

Impact of adherence counselling with hatha yoga on HIV-infected adolescents: a randomized controlled trial

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Abstract

Introduction: Currently, global human immunodeficiency virus (HIV) epidemic enters its' fourth decade. Notable challenge is faced owing to increasing proportion of HIV-infected adolescents and ultimate commitment to life-saving drug therapies. The aim of this study was to evaluate the effectiveness of adherence counselling with hatha yoga in the treatment of HIV-infected adolescents and offering help in improving quality and increasing the span of the patents life.

Material and methods: Randomized controlled trial design was adopted. Through simple random technique, a total of 388 HIV-infected adolescents was divided into experimental ($n = 195$) and control groups ($n = 193$). Data were collected from HIV-infected adolescents/caregivers from four main antiretroviral therapy (ART) centers in Chennai through modified adherence assessment questionnaire. Adherence counselling and yoga practice sessions were given for experimental group alone, and asanas were demonstrated by the researcher. Data were collected from both groups at 0, 3, and 6 months intervals.

Results: In both groups, mean ART adherence scores in pre- and post-tests were 85.36 and 85.60, respectively. Mean difference in ART gain score with 95% CI was 13.4% in experimental and 4.9% in control group. Regarding CD4+ count, baseline mean score was 664.86 in experimental and 669.72 in control group, whereas in 6th month assessment, it rose to 840.30 and 703.35, respectively.

Conclusions: Motivational counseling, along with yoga, shown effective in increasing ART adherence and CD4+ count among HIV-infected adolescents in experimental group compared with control group. Findings of this study proved that adherence counselling and yoga practice contributed significantly to the overall health and well-being of HIV-infected adolescents.

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Key words: adherence counselling, yoga, HIV-infected adolescents, antiretroviral therapy, CD4+ count.

Introduction

With the advent of highly active antiretroviral therapy (HAART) in 1998, a large number of children infected by vertical transmission have reached adolescence and adulthood [1]. HAART treatment for human immunodeficiency

virus (HIV) infection is a life-long commitment to all people living with HIV/AIDS (PLHIV), especially adolescents living with HIV (ALHIV), who are facing many challenges for optimal adherence to antiretroviral therapy (ART), when compared with children and adults, due to dependency on caregivers/parents, need of autonomy, attitudes of defiance/

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denial, and delay in disclosure status [2]. The optimal adherence (> 95%) to ART is the main significant indicator to restrain HIV imitation, reject the emergence of drug resistance, and reduce opportunistic infections (OIs) [3].

Adherence rates exceeding 95% are vital to maximize the benefits of antiretroviral medications, and to enhance well-being of ALHIV. Non-adherence of less than 95% is eventually associated with ART failure, including increase of viral resistance, treatment failure, and increase of risk towards the end stage of the disease [4]. Globally, only 62% of adolescents and young adults are adherent to ART compared with adults. There is discrepancy between regions, such as poorer adherence in Europe, South and North America (50-60%) and elevated levels (> 70%) in Africa and Asia [5]. Middle and late adolescents are at major risk of non-sub-optimal adherence when compared with younger adolescents. High prevalence of sub-optimal adherence in management during adolescence, boosts the morbidity and OIs, ends the progress towards poorer state of life, and overuse of healthcare system [6]. Common barriers, such as pill burden, forgetfulness, regimen fatigue, busy schedule, depression, stigma, and disclosure contributes to poor retention in care, and sub-optimal and non-adherence to antiretroviral therapy in this population [7]. Indian studies, particularly among older adolescents, encompass the majority of HIV-infected children being hospitalized and having maximum rates of mortality and morbidity. However, optimal levels of adherence are essential for clinical improvement and prevention of HIV-related OIs [8].

Today, yoga has become popular in therapeutic practice; it aids to relax and strengthen the muscles, regulates the body's energy levels, calms down the mind, increases the immunity, and brings down the negative effects of stress. Regular yoga practices, along with adherence to ART regimen, leads to stress reduction in people affected with HIV and can contribute to longevity and can enhance well-being by increasing the immune power. Many researchers have reported that reducing stress has emerged to be a key benefit for supporting people with HIV [9, 10]. Adolescents require improved adherence support and information about their treatment schedules from healthcare professionals. Hence, they feel motivated to take their medication, and are confident about the responsibility for their own health. Therefore, the investigator focused on identifying and boosting the adherence rate and sustaining the immunity with yoga among HIV-infected adolescents.

Material and methods

Study design and setting

A quantitative and evaluative research approach was adopted, and experimental design for randomized controlled trial was used to collect data from four main ART centers in Chennai, India. The study was in accordance with all ethical principles, and institutional ethical committee permission was obtained from Rajiv Gandhi Government General Hos-

pital, Chennai, India. Formal permission was obtained from National AIDS Control Organization and Tamil Nadu State AIDS Control Society, and the trial was registered in Clinical Trial Registry of India in New Delhi.

Sample size

Based on previous study value, using G*power software with statistical value of $\alpha = 5\%$, $\beta = 20\%$, and power = 95%, sample size was calculated as 191 in each group. With 10% drop-out rates, final required sample size was $191 + 19 = 210$ per group (minimum). For statistical significance, the investigator fixed the sample size as 200 per group. Through simple random technique, subjects were divided equally into experimental and control groups, based on inclusion and exclusion criteria. Figure 1 depicts the flow of participants in the study.

Instruments description

The tool used consists of two main parts. In part 1, a structured questionnaire for demographic data of HIV-infected adolescents/caregivers was included. In part 2, a modified adolescent adherence questionnaire adopted from pediatric AIDS clinical trial group (PACTG) was applied. Based on our regional background, the following method of five-point response scale (0 = 'never', 1 = 'rarely', 2 = 'sometimes', 3 = 'often', 4 = 'always'), visual analog method, '3' day recall method, and pill count method were used to assess the level of adherence in this study. Based on maximum level of adherence, a score was interpreted as optimal (> 95%), sub-optimal (> 80-95%), and poor adherence (< 80%). Reliability of the tool was assessed by using Cronbach's α method, and correlation coefficient r -value was found to be 0.87. As the value of correlation coefficient was very high, the tool was reliable to implement in the study.

Data collection procedure

After attrition of 12 samples, data were collected from 388 participants in four main ART centers in Chennai. The pictorial representation of selection of samples is presented in Figure 2. Data were collected from both groups of caregivers/adolescents through in-depth interview, observation of hospital records, structured questionnaires, and initial assessment taken as pre-test in both groups. To experimental group, the adherence counselling was applied on the same day; selected asanas of Padmasana, Vajrasana, Trikonasana, Bhujangasana, Ardhamatsyendrasana/Ushtrasana, Shavasana, and Pranayama were demonstrated by the researcher and participants were instructed to do re-demonstration on the same day. Brochures on yoga were distributed to participants for the selected asanas, every day, for 15-20 minutes on their own at home, and individuals were instructed to maintain diary after drug intake and yoga practice. In control group, the subjects received only routine care as conventional management, and at the end

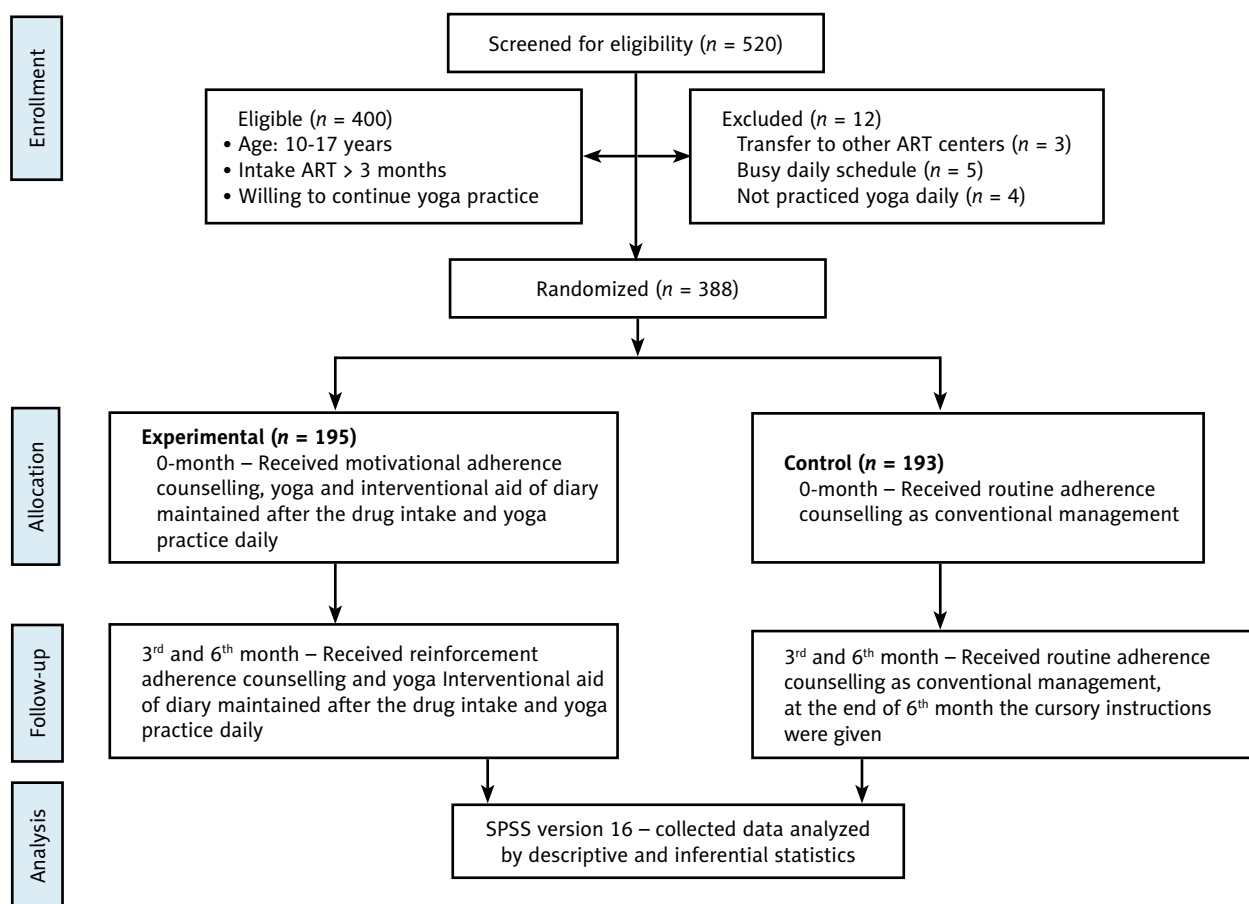


Figure 1. Flowchart showing the recruitment of participants in the study

of 6th month, cursory instructions regarding intervention were given to control group. Simultaneously in both groups, data were collected at respective intervals of 0, 3rd, and 6th month. The collected data were analyzed with SPSS version 16 using descriptive and inferential statistics methods.

Results

General measures

The mean \pm SD of age in the intervention group was 13.6 ± 2.2 years, and in the control group was 13.8 ± 2.4 years. Gender wise, in both the groups, nearly half of the participants were males (50% and 56%). In educational status, the majority (77% and 85%) had middle level of education, and considering religion, 85% and 77% participants were Hindus in both the groups. The mean age of caregivers was 44.3 ± 13.5 , and in the control group was 45.5 ± 12.2 years. Gender wise, the majority (70% and 66%) were females. In regard to relationship of adolescents, 61% and 66% of children were taken care by caregivers, especially 27% and 22% by mothers and nearly 12% by fathers in both the groups. In educational status, nearly 50% of them completed school level of education in both the groups. Concerning occupa-

tional status, 44% and 49% in both the groups were employed, and nearly half of the participants (55% and 53%) resided in urban areas.

Level of antiretroviral therapy adherence

The overall level of ART adherence in the experimental group of HIV-infected adolescents was calculated by various methods (Table 1). In five-point response scale, only 15% of the participants had optimal level adherence in baseline assessment, but it reached 100% in the 6th month evaluation. Regarding visual analog method in baseline assessment, only 15% has optimal level of adherence, whereas in the 6th month, it increased to 78%. Considering three days recall method, 63% presented optimal level of adherence in baseline method, but it increased to 94%. In pill count method, it was found that 44% of the participants had optimal level of adherence in baseline method, but it increased to 93%. In all these methods of assessment, χ^2 value was significant at $p = 0.001^{***}$. It indicates that there was significant improvement in the adherence level among HIV-infected adolescents in the experimental group, whereas in the con-

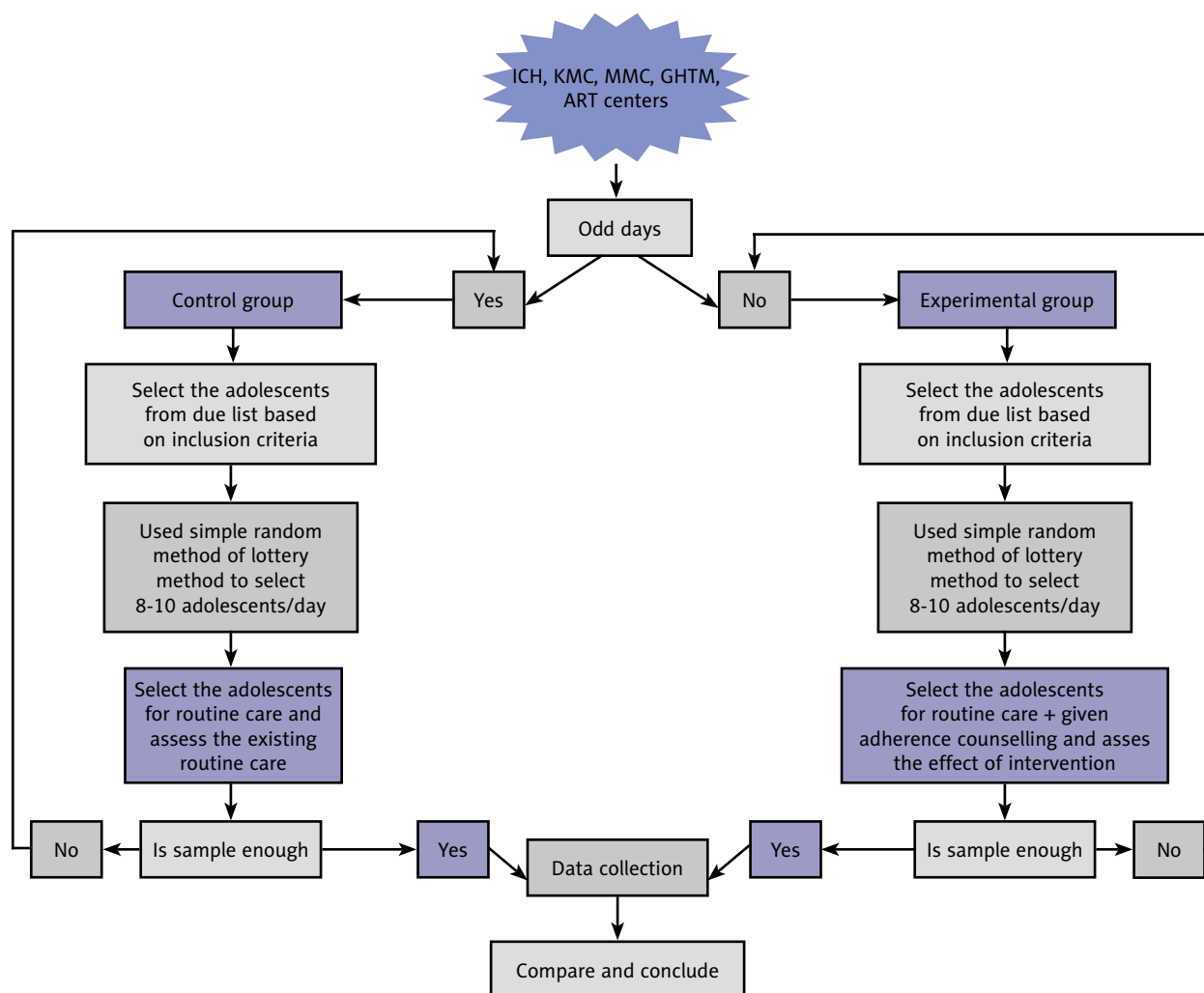


Figure 2. Sample selection procedure of HIV-infected adolescents

control group, among all these methods except visual analog method, there was no marked improvement. Table 2 shows that there were no significant changes in the control group of HIV-infected adolescents. According to pill count method, the pre and post-test mean difference scores were 85.36 and 85.60, respectively. The mean difference in ART score with 95% CI was 13.38, and in the control group it was 4.94. Table 3 demonstrates an improvement in the adherence level of HIV-infected adolescents in the experimental group compared with the control group.

Level of CD4+ count

Regarding the CD4+ count level of HIV-infected adolescents before ART management, 68-70% of the adolescents had less than 300 cells/mm³, 28-30% of them had 300-600 cells/mm³, and only 1% of the participants had 600-900 cells/mm³ in both the groups. After 1-3 years of ART management, 40-42% of the adolescents had 601-900 cells/mm³, and less than 4% had more than 1,200 cells in both the groups. However, in the 6th month after intervention, it increased

to 61% and 6% in the respective CD4+ count in the experimental group. However, there was no significant improvement in the control group (Figure 3). In baseline assessment, the CD4+ count mean score was 664.86 in the experimental group and 669.72 in the control group, whereas in the 6th month assessment, mean scores in the experimental and the control groups were 840.30 and 703.35, respectively. Paired *t*-test value of 7.21 was significant at $p = 0.001^{***}$ in the experimental group. In Table 4, CD4 count was greater in the experimental group than in the control group.

Discussion

Even though many different adherence rates were estimated through various methods, the missed dose history was correlated with pill count method only. Therefore, the investigator took the mean adherence score of pill count method in order to evaluate the effectiveness of adherence improvement in both the groups. In the present study that employed pill count method from baseline to 6th month evaluation in the experimental group, 44-93% of the participants had

Table 1. Level of antiretroviral therapy adherence in experimental group of HIV-infected adolescents

Methods	Experimental group			χ^2 -value
	0 month	3 rd month	6 th month	
	n (%)	n (%)	n (%)	
'5' point response				
Optimal	30 (15.4)	177 (90.8)	195 (100.0)	392.99***
Sub-optimal	135 (69.2)	18 (9.2)	0 (0.0)	
Poor	30 (15.4)	0 (0.0)	0 (0.0)	
Visual analog				
Optimal	29 (14.9)	99 (50.8)	152 (77.9)	191.4***
Sub-optimal	134 (68.7)	96 (49.2)	43 (22.1)	
Poor	32 (16.4)	0 (0.0)	0 (0.0)	
'3' days recall				
Optimal	123 (63.1)	160 (82.1)	184 (94.4)	60.1***
Sub-optimal	72 (36.9)	35 (17.9)	11 (5.6)	
Pill count				
Optimal	85 (43.6)	170 (87.2)	181 (92.8)	149.14***
Sub-optimal	110 (56.4)	25 (12.8)	14 (7.2)	

Table 2. Level of antiretroviral therapy adherence in control group of HIV-infected adolescents

Methods	Control group			χ^2 -value
	0 month	3 rd month	6 th month	
	n (%)	n (%)	n (%)	
'5' point response				
Optimal	33 (17.1)	35 (18.1)	35 (18.1)	0.19
Sub-optimal	132 (68.4)	130 (67.4)	132 (68.4)	
Poor	28 (14.5)	28 (14.5)	26 (13.5)	
Visual analog				
Optimal	27 (14.0)	31 (16.1)	35 (18.1)	13.1
Sub-optimal	132 (68.4)	131 (67.9)	146 (75.6)	
Poor	34 (17.6)	31 (16.1)	12 (6.2)	
'3' days recall				
Optimal	121 (62.7)	123 (63.7)	128 (66.3)	0.58
Sub-optimal	72 (37.3)	70 (36.3)	65 (33.7)	
Pill count				
Optimal	73 (37.8)	81 (42.0)	93 (48.2)	4.29
Sub-optimal	120 (62.2)	112 (58.0)	100 (57.8)	

optimal level of adherence, whereas in the control group, 38-48% of the participants presented optimal level of adherence, with $p = 0.001$. Similarly, in Spanish participants had positive effect after 24 weeks of individual counselling session, 76% of the intervention group, and 52% of the control group had > 90% of self-reported adherence [11]. In another study, Tran *et al.* investigated prevalence of optimal ART adherence using visual analog method. The mean dif-

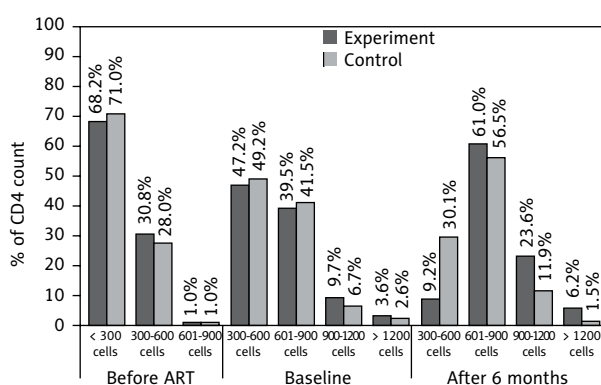
ference ranged from 40% to 100%, and the rate of sub-optimal adherence was 25.9%, with missed doses of 25.2% [12]. Another cross-sectional survey on caregiver's reported adherence among 193 participants in Mekelle study showed '7' days recall adherence as 83.4%, and the major cause was depression (24.4%) [13]. In a study by Nicholas *et al.*, perinatally HIV-infected participants had significantly lower scores in visual recognition memory and verbal delayed re-

Table 3. Effectiveness of mean level of antiretroviral therapy adherence score of HIV-infected adolescents

Group	Mean ART adherence	Mean difference in ART score (95% CI)	% of adherence gain score (95% CI)
Experimental			
Pre-test	85.36	13.38 (11.91-14.84%)	13.4% (11.9-14.8%)
Post-test	98.74		
Control			
Pre-test	85.60	4.94 (3.26-6.61%)	4.9% (3.3-6.6%)
Post-test	90.54		

Table 4. Mean score level of CD4+ count of HIV-infected adolescents in both groups

Group	Baseline			6 th month			Paired <i>t</i> -test
	Mean	SD	Mean difference	Mean	SD	Mean difference	
Experimental	664.86	221.688	4.86	840.30	231.671	136.96	7.21***
Control	669.72	174.703		703.35	165.724		1.62

**Figure 3.** Level of CD4+ count of HIV-infected adolescents

call compared with perinatally HIV-exposed but uninfected (PHEU) participants [14].

In the present study, the reasons for non-adherence to ART of HIV-infected adolescents in the experimental and the control groups, included 'forgot' (33% vs. 40%), 'boring' (6% vs. 5%), 'busy schedule' (10% vs. 7%), 'travelling' (7% vs. 9%), 'not having money to come and collect the drugs' (2% vs. 1%), and 'adverse effects of drugs' (1% vs. 0.5%). Similarly, nearly 40% of the participants were non-adherent with major reasons including 'busy' (97%), 'forgot' (62.2%), 'side effects' (52.3%), and 'lack of money to travel to the health center' (32.6%). Categories, such as 'forgot' (62%), 'busy schedule', and children refuse to take medications (27.3%) were reported in Ethiopia and Laos [15, 16]. In another study by Koole *et al.*, it was found that 29% of cases showed at least one reason for missed dose, 53% said they forgot, 18% were travelling and migrating, and 12% needed money to collect drugs [17]. Yet another study found that the primary causes for non-adherence included 'forgetting to take the pills', 'financial constraints', 'side effects and lack

of access to drug', and 'poor knowledge about in the benefits of the drugs' [18].

In the present study, half of HIV-infected adolescents (47% vs. 50%) used pillboxes in baseline assessment for the improvement of adherence. Nearly 44% and 46% of the adolescents were not using any aid or assistance, and the remaining 2% to 4% used only reminders in mobiles and buddy systems in both the groups. However, in the experimental group, the investigator provided motivational counseling during the study period along with diary used as a reminder, along with previous aids. But, in the control group, there were no special aids used to improve the adherence and no marked changes in the aids from baseline to the 6th month evaluation. The χ^2 values of 189.50 and 182.45, respectively, were significant at $p = 0.001^{***}$. These indicate that the diary reminder showed effectiveness in improving the adherence among HIV-infected adolescents in the experimental group. A similar study suggested that motivational counselling and educational strategies of diary might help to sustain ART adherence among this vulnerable group [11, 19].

In the present research, the pre- and post-test mean differences of CD4+ count were evidenced with paired *t*-test value of 7.21, which was significant at $p = 0.001^{***}$ in the experimental group compared with the control group. A similar study reported that the combination of yoga intervention and peer support had beneficial effect on CD4+ count ($p < 0.05$) in Zambian adolescents [20]. Another research showed that the outcome of yoga intervention and naturopathy for 30 days resulted in a significant improvement of CD+ counts in PLHIV [10]. The findings of the current study concluded that the motivational counseling with yoga and interventional diary were effective in increasing the adherence to ART among HIV-infected adolescents in the experimental group (13.4%) compared with the control group (4.9%). The gain score differences of 8.5% confirmed the ef-

fectiveness of HIP in the improvement of adherence level in the experimental group of HIV infected adolescents.

The limitation of our study was that there is no advanced objective method to confirm their claim of 100% adherence. The adherence maintenance of diary and yoga practices mainly relied on adolescents/caregiver's subjective reports. We suggest that mixed method study can be undertaken to identify psychological barriers of ALHIV, and need-based intervention studies can be conducted in order to address unmet needs of adolescents for their safe transition to adulthood.

Conclusions

The findings of this study revealed that motivational/reinforcement counseling and behavior modifications with yoga are vital to increase optimal adherence rate and help to sustain CD4+ count of ALHIV. The global target of 'let's get into zero together' in the adolescent population is within our reach, but adolescent-centered interventions are required for tailored approach of this population to reduce the spread of HIV and promote the overall health and well-being of the youths.

Conflict of interest

The author declares no conflict of interest.

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