

Sudarshan Kriya Yoga Program in Posttraumatic Stress Disorder: A Feasibility Study

Abstract

Background: Sudarshan Kriya Yoga (SKY), a breath-based yoga intervention, has demonstrated safety and efficacy in posttraumatic stress disorder (PTSD) patients subsequent to natural disaster or war, but has not been explored in civilians with PTSD from a wider range of trauma. We hypothesized that it would be feasible to conduct a clinical trial of SKY in PTSD resulting from a wide range of trauma. **Methods:** Outcomes were feasibility measures including rates of enrollment and retention, adherence to study protocol; as well as changes in PTSD symptoms, other mood symptoms, and physiological measures. Male and female participants aged 18–75 years were enrolled in a feasibility trial. They attended a 6-day learning phase of SKY followed by 7 sessions over 11 weeks as an adjunct to their usual treatment. **Results:** Forty-seven participants were screened and 32 were enrolled over 9 months. Consistent with retention rates of other PTSD trials, 13 withdrew from the study prior to week 12. Twenty-one participants met intervention attendance requirements, completed 95% of planned study assessments and were included in final analyses. Participants experienced clinically significant decrease in PTSD symptoms on the posttraumatic stress disorder checklist (PCL-5) scores at week 12 mean difference, M_{diff} (standard deviation [SD]) = -10.68 (14.03), $P = 0.004$; Cohen's $d = 0.58$, which was sustained at week 24 M_{diff} (SD) = -16.11 (15.20), $P < 0.001$; Cohen's $d = 0.91$. **Conclusions:** It is possible to conduct a clinical trial of SKY in a routine psychiatry clinic serving patients with PTSD due to a wide range of trauma. Future studies should include an RCT design.

Keywords: Civilian posttraumatic stress disorder, feasibility study, meditation, mind-body intervention, posttraumatic stress disorder, Sudarshan Kriya Yoga

Introduction

Posttraumatic stress disorder (PTSD) is the third most common mental illness with a prevalence of 6.8% to 9.2%. PTSD can occur subsequent to a wide range of trauma such as witnessing someone's death or injury, sustaining a serious and/or life-threatening assault or injury, experiencing a natural disaster, rape, sexual abuse, and intimate partner violence. Patients with PTSD have a high risk of developing another mental health condition such as major depressive disorder, substance use disorder, and other anxiety disorders.^[1] The current treatment options include pharmacotherapy and/or psychological therapies which offer an overall response rate of only 60%, with remission in only 20%–30%.^[2,3] Hence, there is an urgent need for alternative forms of therapies.

Sudarshan Kriya Yoga (SKY), a breath-based yogic intervention has been previously reported to offer benefits following trauma. In survivors of the 2004 South-East Asia Tsunami ($n = 183$), SKY intervention led to a 60% drop in mean scores on the posttraumatic stress disorder checklist (PCL-17), and a 90% drop in depression scores.^[4] SKY was also effective in reducing PTSD symptoms in military veterans.^[5,6] We wished to investigate (a) the feasibility of applying the SKY program in PTSD patients seen in a routine psychiatry clinic and (b) estimate effect sizes of SKY on clinical and other relevant physiological measures.

Methods

Study design

This was a single-center, prospective, feasibility trial of a 12-week intervention

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of a SKY program offered as an adjunct to usual care. The study was registered at ClinicalTrials.gov (identifier: NCT02749253) and followed procedures and ethical standards as outlined in the Helsinki Declaration of 1975. Research participants were consenting men and women, 18–75 years of age recruited between May 2016 and January 2017 from a secondary care hospital, who were not currently practicing any other types of meditation technique.

Screening and initial assessments

Potential participants previously diagnosed by a psychiatrist as meeting DSM-5 criteria of PTSD were screened as per the inclusion and exclusion criteria [for a list of criteria see the Supplement 1]. The PTSD diagnosis was confirmed through a structured clinical interview, the clinician-administered PTSD Scale for DSM5-past month version (CAPS-5).^[7] The mini-international neuropsychiatric interview^[8] was used to diagnose other potential psychiatric comorbidities.

Intervention

The SKY PTSD intervention is a breath based yogic mind-body resilience building program delivered by trained and certified instructors from “The International Association for Human Values” (IAHV), 2401 15 Street NW, Washington, D. C., USA, 2009. Enrolled participants attended a week-long (6 day) course in groups of 3–8 over 2.5–3 h daily sessions (for details of the technique see^[9]). This was followed by weekly follow-up sessions (90 min/wk) for 3 weeks and then bimonthly sessions for the next 8 weeks. Participants were asked to practice SKY at home daily (25 min/day) during the study.

Feasibility outcomes

Key feasibility measures included (i) the number of potentially available eligible participants at this site, (ii) proportion of those successfully screened and then enrolled, (iii) rate of adherence to study procedures (measured by site attendance as well as home practice), (iv) retention rate, and v) time required to meet recruitment targets.

Key efficacy and safety assessments

At week 0 (Baseline), demographic information was collected and the following scales were administered: The clinician-rated Hamilton Depression Scale (HAM-D 17 items)^[10] and Hamilton Anxiety Scale (HAM-A);^[11] and the self-rated PCL-5,^[12] and Beck Depression Inventory (BDI).^[13] Participants were asked to attend further assessments at weeks 4, 8, 12, and 24. Adverse effects potentially related to SKY were monitored using a structured questionnaire. At each visit medication changes and adherence to study procedures were recorded.

Physiological outcome measures assessed at week 0, 12, and 24

(1) Inflammatory Markers: Participant blood was analyzed through enzyme-linked immunosorbent assay^[14] to assess C-reactive protein (CRP), interleukin-6, malondialdehyde (MDA), and total antioxidant capacity (including glutathione). (2) Mean of three sitting blood pressure values was collected. (3) Mean resting respiratory rate was measured from three 1-min readings.

Data analysis

All analyses were completed using IBM SPSS Statistics 23.0., International Business Machines Corporation, Armonk, New York, United States. Descriptive statistics included mean and standard deviation (SD) for continuous variables, and frequencies and percentages for categorical variables. Paired samples *t*-tests were used to compare outcomes at baseline and at 12 weeks, as well as baseline and 24 weeks. Last observation carried forward was used for missing data where participants had completed the 6-day instructional phase of the intervention and attended the baseline and week 4 study assessments. Standardized effect size (Cohen’s *d*) was calculated as the mean change score from baseline to 12 weeks, divided by the pooled SD as an estimate of clinical significance. The level of statistical significance was set at $\alpha = 0.05$.

Results

Baseline demographics are presented in Table 1.

Study recruitment and feasibility

Over a period of 9 months (May 2015–January 2016), 95 potential participants were approached. Of these, 47 were screened and 32 (68%) met eligibility criteria who were enrolled at a recruitment rate of 3.6 per month. Thirteen (40.6%) withdrew prior to the week 12 follow-up, 9 (28.1%) for reasons unrelated to the study intervention [Figure 1]. Most participants ($n = 14$, 66.7%) practiced SKY at-home regularly (3 or more times per week). In addition, such participants completed 95.2% (80 of 84) of the planned assessments delivered between baseline and week 12. There were no protocol violations by study staff or IAHV collaborators. Participants who completed the study intervention had a mean (SD) baseline PCL-5 score of 44.57 (14.25) compared to drop-outs 51.15 (10.64). An independent *t*-test showed this difference was not significant confidence interval (CI) (−16.08, 2.93), $t = -1.413$, $P = 0.516$.

Preliminary estimates of efficacy

Table 2 shows a summary of results on changes (paired *t*-test) in PTSD symptom severity (PCL-5) as well as depression (HAM-D, BDI) and anxiety

symptoms (HAM-A). There was a clinically significant improvement in PCL-5 scores at week 12, compared to baseline (mean difference, M_{diff} (SD) = 10.68 (14.03), $t = 3.472$, $P = 0.002$, Cohen's $d = 0.58$, d 95% CI (-0.07, 1.22), which was sustained at week 24.

PCL-5 scores indicated that 12 of 19 (63.16%) responded to the study intervention and 8 of 19 (42.11%) experienced a clinically significant reduction in PTSD symptoms [Figure 2].

Table 1: Description of participant demographics at baseline (n=19)

Age (range), mean (SD)	25-79, 51.9 (13.2)
Gender	<i>n</i> (%)
Female	16 (84.2)
Male	3 (15.8)
Ethnicity	
Caucasian	17 (89.5)
Other	2 (10.5)
Education	
High school or less	8 (42.1)
Postsecondary	11 (57.9)
Relationship	
In a relationship	8 (42.1)
Not in a relationship	11 (57.9)
Occupation	
Employed	6 (31.6)
Unemployed	8 (42.1)
Retired	5 (26.3)
Trauma	
Single exposure	6 (31.6)
Multiple exposures	13 (68.4)
Trauma type	
Sexual abuse	8 (42.1)
Physical abuse	5 (26.3)
Emotional abuse	3 (15.8)
Rape	3 (15.8)
Motor vehicle accident	3 (15.8)
Work related	3 (15.8)
Death of a loved one	2 (10.5)
Witnessed death	1 (5.3)
Animal attack	1 (5.3)
Comorbid mood and/or anxiety disorder	12 (63.2)

SD=Standard deviation

Preliminary estimates of physiological measures

There were no statistically significant changes between baseline and week 12 values on any of the physiological outcome measures. However, from baseline to week 24 total antioxidant capacity increased significantly ($M_{diff} = 0.57$, $P = 0.007$) and respiratory rate reduced significantly ($M_{diff} = -1.52$, $P = 0.054$). There was a reduction in levels of inflammatory markers including CRP and MDA, though not statistically significant, at weeks 12 and 24.

For a description of adverse events and positive reported effects see the Supplement 1.

Discussion

The retention rate ($n = 19$, 59.4%) in our study is comparable to that (32 of 41, 68.4%) found in a previous study of yoga in PTSD.^[15] Our findings suggest that most participants who withdrew did so for reasons likely unrelated to the SKY intervention. Improvement in retention could be achieved by expanding the exclusion criteria, for example, participants who object to group based interventions, those displaying strong environmental triggers or those with significant social phobia or anxiety.

We asked participants to report any changes in physical health and/or mood symptomatology which likely led to high reporting of beneficial and negatively perceived effects. Our attempt tries to address a large knowledge gap with yoga and meditation-based intervention trials. A recent meta-analysis^[16] showed that only 3% of original publications of RCTs of psychological interventions for patients with mental and behavioral disorders included a description of adverse events as well as adequately described the methods used for collecting such data.

The study showed that SKY offers potentially clinically significant effects on symptoms of PTSD, as well as accompanying depression and anxiety. Symptom reduction persisted at week 24 even though there was no formal intervention support after week 12. This suggests that the effects of SKY are sustained as demonstrated in other SKY PTSD studies.^[4,5] This study was designed as a feasibility study and may not have been adequately powered to detect statistically significant results in all outcome measures.

Table 2: Clinical outcomes analysis

	Baseline	Change from baseline to week 12 (n=19)			Change from baseline to week 24 (n=18)		
	Mean (SD)	Mean (SD)	P	Cohen's D	Mean (SD)	P	Cohen's D
PCL-5	44.58 (14.25)	-10.68 (14.03)	0.004	0.58	-16.11 (15.20)	<0.001	0.91
HAM-D	19.37 (5.99)	-1.00 (5.42)	0.431	0.14	-3.94 (6.97)	0.028	0.49
BDI	25.53 (8.94)	-6.05 (10.34)	0.020	0.52	-7.44 (11.02)	0.011	0.55
HAM-A	26.11 (8.03)	-3.11 (8.08)	0.111	0.32	-6.94 (10.69)	0.013	0.70

Baseline mean values (M), SD, the change in mean scores from baseline to week 12 and baseline to week 24, and the results of a paired samples t-test from week 0 to week 12, and week 0 to week 24 as well as effect size (Cohen's d). Negative values denote improvement, bolded values denote $P < 0.05$. PCL-5=PTSD Checklist- 5, HAM-D=Hamilton Depression Scale, BDI=Beck depression inventory, HAM-A=Hamilton Anxiety Rating Scale

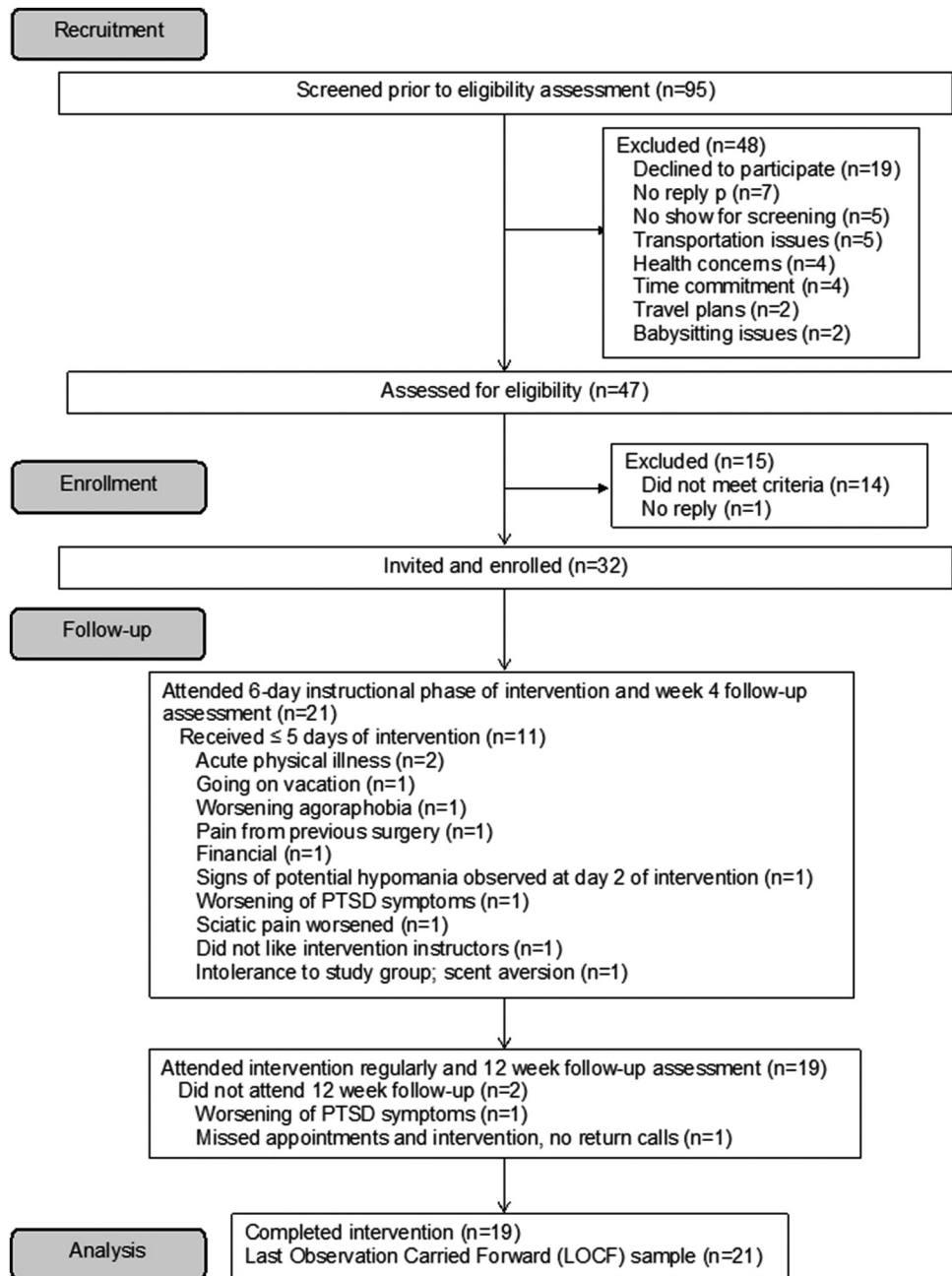


Figure 1: CONSORT flow diagram

SKY may offer physiological benefits via increased parasympathetic drive, reduced sympathetic drive, and calming of stress-related oxidative damage.^[17-20] For further details see the Supplement 1.

We also found that the percentage of participants in our study who experienced clinically meaningful improvement ($n = 8, 42.11\%$) in PTSD symptoms is comparable with response rates with psychotherapy-based interventions (44%).^[21] The response rate observed in this study 12 of 19 (63.16%) is also comparable to the overall PTSD response rate (60%) observed with pharmacotherapy and/or psychological therapies.^[2,3]

The study findings confirm that it is feasible to recruit, enroll, and retain participants with PTSD survivors of a wide range of trauma to a SKY group-based intervention. Our findings should be considered preliminary and need further investigation and confirmation in subsequent adequately powered RCTs. Such studies should include an appropriate active control, matched to group size, facilitator contact, and intervention time.

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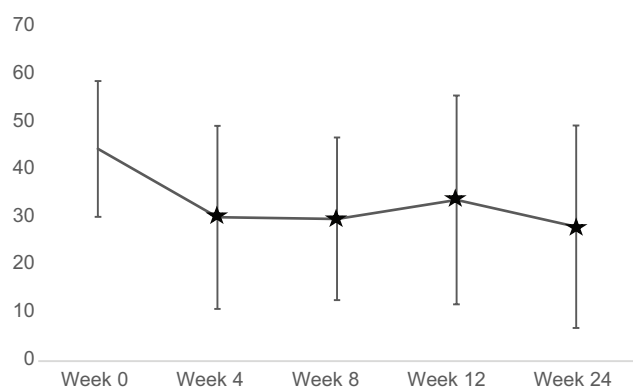


Figure 2: PTSD checklist-5 (PCL-5) scores. Mean PCL-5 scores with standard error bars are plotted for all study assessments (weeks 0, 4, 8, 12, and 24). ★ Indicates a significant difference from baseline

teachers from the International Association of Human Values who taught the intervention to study participants and provided follow-up sessions. We acknowledge Klajdi Puka HBS, Department of Epidemiology & Biostatistics, Western University, London, Ontario, Canada, for his critical support with statistical analysis of the data.

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Conflicts of interest

Ronnie Newman is Director of Research for the nonprofit International Association for Human Values, which provided the SKY PTSD intervention. The other authors report no conflict of financial interest relevant to the subject of this article.

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Supplement

Supplement 1: Sudarshan Kriya Yoga Program in posttraumatic stress disorder: A feasibility study supplement

Inclusion and exclusion criteria

If participants were using antidepressants or antipsychotics as mood augmenting agents, they were required to be at therapeutic doses for a minimum of 4 weeks prior to recruitment; patients currently not taking any medications were also permitted. Participants needed to demonstrate sufficient hearing to be able to follow verbal instructions and to be able to sit without physical discomfort for 60 min. Participants needed to be willing and able to attend all of the 6 initial SKY training sessions as well as 75% of the follow-up sessions.

Individuals were considered ineligible for participation if they (1) were currently participating in a similar trial; (2) currently regularly practicing any other meditation technique; (3) scored severe/extreme on depersonalization (item 29) or derealization (item 30) of CAPS-5; (4) met criteria for another significant mental health disorders including substance use disorder, major neurocognitive disorder, current panic disorder, bipolar disorder and/or personality disorder; (5) considered to be at high risk of suicide as elicited by clinical interview; (6) psychotic episodes within the past 12 months; (7) had a traumatic brain injury (TBI), as defined by loss of consciousness for more than 20 minutes and/or Glasgow Coma Scale score less than or equal to twelve; (8) serious cardiovascular disease in the past 12 months (i.e., myocardial infarction, stroke, transient ischemic attack, and uncontrolled hypertension), or a past history of neurological disease (including Parkinson’s Disease), seizures, or diabetic neuropathy; (9) major surgery within 6 weeks prior to enrollment, or a scheduled major surgery during the intervention period; (10) pregnant women, or women who had given birth within the past 12 weeks.

Outcomes of last observation carried forward analysis

For comparison, all statistical analyses were completed for both a completers sample and last observation carried forward sample (LOCF). Participants included in the completers sample ($n=19$) completed all 12 weeks of the study intervention and attended a week 12 follow-up assessment. Participants included in the LOCF sample ($n=21$) attended at a minimum the first full week of the study intervention and attended a week 4 follow-up. Results of the LOCF analyses are included below in Supplementary Tables 1-4.

Adverse effects and participant feedback

One patient was observed to have potential signs of hypomania including elated mood and talkativeness at day 2 of the intervention and hence it was decided to withdraw this participant from the study to prevent further escalation

Table 1: Description of participant demographics at baseline, last observation carried forward sample ($n=21$)

Age (range), mean (SD)	25-79, 51.9 (13.2)
Gender	<i>n</i> (%)
Female	18 (85.7)
Male	3 (14.3)
Ethnicity	
Caucasian	19 (90.5)
Other	2 (9.5)
Education	
High school or less	8 (38.1)
Postsecondary	13 (61.9)
Relationship	
In a relationship	9 (42.9%)
Not in a relationship	12 (57.1)
Occupation	
Employed	7 (33.3)
Unemployed	9 (42.9)
Retired	5 (23.8)
Trauma	
Single exposure	6 (28.6)
Multiple exposures	15 (71.4)
Trauma type	
Sexual abuse	10 (47.6)
Physical abuse	6 (28.6)
Emotional abuse	4 (19.0)
Rape	4 (19.0)
Motor vehicle accident	3 (14.3)
Work related	3 (14.3)
Death of a loved one	2 (9.5)
Witnessed death	1 (4.8)
Animal attack	1 (4.8)

SD=Standard deviation

of symptoms. It was later confirmed by the treating psychiatrist that for this participant mood instability was a feature of her PTSD pathology. Hence, this drop out was considered to be unrelated to study intervention.

A minority of the participants (4 out of 32) withdrew from the study due to adverse events possibly related to the intervention. Two participants withdrew due to worsening of underlying symptoms of PTSD. One of these was able to complete the six instructional days, as well as some follow-up sessions but withdrew prior to the week 4 assessment as they experienced hypervigilance, flash backs, insomnia, anxiety, panic attacks, and a rapid heart rate. The other participant withdrew following the week 8 follow-up assessments due to tingling in the legs, flashbacks, and a running nose. The other two possible intervention related withdrawals were due to experiencing worsening of pre-existing sciatic pain, and disliking the course instructors.

Other participant reported side effects including increased stress, anxiety or agitation, tingling or numbness in the hands, arms, legs, or feet while practicing SKY, arm pain,

Table 2: Clinical outcomes analysis last observation carried forward sample (n=21)

	Baseline	Change from baseline to week 12			Change from baseline to week 24		
	Mean (SD)	Mean (SD)	P	Cohen's d	M (SD)	P	Cohen's d
PCL-5	45.24 (15.01)	-10.19 (13.45)	0.002	0.54	-13.90 (5.34)	<0.001	0.72
HAM-D	20.33 (6.54)	-1.10 (5.19)	0.345	0.15	-3.43 (6.65)	0.028	0.42
BDI	25.33 (8.54)	-3.95 (12.76)	0.171	0.32	-4.81 (13.30)	0.113	0.37
HAM-A	27.33 (8.75)	-2.86 (7.89)	0.113	0.27	-6.14 (10.21)	0.012	0.54

Baseline mean values (M), SD, the change in mean scores from baseline to week 12 and baseline to week 24, and the results of a paired samples t-test from week 0 to week 12, and week 0 to week 24 as well as effect size (Cohen's d). Negative values denote improvement, bolded values denote $P < 0.05$. PCL-5=PTSD Checklist- 5, HAM-D=Hamilton Depression Scale, BDI=Beck depression inventory, HAM-A=Hamilton Anxiety Rating Scale, SD=Standard deviation

Table 3: Blood marker outcomes analysis (n=19)

	Baseline	Change from baseline to Week 12			Change from baseline to week 24		
	Mean (SD)	Mean (SD)	P	Cohen's d	Mean (SD)	P	Cohen's d
CRP	1077.60 (1274.48)	-277.18 (608.06)	0.062	0.23	-279.81 (665.65)	0.084	0.26
IL-6	17.20 (53.39)	12.78 (46.40)	0.246	-0.16	-8.24 (42.66)	0.411	0.21
MDA	2.31 (1.30)	-0.39 (1.09)	0.139	0.41	-0.40 (1.52)	0.269	0.41
TAC	0.50 (0.21)	0.53 (1.15)	0.062	-0.67	0.57 (0.81)	0.007	-0.94
Glutathione	0.59 (0.80)	0.26 (1.35)	0.404	-0.27	-0.16 (0.72)	0.366	0.25

Baseline mean values (M), SD, the change in mean scores from baseline to week 12 and baseline to week 24, and the results of a paired samples t-test from week 0 to week 12 and week 0 to week 24, and effect size (Cohen's d) are presented. Negative change values denote improvement, except TAC and Glutathione, bolded values denote $P < 0.05$. No LOCF sample is provided for comparison as only completers blood samples were analyzed. LOCF=Last observation carried forward, TAC=Total antioxidant capacity, MDA=Malondialdehyde, IL-6=Interleukin 6, CRP=C-reactive protein, SD=Standard deviation

Table 4: Other physiological outcomes analysis last observation carried forward sample (n=21)

	Baseline	Change from baseline to week 12			Change from baseline to week 24					
	Mean (SD)	Mean (SD)	P	Cohen's d	Mean (SD)	P	Cohen's d			
BMI (n=20)	32.53 (5.15)	-0.06 (1.06)	0.800	0.01	0.08 (1.45)	0.818	-0.02			
Systolic BP (n=21)	126.76 (14.79)	1.18 (9.87)	0.591	-0.07	-0.29 (12.67)	0.917	0.02			
Diastolic BP	78.93 (6.98)	0.61 (4.75)	0.566	-0.10	-1.93 (8.12)	0.288	0.31			
Respiration Rate	13.68 (4.69)	-0.17 (4.00)	0.844	0.03	-1.24 (2.69)	0.048	0.26			
Completers sample										
		n=13				n=15				
BMI	31.80	4.89	-0.09	1.33	0.804	0.12	0.18	1.65	0.685	-0.05
		n=19				n=18				
Systolic BP	127.40	15.34	1.30	10.40	0.593	-0.08	0.47	13.27	0.881	-0.01
Diastolic BP	78.65	7.28	0.67	5.00	0.568	-0.10	-2.11	8.78	0.323	0.35
Respiration rate	13.26	4.58	-0.19	4.22	0.845	0.04	-1.52	2.81	0.035	0.46

Baseline mean values (M), SD, the change in mean scores from baseline to week 12 and baseline to week 24 with SD, the results of a paired samples t-test from week 0 to week 12 and week 0 to week 24 and Cohen's d are presented for both the LOCF and completers sample. Negative change values denote improvement. LOCF=Last observation carried forward, SD=Standard deviation, BMI=Body mass index, BP=Blood pressure

headaches, dizziness or light headedness, stiffness and/or pain in the neck, increased fatigue, feeling faint, crying, feeling detached from the body, and feeling addicted to the SKY technique. None of these side-effects were severe enough for the participants to want to withdraw from the study.

Majority (17 of 21) of the participants who attended SKY reported a variety of subjective positive effects. Most commonly reported (n=8) was being more relaxed, peaceful, or calm after practicing SKY. Seven participants

enjoyed the group aspect of the program and found this to be a positive opportunity for support. Seven participants felt SKY provided them with a tool that could help them to deal with stress and crises. Three participants felt SKY improved their sleep. A decrease in pre-existing pain was reported by 3 participants including relief in general body pain, knee pain, and tingling in hands. Less common improvements subjectively reported by two participants included having more energy, a more positive outlook on life, more focus or clear-headedness, and improved

self-confidence. Two participants reported that SKY helped to relieve their symptoms of PTSD when they had tried many other interventions that did not work. Rare improvements reported by only one participant included hope for the future, life changing experience, exceptional and continuous mental health benefits, lightness of spirit, decreased depression, decreased anxiety, and decreased tinnitus.

Potential mechanisms of posttraumatic stress disorder improvement due to Sudarshan Kriya Yoga

PTSD is associated with a number of biological features which likely cause or maintains the symptoms of the disease. Such physiological changes include impaired autonomic control including increased sympathetic and reduced parasympathetic output;^[1] impaired neuroendocrine control,^[1] which in turn likely affects the inflammatory system including cytokines^[2] and associated anti-inflammatory molecules.^[3] While it is not yet clear which of these associated physiological changes are “up-stream” or “down-stream” in the etiopathological pathway, a successful treatment which affects one or more of these physiological systems, will likely have whole body benefits and could be a predictor of short-term and long-term benefits.

Ancient yoga practices have been adopted in most countries worldwide to help improve health and wellbeing. Two central aspects of yoga practice are physical postures (asanas) and breathing exercises (pranayamas). Research suggests different yogic breathing practices yield to beneficial physiological effects such as increased parasympathetic drive and the calming of stress response systems including neuroendocrine release of hormones^[4] in various healthy and diseased populations. Sudarshan Kriya Yoga (SKY) may offer additional benefits in individuals suffering from PTSD.

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