THE EFFECT OF COGNITIVE BEHAVIORAL INTERVENTIONS ON ADHERENCE TO ANTI RETROVIRAL TREATMENT AMONG HIV PATIENTS.

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ABSTRACT

Adherence to the antiretroviral treatment (ART) regimen appears to be the single most important variable that predicts a patient’s ability to achieve and maintain suppression of HIV viremia to below the level of detection. Adherence behaviour is the self-initiated actions to promote optimal wellness, recovery, and rehabilitation. The consequences of non-adherence are not only limited to the patient but lead to higher costs to the individual and ART program, hence a risk for society. Success of treatment of HIV infected patients is directly related to the adherence to ART. The effect of cognitive behavioural interventions on adherence to Anti-Retroviral Treatment in HIV patients was the aim of this study. In the present study total 390 HIV infected patients taking anti-retroviral treatment for more than 6 months were selected. All the patients included were from different regions of Maharashtra majority were from Marathwada. Morisky medication Adherence Scale a 9-item questionnaire was used for assessment of adherence to ART. After Pre and post cognitive behaviour interventions, collected data was analysed. Conclusions-Cognitive behavioural interventions significantly improved adherence to antiretroviral treatment.

KEYWORDS: cognitive behavioral interventions, adherence, Antiretroviral.

INTRODUCTION

Adherence is defined as a patient’s ability to follow a treatment plan, take medications at prescribed times and frequencies, and follow restrictions regarding food and other
Both patients and health care providers face significant challenges with respect to adherence to ART. Once initiated, HAART is a life-long treatment that consists of multiple medications to be taken two to three times a day with varying dietary instructions. Adherence to ART regimen involves taking all pills in the correctly prescribed doses, at the right time, and in the right way (Carter, 2005). It involves the following elements: 1. Taking all the medicines which make up the ART combination in the correct quantities. 2. Taking the pills at the right times. Delay in taking the medication or taking medications at the wrong time can cause a rise in viral load, because of fall in drug levels and this may lead to the development of drug resistance. 3. Ensuring that the medication is taken with or without food, according to the instructions. Some medicines need to be taken with food to ensure that the body absorbs them properly while others need to be taken on an empty stomach, a certain amount of time before or after eating. It can also be important that the patient eats the right kind of food; for example, the amount of fat eaten can make a difference to how well some drugs are absorbed.

4. Checking for interactions with any other medication or drugs. This includes medicines that have been prescribed for the patient, or bought at a pharmacy, or medical store, including complementary or alternative therapies. Some recreational and illegal drugs can have potentially dangerous interactions with ART. The best response to ART is seen when adherence is 100%. Levels of adherence below 95% have been associated with poor suppression of HIV viral load and a lower increase in CD4 count. 5. If a patient is taking once-daily treatment, 95% adherence means missing no more than one dose a month. 6. If a patient is taking treatment twice a day, 95% adherence means missing no more than three doses a month. 7. If a patient is taking treatment three times a day, 95% adherence means missing no more than four doses a month.

Non adherence is missing one dose of a given drug, multiple doses of one or more prescribed medications or whole days of treatment, not observing the intervals between doses, not taking drugs in prescribed doses or not observing the dietary instructions. Consequences of non-adherence are incomplete viral suppression, continued destruction of the immune system, disease progression, and emergence of resistant viral strains. The consequences of non-adherence are not only limited to the patient but lead to higher costs to the individual and ARV program. If a patient with a resistant virus infects another person, the resistant virus is transmitted. This is hence a risk for society. Numbers of factors are responsible for
nonadherence. As observed in different studies following barriers were found to be associated with nonadherence.

**Barriers to Adherence:** 1. Communication difficulties like language, cultural differences, patient attitudes regarding treatment efficacy, lack of comprehension about treatment plan or regimen. 2. Literacy levels illiterate patients 3. Inadequate knowledge or awareness about HIV disease. 4. Inadequate understanding about effectiveness of medications 5. Lack of social support. 6. Discomfort with disclosure of HIV status. 7. Difficult life conditions like lack of income, housing and food; lack of support for childcare. 8. Alcohol and drug use.

9. Depression and other psychiatric problems. 10. Negative or judgmental attitude of providers. 11. System barriers like no availability of drugs, shortage of staff, health facility closed

**Measurement of adherence:** Measuring adherence is complex and difficult since there is no optimal approach available. The approaches are divided into direct and indirect methods⁴.

The direct approach is to measure the plasma concentrations of the antiretroviral drugs by viral load⁵. Indirect approach methods rely on less objective measures. The indirect methods mainly include: Self-reported adherence⁶, Pill count⁷, Pharmacy refill records⁸, Medical event monitoring systems (MEMS), Assessment of adherence by doctor or nurse.⁹ Other indirect methods include reviews of patient charts (documented patient report of adherence to provider), missed clinic visits, direct observed therapy (DOT) and therapeutic outcomes (i.e. viral load, CD4 lymphocyte count, stage of disease progression and mortality).

Cognitive behavior therapy (CBT) is a process of teaching, coaching and reinforcing positive behaviors. CBT helps people to identify cognitive patterns or thoughts and emotions that are linked with behaviors.¹⁰ It is directive, time-limited, structured, and place great emphasis on homework exercises. While cognitive therapy emphasizes the role of cognitive processes in the origin and maintenance of psychological disorders, behavior therapy focuses on principles of learning theory and the role of reduced reinforcement in the creation and maintenance of these disorders.¹¹ In cognitive therapy, individuals learn to identify and monitor distorted, negative thinking, to become aware of the relationship between such thoughts and negative assumptions about oneself and of the association between thoughts and feelings. Individuals also learn to apply techniques to challenge these thoughts. In behavior therapy, individuals
are taught to track the frequency of targeted behaviors and to understand the relationship between these behaviors and their antecedents and consequences.\textsuperscript{[11]}

The process of CBT therapy mainly involves following steps- (a) Building a relationship with the client. (b) Prepare the client for therapy. Clarify treatment goals. Assess the client’s motivation to change. (c) Implement the treatment program (d) Evaluate progress (e) Prepare the client for termination; It is usually very important to prepare the client to cope with setbacks. Many people, after a period of wellness, think they are ‘cured’ for life. Then, when they slip back and discover their old problems are still present to some degree, they tend to despair and are tempted to give up self-help work altogether.

Thus adherence to ART in HIV infected patients is very important for the success of treatment and to maintain necessary adherence cognitive behaviour interventions may help.

**MATERIAL AND METHODS**

The present study was conducted in the antiretroviral (ART) centre which runs under National AIDS Control organization (NACO) by Maharashtra State AIDS Control Organization (MSACS). All the patients enrolled under ART centre and require antiretroviral treatment as per NACO Guidelines are provided free antiretroviral drugs.

1 Statement of the problem “To study the effect of cognitive behavioral interventions on death anxiety and adherence to Anti-Retroviral Treatment in HIV patients.”

2. Objectives of the study - To find out the effect of Cognitive Behavioral interventions on adherence to antiretroviral treatment of HIV infected patients.

3 Hypothesis tested in the study: To attain the objectives of this study, following hypotheses (H) had been put forth for testing. H1. Level of adherence to antiretroviral treatment would be improved after cognitive restructuring. H2. Level of adherence to antiretroviral treatment would be improved after structured relapse prevention. H3. Level of adherence to antiretroviral treatment would be improved after structured problem solving.

3.5 Population and sample

A purposive sample of HIV infected patients diagnosed to have HIV infection and registered in the antiretroviral treatment centre was selected. The sample size was based on population proportion of 81 percent and confidence level of 95 percent, with absolute precision of 5
percent points to have sufficient variation in the population characteristics (e.g., sex, education, economic status) that may influence adherence. Both male and female HIV infected patients of 18 to 55 years of age, taking anti-retroviral treatment for more than 6 months who could understand, read and write Marathi and Hindi language were selected. Diagnosis of HIV infection was confirmed under ICTC- Integrated counseling and testing centre of a tertiary care Hospital in Aurangabad, Maharashtra, India. Pretest questionnaire were filled by these patients and the same sample of population underwent cognitive behavioral interventions, after which posttest questionnaire were filled. Those who gave consent to the questionnaire, filled pretest, posttest, questionnaire and underwent all the interventions as specified were included in the study. Total 390 out of 400 patients fulfilled the criteria’s of selection and underwent all the interventions as per the plan of the study. Those patients not fulfilling all the above criteria, seriously ill patients, those who were lost to follow up and failed to undergo planned sessions of CBT interventions were excluded from the study. CD4 count of every patient was done at six 6 monthly interval. As per the Free ART program under NACO guidelines, viral load test was not routinely recommended so it was not done of these patients.

Variables under study - Dependent variables involved in the present research is adherence to antiretroviral treatment. Independent variables were cognitive behavioral interventions like 1. Cognitive restructuring, 2. Structural relapse prevention 3. Structured problem solving are independent variables.

Study design: Pretest and post test study to compare participant groups and measure the degree of change occurring as a result of treatments or interventions.

Cognitive behaviour interventions applied were - Cognitive restructuring, Structured relapse prevention, Structured problem solving.

**Tools of data collection**

To assess the adherence to antiretroviral treatment Morisky medication Adherence Scale (MMAS) was used. The scores of the 9-item MMAS range from 1-13, where 13 indicates perfect adherence. The MMAS test measures adherent behavior rather than dose adherence. Internal consistency reliability (measured by Crohnbach α) has been reported to be 0.89 for the MMAS. MMAS has been used internationally to measure adherence to antiretroviral treatment.\[12\]
MMAS scoring for Adherence

<table>
<thead>
<tr>
<th>Q. No.</th>
<th>Question</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Have sometimes forgotten medicines</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>2.</td>
<td>Have forgotten medicines during last two weeks</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>3.</td>
<td>Have reduced doses without the doctors knowledge</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>4.</td>
<td>Have forgotten medicines during travelling</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>5.</td>
<td>Took medicines yesterday</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>6.</td>
<td>Have reminder system for medicines</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>7.</td>
<td>Have had treatment interruptions because he/she considers the infection under control</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>8.</td>
<td>Consider it a difficult treatment</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>9.</td>
<td>Difficulty in remembering treatment</td>
<td>Never 5, Occasionally 4 Sometimes 3 Usually 2 Always 1</td>
<td></td>
</tr>
</tbody>
</table>

Score > 11 are adherent to medication, corresponds to 95 % dose adherence

Scoring Method

Adherence was calculated using MMAS scale.

MMAS is presented as a summary score where answers indicating adherent behavior result in 1 point per item for first eight items. The last item is scored 1-5 where 1 indicates the least and 5 indicates the most adherent behavior, giving a range for summary score 1 to 13.[13] In this scale patients with a summary score > 11 are classified as ‘adherent’ and those scoring below were classified as non adherent and corresponds to 95 % dose adherence level. MMAS scale was chosen over widely used AACTG scale because of studies which suggested superiority of MMAS due to lesser internal attrition, less complexity and also association between MMAS and viral load.

Data collection

This study was conducted in three sessions-

First session

All the selected 390 HIV infected patients attending antiretroviral centre were subjected to fill Morisky Medication adherence scale. Every patient was interviewed by the investigator and all the questionnaires were checked for completeness. They were called every month for collection of their medication and cognitive behavioral interventions.
Second session
Out of these 390 patients three groups of 130 patients each were made randomly. The first group of 130 patients was subjected to the intervention, cognitive restructuring, second group of 130 patients underwent structured relapse prevention and to the third group of 130 patients, structured problem solving was applied. Adherence counseling was done by the ART counselor to every patient as a part of protocol by National AIDS control organization. If the patients miss medication or do not report on time to collect medication, adherence counseling was repeated. Every patient had to visit ART centre once in a month to collect their monthly quota of medication and selected cognitive behavioral interventions which were administered by the investigator. Every session of intervention lasted for one hour for every patient. All the patients were given booklets written in local language by the investigator which included- 1) Part1-containing education about the HIV virus and natural history of HIV infection and AIDS. 2) Part2- containing information regarding cognitive behavioral interventions selected for them. They were given the homework of reading it everyday preferably in the morning or the time suitable for them. Every patient was asked to bring the booklet every time they visited investigator.

Third session
All the patients who completed first and second sessions satisfactorily were administered posttest questionnaires. The questionnaire was reapplied to the same sample and then were assessed for change in their behavior.

3.10 Cognitive behavioral interventions
1. Cognitive restructuring: The procedure followed was as follows.
Step I - To identify the specific cause of the anxiety, patients were interviewed in detail to find out their irrational thoughts, beliefs.

Step II - The therapist helped the patient dispel the irrational thoughts that provoke Anxiety. With the help of education material like charts, lectures, television educational programs, by giving live examples as role models and roll plays and take home assignments these patients were helped to change their behavior.

Step III - To convert the anxiety-provoking thought into something that, instead, induces relaxation. The final goal of therapy is to give the patient the tools he needs to remain calm under difficult circumstances. Deep breathing exercises were taught to every
patient. Patients were taught how they can change their negative and irrational thoughts into positive and constructive thinking. Every patient underwent 12 sessions of one hour duration.

2. Structured relapse prevention

II. A number of basic principles and procedures underlie the Gorski Cenaps model of relapse prevention therapy (developed by terence t. Gorski. Published 2007 by herald publ. In independence, mo. Written in english). Each principle forms the basis of specific relapse prevention therapy procedures. It was used as per the following principles and procedures to develop appropriate treatment plans for relapse-prone patients. Following a description of each principle is the relapse prevention procedure for that principle.

A. Principle 1: Self-Regulation
The risk of relapse will decrease as a patient’s capacity to self-regulate thinking, feeling, memory, judgment, and behavior increases.

1) Relapse Prevention Procedure 1: Stabilization-
An initial treatment plan was established that allows relapse-prone individuals to stabilize physically, psychologically, and socially. The stabilization process included-

   - Detoxification from alcohol and other drugs
   - Solving the immediate crises that threaten sobriety
   - Learning skills to identify and manage Post Acute Withdrawal and Addictive Preoccupation
   - Establishing a daily structure that includes proper diet, exercise, stress management, and regular contact with treatment personnel and self-help groups.

Any irrational thoughts (thoughts that don't make sense to a healthy person) that are creating immediate justification for relapse were identified and discussed. The patient then was helped to remember the consequences of past chemical use and to develop new coping strategies.

An early relapse intervention plan was developed by the counselor and patient to decide what action to take if the patient begins to use alcohol or drugs. This early intervention plan motivates the patient to stay sober and provides a safety net should chemical use occur.

B. Principle 2: Integration-
The risk of relapse will decrease as the level of conscious understanding and acceptance of situations and events that have led to past relapses increases.

1) Relapse Prevention Procedure 2: Self-Assessment
Self-assessment involved a detailed reconstruction of the presenting problems (problems that caused the patient to seek treatment) and the alcohol and drug use history. As a homework these patients were asked to make a list of all relapse episodes and identifying the problems that led to relapse. These assignments were reviewed in group and individual sessions.
C. Principle 3: Understanding- The risk of relapse will decrease as the understanding of the general factors that cause relapse increases.

1) Relapse Prevention -Relapsers need accurate information about what causes relapse and what can be done to prevent it. This is typically provided in structured relapse education sessions and reading assignments, which provide specific information about recovery, relapse, and relapse prevention planning methods.

The following format for a relapse education sessions was followed

- Educational presentation lecture, film, or videotape (30 minutes)
- Educational exercise conducted in dyads or small groups (15 minutes)
- Large group discussion (15 minutes)
- Post-test session and review of correct answers (15 minutes).

3. Structured problem solving: Some simple steps suggested by Carroll 7 and Mynors-Wallis 8 were used to guide patients

- Identify the problem (try to break it down) and define it. • Step back from the problem and try to view it as an objective challenge. • Brainstorm possible solutions (realistic and unrealistic). • Think about each solution in practical terms, and evaluate the pros and cons. • Decide on the best solution (and a second, “back-up” solution). • Put the solution into action. • Evaluate how effective it was and whether it can be improved.

All these steps with their detailed explanation were written in local language by the investigator for all the patients. The patients were asked to read and follow it.

Statistical analysis

Data analysis: Statistical analysis was done using dependent T test and the data was computed using EPI info version 6. T tests were used to assess significance between pretest and posttest groups. A P-value of < 0.05 was considered significant. Pearson’s correlation was used to find relationship between death anxiety, mental health and adherence to ART.

RESULTS AND DISCUSSION

On statistical analysis hypothesis were tested and following results were obtained which were compared with other similar studies.
Hypothesis 1- Level of adherence to antiretroviral treatment would be improved after cognitive restructuring. The best response to ART is seen when adherence is 100%. Adherence to antiretroviral treatment is the most important part of treatment of HIV/AIDS along with psychological support.

Before intervention 285 patients in the 390 study population were adherent to treatment using MMAS (MMAS > 11). The prevalence of adherence before intervention was 73 %. After intervention 325 patients in the 390 study population were adherent to treatment. The prevalence of adherence increased to 83.33%.

Table no.1. Table shows Mean, Standard deviation, t values for pretest and posttest total scores of effect of cognitive restructuring on adherence to ART.

<table>
<thead>
<tr>
<th></th>
<th>MMAS1</th>
<th>N</th>
<th>Std. Deviation</th>
<th>Std. Error Mean</th>
<th>t value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pair 1</td>
<td>10.4615</td>
<td>130</td>
<td>2.19991</td>
<td>.19294</td>
<td>-3.879**</td>
</tr>
<tr>
<td>MMAS2</td>
<td>11.4000</td>
<td>130</td>
<td>2.17669</td>
<td>.19091</td>
<td></td>
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</tbody>
</table>

Table No. 1.2 Paired sample test

Thus the difference in adherence rate is statistically significant.

As per table no.1, the means of scores of MMAS before and after intervention are 10.46 and 11.40 respectively and the difference is significant at df 129 and t value of -3.879 P< 0.01.
The results indicate that there is statistically significant effect of cognitive restructuring on adherence to antiretroviral therapy. This supports the hypothesis that the level of adherence to antiretroviral therapy would be improved after cognitive restructuring.

In a similar study of a cognitive-behavioral adherence intervention for patients initiating or changing an antiretroviral (ART) regimen conducted by Wagner GJ, Kanouse DE(2006 June)^14^, The five-session adherence interventions were applied to 230 patients. At week 4 mean adherence in the intervention group was significantly higher than the control group at week 24 (89 versus 81%; P < 0.05). Pradier C, Bentz L, Spire B, Tourette-Turgis C, et al evaluated the impact of an intervention for improving adherence to HAART in HIV-infected patients on 244 patients. This study brings evidence of the feasibility and efficacy of a counseling intervention to increase adherence to HAART that could be easily implemented in most clinical settings.\(^{15}\)

In a study of cognitive-behavioral therapy for antiretroviral treatment medication adherence and depression by Safren, Steven A.; Hendriksen, Ellen S,(2004) each session addressed HIV medication adherence in the context of modules for activity scheduling, cognitive restructuring, problem-solving training, and relaxation training/diaphragmatic breathing. These patients showed improvements in both depression and medication adherence.\(^{16}\)

H2. Level of adherence to antiretroviral treatment would be improved after structured relapse prevention. It was observed that after structured relapse prevention the level of adherence to antiretroviral treatment increased from mean of 10.84 to 11.85.

**Table No. 2. Table shows Mean, Standard deviation, t values for pretest and posttest total scores of effect of structured relapse prevention on adherence to ART.**

<table>
<thead>
<tr>
<th>Before and After Structured relapse prevention</th>
<th>Mean</th>
<th>N</th>
<th>Std. Deviation</th>
<th>Std. Error Mean</th>
<th>t value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pair 1 MMAS1</td>
<td>10.8462</td>
<td>130</td>
<td>2.26350</td>
<td>.19852</td>
<td>-5.642**</td>
</tr>
<tr>
<td>MMAS2</td>
<td>11.8538</td>
<td>130</td>
<td>1.80487</td>
<td>.15830</td>
<td></td>
</tr>
</tbody>
</table>

Table No.2.2 Paired sample test.
As observed in table no.2, the means of scores of MMAS before and after intervention are 10.8462 and 11.8538 respectively and the difference is significant at df 129 and t value of -5.642 P< 0.01. It indicates that there is statistically significant effect of structured relapse prevention on adherence to antiretroviral therapy and thus support the hypothesis that the level of adherence to antiretroviral therapy would be improved after structured relapse prevention.

In a study of 60 HIV-infected persons on stable antiretroviral combination therapy and viral load less than 50 copies per ml Weber R, Christen L, Christen S, Tschopp S.et al (2004 Feb) observed that cognitive behavioral support in addition to standard of care of HIV-infected persons is feasible in routine practice, and can improve medication adherence and mental health.\[17\]

Hypothesis 3. Level of adherence to antiretroviral treatment would be improved after structured problem solving. In the total study population the prevalence of adherence increased to 83.33 %.The adherence rate to ART was high in the study population as compared to other studies. This could be because all patients in the study population were receiving free ART. In different studies majority of the study population had to bear the financial burden of medication. Meilo H, Guiard-Schmid JB et al (2002 Jul) studied adherence to ART in Cameroon. They found great disparity between adherence rates in those receiving free drugs and those paying for ART. Adherence rate was high in patients receiving free ART. The investigators advocated African governments, international organizations to provide free treatments to PLWHA.\[18\]

Table No.3. Table shows Mean, Standard deviation, t values for pretest and posttest total scores of effect of structured relapse prevention on death anxiety.

Table No. 3.1 Paired Samples Statistics

<table>
<thead>
<tr>
<th>Before and After structured problem solving</th>
<th>Mean</th>
<th>N</th>
<th>Std. Deviation</th>
<th>Std. Error Mean</th>
<th>t value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pair 1 MMAS1</td>
<td>10.6231</td>
<td>130</td>
<td>2.44399</td>
<td>.21435</td>
<td>-9.701**</td>
</tr>
<tr>
<td>MMAS2</td>
<td>12.2769</td>
<td>130</td>
<td>1.45216</td>
<td>.12736</td>
<td></td>
</tr>
</tbody>
</table>

Table No.3.2 Paired sample test
As observed in table no.3, the means of scores of MMAS before and after intervention are 10.6231 and 12.2769 respectively and the difference is significant at df 129 and t value of -9.701 P< 0.01. The results indicate that there is statistically significant effect of structured problem solving on adherence to antiretroviral therapy. The results support the hypothesis that the level of adherence to antiretroviral therapy would be improved after structured relapse prevention.

Initial published reports of randomized controlled trials testing interventions designed to improve adherence show modest success. For example, Tuldra and colleagues (2000) conducted an randomized control trials in which patients were randomly assigned to receive either a psycho educational intervention aimed at increasing self efficacy or routine medical follow-up. At week 48, 94% of patients in the intervention group versus 69% of the controls maintained high levels of self-reported adherence (>= 95%). Intervention patients also had lower viral loads. However, differences in adherence did not reach statistical significance in the intention to treat analysis although a tendency toward benefit was observed in treatment group.

In another pharmacist-led education plus phone support intervention conducted by Knobel and colleagues (1999), significantly more patients in the intervention group achieved adherence rates of at least 90% compared to a randomly-assigned control group, however, the rate achieving an undetectable viral load in this group was not significantly better than the control group.

In the present study some patient had problem in taking too many pills a day at different times. When antiretroviral treatment is prescribed with many other medications for tuberculosis or prophylactic medications there is high risk for drug – drug interaction. So any other medication is given after a gap of 2-3 hours after antiretroviral medicines.

Some patients had problem in taking medication on time when they were on shift duties. As they had to go for the job as per the shift schedule they used to find it difficult to follow the timings of the medicines. Such patients were advised to keep some of tablets of medicines in the locker of their room especially where temperature of the room is proper for the medication.

In the present study the most common reason for nonadherence (missing pills) was being out of home or travelling, too busy in some other work to take medications, some patients said
that they simply forgot medications without giving any reason. Gastrointestinal side effects like nausea, vomiting, and decreased appetite were the most common. Tingling and numbness in feet, rashes, fatigue, body ache and change in facial appearance (lipoatrophy) were also seen. Giddiness and weakness developed in a few patients, which they attributed to medications and had hence stopped taking ART pills.

All such problems were dealt with by the investigator with the help of the therapist and patients were helped to prevent relapse of nonadherence by giving them solutions for these problems.

Some patients had found lipodystrophy as a cosmetic and embarrassing side effect of a drug stavudine which was prescribed as a first line drug. In these cases this drug was changed to Zidovudine.

Living alone and a lack of support have been associated with an increase in non adherence (Williams and Friedland, 1997), and social isolation is predictive of non adherence. Not living alone, having a partner, social or family support, peer interaction, and better physical interactions and relationships are characteristics of patients who achieve optimal adherence (Motashari et al., 1998).

**Conclusions of the study**- As these patient have to take multiple drugs at a time and treatment of HIV disease is lifelong there is a risk of nonadherence and relapse of nonadherence to antiretroviral treatment.

On analysis of the data following conclusions are drawn.

1) Before intervention 285 (73%) and after intervention 325 (83.33 %) patients were adherent to the treatment.
2) The level of adherence to antiretroviral treatment significantly improved after cognitive restructuring. Mean= -0.94. SD= 2.76. T value= -3.879. Degree of freedom is 129. Significance is less than 0.05 and statistically significant.
3) The level of adherence to antiretroviral treatment significantly increased from mean of 10.84 to 11.85 after structured relapse prevention. Mean =-1.01. SD= 2.036. T value=-5.64. Our significance is less than 0.05 and statistically significant.
4) The level of adherence to antiretroviral treatment statistically improved after structured problem solving. Mean = -1.65. SD= 1.94. T value=-9.701. Significance is less than 0.05 and is statistically significant.

In summary, CBI appears to have a significant role to play in the management of HIV spectrum disease. This includes ameliorating distress, improving patient adherence to medical regimens, and facilitating the efforts of HIV-infected women and men to cope effectively with their chronic disease. The results should be seen in increased quality and quantity of life.

**Recommendations for further research**

Further multicentric studies with large number of sample are suggested to confirm findings of this study.

**1.5 Limitations of the study**

Considering the randomized selection of the study population maturation and history are major problems for internal validity in this design, whereas the interaction of pretesting and treatment is a major threat to external validity.

Along with adherence counselling different cognitive behavioural interventions were used simultaneously, so the affectivity of each of these separately needs to be investigated.

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