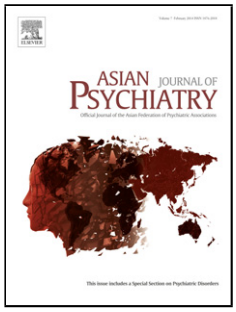

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TITLE PAGE

EFFECT OF SUDARSHAN KRIYA ON MALE PRISONERS WITH NON PSYCHOTIC PSYCHIATRIC DISORDERS: A RANDOMIZED CONTROL TRIAL

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ABSTRACT

Objectives: To investigate whether Sudarshan Kriya and Related Practices (SK&P) can lead to increased Global Assessment of Functioning (GAF) and increased feeling of wellness in male prisoners with non psychotic psychiatric disorder.

Methodology: This is a 6 month parallel randomized controlled study with sample size of 230 male prisoners. Participants meeting inclusion and exclusion criteria were assigned to a study or control group by simple random allocation in which random allocation sequence was generated using a random number table. Each individual study participant was involved in a daily program of SK&P for 6 weeks. Each individual control participant was instructed to sit in an armchair with his eyes closed and gentle attention to their breath for duration of 6 weeks. To be included in this study, participant must be a male prisoner diagnosed to be suffering from Psychiatric disorder (except psychosis and Bipolar Affective Disorder [BPAD]) by ICD-10 (DCR) criteria with age between 18-65 years.

Results: Majority of subjects were unemployed married individuals, educated till undermatric level not having occupational skills of more than unskilled labor level. Practicing SK&P for 6 weeks led to improvement in mean+/- SD score of study participants in Global Assessment of Functioning (GAF) , Anxiety (ANX) , Depressed mood (DEP) , Positive Well Being (PWB) , General Health (GH), Self Control (SC), Vitality(VT) and Total Positive General Well Being (PGWB). Change in mean± SD score of study participants when compared with control participants was statistically significant in terms of GAF, ANX, DEP, PWB, GH, PGWB. Increase in SC and VT scores were statistically insignificant when compared with control participants.

Conclusion: Practicing SK&P helps in improving GAF, PWB, GH and Total PGWB of an individual. SK&P also causes significant reduction in anxiety and depression levels. Effect of SK&P on SC and VT is insignificant.

Keywords: Psychiatric Disorder, male, Sudarshan Kriya

INTRODUCTION

Sudarshan Kriya Yoga (SKY) is a multi-component program that includes yoga movement, breathing, meditation techniques, group processes and yoga philosophy [1]. Sudarshan Kriya and related practices (SK&P) includes (1) 3 stage slow Resistance breathing (Ujjayi) (2) Bellows breath (Bhastrika) a high frequency forceful breathing technique (3) Om chant (4) Sudarshan Kriya (SK) and (5) Alternate nostril breathing (ANB) [2]. This breathing technique is practiced by millions worldwide. It is claimed to be effective in improving well being and peace of mind. In practitioners of SK&P, significant increase in mental alertness (beta activity) was observed in the left frontal, parieto-occipital and midline regions of the brain, as compared to controls [3]. Practitioners of SK&P were found to have significantly greater antioxidant production and lower blood lactate level which might be one of the contributing reasons of greater resilience to daily life stress as noticed in SK&P practitioners [4].

SK&P has been most widely studied in depression; on practicing SK&P 68% dysthymic patients [3] and 73% patients suffering from melancholic depression [5] showed remission. SK&P takes 3 weeks in showing its antidepressant effects [5] and in patients suffering from dysthymia and melancholic depression after 90 days of using SK&P, P300 Evoked response potential (ERP) amplitude readings returns to normal [6]. SK&P although inferior to Electro-convulsive therapy (ECT) can be a potential alternative to drugs in melancholia as a first line treatment [1]. Due to it's advantage of fostering the patient's autonomy and self reliance SK&P is likely to be a more acceptable and efficacious alternative to

medical management of dysthymia for both acute treatment and relapse prevention. It also has the advantage of cutting health care costs [7]

The practice of SK&P has been found to reduce tension and anxiety. The autonomic symptoms of high anxiety such as headache, dizziness, chest pain, palpitations, sweating and abdominal pain responds well [8]. Benefits of SK&P as potentially valuable adjunct to standard pharmacotherapy is also proven in patients with Generalized Anxiety Disorder (GAD) or treatment resistant GAD [9] and PTSD [10] . PTSD from sexual abuse benefit when SKY breathing is combined with traditional psychiatric and psychological therapies [11] though it's independent effectiveness still needs to be proven.

SK&P is also effective in mass disaster [12] and increasing longevity [13]
Though efficacy of SK&P has been proven in multiple disorders and situations but comparing various studies so far has been difficult due to variable expertise of therapist, sampling techniques, geographical variations, daily time spent in doing SK&P, use of control and time period of the study.
The current study is an attempt to evaluate effectiveness of SK&P in prison population.

Objective:

To investigate whether SK&P can lead to increased GAF and increased feeling of wellness in male prisoners with non psychotic psychiatric disorder.

Materials and Methods:

This is a parallel randomized controlled study. The study was conducted at Central Jail Hospital (CJH), New Delhi which is the largest prison hospital setting in India with both inpatient and outpatient departments. During study period of 6 months (between 11/1/13 to 10/7/13) participants were enrolled in and randomly assigned to either a 6 week SK&P intervention or a 6 week comparision control group. The study was approved by the Ethics review committee of CJH. Randomization was done using Simple random allocation in which random allocation sequence was generated using a random number table. One investigator uninvolved in the treatments or assessments generated random numbers for 232 male prisoners to be allocated to two groups in equal numbers with allocation ratio of 1:1. All male prisoners admitted in Central Jail (CJ) fulfilling study criteria were taken. The sample size was decided on the basis of the number of male prisoners suffering from non psychotic psychiatric disorder admitted in Central Jail for more than six weeks in previous year.

Each individual study participant was involved in a program of SK&P which he practiced daily for 6 weeks. Each individual control participant daily sat on an armchair with his eyes closed and gentle attention on his breath for duration of 6 weeks. Two certified SK&P teachers (trained to lead sessions at Art of Living) taught the procedure to all participants throughout the course of treatment. Only SK&P therapists involved in the study were informed to start the corresponding intervention; the rest of the research team was unaware of the current group allocation. All participants signed consent forms and they were treated according to the ethical guidelines of Helsinki in 1995 (as revised in Edinburgh 2000). Participants at time of inclusion in study signed informed consent form. At time inclusion in study participants were clearly explained about practicing SK&P is part of research project and that they will continue to receive pharmacological therapy during the course of study. They were also explained that they are free to drop out of study at any point of time without any penalty or impact on pharmacological treatment. The assessment tools were applied in the order starting from the Basic Socio-demographic Proforma, Mini-mental state examination (MMSE), Schedule for clinical assessment in neuropsychiatry (SCAN) based clinical interview, Global assessment of functioning (GAF) and Psychological general well being (PGWB). These assessments were conducted in all participants before starting the intervention and six weeks thereafter. Confidentiality and privacy were maintained throughout the assessment process.

Assessment of all participants took place in Psychiatry ward of CJH. As pre-decided trial was stopped after six months due to non availability of trained therapists, SK&P sessions were continued by some group volunteers who were trained to take SK&P sessions.

Inclusion criteria for participants:

1) Having an interest in SK&P and that they would like to practice it daily for 6 weeks.
2) Age between 18-65 years
3) Male prisoners diagnosed to be suffering from psychiatric disorder (except psychosis and BPAD) by ICD-10 (DCR) criteria
4) Patient willing to give written informed consent

Exclusion criteria for participants:

1) History of substance dependence in past one year.
2) Prisoners with co-morbid severe physical illness (like hepatic encephalopathy, severe debilitating illness) that might have hampered the assessment process were ruled out.
3) Prisoners with severe cognitive deficits that might have hampered the assessment process.

   Prisoners with MMSE score of less than 23 were excluded from the study.

Procedure followed during SK&P [14]: In Study participants SK&P components were applied in order of (1) 3 staged Ujjayi breathing (2) Bellows breath (Bhastrika) (3) Om chant (4) Sudarshan Kriya (SK) and (5) Alternate nostril breathing (ANB). The breathing practices were done in a sitting posture on the floor. Eyes and mouth were kept closed while breathing through the nose throughout the sessions.

Three stage Ujjayi is a slow, deep resistance breathing technique with respiratory rate of 4 to 6 breaths per minute. This is accomplished by a slight voluntary contraction of the laryngeal muscles and partial closure of the glottis to increase airway resistance and breath control. Each breath cycle is timed with counts of 4 during inhalation, 4 holding the breath, 6 during exhalation, and 2 holding the breath. Supplementary instructions were given in three stages that included specific breath cycle ratios, extended expiration duration while shortened inspiration, distinct arm postures, and breath-holds, all of which served to augment the effects of this particular breathing technique. During SK&P this is practiced for approximately 8 min. Ujjayi tends to be calming and to produce a sense of well-being.

Bhastrika involves forceful rapid deep breathing through the nose at a rate of 20 to 30 breaths per minute. Three one minute rounds of Bhastrika are each followed by 30 seconds of normal breathing. Arm movements are used to increase the force and depth of respiration. This breathing exercise was practiced for approximately 5 minutes.

Next, the participants engaged in the prolonged chanting of the sound ‘om’ which creates vibrations in the abdomen, chest, throat and jaw. ‘Om’ was chanted 3 times.

SK involves rhythms, cyclical forms of breathing in which there are no pauses between inhalation and exhalation. SK involves multiple rounds of slow (8-14 respiratory cycles per minutes), medium (40-50 respiratory cycles per minute) and fast (60-100 cycles per minute) cycles with varying rhythms and intensities SK lasts about 10 min.

ANB was practiced for 5 minutes.

As part of study daily spending 30minutes in doing SK&P was mandatory for all study participants. After session time of an hour used to be spent by therapist in correcting flaws in SK&P technique of various participants which were either noticed by therapist during session or brought to his/her notice by individual participant.

For similar duration of 30 minutes the control participants were instructed to sit in an armchair with their eyes closed and gentle attention on the breath.

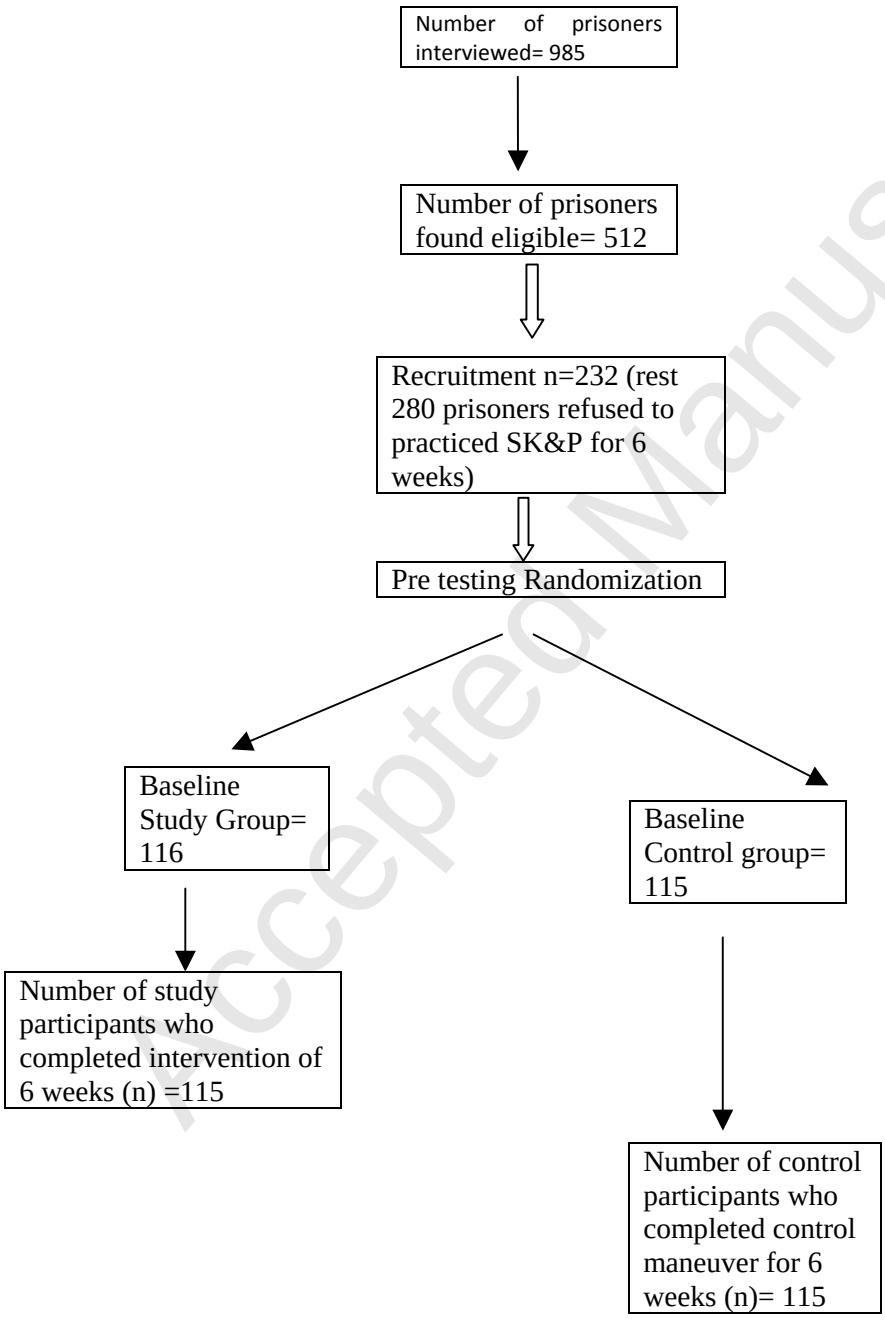

Figure 1: Flowchart of steps followed in study

Instruments used in study

1. **BASIC SOCIO-DEMOGRAPHIC PERFORMA**: Socio-demographic characteristics such as age, sex, marital status, education, occupation, employment status, religion, residence and family history of psychiatric illness and substance/alcohol use were recorded.

2. **THE MINI- MENTAL STATE EXAMINATION (MMSE):** The MMSE is a 30-point questionnaire test designed by Folstein et al was used to rule out cognitive deficits in the participants [15].

3. **Global assessment of functioning scale (GAF):** The GAF is a 100 point scale designed by Luborsky et al. is divided into 10 equal 10 point intervals. Patients with 81 to 90 and 91 to 100 intervals exhibit superior functioning; 71 to 80 intervals are for persons with minimal psychopathology. Most patients in outpatient settings will receive ratings between 31 and 70 and most inpatients between 1 and 40 [16].
4. **Psychological general well being schedule (PGWB):** The PGWB scale developed by HJ Dupuy et al. has 22 items that are aggregated to provide scores in six subscales. The scale, a self administered questionnaire, includes both positive and negative questions with a time frame and a six point response representing intensity or frequency for the first 14 questions. The last four questions use a 0 to 10 rating [17].

5. **SCHEDULE FOR CLINICAL ASSESSMENT IN NEUROPSYCHIATRY (SCAN):** The assessment of the psychiatric morbidity in the participants was performed by a SCAN based clinical interview in which clinical interview was conducted on the line of various sections of SCAN to enhance the thoroughness of clinical interview [18].

Wherever required for better clarification, additional information from clinical records and staff observations were incorporated in the assessment process.

STATISTICAL ANALYSIS AND DATA COLLECTION

Data was entered in the data based computer program and analyzed using the statistical package for social sciences (SPSS 15.0.1) [19]. Descriptive (frequency and percentage) and inferential statistics (Chi-square test, t-test and Cohen's effect size) were used to interpret the data.

RESULTS:

In Table1, Mean age for the study participants was 35.7 yrs (SD= 10.17), for the control group M= 36.4 yrs, SD= 12.67. Difference between age of study and control participants was not statistically significant (p value= 0.64, t value= 0.46, cohen's d= -0.06). p value of <0.05 was considered as statistically significant.
According to Table2, majority of patients in both study and control groups had education level of undermatric or below, were married unemployed males with occupational skills of unskilled worker or below level. Difference between socio-demographic variables in study and control participants was not statistically significant. p value of <0.05 was considered as statistically significant.

According to Table 3, Depressive episode/Recurrent Depressive Episode (RDD) was most common disorder in both study (34.5%) and control (36.2%) participants. Adjustment disorder (17.2%) in study participants and Generalized Anxiety Disorder (GAD) (19%) in control participants were second most common disorder in respective group. No statistical difference between study and control participants in terms of psychiatric disorders was found (X^2= 2.25, dof=4, p-value= 0.69). p value of <0.05 was considered as statistically significant.

According to Table 4, after 6 weeks of SK&P mean GAF score in study participants increased from 48.1+/-18.33 to 59.67+/-21.10. In same period mean GAF score in control participants decreased from 53.42+/- 19.13 to 52.28+/- 19.81.

According to table 5, practicing SK&P for 6 weeks in study participants lead to increase in mean score of Total PGWB and various subgroups. In same period mean score of control participants [except SC (8.01+/-4.52) and Total PGWB (40.91+/- 27.44] also increased but this increase was much lesser than study participants.

According to Table 6, on completion of 6 weeks change in Mean+ SD score of study participants when compared with control participants was statistically significant (p<0.05) in terms of GAF, ANX, DEP, PWB, GH and PGWB. Though there was increase in SC and VT scores but increase was insignificant when compared with control participants.
There were no safety issues. During course of study, 1 dropout in each SK&P and control group occurred, both dropouts occurred because participants got released from prison.

DISCUSSION

Period for doing SK&P was set at 6 weeks because according to an earlier study percentage of patient experiencing remission in depression was similar at one month and three month after initiation of SK&P [7]. Also neither severity of depression nor severity of biological dysfunction influenced the quick response time or degree of effectiveness of SK&P. Antidepressant effect of SK&P are exerted in about 3 weeks [5].
Cases with severe medical co-morbidity were excluded because patients with lung disease, asthma, hernia, recent surgery, recent myocardial infarction, high blood pressure, cerebral vascular disease, or migraine may not tolerate breath holding, *Bhastrika*, or head-down postures [20]. *Also practicing unmodified pranayama* can lead to occurrence of risk of seizure in patients with epilepsy [21]. Prisoners suffering from psychosis and BPAD were not included in study as earlier study had stated that incorrect technique or the overuse of SK&P beyond the prescribed time limits can cause dizziness, lightheadedness, irritability, euphoric states, or psychosis in vulnerable patients, particularly those with bipolar disorder, dissociative disorders, or schizophrenic spectrum illnesses [22]. Rapid or forceful breathing practices

such as Bhastrika (Bellows breath) can trigger manic episodes in patients suffering from BPAD [2]. Furthermore rapid breathing can increase the rate of lithium excretion which might have required change of Lithium dose in some patients [22].
Because of difficulty in proving that which component of multi-component intervention was responsible for outcome, in current study no asanas, meditations or any other kind of intervention (apart from SK&P) was provided to participants.
Statistically significant improvement in anxiety scores of study participants was consistent with findings of earlier studies that yoga programs that include yoga postures and meditation have shown benefits in medical patients with anxiety disorders [23] and medical students with examination anxiety [24].
The findings of current study is also similar to those of earlier studies that SK&P led to decreased levels of psychological distress [1,3]Among various subcomponents of SKP, Pranayama can rapidly bring the mind to the present moment and reduce stress [13]. Though earlier studies had reported beneficial effects of SK&P or its specific components on sleep, mental alertness [25] and overall quality of life [4] but these aspects were beyond the scope of this study.

Ujjayi breathing increases parasympathetic activity through vagal afferent inputs to the brain and improves heart rate variability (HRV) [26].
Low score in dimension of total GAF, General Health (GH) and Vitality (VT) which cannot be completely explained by diagnosed psychiatric disorder points towards subsyndromal morbidity [27] in these patients but since no specific scale was applied to assess subsyndromal morbidity, this aspect cannot be conclusively commented upon.
SK&P might be a suitable alternative for patients who are unwilling to take medication. Compliance with SK&P ranges from 56 to 80% compared to 50% compliance with prescription antidepressants (with complaints of significant side effects from medication) [28].
Due to limitation of sample size in this study relation of individual psychiatric disorder with SK&P was not studied Also being a prison hospital based study including only male prisoners the results cannot be applied to the general population. Larger studies with more diverse populations are needed in order to extrapolate these findings to a more general population. As participants got enrolled in an ongoing SK&P program at various cross section of time providing training in SK&P before enrollment in program was not possible. Some benefits of SK&P could have been possibly minimized due to time taken by any individual in mastering SK&P technique. Though therapist used to spend post session time in correcting SK&P related flaws of various participants but there was no specific mechanism to ensure that each study participant had mastered SK&P.

Conclusion: The data obtained suggest that practicing SK&P by male prisoners helps in improving GAF, PGWB, PWB and GH of an individual suffering with non psychotic psychiatric disorder. SK&P also causes significant reduction in anxiety and depression levels of an individual but does have significant effect on VT and SC of an individual. SK&P can be considered as an important additional treatment option in patients suffering from non psychotic psychiatric disorder.

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Table 1 Socio-demographic profile of study and controls participants I

	N	Minimum	Maximum	Mean+/- SD
Age of participants in yrs.	116	21.5	63.8	35.7+/- 10.17
Age of control participants in yrs.	116	21	64.3	36.4+/- 12.67

Table 2: Socio-demographic variables of study and control participants II:

		Number of study participants (n= 116)	Percentage (%)	Number of control participants (n=116)	Percentage (%)	Chi-square test	dof
Education	Illiterate	37	31.9	32	27.6	3.27	3
	Undermatric	44	37.9	39	33.6		
	Higher Secondary	18	15.5	29	25		
	Graduate and above	17	14.7	16	13.8		
Occupation	No occupation	28	24.1	31	26.7	0.712	5
	Unskilled worker	34	29.3	30	25.9		
	Skilled worker	24	20.7	26	22.4		
	Professional	10	8.6	11	9.5		
	Business	12	10.3	10	8.6		
	Student	8	6.9	8	6.9		
Employment	Unemployed	67	57.76	64	55.17	0.16	1
	Employed	49	42.24	52	44.83		
Marital status	Married	60	51.72	66	56.90	0.64	2
	Unmarried	42	36.2	38	32.76		
	Separated/Widowed	14	12.07	12	10.34		

p-value less than 0.05 considered statistically significant.

Table 3: Prevalence of various psychiatric disorders in study and control participants:

Psychiatric Disorder	Number of study participants (n=116)	Percentage (%)	Number of control participants (n=116)	Percentage (%)
Obsessive Compulsive Disorder	14	12.1	14	12.1
Generalized anxiety disorder	14	12.1	22	19
Depressive episode/ Recurrent depressive disorder	40	34.5	42	36.2
Somatoform Disorder	16	13.8	12	10.3
Adjustment Disorder	20	17.2	16	15.5
Habit and impulse disorder	12	10.3	10	6.9

Table 4 GLOBAL ASSESSMENT OF FUNCTIONING (GAF) SCORE:

Score Range	Baseline number of study participants (n=116)	Post intervention number of study participants (n=115)	Baseline number of control participants (n=116)	Post 6 weeks number of control participants (n=115)
0-10	0	0	0	0
11-20	5	0	0	0
21-30	19	12	18	20
31-40	18	13	11	13
41-50	22	16	26	26
51-60	23	17	20	20
61-70	14	19	18	14
71-80	10	16	12	8
81-90	5	13	8	11
91-100	0	9	3	3
Mean+/- SD	48.1+/- 18.33	59.67+/- 21.10	53.42+/-19.13	52.28+/-19.81

Table 5: Psychological General Well Being Schedule (PGWB) score

Dimensions	Score Range	Baseline number of study participants (n=116)	Post-intervention number of study participants (n=115)	Baseline number of control participants (n=116)	Post 6 weeks number of study participants (n=115)
Anxiety (ANX)	0-5	40	21	38	36
	6-10	28	13	28	27
	11-15	22	19	20	21
	16-20	18	33	19	20
	21-25	8	29	11	11
	Mean+/-SD	9.64+/- 6.79	14.47+/-7.45	10.12+/- 7.07	10.37+/- 7.07
Depressed Mood (DEP)	0-5	40	17	42	42
	6-10	38	46	42	40
	11-15	38	52	32	33
	Mean +/- SD	7.74+/-4.57	9.45+/-4.00	7.39+/-4.46	7.43+/- 4.50
Positive well being (PWB)	0-5	32	18	36	31
	6-10	30	14	24	26
	11-15	28	31	34	36
	16-20	26	52	22	22
	Mean+/-SD	9.93+/-5.96	13+/- 5.85	9.66+/-5.95	10+/-5.79
Self control (SC)	0-5	40	29	36	38
	6-10	38	26	40	41
	11-15	38	60	40	36
	Mean+/-SD	7.74+/-4.57	9.22+/-4.65	8.01+/-4.52	7.75+/-4.49
General Health (GH)	0-5	40	19	38	35
	6-10	38	40	40	41
	11-15	38	56	38	39
	Mean+/-SD	7.74+/- 4.57	9.53+/-4.16	7.84+/-4.52	8.02+/- 4.49
Vitality (VT)	0-5	30	20	28	20
	6-10	28	18	26	22
	11-15	30	39	32	37
	16-20	28	38	30	36
	Mean+/-SD	10.28+/-6.01	12.04+/- 5.72	10.64+/- 5.96	11.78+/- 5.71
Total	0-10	16	7	18	16
	11-20	14	6	16	20
	21-30	12	8	16	14
	31-40	14	12	12	10
	41-50	10	8	12	14
	51-60	12	8	12	10
	61-70	14	18	10	8
	71-80	10	16	6	13
	81-90	10	12	6	5
	91-100	4	20	8	5
	Mean+/-SD	44.22+/-27.58	59.9+/- 28.06	41.11+/-28.01	40.91+/-27.44

Table 6: Comparison of difference in pre and post intervention score of study and control participants

	Difference in pre and post intervention score in study participants	Difference in baseline and post 6 weeks score in control participants	t-value	Standard Error of difference	p value	Cohen 'd' value
GAF						
-6 to -10	0	19	18.29	0.687	<0.01*	2.41
-1 to -5	0	48				
0-5	22	37				
6-10	24	11				
11-15	32	0				
16-20	37	0				
Mean+/- SD	11.56 +/- 5.71	-1 +/- 4.65				
ANXIETY (ANX)						
-6 to -10	15	0	6.05	0.76	<0.01*	0.80
-1 to -5	14	59				
0-5	25	44				
6-10	28	12				
11-15	33	0				
Mean +/- SD	4.83+/-7.22	0.25+/- 3.71				
Depressed Mood (DEP)						
-1 to -5	45	77	2.83	0.59	<0.01*	0.37
0 to 5	42	12				
6 to 10	28	28				
Mean +/- SD	1.71+/- 4.32	0.04+/- 4.62				
Positive Well Being (PWB)						
-1 to -5	37	68	4.14	0.66	<0.01*	0.55
0 to 5	41	29				
6-10	24	13				
11-15	13	5				
Mean +/- SD	3.07+/- 5.33	0.34+/- 4.64				
Self Control						
-6 to -10	0	27	0.17	0.66	0.87	0.02
-1 to -5	64	30				
0 to 5	38	29				
6 to 10	13	29				
Mean +/- SD	0.08+/- 3.80	- 0.03+/- 5.95				
General Health (GH)						
-1 to -5	57	63	2.78	0.58	<0.01*	0.37
0 to 5	24	38				

6 to 10	25	14				
11 to 16	9	0				
Mean +/- SD	1.79+/- 4.99	0.18+/- 3.70				
Vitality (VT)						
-1 to -5	48	55	1.04	0.60	0.30	0.14
0 to 5	34	33				
6 to 10	33	27				
Mean +/- SD	1.76+/- 4.58	1.14+/- 4.47				
Total PGWB						
-1 to -5	0	65	18.44	0.84	<0.01*	2.43
0-5	16	33				
6-10	17	17				
11-15	21	0				
16-20	22	0				
21-25	19	0				
26-30	20	0				
Mean+/- SD	15.68+/- 8.04	0.2+/- 4.05				

*p value less than 0.05 considered statistically significant