials and Methods: A total of 104 patients: 45 males (43.3%) and 59 females (56.7%) participated in the study. They were randomized into intervention and control groups. The intervention group received monthly adherence counseling and twice weekly short message reminders for four months, while the control group received only standard care. Self-reported adherence and CD4+ cell counts were measured pre- and post-intervention.

Statistical Analysis Used: Data was analysed using Statistical Package for Social Sciences (SPSS) version 18. Risk rates, Chi-square, Mann-Whitney U test and Cohen's effect size were calculated. Level of significance was set at $P = 0.05$.

Results: At post-intervention, 76.9% of the intervention group and 55.8% of the control group achieved adherence ($\chi^2 = 5.211$, $P = 0.022$, RR = 0.75 (0.55-0.96), Cohen's w = 0.224). Also, median CD4+ cell count of the intervention group increased from 193 cells/ml to 575.0 cells/ml against 131.0 cells/ml to 361.5 cells/ml in the control group ($P = 0.007$).

Conclusion: Adherence counseling and text message reminders improved adherence among HIV patients. Its adoption for HIV patient management is advocated.

Key words: Adherence, antiretroviral treatment, counseling, human immunodeficiency virus/acquired immunodeficiency syndrome, people living with human immunodeficiency virus, text message reminders

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Introduction

HIV/AIDS clearly is one of the world's most challenging pandemics and greatest health crisis today,[1] and sub-Saharan Africa remains the worst affected region. In 2007, over 68% of all adults and 90% of all children infected with the virus lived in the region, while more than 76% of all deaths related to the virus also occurred in the region. Nigeria is one of the countries most affected in the region, with a national prevalence rate of 4.1%, while Rivers State of Nigeria is ranked 10th among states with a prevalence rate of 6.0%.[2] Efforts at controlling the epidemic witnessed the introduction of HAART, which has turned what was once a death sentence into nothing more than a chronic illness.[3] The main aim of

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treatment with HAART is to achieve a reduction in viral load to undetectable levels. This allows immune reconstitution and leads to marked clinical improvement. It has also proven to prevent episodes of opportunistic infections.[4]

However, a major concern has remained adherence to treatment regimen. Indeed adherence is one of the key factors that determines the success or failure of HAART. It is crucial to achieving treatment goals of undetectable viral load, increasing CD4+ cell counts and improvement in the clinical condition of people living with HIV-AIDS (PLHIV).[5] Adherence has been defined as the extent to which the patient continues the agreed upon mode of treatment under limited supervision.[6] In contrast, non-adherence is defined as the discontinuity or cessation of part or all of the treatment such as dose missing, under dosing, overdosing or drug holidays.[7] Most experts agree that for best results treatment adherence to HAART therapy should be as high as 95%.[8,9] The Nigerian National Guidelines for HIV and AIDS Treatment and Care in Adolescents and Adults concurs with this cut off, asserting that for a patient to be tagged as adherent he/she must not miss more than one dose in ten days if on a twice daily regimen.[10]

If adherence of 95% and above is not achieved, treatment failure is most likely to occur. Treatment failure is typified by detectable viral load usually accompanied by a falling CD4+ cell count and ultimate deterioration in clinical response. Of all the factors thought to influence treatment failure, patient adherence to medication is the most important and most modifiable.[3] This underscores the need for HAART clinics to implement various strategies that go beyond the casual provider admonitions to patients to take their medication so as to help these patients achieve and maintain optimum adherence.[11]

Studies done in Rivers State in 2006 and 2010 showed adherence rates of 49.2% and 72.2%, respectively.[12,13] This suboptimal adherence rate has been corroborated by other studies done in Nigeria,[14-16] indicating that there is still much to be done in terms of achieving and sustaining optimal levels of adherence in the country. This position is supported by the growing number of people on second-line treatment in Nigeria.[17] Two randomized control trials carried out in Kenya showed that the use of weekly short message sending improved adherence in patients on HAART. The first improved adherence over a period of one year (relative risk [RR] 0·81, 95% CI = 0·69-0·94; P = 0·006) and rates of viral suppression (RR 0·84, 95% CI = 0·71-0·99; P = 0·04) compared with the control individuals,[18] while the second achieved adherence of at least 90% during the 48 weeks of the study, compared with 40% of participants in the control group (P = 0.03).[19] However, a number of researchers have made the assertions that a combination of two or more interventions give far better results than a single intervention strategy, and that interventions targeted at non-adherents give better outcomes than those that do not.[11,20,21]

This study was therefore carried out to determine the effect of the combination of cognitive and behavioral interventions (adherence counseling and text message reminders) in improving treatment adherence among non-adherent HIV patients on HAART. The result of the study will be useful in examining the desirability of integrating a combination of adherence interventions into normal HAART clinic activity of antiretroviral service providers.

Materials and Methods

The study was carried out in a tertiary health care institution in Nigeria. The hospital is a referral centre to many health facilities both within and outside the state. It is a 600 bed hospital with several departments. It hosts one of the eight antiretroviral (ART) centers in the state and is funded by the Federal Ministry of Health. The ART clinic runs twice weekly and has an average of 6000 registered patients.

Eligibility criteria

Inclusion

- HIV positive clients who had been HAART experienced for at least three months prior to commencement of the study. This was done to give adequate time for adherence issues if any to emerge
- Clients who had a history of non-adherence (adherence below 95%) to HAART at the time of the study, since it has been shown that interventions targeting the non-adherent are more successful than generalized interventions[20]
- Clients who owned a mobile phone or had daily access to a phone and were able to use the SMS (Short Message Sending) feature on these phones.

Exclusion

- HIV positive clients who were HAART naive or had been on therapy for less than three months before the study
- Clients on HAART who also had other chronic diseases that necessitated daily medication e.g., tuberculosis, hypertension. This was because of the increased pill burden from co-morbidities that could introduce undesirable effects into the study
- Clients on HAART who were on admission since drug adherence would be ensured via provider administered treatment.

Study design

This was an experimental study, employing a randomized control trial, to determine the effect of two interventions on adherence among non-adherent clients on HAART.

Sample size determination

Sample size of 104 for the study was estimated using the formula to determine the difference between two proportions,[22] with expected power of 90%, using a study where proportion of

clients in intervention and control groups who achieved adherence at post-intervention assessment were (94%) and (69%), respectively[23] with significance level set at 5%.

Sampling method

Purposive sampling was used to recruit participants for the study via announcements at the clinic's waiting area during the health education sessions. Recruitment was done over a six-week period and only those who met the eligibility criteria were enrolled into the study [Figure 1].

Randomization protocol

All enrolled participants were allocated to intervention and control groups via the process of randomization. The researchers generated study codes and random assignments using the randomization function of the WINPEPI (VERSION 9.7) statistical software.[24] Written allocations of these assignments with study identification codes were sealed in individual opaque envelopes and placed in a bag. A research assistant was responsible for presenting this bag of envelopes to eligible participants during the recruitment process and recording each participant's allocation after they had opened their envelopes in the study register. Adherence counselors and research assistants were blinded to the study group allocations. Based on these allocations, 52 persons were assigned to Group B (Intervention), while 52 persons were assigned to Group A (Control). In order to avoid contamination between study and intervention groups, each group was assigned a separate clinic day such that throughout the course of the trial, study and intervention groups did not meet.

Description of intervention

Intervention group

- Cognitive intervention (Adherence counseling)

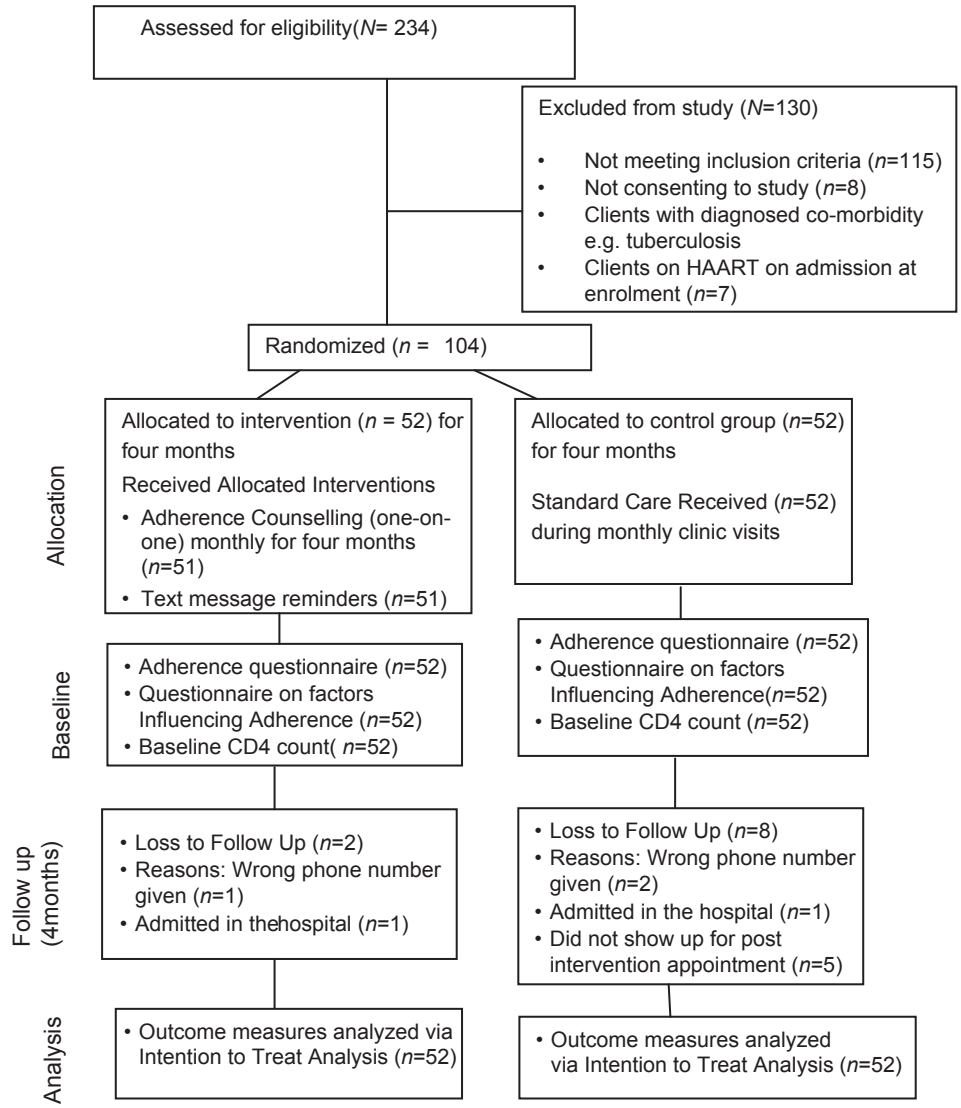

Figure 1: The consolidated standards of reporting trials (CONSORT) diagram for the study

One adherence counseling session per month for four consecutive months was conducted for each client. Each session lasted between 45 and 60 min. These sessions were facilitated by four junior resident doctors of the department of community medicine who were trained to deliver adherence counseling in line with a national adherence counseling training curriculum.[25] One counselor was assigned to a client and worked with that client for the duration of the intervention. All sessions were recorded for the purpose of providing feedback to counselors and ascertaining the quality of sessions. Each counselor made use of an adherence checklist to maintain a client adherence management chart for each client

- Behavioral intervention [SMS reminders]
  Twice a week (Monday and Thursday mornings) for the duration of four months, each client enrolled into the intervention group of the study was sent a pre-scripted text message containing adherence-related information and a reminder to take HAART medications. These messages were sent out via an Internet-based bulk SMS facility known as '*Light Edge SMS*' powered by Light Edge Systems (www.lightedgesystems.com). The researchers were responsible for sending out these messages. In order to ensure that these messages were received, two measures were put in place. Firstly, one of the researcher's phone contacts was added to the receiver category of every message, such that she received the messages being sent out. Secondly, designated phone number contacts were sent with each message and study participants were encouraged to call, '*flash*' or send an SMS to those numbers to acknowledge receipt of SMS as well as indicate their need for further counseling or information. The researchers manned these phones and provided counseling support on a need basis via telephone. Details of all text messages sent and phone conversations were recorded in a log book developed for this purpose.

Control group – standard care

The control group received standard care only. This meant that they did not get any adherence counseling and SMS message reminders. Standard care consisted of:

- Group health education and information on varying topics such as the importance of adherence, methods of transmission of HIV, dietary advice and nutrition information, as conducted by the nurses and/or counselors before the commencement of each clinic
- Occasional admonitions by the doctors (during clinic consults) and pharmacists (during drug dispensing) to clients to take their medications as prescribed
- Quarterly assessment of CD4+ results such that clients with decreasing CD4+ are questioned about their adherence and further managed based on their responses as to whether they are adhering to medication or not.

Outcome variables

- Self-reported adherence
  This was calculated based on client self-report of number of pills missed in the past seven days. The formula used for calculating adherence was the number of doses taken/number of doses prescribed × 100%.[7] A cut-off of 95% was used to distinguish those who were adherent from those who were not. Adherence was assessed at recruitment (before the commencement of the intervention), at every monthly counseling visit and at the end of the intervention in the fourth month. The two adherence values used for comparison were the pre-intervention and post-intervention adherence rates in the intervention and control groups.
- CD4+ cell count Pre-and post-intervention CD4+ cell counts were carried out for all study participants. The results for the intervention and control groups were compared to ascertain any changes in CD4 levels pre- and post-intervention and the magnitude of such changes if present. CD4+ count has been shown to be useful as a biological measure of response to HAART treatment, which is dependent among other things on adherence to treatment.[3]

Data analysis

All data obtained from the study was entered and analysed on SPSS version 18.0. Data was entered, cleaned and analysed by the researchers with the assistance of a statistician. Risk rates andtests of significance using Chi-square and Mann-Whitney U tests were used to compare the intervention and control groups. Cohen's effect size (w) was also calculated. Level of significance was set at $P = 0.05$.

Ethical considerations

Ethical clearance was sought and received from the Ethics Committee of the institution before the study commenced and all participants gave written informed consent by signing and returning a consent form prepared for this purpose.

Study limitations

- Client self-report as a measure of adherence is prone to biases such as recall bias. However, studies show that clients who report poor adherence are most likely to be telling the truth as opposed to those who claim good adherence.[26]
- Use of CD4+ estimation as a proxy measure of adherence instead of measurement of viral load. However, CD4+ cell count is accepted by the national guidelines for HIV and AIDS treatment and care.[27]
- Possible contamination of intervention and control groups through interactions outside the hospital environment.

Results

One hundred and four participants were enrolled for the study, consisting of 45 (43.3%) males and 59 (56.7%) females.

The mean ages of the control and intervention groups are 35.27 ± 9.04 and 36.62 ± 11.77, respectively. There was no significant difference in the distribution of males and females into intervention and control groups ($\chi^2 = 1.919$, $P = 1.919$, $P = 0.166$). Similarly, the groups were comparable with regard to other demographic variables of age, education, marital status, employment and income level [Table 1].

Pre-intervention, adherence-related knowledge of the study participants was assessed. Most participants in both groups understood what HIV is and what its drug treatment entails ($\chi^2 = 0.058$, $P = 0.810$) but their knowledge of drug names was very low in both groups [Table 2]. Similarly, pre-intervention median CD4+ cell counts in the control and intervention groups were measured and the results showed no significant difference among the groups.

Post-intervention, there was significant improvement in knowledge of the dosage and dosing instructions of the antiretroviral drugs $P = 0.046$). The comparisons between the groups pre-and post-intervention are as shown in Table 3. In the same vein, results using the Intention to Treat Analysis (non-response = non-adherent) showed that 76.9% of those in the intervention group had achieved adherence to drug treatment as opposed to 55.8% in the control group. This difference was significant ($\chi^2 = 5.211$, $P = 0.022$). In addition, there was a small effect size (Cohen's w) of 0.224 and risk ratio of 0.75 (0.55-0.96) [Table 4]. Similarly, the post-intervention median CD4+ cell count of the intervention group increased to 578.0 cells/ml compared to 361.5 cells/ml recorded in the control group. Using Mann-Whitney U test, the observed difference was significant ($P = 0.007$) [Table 5].

Table 1: Demographic profile of intervention and control groups

Variable	Study groups		Test statistic χ2 (*P* value)
	Control group (*n*=52)	Intervention group (*n*=52)	
Sex			
Male	19 (42.2%)	26 (57.8%)	χ^2=1.919
Female	33 (55.93)	26 (44.07)	*Pr*=0.166
Age			
20-29	15 (28.8%)	17 (32.7%)	χ^2=6.104
30-39	22 (42.3%)	18 (34.6%)	*P*=0.729
40-49	11 (21.2%)	9 (17.3%)	
50-59	4 (7.7%)	5 (9.6%)	
60-69	0 (0.0%)	3 (5.8%)	
Highest level of education			
None	3 (5.8%)	1 (1.9%)	χ^2=1.533
Primary	6 (11.5%)	8 (15.4%)	*P*=0.821
Secondary	26 (50.0%)	26 (50.0%)	
Post secondary	9 (17.3%)	9 (17.3%)	
Tertiary	8 (15.4%)	6 (11.5%)	
No response	0 (0.0%)	2 (3.8%)	
Marital Status			
Single	23 (44.2%)	21 (40.4%)	χ^2=1.254
Married	24 (46.2%)	25 (48.1%)	*P*=0.740
Separated/Divorced	4 (7.7%)	3 (5.8%)	
Widowed	1 (1.9%)	3 (5.8%)	
Employment status			
Working full time	31 (59.6%)	29 (55.8%)	χ^2=1.07
Working part time	4 (7.7%)	5 (9.6%)	*P*=0.898
Unemployed	8 (15.4%)	11 (21.2%)	
Looking for work	6 (11.5%)	5 (9.6%)	
Full time house wife	0 (0.0%)	1 (1.9%)	
Retired	1 (1.9%)	0 (0.0%)	
Student	2 (3.8%)	1 (1.9%)	
Income			
<N10,000	15 (28.8%)	15 (28.8%)	χ^2=1.124
N10,000-N29,000	14 (26.9%)	17 (32.7%)	*P*=0.952
N30,000-N49,000	4 (7.7%)	5 (9.6%)	
N50,000–N99,000	4 (7.7%)	4 (7.7%)	
N100,000 and above	5 (9.6%)	3 (5.8%)	
No response	10 (19.2%)	8 (15.4%)	

Discussion

These results highlight the association between adherence

Table 2: Pre-intervention adherence-related knowledge (Intention to treat analysis)

Adherence knowledge	Pre-intervention		Test statistics χ2 (*P* value)
	Control group (%)	Intervention group (%)	
Drug name			
I Know	18 (34.6)	19 (36.5)	0.042 (0.838)
I don't know	34 (65.4)	33 (63.5)	
Dosage			
I know	41 (78.8)	41 (78.8)	0.000 (1.000)
I don't know	11 (21.2)	11 (21.2)	
Dosage instructions			
I know	31 (59.6)	31 (59.6)	0.000 (1.000)
I don't know	21 (40.4)	21 (40.4)	

Table 3: Post-intervention adherence-related knowledge (Intention to treat analysis)

Adherence knowledge	Post-intervention		Statistics χ2 (*p* value)
	Control group (%)	Intervention group (%)	
Drug name			
I know	11 (21.2)	14 (26.9)	0.474 (0.491)
I don't know	41 (78.8)	38 (73.1)	
Dosage			
I know	44 (84.6)	50 (96.2)	3.983 (0.046)
I don't know	8 (15.4)	2 (3.8)	
Dosage instructions			
I know	44 (84.6)	50 (96.2)	3.983 (0.046)
I don't know	8 (15.4)	2 (3.8)	

Table 4: Comparison of post-intervention adherence behaviors among study participants

Do you forget to take your medications?						
Do not forget		Forgets		Test statistics χ^2 (*P* value)	Effect size (Cohen's w)	Risk ratio (95% C.I)
Control (%)	Intervention (%)	Control (%)	Intervention (%)			
29 (55.8)	41 (78.8)	23 (44.2)	11 (21.2)	6.292 (0.012)	0.246	1.414 (1.07 to 1.87)
Adherence assessment						
Adherent		Non adherent		Test statistics χ^2 (*P* value)	Effect size (Cohen's w)	Risk ratio (95% C.I)
Control	Intervention	Control	Intervention			
29 (55.8)	40 (76.9)	23 (44.2)	12 (23.1)	5.211 (0.022)	0.224	0.725 (0.55 to 0.96)

Table 5: Comparisons of differences in pre- and post-intervention median CD4+ cell counts

Variable	Control group	Intervention group	Tests of significance (Mann-Whitney's U test)	*P* value
Pre-intervention median CD4+ cell count	131	193	1.13	0.130
Post-intervention median CD4+ cell count	361.5	578.0	2.44	0.007

behavior and knowledge of drug dosages and dosage instructions. Ogunbanjo and Heyer had in their review of effective interventions that improve adherence revealed that while cognitive interventions such as text messaging alone may increase adherence knowledge, they may not translate into changes in adherence behavior.[20] They postulated that a combination of both cognitive and behavioral interventions had greater potential to affect both knowledge and practice of adherence.[20] The findings of this study corroborates their position by showing significant difference of 20% and above between the intervention group who benefited from counseling and text message reminders and control groups who only had standard care. Recent studies by Chung *et al.* in Kenya using counseling and alarm devices as interventions[28] and those of Pop-Eleches *et al.* and Lester *et al.* have equally demonstrated the positive effect of including SMS facilities to reinforce cognitive intervention of adherence counseling in order to improve adherence among HIV patients.[18,19]

Similarly, post-intervention median CD4+ cell counts showed significant increase from pre-intervention values, indicating an improvement in adherence and immunological competence in the intervention group as against the treatment failure usually typified by a detectable viral load and accompanying falling CD4+ cell count and ultimate deterioration in clinical response. This finding was in agreement with other studies such as that by Wang *et al.*, which showed that an increase in adherence was tied to increases in mean CD4+ cell count levels and the prevention of opportunistic infections.[29]

The study revealed generally poor knowledge of the names of the ARV medication among the study participants. This was not totally surprising as the study was carried out among non-adherent patients and their lack of interest in the drugs might have been responsible for their behavior. The technical nature of drug names, coupled with the low education and social status of most participants could also have contributed to the finding. Studies by Hulka *et al.* had demonstrated that patients who learned the name of their drugs had better adherence than those who did not.[30] This notwithstanding, adherence rates improved among the study participants at post-intervention even when their knowledge of the drug names did not. With regard to drug dosages and dosing instructions, knowledge of participants was found not only to be high in both control and intervention groups at pre-intervention, they improved further at post-intervention four months later. This was good for ARV drug adherence and could have resulted from the simplicity of doses and dosing instructions of ARV medications. It also corroborated the findings by Agu *et al.* who evaluated treatment outcomes among HIV patients receiving combination treatment in Benin city, Nigeria.[14] However, the study by Wang *et al.* carried out in rural China revealed a lower knowledge of dosages and dosing instructions among the HIV patients receiving care.[29] The lower educational level of most rural residents might have been responsible for the difference.

Conclusion

The outcome of this study support the results from other studies, which highlighted that a combination of counseling and text message reminders significantly improved drug adherence as well as the CD4+ cell counts among non-adherent HIV patients on HAART. Therefore, integrating drug adherence assessment as part of routine HIV clinic consultations and adherence counseling and text messaging to address adherence challenges among PLHIV is advocated.

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