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Research Article

# Effectiveness of HIV Intervention Package (HIP) on HIV Infected Adolescents: Pilot Study Report

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## I N F O

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## A B S T R A C T

*Background:* Adolescents are the fulcrum of the population. HIV affects this precious population, which faces many barriers in achieving optimal adherence to Anti Retroviral Therapy (ART) as compared to the children and adults living with HIV. The aim of the study is to evaluate the effectiveness of HIV Intervention Package (HIP) on HIV infected adolescents.

*Methods:* Randomised controlled trial was conducted in the ART Centre, Institute of Child Health and Hospital for Children, Egmore. By simple random technique, 40 (10% from total sample size) samples were selected and divided equally into experimental and control groups. Relevant structured questionnaires were used to collect the data through face-to-face interview methods. The experimental group received HIP including asana demonstration along with routine care and the control group received only the routine care as conventional management.

*Results:* At the end of the 6th month after the intervention, data were interpreted in the improvement of HIP components in the experimental and control groups and the results were recorded as follows: adherence rate: 6.4% in the experimental group and 2.2% in the control group, and Quality of life (QOL) 7.2% in the experimental group and 0.4% in the control group; it was significant at 95% Confidence Interval (CI). The other component of nutritional gain score increased by 4.5% in the experimental group and by 0.8% in the control group.

*Conclusion:* Our study report revealed that HIP is more effective in achieving the targets of optimal adherence, increasing nutritional status, and enhancing QOL among HIV infected adolescents.

**Keywords:** Effectiveness, Adherence, Nutrition, Quality of Life, Yoga, HIV Infected Adolescents

## Introduction

As the global HIV epidemic enters its fourth decade, though it is evident that the developing world has made various improvements in HIV prevention and treatment, yet many challenges are still seen in this path. The increased proportion of HIV infected children going through the school age and attaining adolescence, i.e., Perinatally Infected Adolescents (PIA) and also Behaviorally Infected Adolescents (BIA), enduring commitment to life-saving drug therapies constitutes one such challenge.[1] Adolescents Living with

HIV (ALHIV) are facing many problems to ensure optimal adherence to ART, maintain nutritional status, and good QOL as compared to children and adults living with HIV. It may be due to parental death, dependency on caregivers/ parents, desire of autonomy, breaking of parental bonding, attitudes of defiance/ denial, and disclosure status. Subsequently, it causes poor adherence to ART, leading to lower immunity levels, reduced nutrition intake, and decreased QOL of HIV infected adolescents.[2] In the current trend, yoga has become popular as a therapeutic practice. It is helpful in increasing immunity, longevity and QOL of people living with HIV (PLHIV).[3]

Nurses have a vital role in the centre of patient care in ART multidisciplinary team for coordinating successful management of PLHIV. However, adolescents are most vulnerable to be infected with HIV/ AIDS in the community, and are also the main source of its spread. This may be contributed to the fact that they undergo a change from family-oriented relationships to peer-oriented relationships. In addition to this, they also undergo pubertal changes.[4] In India, about 31% of HIV prevalence is among the young people belonging to the age group of 10-24 years. The overall goal of optimal level of adherence to ART is reduction of AIDS morbidity and mortality by 60-90%, and enhancement of the quality and survival of life of all ALHIV. The adherence improvement, early nutritional assessment and intervention may prevent severe malnutrition, and help in reducing the incidence and severity of infection, and providing protection of immune system for enabling better QOL for children/ adolescents infected with HIV.[5,6]

A systematic review revealed that interventional strategies like adherence counselling, use of reminder systems, and treatment supporters are useful in public health interventions for improving the adherence of youth to ART.[7] In our study, the first three HIP components of adherence counselling, nutritional counselling and strategies to enhance QOL benefits were enhanced by the fourth component of selected asanas like Padmasana, Vajarasana, Pranayama (alternate nostril breathing), Trikonasana, Bhujangasana, Ardhamayentrasa or Ustrasana, and Shathiasana. The focus of HIP is to improve adherence rate, increase CD4 count and nutritional status, and enhance QOL of ALHIVto promote overall health and prevent HIV transmission in future. This study also aims to help in achieving the global targets of "Getting to zero" - over the next five years.[8]

## Objectives

The objectives of this study are:

- To assess the level of ART adherence, nutritional status, QOL (HIP components) of HIV infected adolescents before and after HIP in experimental and control groups
- To compare and evaluate the effectiveness of HIP on HIV infected adolescents in experimental and control groups
- To correlate the ART adherence score with nutritional status and QOL of HIV infected adolescents in experimental and control groups

## Methodology

Ethical permission was obtained from the National AIDS Control Organisation (NACO) New Delhi, Tamil Nadu State AIDS Control Society (TANSACS) and Madras Medical College and Hospital, Chennai. Formal approval was obtained from the Director & Superintendent, Institute of Child Health, Egmore, Chennai-8 The experimental design of randomised controlled trial was adopted. The duration of study was 6 months. Informed consent was obtained from the caregivers and assent form was obtained from the adolescents who knew their disclosure status. Simple random technique of lottery method was used to select 40 adolescents (10% of the total sample size) who were divided equally into experimental and control groups.

The following adolescents were included in the study:

- Adolescents who were in the age group of 10 to 17 years
- Adolescents who were on ART for more than 3 months attending the ART clinic

The following adolescents were excluded from the study:

- Adolescents who were not on ART/ not attending ART clinic
- Adolescents who were in the clinical stage IV of HIV/ AIDS
- Hospitalised adolescents

Based on regional background and updated interventions, the various questionnaires mentioned below were modified. The content validity was obtained from the panel of experts. The reliability of the tool was assessed by using Cronbach alpha and inter-rater method. The correlation coefficient 'r' values for the following tools were: ART adherence - 0.87, nutritional status - 0.90 and QOL - 0.88. It shows that the correlation of coefficient value was very high and internal consistency of the tool was reliable to execute the main study. The tools were divided into the following sections:

- Demographic variables of HIV infected adolescents/ caregivers and background information of HIV infected adolescents
- Adherence Assessment Questionnaire (AIDS Clinical Trial Group - ACTG) - The various methods of five-point response scale, Visual analogue method, '3' days recall method and Pill count method were used. Based on the maximum level of score, it was interpreted as optimal (95-100%), sub-optimal (80-95%), and poor adherence (< 80%)

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- Nutritional Assessment Questionnaire - It includes height, weight, Body Mass Index (BMI), mid-upper arm circumference, waist circumference, skinfold thickness (Triceps) and 'Z' score. Based on the Z score, it was interpreted as normal (-2.0 < Z score), moderately malnourished (-3.0 < Z score < -2.0), and severely malnourished (Z score < -3)
- QOL Assessment Questionnaire (ACTG) - The questionnaire includes 2 categories viz., 5 to 11 years and 12 to 20 years related to the areas of general health ratings, physical functioning, psychological well-being, social role functioning, health care services, and symptom distress management. The maximum QOL score was 338 and the minimum was 71. Based on the highest level of score, it was interpreted as good (76-100%), moderate (51-75%), and poor QOL (0 - 50%)

The initial assessment of the pretest was taken as '0' month in both groups. On the same day, HIP was given to the experimental group. The participants of the experimental group were counselled regarding the significance of adherence, impact of a missed dose, how to improve adherence rate, importance and role of antioxidants in diet, tips to reduce minor alignments, and home care management along with routine counselling and demonstration of selected asanas by the researcher and re-demonstration by study participants. They were also given brochures for practising the selected asanas every day for a minimum of 15-30 minutes on their own at home. The reinforcement counselling was given every month till the study period and the subjects were instructed to maintain a dairy after the intake of drugs and yoga practice daily. The control group received only routine care as conservative management and cursory instructions regarding HIP were given at the end of the 6th month. The data were collected from both the groups at the end of 3rd and 6th months, and were analysed by both descriptive and inferential statistics.

## Results

Regarding demographic variables, out of 40 HIV infected adolescents/ caregivers in both groups, half of the adolescents (50%) were in the age group of 10-12 years and 75% of the caregivers were in the age group of 36-50 years. Nearly 60% of the adolescents were male and about 70% of the caregivers were female in both groups. Regarding the relationship of adolescents, half of the members (50%) belonged to caregivers in both experimental and control groups. The fathers of majority (80%) of the adolescents were deceased in both groups. The mothers of 55% of the subjects were alive in the experimental group and that of 30% were alive in the control group. Regarding residence, 60% and 65% of the adolescents were residing in Non-Governmental Organisations in the experimental and control groups respectively.

Regarding clinical information, all the adolescents had HIV through vertical transmission and all were in stage I of HIV. Majority of children (90%) in both groups knew their disclosure status and were receiving social support from NGOs. In regard to diagnosis and on ART, in the experimental group, nearly 45% of the adolescents were diagnosed 5-10 years before and 78% of the adolescents were on ART since 1-5 years, whereas in the control group, it was 50% and 84% respectively. Table 1, shows the overall level of ART adherence in both groups of HIV infected adolescents by pill count method. In the experimental group, only 60% of the HIV infected adolescents had an optimal level of adherence in the baseline assessment, whereas it increased to 85% in the 3rd month and 100% in the 6th month of evaluation. On the other hand, in the control group, even though there was a slight improvement from baseline assessment to subsequent evaluation of 3rd and 6th month, yet it was not statistically significant.

**Table 1.Overall Level of ART Adherence in both Groups of HIV Infected Adolescents by Pill Count Method**

| Overall Level of Adherence | | Group | | | | Chi-square Test |
|---|---|---|---|---|---|---|
| | | Experimental (N = 20) | | Control (N = 20) | | |
| | | n | % | n | % | |
| Baseline | Poor adherence | 0 | 0.0 | 0 | 0.0 | $\chi^2 = 1.33$ |
| | Sub-optimal adherence | 8 | 40 | 7 | 35 | p = 0.44 |
| | Optimal adherence | 12 | 60 | 13 | 65 | NS |
| 3rd month | Poor adherence | 0 | 0.0 | 0 | 0.0 | $\chi^2 = 91.95$ |
| | Sub-optimal adherence | 3 | 15 | 7 | 35 | p = 0.001*** |
| | Optimal adherence | 17 | 85 | 13 | 65 | S |
| 6th month | Poor adherence | 0 | 0.0 | 0 | 0.0 | $\chi^2 = 93.13$ |
| | Sub-optimal adherence | 0 | 0.0 | 4 | 20 | p = 0.001*** |
| | Optimal adherence | 20 | 100 | 16 | 80 | S |

NS: Not significant at p > 0.05, *** very high, significant at p ≤ 0.001

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Regarding nutritional status, the interpretation of 'Z' score on HIV infected adolescents in the experimental group revealed that 25% of the participants were severely malnourished and 75% were moderately malnourished in the baseline assessment, whereas in the 6th month evaluation, it was found that 45% of the adolescents had achieved normal status and no one was severely malnourished. However, in the control group, no significant improvement was noted from the baseline till the 6th month of evaluation (Table 2).

Regarding QOL, in the experimental group, the QOL of majority (85%) of the adolescents was categorised as poor, and for 15%, it was categorised as moderate in the baseline assessment, whereas in the 6th month, the QOL of 55% of the adolescents was found to be good and for the remaining 45%, it was found to be moderate. On the other hand, in the control group, no significant changes were noted during the assessment period in the QOL of study subjects (Table 3).

Regarding the effectiveness of HIP, in the experimental group, the mean ART adherence score in pre-test was 91.15 and in post-test, it was 97.50. However, in the control group, the mean difference score was low (Table 4). In nutritional status, in the experimental group, all the participants were malnourished in the baseline assessment. However, in the 6th month assessment, 45% of the adolescents had achieved the normal level, and 55% were moderately malnourished. In the control group, no significant changes were noted (Table 5). In regard to QOL, in the baseline assessment, the mean QOL scores of the experimental and control groups were 155.00 and 153.21respectively, whereas in the 6th month evaluation, they had increased to 186.09 and 156.84 respectively (Table 6). The improvement range of the experimental as compared to that of the control group for the various HIP components is illustrated in Figure 1. It revealed that HIP was more effective in the experimental group than in the control group. Regarding correlation, in the baseline assessment, the experimental group had a poor correlation of ART adherence with nutritional status and QOL score, but in the 3rd and 6th month evaluation, there was a fair and moderate correlation noted in ART adherence with nutritional status and QOL score. However, no there was no improvement in the correlation of ART adherence in the control group (Table 7).

**Table 2.Comparison of Z Score of HIV infected Adolescents in Experimental and Control Group**

| Z-score | Experimental (N = 20) | | | | | | Control (N = 20) | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Baseline | | 3rd month | | 6th month | | Baseline | | 3rd month | | 6th month | |
| | n | % | n | % | n | % | n | % | n | % | n | % |
| -4.00 to -3.00 | 1 | 5.0 | | | | | 1 | 5.0 | 1 | 5.0 | 0 | 0.0 |
| -3.00 to -2.00 | 4 | 20.0 | | | | | 2 | 10.0 | 2 | 10.0 | 1 | 5.0 |
| -2.00 to -1.00 | 4 | 20.0 | 3 | 15.0 | | | 2 | 10.0 | 1 | 5.0 | 2 | 10.0 |
| -1.00 to 0.00 | 3 | 15.0 | 4 | 20.0 | 2 | 10.0 | 7 | 35.0 | 8 | 40.0 | 9 | 45.0 |
| 0.00 to 1.00 | 2 | 10.0 | 4 | 20.0 | 2 | 10.0 | 2 | 10.0 | 3 | 15.0 | 3 | 15.0 |
| 1.00 to 2.00 | 6 | 30.0 | 5 | 25.0 | 7 | 35.0 | 6 | 30.0 | 5 | 25.0 | 5 | 25.0 |
| 2.00 to 3,00 | 0 | 0.0 | 4 | 20.0 | 9 | 45.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| $\chi^2$ test | $\chi^2$ = 20.99, p = 0.05, S | | | | | | $\chi^2$ = 2.42, p = 0.90, NS | | | | | |

*significant at p ≤ 0.05

**Table 3.Overall Level of Quality of Life of HIV infected Adolescents in both Groups**

| Variables | Experimental (N = 20) | | | | | | Control group (N = 20) | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Baseline | | 3rd month | | 6th month | | Baseline | | 3rd month | | 6th month | |
| | n | % | n | % | n | % | n | % | n | % | n | % |
| Poor | 17 | 85.0 | 6 | 30.0 | 0 | 0.0 | 17 | 85.0 | 17 | 85.0 | 16 | 80.0 |
| Moderate | 3 | 15.0 | 12 | 60.0 | 9 | 45.0 | 3 | 15.0 | 3 | 15.0 | 4 | 20.0 |
| Good | 0 | 0.0 | 2 | 10.0 | 11 | 55.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| $\chi^2$ test | 14.59, p = 0.001*** Significant | | | | | | 0.24, p = 0.84 Not significant | | | | | |

Not significant at p > 0.05, *** very high, significant at p ≤ 0.001

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**Table 4.Effectiveness of HIP depicted in terms of Mean Level of ART Adherence Score in both Groups of HIV infected Adolescents**

| Groups | | Mean ART Adherence | Mean Difference in ART Score with 95% CI | % Increase in ART Adherence Score with 95% CI |
|---|---|---|---|---|
| Experimental | Pre-test | 91.15 | 6.35 (6.88 - 7.46) | 6.4 (6.9% - 7.5%) |
| | Post-test | 97.50 | | |
| Control | Pre-test | 90.61 | 2.20 (2.26 - 2.61) | 2.2 (2.3% - 2.6%) |
| | Post-test | 92.81 | | |

**Table 5.Effectiveness of HIP depicted in terms of increase in Nutritional Score in both Groups of the HIV infected Adolescents**

| Groups | | Nutritional Status | | |
|---|---|---|---|---|
| | | Baseline n (%) | 6th month n (%) | % Increase in Nutritional Score |
| Experimental | Normal | 0 (0) | 9 (45.0) | 4.5 |
| | Malnourished | 20 (100) | 11 (55.0) | |
| Control | Normal | 0 (0) | 0 (0) | 0.8 (minimal changes from severe to moderate) |
| | Malnourished | 20 (100.0) | 20 (100.0) | |

**Table 6.Effectiveness of HIP in Mean Level of QOL Score in both Groups of the HIV infected Adolescents**

| Groups | Assessment | Mean QOL Score | Mean Difference in QOL Score with 95% CI | % Increase in QOL Score with 95% CI |
|---|---|---|---|---|
| Experimental | Baseline | 155.00 | 31.09 (29.9 - 32.97) | 7.2 (7.6 - 8.2) |
| | 6th month | 186.09 | | |
| Control | Baseline | 153.21 | 3.63 (2.98 - 3.90) | 0.4 (0.3 - 0.9) |
| | 6th month | 156.84 | | |

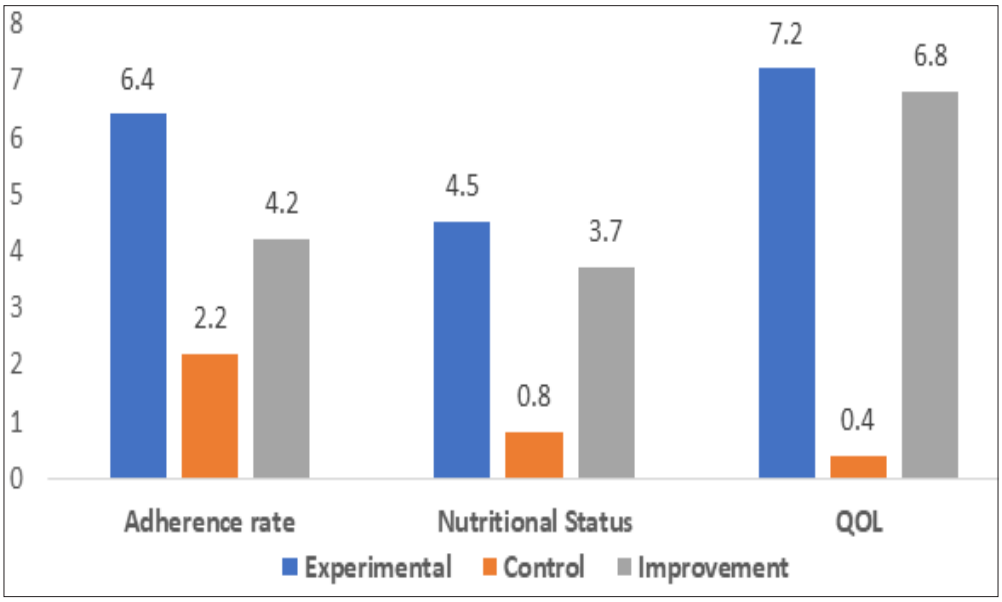


**Figure 1.Effectiveness of HIP depicted in terms of Percentage Increase in Scores of Adherence Rate, Nutritional Status, and QOL in both the groups of HIV infected Adolescents**

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**Table 7.Correlation of ART Adherence with Nutritional Status and QOL of HIV infected Adolescents in both Groups**

| Groups | Assessment | Karl Pearson Correlation Coefficient | Interpretation of ART with Nutritional Score | Karl Pearson Correlation Coefficient | Interpretation of ART with QOL Score |
|---|---|---|---|---|---|
| Experimental | Baseline | r = 0.17 p = 0.26 | Poor correlation | r = 0.17 p = 0.26 | Poor correlation |
| | 3rd month | r = 0.31 p = 0.01** | Fair correlation | r = 0.31 p = 0.05* | Fair correlation |
| | 6th month | r = 0.42 p = 0.001*** | Moderate correlation | r = 0.43 p = 0.001*** | Moderate correlation |
| Control | Baseline | r = 0.16 p = 0.28 | Poor correlation | r = 0.16 p = 0.28 | Poor correlation |
| | 3rd month | r = 0.17 p = 0.25 | Poor correlation | r = 0.18 p = 0.25 | Poor correlation |
| | 6th month | r = 0.19 p = 0.22 | Poor correlation | r = 0.20 p = 0.22 | Poor correlation |

## Discussion

The paradigm of HIV prevention has moved to treatment as prevention strategy. It is essential to identify factors like adherence promotion and retention in care to antiretroviral regimens, promoting nutritional status and QOL among HIV-positive adolescents and youth. In this present study, various methods of adherence assessment were used, but, the pill count method was highly correlated with missed dose history in both groups. In the experimental group, only 60% of HIV infected adolescents had an optimal level of adherence in the baseline assessment, which increased to 100% in the 6th month of evaluation, but in the control group, there was no statistically significant improvement. Identical findings were seen with 170 Spanish participants who were on stable ART. The interventions focused on providing the participants with individual education and supportive counselling session at baseline and a follow-up of telephone sessions regarding medication scheduled as per the patient's lifestyle. After 24 weeks, 76% of the intervention group and 53% in the control group had > 90% of self-reported adherence.[9]

Regarding nutritional status, in the present study findings, all the variables (except height) like BMI, MUAC, waist circumference, and skinfold thickness had a significant improvement in the experimental group at $p < 0.01$.

whereas in the control group there was no significant change. Regarding the interpretation of 'Z' score in the experimental group, 25% of the participants were severely malnourished in the beginning whereas in the 6th month evaluation, no one was severely malnourished. Similar findings were seen in Tang AM et al. (2015) who did a systematic review on 21 studies. The review showed that nutritional assessment and counselling are needed to ensure good clinical outcomes.[10] In another study by Liu E et al. (2011), it was shown that nutritional counselling and interventions played a major role as adjunct therapies to ART and aids to reduce the mortality of HIV infected adolescents.[11]

The health-related QOL assessment is useful for evaluating the perceived burden of chronic disease, and effects of management. Tracking changes in health over time helps to monitor the overall QOL of ALHIV. The findings of the present study showed that in the experimental group, no one had good QOLin the beginning, whereas in the 6th month, 55% of adolescents had good QOL. Similar findings were seen in a study by Gupta R et al. (2015) which emphasise on the need to provide appropriate counselling, education and creative ways to decrease the psychological impact of HIV/ AIDS with a view to improve their QOL.[12]

In the present study, the effectiveness of HIP in mean ART adherence score in both groups denotes that there was a marked improvement in adherence level of HIV infected adolescents in the experimental group than in the control group. This finding suggested that the motivational counselling of HIP and interventional aid of diary are effective in increasing the level of ART adherence among HIV infected adolescents. This finding was supported by RCT done in the Netherlands which revealed that the specific psycho educative interventions are useful in keeping high levels of adherence as well as viral suppression in the study group.[13] Our study findings depicted that HIP of nutritional counselling regarding antioxidant rich foods along with yoga intervention influenced more participants and led to the increase in the nutritional score (4.5%) in the experimental group. This change was just 0.8% in the control group. A study conducted in Tanzania also suggested that better dietary counselling and prerequisite of macro and micro-nutrient supplements are necessary to attain optimal nutrition for most HIV-infected children.[14] The study findings of HIP in QOL revealed its efficiency in increasing

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QOL of HIV infected adolescents. The review article also supported that patients with elevated CD4 count and educational modules had improved QOL than those with low CD4 count.[15]

Regarding correlation, in the control group, a poor correlation was noted throughout the assessment period. It depicted that HIP with optimal adherence is directly proportional to nutritional status and QOL of HIV infected adolescents in the experimental group. A study conducted in Chennai and Madurai revealed that undernutrition and stunting are common among HIV-infected children at all stages of the disease in India. An early and aggressive nutritional intervention along with optimal adherence is required if long-term outcomes are to be improved.[16] Similar findings were supported in a study by Mann Heimer et al. (2005) which reported that the participants who had 100% ART adherence attained significantly good QOL scores when compared to those with poorer ART adherence.[17] Joseph & Nair (2015) evaluated the effect of naturopathy and yoga intervention on CD4 counts of HIV/ AIDS and reported that the growing trend in the CD4 count was proportional to the participants following yoga intervention.[18]

In the control group, at the end of the study period, HIP was provided, as part of the adherence to ethics and because of its benefits to participants. It's difficult to attribute the part played by yoga in improving the outcomes of the study. Hence, the study may be extended to a larger ALHIV sub-population, to perceive if the results are reliable and sustainable.

## Limitations

- Assessment of ART Adherence and QOL was based on the response from the caregivers, since adolescents may not share all the details
- There is no objective method to confirm their claim of 100% adherence

## Conclusion

Our study findings recommend that adolescent focused interventions including behaviour modifications are essential to improve the CD4 count, adherence rate, nutritional status and to enhance the quality of life of ALHIV. The investigator also felt that the need for capacity building of ART centres' staff on a regular basis to improve their skills especially regarding the care of ALHIV. The global targets of let's get into zero together in the adolescent population for HIV is within our reach but adolescent centred interventions are needed in a tailored approach in order to build a chance for a safe, happy, healthy, and productive nation in the future.

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