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## *Sudarshan Kriya* yoga improves quality of life in healthy people living with HIV (PLHIV): results from an open label randomized clinical trial

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**Background & objectives:** Improving quality of life (QOL) of healthy people living with HIV (PLHIV) is critical needing home-based, long-term strategy. *Sudarshan Kriya* yoga (SKY) intervention is acknowledged for its positive impact on health. It is hypothesised that SKY would improve PLHIV's QOL, justifying an evaluation.

**Methods:** In this open label randomized controlled pilot trial, 61 adult PLHIV with CD4 count more than 400 cells/ $\mu$ l and Karnofsky scale score above 70 were enrolled. Those with cardiac disease, jaundice, tuberculosis, or on antiretroviral therapy/yoga intervention were excluded. All were given standard care, randomized to SKY intervention (31: I-SKY) and only standard of care in control (30: O-SOC) arms. The I-SKY participants were trained for six days to prepare for daily practice of SKY at home for 30 min. A validated 31-item WHOQOL-HIVBREF questionnaire was used to document effect in both arms from baseline to three visits at 4 wk interval.

**Results:** Baseline QOL scores, hypertension and CD4 count were similar in both arms. An overall 6 per cent improvement of QOL scores was observed in I-SKY group as compared to O-SOC group, after controlling for baseline variables like age, gender, education and occupation ( $P=0.016$ ); 12 per cent for physical ( $P=0.004$ ), 11 per cent psychological ( $P=0.023$ ) and 9 per cent level of independence ( $P=0.001$ ) domains. Improvement in I-SKY observed at post-training and in the SKY adherence group showed increase in these two domains.

**Conclusions:** A significant improvement in QOL scores was observed for the three health related QOL domains in SKY intervention arm. This low cost strategy improved physical and psychological state of PLHIV calling for upscaling with effective monitoring for sustainability of quality of life.

**Key words** Alternate therapy - clinical trial - healthy PLHIV - low-cost intervention - quality of life - *Sudarshan Kriya* yoga

\*Deceased

With the availability and access to anti-retroviral therapy (ART) the life span of HIV infected individuals has increased leading to the issues of quality of life (QOL) in people living with HIV (PLHIV)<sup>1,2</sup>. Cross-sectional studies with QOL scores in HIV patients have been done in Pune<sup>3</sup> and Puducherry<sup>4</sup>. The need for using QOL scores for ART interventions in Pune, and counselling and family support to improve QOL scores using WHOQOL HIVBREF in the Puducherry study was recommended<sup>4</sup>. Quality of life scores have been assessed and validated in cross-sectional studies in HIV patients using WHOQOL-HIVBREF questionnaires<sup>4-7</sup>. With the availability of assessment tools and positive experiences with interventions, the demand for quality of life interventions for PLHIV has increased<sup>8-10</sup>.

At present there exists an uncertainty about the side effects of long-term treatment for HIV infection. The social isolation along with changes in socio-economic condition may lead to deterioration in quality of life affecting health seeking behaviour of PLHIVs<sup>11-13</sup>. The quality of life score developed by the WHO for HIV/AIDS has been tested and validated for PLHIV<sup>6,7,14,15</sup>. This scale has been used with PLHIVs in Lebanon, Malawi, and Malay and recently in Puducherry for cross-sectional studies<sup>4-7,15,16</sup>.

Interventions using physical exercises, yoga “*asana*” *i.e.* posture and “*pranayams*” involving specific breathing techniques have shown improvement in health among chronic illnesses like hypertension, diabetes, asthma, and depression<sup>8,9,17-20</sup>. Studies on the effect of *Sudarshan Kriya* yoga (SKY) on patients with non-communicable diseases showed pain reduction in cancer patients, improved immunologic response in opiate users and reduced alcohol dependency in addicts<sup>9,10,21-23</sup>. Improvement of patient’s mood state in a wide spectrum of illnesses ranging from cancer and HIV infection to asthma and cardiovascular diseases with SKY has also been reported<sup>24</sup>.

The stigma associated with HIV status at place of work or living, may increase stress, lower self-esteem and lead to absenteeism with low productivity<sup>16</sup>. This also affects their quality of life<sup>3,4</sup>. *Sudarshan Kriya* yoga is a comprehensive breathing technique<sup>21,25</sup>. It being non-invasive, non-pharmacological intervention requiring one time training was considered appropriate in improving quality of life of healthy PLHIV (those tested positive and waiting to initiate free ART available in public health settings). *Sudarshan Kriya* yoga is a composite package of standard methods which includes three rounds each of “*Ujjaiyee*” and

“*Bhastrika*” pranayams (breathing techniques), *Om* chanting followed by rhythmic breathing of *Sudarshan Kriya* meditation in sitting posture<sup>21,24,25</sup>. Breathing techniques are recommended for relaxation, stress management, control of psycho-physiological states and improve organ function<sup>24</sup>. This pilot open label clinical trial was undertaken to assess the changes in quality of life of healthy people living with HIV using *Sudarshan Kriya* yoga intervention. Our hypothesis was that the healthy people living with HIV (our study participants) randomized to SKY intervention would have better quality of life than those receiving only standard of care. Standard of care at the clinic includes medical services and counselling.

### Material & Methods

The present study was planned as a pilot study in healthy PLHIV randomized to intervention arm with *Sudarshan Kriya* yoga and control arm with only standard of care, henceforth referred to as I-SKY (SKY intervention arm) and O-SOC (only standard of care arm). This was an open label study registered with Clinical Trial Registry of India (CTRI/2014/01/004353). The ethical approvals were taken for the protocol and related documents for the study *i.e.* the informed consents in Marathi and English from the institutional ethics committee.

This study was conducted by the research team of Social and Behavioural Research Division at National AIDS Research Institute (NARI), Pune, Maharashtra, India. The study participants were screened at four NARI clinics and were referred for enrolment in SKY study at the OPD Clinic of NARI, Pune, India. Enrolments took place from December 2010 to August 2011.

*Inclusion criteria:* Healthy PLHIV of 18 yr and above with CD4 count above 400 cell/ $\mu$ l and Karnofsky scale<sup>26</sup> score above 70, *i.e.* the normal healthy PLHIV were included in the study.

*Exclusion criteria:* Those suffering from cardiac problems, jaundice, tuberculosis, patients on ART and/or on any yoga therapy were excluded.

The study was designed as a pilot study and no research data for India were available on QOL scores in PLHIV performing SKY. A sample size of 30 in each of the two arms was considered appropriate. The participants from I-SKY arm received 24 hour SKY training along with the standard of care *i.e.* the counselling and medical care given as a routine provided

at the clinic. The control arm, O-SOC received standard of care of routine counselling and medical care (Fig.1).

The computer generated randomization sequence was used to allocate participants into 1:1 ratio in both the arms. It was assumed that participants would be distributed approximately equally by gender and age in both intervention and control arms. Of the 61 participants enrolled, 10 dropped out with five

participants each in the intervention arm (I-SKY) and the control arm (O-SOC) due to long travel distance during the study period. One participant could not complete the SKY training due to personal social emergency and received only partial training for three of six days of SKY training (Fig.1).

One participant randomized in O-SOC had not disclosed his HIV status at home; all other 60

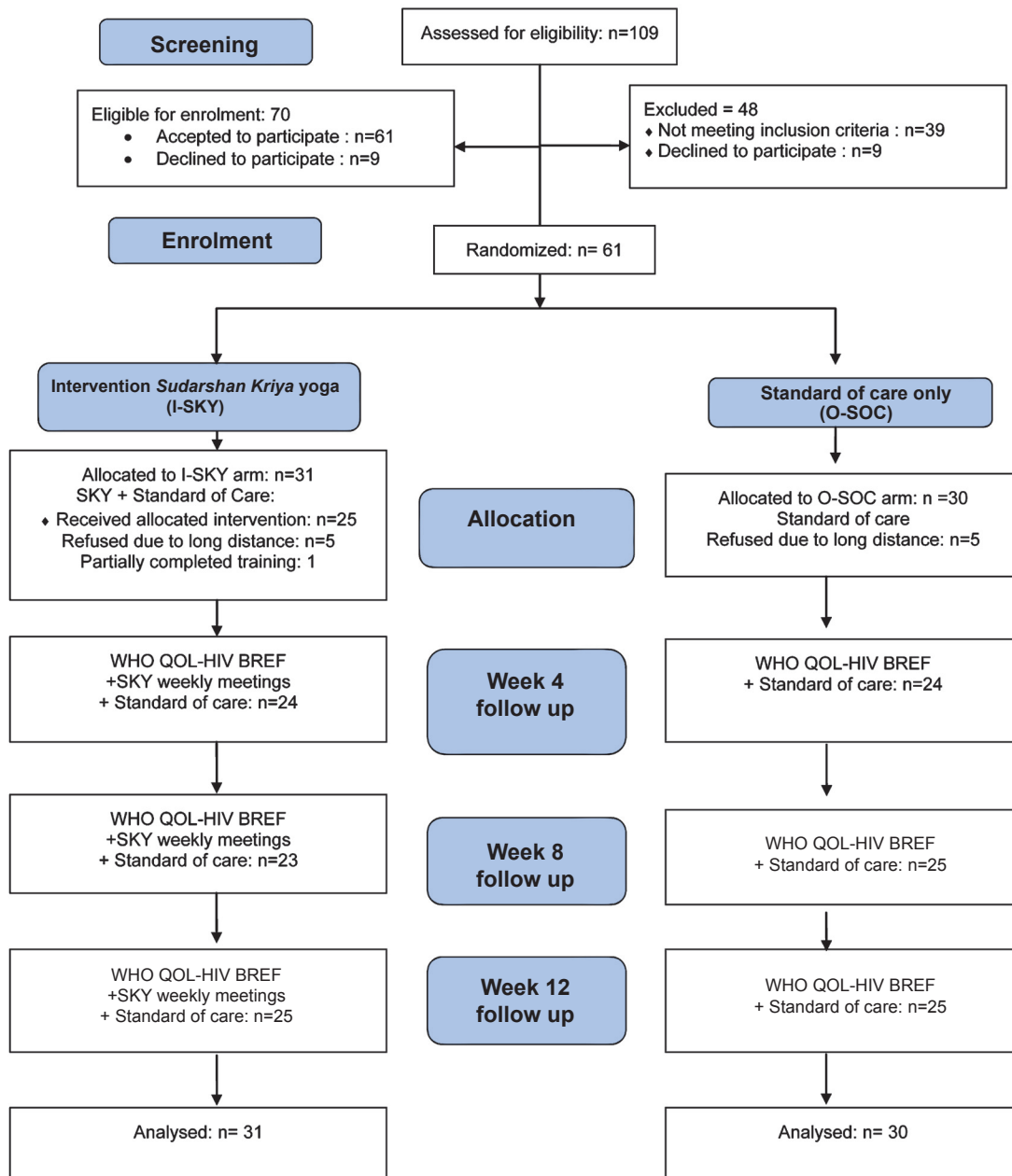


Fig. 1. Flow chart showing the study design and number of patients enrolled during December 2010-August 2011.

participants had disclosed their HIV status at home to their spouse and family members.

**Intervention:** The enrolled I-SKY participants underwent six-days training at NARI Campus. It was conducted in four batches during January, March, May and August 2011 covering 6-8 participants randomized to I-SKY arm. The O-SOC participants received the standard of care and medical consultation at NARI. The SKY training was given by two trained teachers of Art Of Living (AOL) Centre, Novel Institute, Pune, at NARI. This was followed by a six-day practice of SKY meditation at NARI to ensure a correct daily practice of SKY at home. Thereafter the I-SKY participants visited NARI on every Saturday evening for 12 wk for SKY practice under the guidance of an AOL teacher. At the follow up meetings there was an opportunity to meet participants of I-SKY from different batches.

The SKY has four distinct components<sup>25</sup>: (i) “Ujjai” breathing or “victorious breath” that involved the conscious sensation of the breathing touching the throat, with 2-4 breaths per minute. The subjective experience of this breathing is physical and mental calmness with alertness; (ii) *Bhastrika* or “bellows breath”, where air is rapidly inhaled and forcefully exhaled and causes excitation followed by calmness; (iii) “Om” is chanted with very prolonged expiration; and (iv) *Sudarshan kriya* meaning “proper vision by purifying action”, is an advanced form of rhythmic, cyclical breathing: slow, medium and fast cycles<sup>25</sup>. It is performed in sitting position on floor or if necessary on bed keeping the spine erect.

**Tools and techniques:** Karnofsky scale, a performance scale that rates a person’s normal activities, was used by the clinician to evaluate the patient. This was a one-time evaluation at baseline for assessment of physical and mental health for enrolment. Only those with scores above 70 were included in the study.

**Quality of life scales:** The standardized WHOQOL-HIVBREF tool for assessing QOL scores for HIV having 31 items covered in the following six domains was used in this study<sup>14,15</sup>.

1. Physical domain: pain, physical botheration, daily energy and sleep.

2. Level of independence domain: treatment need, getting around ability, daily activity satisfaction and working capacity.

3. Psychological domain: enjoyment, concentration, appearance acceptance, self-satisfaction and negative feelings.

4. Social domain: other’s acceptance, personal relationship satisfaction, sex life and social support.

5. Environmental domain: feeling of security, physical environment, adequacy of finance, access to information and health services, leisure activity opportunity, living-place satisfaction and transport.

6. Spiritual domain: meaningful existence, guilt related to HIV status, botheration/anxiety, fears of future and worry of death.

**Validity and reliability of WHOQOL-HIVBREF questionnaire:** The reliability of WHOQOL-HIVBREF questionnaire ranged between 0.6 and 0.9 and the internal consistency ranged from 0.70 to 0.83 and intra-class correlation coefficient (ICC) ranged from 0.60 to 0.87 across all domains based on previous field test studies<sup>6</sup>. Validation of the scale has been done by Hsiunga *et al*<sup>16</sup>. This SKY pilot study had a smaller sample size (61) for which validity and reliability test was not done independently.

**Biological parameters:** Blood pressure, height and weight were recorded at the three points at 4-weekly visits at the clinic by trained research nurses of the team; medical records were maintained by the clinicians. At baseline and at the end, 6 ml blood was drawn for CD4 counts estimation.

**Interview:** The WHOQOL-HIVBREF questionnaire was interviewer-administered to maintain uniformity. This was done at baseline and at 4, 8 and 12 wk visits. The I-SKY participants were interviewed soon after training within 2-3 days. The socially desirable responses, as a possibility, was minimized to some extent as the WHOQOL-HIVBREF has questions on varied domains in a mixed order rather than being arranged domain-wise. Also the team attempted to change the interviewers at each visit of the participant.

**Outcome:** This study was aimed at comparing the changes in the quality of life scores in healthy PLHIV between the intervention arm (I-SKY) and control arm (O-SOC). The QOL scale WHOQOL-HIVBREF was administered to all participants of both arms at the start of the study, 2-3 days after the initial 6-day SKY training and after 4, 8 and 12 wk of training for I-SKY participants and to O-SOC participants after 4, 8 and 12 wk of baseline study. The QOL data were analyzed according to scores in the six domains<sup>15</sup>.

**Statistical analysis:** The data were analyzed using intention- to- treat (ITT) analysis.

**Outcome variable:** As per WHOQOL-HIVBREF manual, higher scores reflect better quality of life. Six domain-wise scores and the total QOL scores were calculated as per WHO guidelines<sup>14</sup>. Adjusted QOL scores from baseline were calculated and these were used for analysis.

**Exploratory analysis:** For continuous data, medians and inter-quartile ranges were used if the data were skewed. Means and standard deviations were used if the data were normally distributed and compared using a Mann-Whitney test or unpaired t-test as applicable. Paired comparisons of baseline and post-training or week 12 QOL scores and biomarkers were done using a non-parametric Wilcoxon signed-rank test.

In our study the outcome of quality of life scores for repeated time points were nested within individuals and individuals were nested within arms. Hence, random effect model was used to assess the effect of intervention and socio-demographic confounding variables like age, gender, education and occupation on the six domains of adjusted QOL scores as well as overall scores. Analysis was done in STATA version 10.0 (Stata Corp, Texas, USA). Stata command xtreg for random effects (re) was used for analysis<sup>27</sup>.

## Results

A total of 109 participants were screened, of whom 70 were found to be eligible. Of these 70, nine declined to participate in the study mainly for logistic reasons (long distance was a major inhibiting factor and likelihood of HIV status disclosure during SKY weekly follow up visits in the intervention arm). Overall, 61 PLHIV were enrolled and randomly assigned to two arms (Fig. 1).

Among the 61 study participants in both arms (31 in SKY intervention arm, I-SKY and 30 in control arm, O-SOC), most participants were ever-married; with over 40 per cent widowed or living separately; literate with mid-level schooling and with a job. The QOL scores for various domains and baseline data were not significantly different for the participants of both the I-SKY and O-SOC arms at baseline (Table I).

**Comparison between I-SKY and O-SOC groups:** Multivariate analysis was carried out for comparison of QOL scores in both the arms which were adjusted for baseline scores, to assess effect of major confounders like age, gender, education and occupation (Table II). This analysis showed significant increase of total QOL scores by 6 per cent ( $P=0.016$ ) in I-SKY group

as compared to O-SOC group, after controlling for baseline variables. Physical domain score showed an increase of 12 per cent ( $P=0.004$ ) followed by psychological domain score by 11 per cent ( $P=0.023$ ). Level of Independence domain score increased by 9 per cent ( $P=0.001$ ). No significant changes were observed for other domains.

**Comparing within I-SKY and O-SOC from baseline to end of intervention:** During the 12 wk follow up period, quality of life scores increased in the I-SKY arm for all domains and were significant for Physical health: 16.0 to 18.0 ( $P=0.004$ ) and Level of independence domain: 16.5 to 17.0 ( $P=0.02$ ). Scores in the O-SOC decreased for Total and Physical health domains, increased in Psychological domain (not significant) while no change was observed in other domains (Fig. 2).

**Assessment of QOL scores after SKY training:** An improvement in QOL scores 2-3 days after SKY training was observed. QOL score assessment from baseline to completion of 6-day SKY training showed an improvement in the median QOL scores by 1.3 ( $P=0.001$ ). Significant increase for domains scores of Physical health: 16.0 to 18.0 ( $P=0.001$ ), Psychological: 15.2 to 16.0 ( $P=0.007$ ), Level of independence: 16.5 to 17.0 ( $P=0.011$ ) and Social domain: score 14.0 to 16.0 ( $P=0.041$ ) was observed. However, the increase in Environment and Spiritual domains were not found to be significant in the intervention group (data not shown).

**Adherence to SKY in I-SKY:** The influence of degree of adherence to follow up visits of SKY intervention, referred as dose effect was studied by comparing outcomes in those healthy PLHIV who attended at least nine visits, *i.e.* those with  $\geq 75$  per cent adherence to SKY and those with  $<75$  per cent adherence. Significant differences were observed in adhering group for Physical health domain ( $P=0.007$ ) and Level of independence domain ( $P=0.02$ ), while the differences in other scores were non-significant. In the adhering group the body mass index (BMI) increased by 0.3 (21.2 to 21.5 kg/m<sup>2</sup>) while it decreased from 23.3 to 20.9 kg/m<sup>2</sup> in less adhering group, although difference was not significant. (Table III). No adverse event was observed.

## Discussion

The significant role of yoga in improving the physical and mental state and general wellbeing was explored in HIV positive persons through *Sudarshan*

**Table I.** Comparison of baseline characteristics of the participants enrolled in I-SKY arm (n=31) and O-SOC arm (n=30)

	Overall (n=61)	I-SKY arm (n=31)	O-SOC arm (n=30)
Gender at birth n (%)			
Female	39 (64)	20 (65)	19 (63)
Overall median Age in yr (IQR)	32 (28.0-38.0)	34 (28-40)	30.5 (26.0-36.0)
Marital status n (%)			
Never married	3 (5)	1 (3)	2 (7)
Currently married	33 (54)	18 (58)	15 (50)
Widow/divorced/separated	25 (41)	12 (39)	13 (43)
Education n (%)			
Upto middle school	16 (26)	7 (23)	9 (30)
Middle school to High school	31 (51)	19 (61)	12 (40)
Jr. college and above	14 (23)	5 (16)	9 (30)
Occupation n (%)			
Agriculture labour/ Skilled / Unskilled worker	36 (59)	18 (58)	18 (60)
Business/Petty trade	8 (13)	4 (13)	4 (13)
Housewife	17 (28)	9 (29)	8 (27)
Origin n (%)			
Urban	42 (69)	22 (71)	20 (67)
Biomarkers			
Median BMI, kg/m <sup>2</sup> (IQR)	22.0 (19.6-26.0)	21.7 (19.2-26.0)	23.5 (20.7-25.5)
Median systolic BP, mm Hg (IQR)	110 (110-110)	110 (110-110)	110 (110-110)
Median diastolic BP, mm Hg (IQR)	80 (70-80)	80 (70-80)	80 (70-80)
Median Hb, g/dl (IQR)	12.2 (11.3-13.9)	12.2 (11.6-13.9)	11.8 (11.2-14.2)
Median CD4 count, cells/ $\mu$ l (IQR)	614 (507-767)	617(492.5-724.5)	614 (517-796)
Reported HIV transmission mode n (%)			
Heterosexual	53 (86.9)	28 (90.3)	25 (83.3)
Blood products	2 (3.3)	1 (3.2)	1 (3.3)
Do not know	6 (9.8)	2 (6.5)	4 (13.3)
Habits (Smoking/ Tobacco/ Alcohol) n (%)			
Personal problems n (%)	8 (13)	5 (16)	3 (1)
Family problems n (%)	43 (71)	22 (71)	21 (70)
Social problems n (%)	21 (34)	12 (39)	9 (30)
Social problems n (%)	12 (20)	7 (23)	5 (17)
Discrimination problem n (%)	14 (23)	9 (29)	5 (17)
Health problem n (%)	34 (56)	15 (48)	19 (63)
Quality of life score (IQR)	15.2 (13.9-16.1)	15.1 (13.9-15.9)	15.3 (13.9-16.1)

Contd...

	Overall (n=61)	I-SKY arm (n=31)	O-SOC arm (n=30)
Domains of quality of life			
Physical health (IQR)	17.0 (15.0-18.0)	17.0 (14.0-18.0)	17.0 (15.0-18.0)
Psychological (IQR)	14.4 (12.8 -16.0)	15.2 (13.6-16.0)	14.4 (12.8-16.8)
Level of independence (IQR)	17.0 (16.0-17.0)	17.0 (16.0-17.0)	17.0 (16.0-17.0)
Social (IQR)	14.0 (13.0-16.0)	14.0 (12.0-16.0)	13.5 (13.0-16.0)
Environment (IQR)	13.5 (12.5-14.5)	14.0 (13.0-14.5)	13.5 (12.5-14.5)
Spirituality/Personal belief (IQR)	16.0 (14.0-18.0)	16.0 (13.0-18.0)	16.0 (15.0-18.0)
IQR, interquartile range; BMI, body mass index; Hb, haemoglobin No significant difference was observed in any of the parameters between the two groups			

**Table II.** Comparing domain-wise change in the quality of life scores, CD4 counts and BMI for I-SKY arm (n=31) and O-SOC (n=30) arm adjusted for age, gender, education and occupation using random effects model

Domain	Unadjusted difference	95% Confidence interval	P value	Adjusted difference	95% Confidence interval	P value
Total QOL	0.06	0.01, 0.10	0.012	0.06	0.01, 0.10	0.016
Physical health	0.12	0.04, 0.20	0.003	0.12	0.04, 0.20	0.004
Psychological	0.09	0.003, 0.19	0.043	0.11	0.01, 0.20	0.023
Level of independence	0.08	0.03, 0.13	0.004	0.09	0.04, 0.14	0.001
Social	0.06	-0.08, 0.20	0.407	0.03	-0.11, 0.18	0.644
Environment	0.01	-0.05, 0.06	0.785	0.01	-0.05, 0.06	0.803
Spirituality/personal beliefs	0.04	-0.07, 0.15	0.477	0.03	-0.09, 0.14	0.661
CD4 count	-34.54	-175.07, 105.99	0.630	-52.27	-187.8, 83.22	0.450
BMI*	-0.843	3.32, 1.64	0.505	-1.47	-3.81, 0.87	0.219
*BMI, body mass index						

*Kriya* yoga (SKY), a comprehensive composite of controlled yogic breathing techniques. The *Sudarshan Kriya* yoga, an established standardized technique is simple to administer and is a non-invasive, non-pharmacological, is a behavioural intervention that can be used by healthy PLHIV without any fear of stigma when making follow up visits. The improvements in QOL scores in the intervention arm as compared to the control arm indicated an efficacy of SKY intervention. Significant improvement was observed for overall scores, physical, psychological and level of independence domains.

In the sub-group analysis of intervention arm, it was observed that a regular practice of SKY might improve quality of life of healthy PLHIV, their level

of independence, at both physical and psychological level. This may contribute to improving their self esteem and decision-making ability. Higher self esteem and decision-making ability have been documented to influence health seeking behaviour<sup>24</sup>. This improvement in quality of life, if sustained through counselling intervention and regular practice of SKY, may contribute to better adherence to ART intervention with improved decision making ability. No significant changes were observed for biological markers like CD4, BMI and blood pressure during this 12 wk period, indicating a need for a longer duration of observation.

The QOL score assessment at post-SKY training in I-SKY participants showed overall improvement. Need for consistent performance of SKY was highlighted

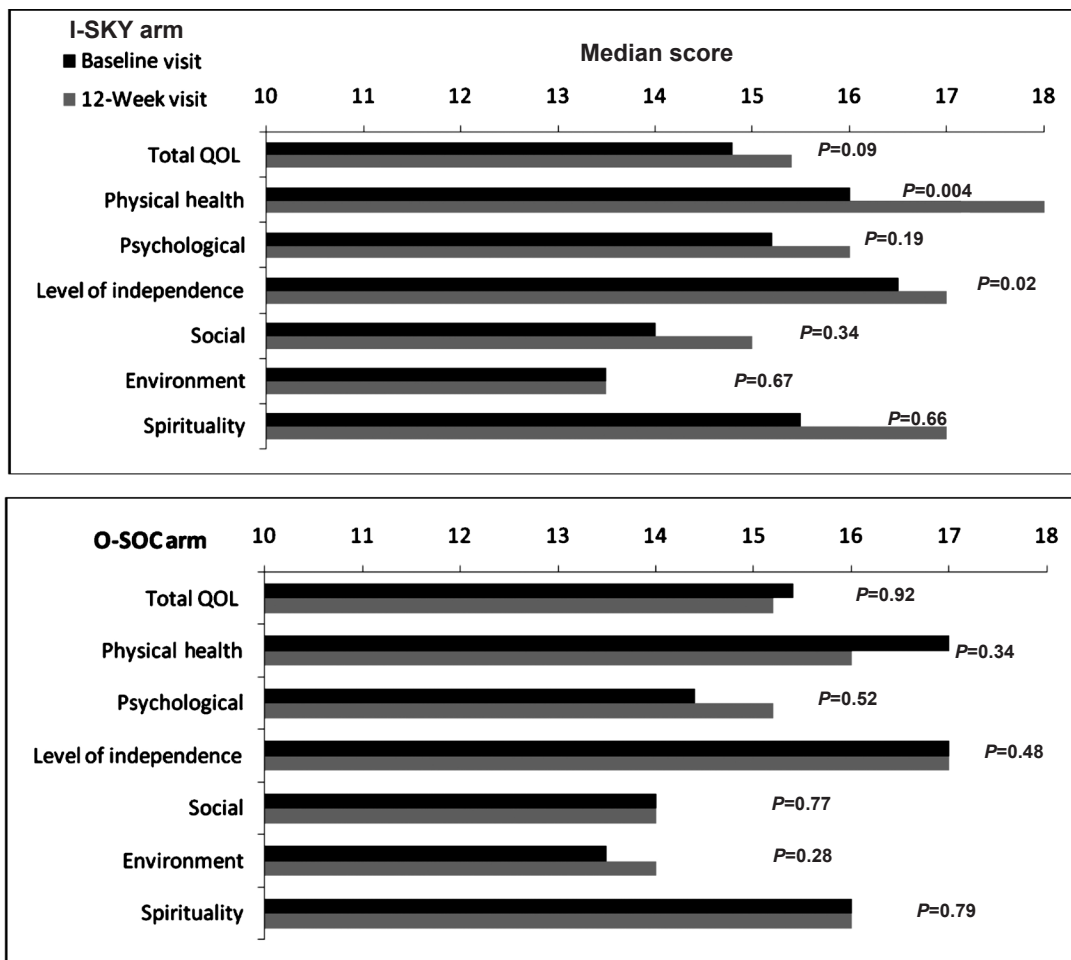


Fig. 2. Comparison of QOL scores (domain-wise) from baseline to 12 wk in two arms: I-SKY arm (n=31) and O-SOC (n=30) arm.

in the dose-response analysis in the I-SKY group. Significant improvement was seen in adherent group with 75 per cent or more follow ups than the less than 75 per cent adhering group. However, these results are only suggestive but may not be considered conclusive due to small sample size.

A pilot study design and a small sample were the major limitations of this study. Further, this observational period of 12 wk was too short to observe changes in biomarkers and also for observing the sustenance of SKY practice and improvement in QOL scores in all domains.

The stigma attached to HIV/AIDS, loss of physical functioning and loss of friends at a young age are among the most pressing stressors that distinguish HIV/AIDS from other chronic-fatal diseases<sup>24</sup>. Yoga is practiced by general population and it is easily available and accessible. However, estimation of effect

of meditation, pranayam and yoga intervention among PLHIV has not been well documented even in Indian set up. On the other hand, many studies done outside India have mentioned the wide usage of yoga with recommendation for its use<sup>28,29</sup>.

In a study at Canada using meditative techniques positive changes in wellbeing on mental health index was noted and the effect was primarily seen immediately following the programme and disappeared at later data points<sup>28</sup>. In our study, similar effect was visible and the difference remained significant for those who were adherent to SKY. There is enough evidence to suggest that SKY is a beneficial, low-risk, low-cost adjunct to treatment of stress, anxiety, post-traumatic stress disorder, depression, stress-related medical illnesses<sup>2,25,28,30</sup>.

The analysis for six QOL domains in the intervention arm and control arm showed marked



**Table III.** Effect of SKY adherence (SKY dose effect) in the quality of life scores in I-SKY arm with <75% and >75% adherence of SKY weekly follow up visits

Scores/biomarkers	Up to 9 SKY weekly follow up visits (< 75% adherence) (n=10)			More than 9 SKY weekly follow up visits (≥75% adherence) (n=14)		
	Baseline visit	Month 3 visit	P value	Baseline visit	Month 3 visit	P value
Total QOL scores	15.2 (13.9-16.1)	16.1 (14.3-16.7)	0.610	14.5 (13.4-15.2)	15.2 (14.3-16.3)	0.133
Physical health	16.5 (15.0-18.0)	17.5 (16.0-19.0)	0.275	15.5 (14.0-17.0)	18.0 (17.0-19.0)	0.007
Psychological	15.2 (13.6-16.0)	16.0 (13.6-16.8)	0.149	14.0 (12.8-16.0)	15.2 (14.4-16.0)	0.394
Level of independence	17.0 (16.0-17.0)	17.0 (16.0-17.0)	0.815	16.0 (15.0-17.0)	17.0 (16.0-18.0)	0.019
Social	15.0 (13.0-16.0)	15.0 (12.0-16.0)	0.638	13.5 (11.0-15.0)	15.0 (14.0-16.0)	0.243
Environment	14.0 (13.5-15.5)	14.8 (12.5-16.0)	0.759	13.5 (12.5-14.0)	13.3 (12.0-15.0)	0.724
Spirituality/personal beliefs	15.5 (13.0-19.0)	18.0 (16.0-19.0)	0.471	16.0 (13.0-18.0)	17.0 (11.0-19.0)	0.975
BMI (kg/m <sup>2</sup> )	23.3 (18.8-26.0)	20.9 (17.6-26.0)	0.222	21.2 (19.3-27.2)	21.5 (20.0-23.7)	0.874
BP (S) (mm Hg)	110 (110-120)	110 (110-120)	.	110 (110-110)	110 (110-110)	.
BP (D) (mm Hg)	80 (80-80)	80 (80-80)	.	70 (70-80)	70 (70-80)	.
CD4 count (cells/μl)	653.5 (565-787)	635.5 (477-916)	0.507	585.5 (470-633)	579.5 (477-709)	0.079

Values represent median and interquartile range. Comparison using Wilcoxon sign rank test  
BMI, body mass index; BP, blood pressure; S, systolic; D, diastolic

differences for the QOL scores pertaining to physical, level of independence and the psychological domains but differences were not significant in social, environmental and spiritual domains. Hence, a larger study should be taken up with adequate sample size at different sites to establish the findings of this study in PLHIV for improvement in quality of life through *Sudarshan Kriya* yoga.

The need for ensuring sustenance of SKY practice through effective monitoring using innovative methods is a pre-requisite. This includes tracking study participants through mobile phone messaging for reminders for its daily practice. Also integrating the follow up visits within the existing network of AOL centres where the study participants may interact on a regular basis may also be explored with robust networking maintaining confidentiality of participants.

This pilot study has formed a base to pursue more such intervention studies in this non-invasive, low cost, non pharmacological technique for improving quality of life of PLHIV. This may be initiated in our country to contribute in improving quality of life of PLHIVs and attempt to bring them to the main stream.

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#### References

- Guidelines for the Use of antiretroviral agents in HIV-1-infected adults and adolescents. Initiating antiretroviral therapy in treatment-naive patients. Available from: <http://aidsinfo.nih.gov/guidelines/html/1/adult-and-adolescent-arv-guidelines/10/initiating-art-in-treatment-naive-patients>, accessed on January 11, 2014.
- Holtgrave DR, Pinkerton SD. Updates of cost of illness and quality of life estimates for use in economic evaluations of

- HIV prevention programs. *J Acquir Immune Defic Syndr Hum Retrovirol* 1997; 16 : 54-62.
3. Kohli RM, Sane S, Kumar K, Paranjape RS, Mehendale SM. Assessment of quality of life among HIV-infected persons in Pune, India. *Qual Life Res* 2005; 14 : 1641-7.
  4. Mahalakshmy T, Premarajan K, Hamide A. Quality of life and its determinants in people living with human immunodeficiency virus infection in Puducherry, India. *Indian J Community Med* 2011; 36 : 203-7.
  5. Abboud S, Noureddine S, Huijjer HA, DeJong J, Mokhbat J. Quality of life in people living with HIV/AIDS in Lebanon. *AIDS Care* 2010; 22 : 687-96.
  6. Saddki N, Noor MM, Norbanee TH, Rusli MA, Norzila Z, Zaharah S, *et al*. Validity and reliability of the Malay version of WHOQOL-HIV BREF in patients with HIV infection. *AIDS Care* 2009; 21 : 1271-8.
  7. Fan AP, Kuo HC, Kao DY, Morisky DE, Chen YM. Quality of life and needs assessment on people living with HIV and AIDS in Malawi. *AIDS Care* 2011; 23 : 287-302.
  8. Babu AS, Padmakumar R, Maiya AG. A review of ongoing trials in exercise based rehabilitation for pulmonary arterial hypertension. *Indian J Med Res* 2013; 137 : 900-6.
  9. Tekur P, Chametcha S, Hongasandra RN, Raghuram N. Effect of yoga on quality of life of CLBP patients: a randomized control study. *Int J Yoga* 2010; 3 : 10-7.
  10. Woodyard C. Exploring the therapeutic effects of yoga and its ability to increase quality of life. *Int J Yoga* 2011; 4 : 49-54.
  11. Creswell JD, Myers HF, Cole SW, Irwin MR. Mindfulness meditation training effects on CD4+ T lymphocytes in HIV-1 infected adults: a small randomized controlled trial. *Brain Behav Immun* 2009; 23 : 184-8.
  12. Mawar N, Saha S, Pandit A, Mahajan U. The third phase of HIV pandemic: Social consequences of HIV/AIDS stigma & discrimination & future needs. *Indian J Med Res* 2005; 122 : 471-84.
  13. Mawar N, Bagul R, Sane S, Katendra T, Tripathy SP, Paranjape R. Lessons learnt from ongoing counseling during follow-up visits by men and women attending a VCTC. *East J Med* 2011; 16 : 137-46.
  14. WHOQOL measuring quality of life. The World Health Organization quality of life instruments. Available from: [http://www.who.int/mental\\_health/media/68.pdf](http://www.who.int/mental_health/media/68.pdf), accessed on December 8, 2011.
  15. Skevington SM, Lotfy M, O'Connell KA; WHOQOL Group. The World Health Organization's WHOQOL-BREF quality of life assessment: Psychometric properties and results of the international field trial. A report from the WHOQOL group. *Qual Life Res* 2004; 13 : 299-310.
  16. Hsiung PC, Fang CT, Wu CH, Sheng WH, Chen SC, Wang JD, *et al*. Validation of the WHOQOL-HIV BREF among HIV-infected patients in Taiwan. *AIDS Care* 2011; 23 : 1035-42.
  17. Cade WT, Reeds DN, Mondy KE, Overton ET, Grassino J, Tucker S, *et al*. Yoga lifestyle intervention reduces blood pressure in HIV-infected adults with cardiovascular disease risk factors. *HIV Med* 2010; 11 : 379-88.
  18. Agte VV, Tarwadi K. *Sudarshan kriya* yoga for treating type 2 diabetes: a preliminary study. *Altern Complement Ther* 2004; 10 : 220-2.
  19. Sivasankaran S, Pollard-Quintner S, Sachdeva R, Pugged J, Hoq SM, Zarich SW. The effect of a six-week program of yoga and meditation on brachial artery reactivity: do psychosocial interventions affect vascular tone? *Clin Cardiol* 2006; 29 : 393-8.
  20. Brown RP, Gerbarg PL. *Sudarshan Kriya* Yogic breathing in the treatment of stress, anxiety, and depression: Part II - Clinical applications and guidelines. *J Altern Complement Med* 2005; 11 : 711-7.
  21. Kjellgren A, Bood SA, Axelsson K, Norlander T, Saatcioglu F. Wellness through a comprehensive yogic breathing program - a controlled pilot trial. *BMC Complement Altern Med* 2007; 7 : 43.
  22. Rao RM, Nagendra HR, Raghuram N, Vinay C, Chandrashekara S, Gopinath KS, *et al*. Influence of yoga on mood states, distress, quality of life and immune outcomes in early stage breast cancer patients undergoing surgery. *Int J Yoga* 2008; 1 : 11-20.
  23. Sengar M, Bhutani M, Aggarwal D, Kochupillai V. Cancer treatment: role of yoga, naturopathy and prayer. *Health Adm* 2012; 17 : 151-7.
  24. Art of Living. Scientific research on Art of living practices. Available from: [http://aolresearch.org/published\\_research.html](http://aolresearch.org/published_research.html), accessed on April 22, 2014.
  25. Zope SA, Zope RA. *Sudarshan kriya* yoga: breathing for health. *Int J Yoga* 2013; 6 : 4-10.
  26. National Marrow Donor Program and the Medical College of Wisconsin 2009: From Manual, Appendix L-Karnofsky/Lansky Performance status Doc No A00428 1/5. Available from: <http://www.cibmtr.org/DataManagement/TrainingReference/Manuals/DataManagement/Documents/appendix-1.pdf>, accessed on February 6, 2015.
  27. Rabe-Hesketh S, Skrondal A. *Multilevel and longitudinal modeling using stata*, 2<sup>nd</sup> ed. College Station, TX: Stata Press; 2012.
  28. Jerath R, Edry JW, Barnes VA, Jerath V. Physiology of long pranayamic breathing: neural respiratory elements may provide a mechanism that explains how slow deep breathing shifts the autonomic nervous system. *Med Hypotheses* 2006; 67 : 566-71.
  29. Brazier A, Mulkins A, Verhoef M. Evaluating a yogic breathing and meditation intervention for individuals living with HIV/AIDS. *Am J Health Promot* 2006; 20 : 192-5.
  30. Asthana S. AIDS-related policies, legislation and programme implementation in India. *Health Policy Plan* 1996; 11 : 184-97.

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