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Research Article

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Multi-Component Yoga Breath Program for Vietnam Veteran Post Traumatic Stress Disorder: Randomized Controlled Trial

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Abstract

Objective: It is appropriate to acknowledge that despite treatment, Post Traumatic Stress Disorder (PTSD) continually debilitates many Vietnam veterans. Although therapies have been developed, remission is hard to obtain with either pharmacotherapy or psychotherapy. Evidence has suggested that some forms of yoga may reduce sympathetic overactivity and increase parasympathetic activity, thereby improving stress resilience. Sudarshan Kriya Yoga (SKY) was hypothesized in this study to be potentially useful for lessening symptom severity on the Clinician Administered PTSD Scale (CAPS) in Vietnam veterans with treatment-resistant PTSD.

Method: Fifty male Vietnam veterans with PTSD (DSM-IV) were referred to the study. Thirty-one participants meeting criteria were subsequently randomized to either the SKY Intervention (adapted for veterans) group or a 6-week wait-list Control. The intervention consisted of 22 hours of guided group yoga instruction over a duration of 5 days, followed by a 2-hour group session which was held weekly for the first month and monthly thereafter for the following 5 months. Severity of PTSD symptoms was assessed at pre-intervention, 6-week post-intervention, and 6-month follow-up for both groups using the CAPS. Additional questionnaires to measure PTSD, depression, quality of life, and alcohol consumption were administered at pre-intervention, post-intervention and follow-up time frames as well.

Results: Twenty-five of the thirty-one enrolled participants completed the study, of which 14 received immediate intervention while 11 constituted the Control group. The Intervention group showed a significant decrease in CAPS scores 6 weeks following intervention completion, while the Control group had zero decline within this period. At this point, the Control group received the SKY intervention, and also improved significantly on the CAPS. These improvements were maintained in both groups 6 months following receipt of treatment. The results indicate that multi-component interventions with yoga breath techniques may offer a valuable adjunctive treatment for veterans with PTSD.

Keywords

Veteran; Yoga; Trauma; Breathing; Post traumatic stress disorder; Stress; Mind-body

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Introduction

Posttraumatic stress disorder (PTSD) can be understood as an anxiety disorder occurring subsequent and in response to a traumatic event. The disorder results from directly experiencing, witnessing, or hearing about an event or threat that involves actual or threatened death or serious injury. A constellation of symptoms and behaviors then manifests, such as persistent re-experience of the trauma, avoidance of any reminders of the trauma, numbing of positive emotions, social withdrawal, and periods of increased autonomic arousal. Diagnostic symptoms of PTSD [1] are listed in Figure 1.

Epidemiological studies suggest the lifetime prevalence of PTSD [2,3] to be somewhere in the range of 8% and 12% and note that 10%–50% of severe trauma survivors develop chronic PTSD. Chronic PTSD may persist for years if untreated [2-4]. A multitude of comorbid psychiatric disorders contribute to its morbidity and mortality with 80% of the individuals meeting criteria for PTSD also meeting criteria for at least one other DSM-III-R disorder [2]. As such, PTSD can be significantly and pervasively disabling, resulting in severe impairment in occupational and social functioning [3-5], as well as higher incidences of suicidality [3,6] and medical illness [7].

A wide range of treatments are used for PTSD, including pharmacotherapy (eg. fluoxetine, paroxetine, sertraline, venlafaxine) [8-12], individual and group psychotherapy (cognitive-behavioral, supportive, dynamic, and others) [13-16], psychosocial rehabilitation [17], psychological debriefing [18,19], virtual reality therapy [20,21], acupuncture [22] and marital and family therapy [23]. In Australia, the Department of Veterans Affairs provides extensive treatment services for Australian Vietnam veterans and their families. These programs report modest but clinically significant improvements, with

Symptoms
After exposure to a traumatic event
response involving intense fear, helplessness, or horror*
Traumatic event persistently re-experienced through
recurrent and intrusive recollections of event**
recurrently distressing dreams of event***
acting or feeling as if event was reoccurring (including reliving the experience, illusions, hallucinations, dissociative flashback episodes)****
intense psychological distress at exposure to cues symbolizing or resembling event
physiological reactivity on exposure to cues symbolizing or resembling event
Persistent avoidance of stimuli associated with trauma (not present before trauma)
efforts to avoid thoughts, feelings, or conversations associated with trauma
efforts to avoid activities, places, or people that arose recollections of trauma
inability to recall an important aspect of trauma
markedly diminished interest or participation in significant activities
feelings of detachment or estrangement from others
restricted range of affect
sense of a foreshortened future
Persistent symptoms of increased arousal
difficulty falling or staying asleep
irritability or outbursts of anger
difficulty concentrating
hypervigilance
exaggerated startle response

*In children, may be expressed by disorganized or agitated behaviour
**In young children, repetitive play with themes or aspects of trauma may be expressed
***In children, may be expressed as frightening dreams without recognizable content
****In young children, trauma-specific re-enactment may occur

Figure 1: Symptoms of Post-traumatic Stress Disorder according to the DSM-IV-TR.

gains maintained to 9-month follow-up [24,25]. Nevertheless, despite active treatment, many veterans with PTSD remain chronically ill and disabled [26-29].

Preliminary evidence suggests that yoga practices may relieve symptoms of stress, anxiety, PTSD, and depression [30-35]. This is based on studies of Generalized Anxiety Disorder [36], PTSD [35,37,38] and depression [34,37-41]. Benefits of yoga based practices have been attributed to their ability to improve sympatho-vagal balance by reducing the over activity of the sympathetic system and increasing the underactivity of the parasympathetic system in these disorders [38,42-46]. Slow paced breathing and other pranayamic breathing techniques incorporated in yoga courses such as *Sudarshan Kriya Yoga* (SKY) modulate the autonomic nervous system through changes in the patterns of breathing [42,47]. Such voluntary changes in breathing have also been correlated with changes in negative emotional states involved in PTSD [48]. In this way, pranayamic breathing may improve the balance and resilience of the stress response system [47,49-51]. These effects suggest a potentially significant contribution to the reduction of anxiety, depression, and hyperarousal in individuals with PTSD who are given training in yoga breathing. Despite encouraging results these studies have not provided definitive data on the efficacy of yoga breathing due to methodological limitations, such as the absence of adequate control groups [30-34], low statistical power due to sample size [31,33,34] and the presence of clinician and patient expectations of therapeutic initiatives [34]. The current paper attempted to relieve these concerns, however, these factors continue to be problematic. The intervention chosen for this study differs from previous studies in that participants were taught more complex, advanced breathing practices. In addition, the program was modified to be culturally acceptable to veterans.

Specifically, the SKY intervention is a yoga-based stress reduction program sponsored by the Art of Living Foundation, a non-profit organization [52]. The yogic breathing and techniques incorporated in the program have been postulated to impact psychological and stress-related symptoms and/or impairments by balancing the autonomic nervous system [53]. It is often practiced within programs that combine *pranayama* (yogic breathing), *asanas* (yoga postures), and meditation [54]. The Sudarshan Kriya practice is comprised of three rounds of cyclical breathing (no pause between inhalation and exhalation), each round using three different breathing rates. The first is slowly paced with ten breaths per minute, followed by a medium speed cycle with 15-20 breaths per minute and finished with a fast paced cycle of 60 breaths per minute. The Sudarshan Kriya Yoga course is a manualized 22-hour program that includes psychoeducation about stress reduction and group processes [53].

Evidence in support of SKY breathing includes case reports of patients with abuse-induced PTSD improving with SKY breathing in combination with individual and group psychotherapies [55-57], controlled trials [37], and one larger randomized controlled trial (RCT) [58]. Janakiramaiah et al. (2000) reported positive findings in a 4-week RCT with 45 hospitalized patients diagnosed with Major Depressive Disorder. In this trial patients were randomly assigned to three groups: bilateral electroconvulsive therapy (ECT) administered three times a week; imipramine (IMN), 150 mg being consumed at night; or practice of Sudarshan Kriya Yoga (SKY) six times a week. Mean Hamilton Rating Scores for Depression (HRSD) dropped significantly in all 3 groups by the end of 4 weeks. Concerns raised about this data must be directed at the lack of control built into the study for patient expectation. Nevertheless, based on the severity of the patients' depression (baseline HRSD 22.7 to 26.7), the 67% rate of remission (defined by HRSD < 8.0) with SKY practice is notable.

In view of the preliminary evidence for the efficacy of yoga breathing for symptoms of PTSD, the authors conducted a randomized controlled study of the effects of multi-component Sudarshan Kriya Yoga as an adjunctive treatment for PTSD in Australian Vietnam Veterans who were disabled by chronic treatment-resistant PTSD.

Materials and Methods

Objectives

The primary objective of this study was to evaluate the effects of the SKY intervention on symptoms of PTSD as measured by changes in the Clinician Administered PTSD Scale (CAPS) [59] scores. It was hypothesized that participants to whom the SKY intervention was administrated would experience significantly greater reductions in the severity of PTSD. Secondary outcome measures included the CES-D [60], WHOQoL [61], AUDIT [62], and PCLM-17 [63].

Recruitment of participants

Participants were recruited between March 1 and July 15, 2005 through referral by author JC from her Private Practice Psychiatry Clinic, as well as through written and telephone advertisement. Participants were treated in accordance with the Australian National Health and Medical Research Councils guidelines and ethical principles. Ethics approval was received from the Research Ethics Committee of the University of Queensland. Each participant received full information about the nature, purpose, risks and benefits of the study and was informed that she/he could withdraw consent from the study at any time. All participants in the study had signed the informed consent prior to the commencement of any study procedures.

Randomization

Subjects meeting inclusion and exclusion criteria were ranked according to baseline CAPS and assigned to a control or treatment group using a computer generated randomization procedure. Numbers were used to assign one participant from each successive pair into each of the study groups.

Blinding (masking)

It was not possible to blind the participants about the intervention, but each participant was asked not to disclose his or her assigned randomization group to the CAPS assessor. The CAPS administrator and those who scored tests and performed data entry were blinded to group assignment. The CAPS assessor was not a SKY practitioner or teacher.

Participant characteristics

The study population consisted of male Vietnam veterans (average age 58 years) classified as disabled due to service-related PTSD. All had previously received multiple trials of individual and group therapy, cognitive therapy, and numerous trials of psychotropic medications. At the time of entry into this study, all participants were being treated with multiple medications including serotonin reuptake inhibitor antidepressants. Additional psychotropics including buspirone, atypical antipsychotics, and/or mood stabilizers were also being used to manage this complicated and very symptomatic patient population. Medication intake was kept unaltered for the duration of the study.

Method

Following randomization, PTSD (CAPS and PCLM-17), depression (CES-D), quality of life (WHOQoL), and alcohol consumption (AUDIT) were then assessed for both groups (T1). Following evaluations, the randomized Intervention group entered the SKY intervention, which consisted of 22 hours of guided yoga instruction over a period of 5 days. After the intervention a 2-hour group session was held weekly for the first month and monthly thereafter for the following 5 months. At the end of a 6-week waiting period after the Intervention group completed the workshop, the Control group did another pre-evaluation on scale measures (T2) and subsequently received the SKY Intervention. CAPS scores were assessed for both groups at 6-weeks post-intervention and 6-month follow-up as this was designated the primary outcome measure. The remaining scales were assessed at a post-intervention period, roughly 1-month after completing the SKY intervention.

The SKY intervention

A standardized, manualized SKY program adapted for veterans was taught by certified SKY instructors Dr. Richard Brown and Ms. Bernice Bailey. The SKY program was modified for veterans by removing religious content, adding joint mobility exercises, and addressing warrior values. The intervention was administered over 5 days for a total of 22 hours. Subsequently, participants were provided with a 2-hour group follow-up session with a yoga instructor once weekly for the first month and once monthly thereafter for a total of 6 months. They were encouraged to maintain a daily 30-minute yoga breath practice on their own time. The 5-day course was videotaped and audio recorded (Figure 2) and the program was structured as follows.

Day 1 began with a 10-minute discussion of the nature of stress. Training consisted of three distinct breathing cycles along with standing and joint mobility exercises. Breathing began with *Ujjayi* (Victorious Breath), which consists of creating a sound during inhalation and exhalation resembling ocean waves. 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. This technique is performed at a rate of 3 to 6 breath cycles per minute. 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. A second breathing technique, *Bhastrika* (Bellows Breath), was undertaken consisting of three rounds, each round comprised of 20 forceful breaths at a rate of 50 to 60 breaths per minute. Each round is followed by a period of rest for 30 seconds. In this exercise specific arm postures are used to augment force of inhalation and exhalation. 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.

Day 2 of the program began with mild yoga stretches (Figure 3) with Basic *Ujjayi* followed by Yoga Nidra which entails guided meditation instructing a body scan while lying supine with eyes closed. A prerecorded audiotape assisted training in *Sudarshan Kriya*, consisting of voice-paced cyclical breathing at slow, medium, and fast rates. This was followed by a body scan and rest. Psychoeducation on stress management and homework from Day 1 were discussed for 10 minutes. The day included discussion of the veterans' experiences during yoga breathing (15 minutes), a 60-minute group process in which veterans shared their life stories and a self-awareness process of being asked, "Who are you?" repeatedly, culminating in a meditative state (20 minutes).

Day 1: 3 hours	**Day 2: 5 hours**	**Day 3: 5 hours**
Discuss stress management (10 minutes) 3-stage Ujjayi training Bhastrika training "Om" chant Lunch 30 minutes Repeat breath practices Homework: practice Ujjayi and Bhastrika. Record thoughts about a life issue.	Mild yoga stretches with slow Basic Ujjayi, no counts, no holds. Yoga Nidra: guided body scan lying supine, eyes closed. Discuss homework and stress management (10 minutes) 3-stage Ujjayi, Bhastrika, 'om' Sudarshan Kriya Training (40 min), body scan, rest. Discuss experiences during the yoga breathing (15 min) Lunch: 30 min Group process: share life stories (60 min) Break: 15 min Group process: self-awareness (20 min). Homework: Ponder question about a life issue.	Yoga stretches/Basic Ujjayi Discuss homework and stress management (5 min) Group process: enthusiasm (10 min) 3-stage Ujjayi, Bhastrika, 'om,' long Sudarshan Kriya, body scan, rest. Discuss experiences during yoga breathing (15 min) Lunch: 30 min Alternate Nostril Breathing training (10 min). Repeat Ujjayi, Bhastrika, 'om.' Homework: reflect on a life issue.
Day 4: 5 hours	**Day 5: 4 hours**	
Mild yoga stretches with Basic Ujjayi, Yoga Nidra Homework review (5 min) 3-stage Ujjayi, Bhastrika, 'om,' long Sudarshan Kriya, body scan, rest. Discuss experiences during breath practice. Alternate Nostril Breathing. Lunch: 30 min. Warrior Virtue Process.(15 min total) Group discussion of Warrior Virtues: loyalty, responsibility, perseverance, honesty, stoicism, and honor. Discuss how learning warrior virtues related to their having gotten an opportunity most others do not have. Discuss the benefits of military service and what they got from it. Teach home practice of yoga breathing. Homework: the home practice.	Yoga stretches/Basic Ujjayi Discuss homework (5 min) Participants review what they have learned, information about yoga courses, follow-up sessions. Instructions for home practice: a. 3-stage Ujjayi, Bhastrika, 10-minute Sudarshan Kriya, rest, (total 30) min every morning. b. Alternate Nostril Breathing 10 to 20 min later in the day. Distribute CD of instructor's voice leading breath practices. Pot luck shared meal. Goodbyes.	

Figure 2: Daily Course Schedule of SKY Intervention Workshop.

Day 1:
Standing exercises, joint mobility and stretches.

Day 2-5:
Joint mobility and muscle stretches: neck, shoulders, wrists, sides, upper and lower spine, hips, knees, ankles.

Cat pose, Up Dog and Down Dog with The Pump (up and down hip movements), Cat stretch, Child's Pose.

Lying prone with arms and legs stretched out. Alternate contralateral arm and leg raises.

The Locust: Lying prone, raising both legs with one fist in each groin creating acupressure.

Sphinx position raising upper body from floor.

Cobra with head facing downward while upper body is raised from the floor.

Superman: Lying on the belly, raising both arms and legs.

Supine: Raise each knee to the chest alternating sides.
Hug both knees to the chest and rock forward and backward. Then rock from side to side.

Spinal twists, Pelvic Bridge, Hip relaxation, Stretch and rest supine.

Additional practices used:

Alternate nostril breathing: Day 2 – 5 min; Day 3 – 8 min; Day 4 – 10 min.

Figure 3: Physical practices used during the SKY intervention.

Day 3 included 5-minutes psychoeducation on stress management and an enthusiasm group meditative process in which participants re-experience childhood enthusiasm (10 min) followed by yoga stretches with Basic *Ujjayi*, 3-Stage *Ujjayi, Bhastrika*, chanting 'om' long *Sudarshan Kriya*, body scan, rest, verbalization of experiences, and training in Alternate Nostril Breathing.

Day 4 included yoga stretches with Basic *Ujjayi*, Yoga *Nidra*, 3-Stage *Ujjayi, Bhastrika*, chanting 'om' long *Sudarshan Kriya*, body scan, rest, verbalization of experiences, Alternate Nostril Breathing, the Warrior Virtues Process (15 minutes discussing Warrior Virtues such as loyalty, responsibility, perseverance, honesty, stoicism, and honor), and instruction for solitary home practice. Day 5 provided yoga stretches with Basic *Ujjayi*, review of home practice, and discussion of what had been learned. Each participant was given a CD recording of the instructor's (RP Brown) voice pacing the breath practices for use at home.

Measures

The MINI-Plus [64] was administered at baseline (pre-treatment) along with the CAPS, CES-D, PCLM-17, WHOQoL, and AUDIT. The Control group was evaluated a second time using these measures (excluding the MINI-Plus) just prior to receiving the SKY intervention (pre-treatment, time 2). At 6 weeks and 6-months after baseline assessments, a CAPS was administered again (Figure 4). The CES-D, PCLM-17, WHOQoL and AUDIT were evaluated approximately 1-month after each group completed the intervention.

Primary outcome measure, CAPS: The Clinician Administered PTSD Scale is a 30-item structured interview corresponding to DSM-IV criteria for PTSD. This measure is utilized to make a current (within the past month) or lifetime diagnosis of PTSD while assessing symptoms over the past week. In addition to rating the frequency and intensity of 17 PTSD symptoms, questions target the impact of symptoms on social and occupational functioning to evaluate severity of PTSD symptomology. The structured interview takes 45-60 minutes. Scores can range from 0 to 88, with assessments <19 considered asymptomatic and levels >80 representing extreme PTSD symptomology [65]. It is considered the "gold standard" in assessing PTSD.

MINI-Plus: The Mini International Neuropsychiatric Interview-Plus, a structured interview, assesses all symptom criteria of 24 major Axis I diagnostic categories, one Axis II disorder, and suicidality as defined within the DSM-IV and ICD-10. It is used to determine which of these clinical diagnoses an individual may present.

CES-D: The Center for Epidemiological Studies Depression Scale is a non-diagnostic self-report scale containing 20 items assessing current depressive symptomatology. Items include general statements depicting affect and emotional reactivity. Participants are asked to indicate on a Likert scale from 0 (rarely/ none of the time/ less than one day) to 3 (most or all of the time/ 5-7 days) how often they have felt a certain way in the past week. Scores range from 0 to 60, 70-74% of those who score above 16 meeting clinical depression criteria [60,66]. The scale demonstrates good construct validity, internal consistency, adequate test-retest reliability, and good concurrent validity by clinical and self-report criteria [60].

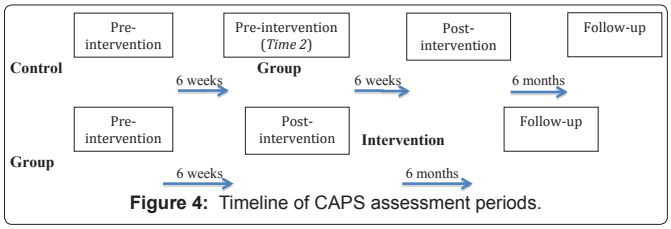

Figure 4: Timeline of CAPS assessment periods.

PCLM-17: The Posttraumatic Stress Disorder Checklist Military Version is a 17 item self-report scale covering all DSM-IV diagnostic criteria for current PTSD including re-experiencing an event, avoidance and emotional numbing, persistent increased arousal, duration and impairment. Items on the PCLM-17 describe PTSD symptomatology, each item being rated on a Likert scale from 1 (not at all) to 5 (extremely). The score is derived from summing the 17 items and can range from 17 to 85.

WHOQoL-BRIEF: The Australian Version of the World Health Organization's Quality of Life inventory is a 26-item scale with ratings of 1 to 5 on each item measuring quality of life as a result of the impact of disease. This measure includes four distinct domains: physical health, psychological, social relationships and environment. It has excellent test-retest reliability, excellent inter-rater reliability, and good concurrent validity for domains 1 (physical health), 2 (psychological) and 4 (environment), but relatively poor concurrent validity for domain 3 (social relationships) [67].

AUDIT: The Alcohol Use Disorders Identification Test (AUDIT) has been developed by the World Health Organization for the purpose of screening for excessive drinking. The Department of Veteran Affairs (DVA) version is designed for early detection of high risk drinking. It is suitable for self-administration and contains 10 items clustering into three domains: hazardous alcohol use, dependence symptoms and harmful alcohol use. Each item is rated with a score from 0 to 4, where a higher score indicates current acute excessive alcohol intake. The score of 8 has been suggested as a cut-off point, the scale demonstrating good sensitivity at this cut-off [68]. The scale displays high internal consistency, good test-retest reliability and overall adequate validity for clinical use [68].

Statistical methods

Baseline data is displayed as Mean, *M* (Standard Deviation, *SD*) for continuous variables and Number (percentage) for categorical variables (Table 1). Comparison between groups at baseline was undertaken using Student's t-test (for continuous data) and Fisher's Exact Test (for categorical data). The difference between CAPS scores for treatment groups at 6-week and 6-month assessment periods was analyzed using an analysis of covariance, in which baseline scores were designated as a covariate. There was no adjustment for multiple comparisons [69]. A Student's t-test was performed to evaluate the significance of CAPS mean scores at follow-up periods between the two groups. For the remaining secondary outcomes, a paired-samples t-test assessed the significance between pre-treatment and post-treatment scores for both groups. Participants' outcome measures were analyzed in accordance with their assigned groups, regardless of treatment compliance. Statistical analysis was performed using IBM SPSS Statistical Software version 20.0.

A Last Observation carried Forward (LOCF) analysis was undertaken with all participants for whom an assessment on the scales utilized was recorded at baseline. When participants did not have a score following their baseline evaluation, their last reported/ observed score was used. We chose this more conservative analysis as opposed to the Completer Analysis (only those who completed entire intervention analysed) as it generally gives a better understanding of the overall impact for all participants that initiated treatment due

to it considering all participants but only acknowledging reported scores; by utilizing a LOCF, it suggests that participants may not have had any alterations from the intervention. This analysis method, of course, is less likely to show benefit of the treatment and penalize treatments with higher dropout rates.

Results

Of the 50 veterans recruited, 31 met eligibility criteria, completed pre-tests and were randomized to either the immediate Intervention or Control group (Figure 5). Of the 16 assigned to the Intervention Group, one could not perform yoga breathing due to severe dyspnea secondary to advanced chronic obstructive pulmonary disease (COPD). He subsequently withdrew consent from the study. Another subject refused to participate in testing after the intervention, in part, related to specific worries that documentation of his improvements could affect his disability benefits. Out of 15 assigned to the Control Group, a total of four participants withdrew from the study during the waiting period. Reasons included work schedule conflicts, social anxiety, pre-existing severe dyspnea, and failure to participate in the baseline testing. Thus, a total of 25 participants completed the study.

Within group analyses

Table 1 compares baseline scores for each group at the first assessment. Table 2 displays the CAPS mean scores at 6 weeks post-intervention and 6-month follow-up. Note that 6-week and 6-month follow-up questionnaires were administered respective to when each group finished the intervention. Table 3 outlines the significance between pre-treatment and post-treatment scores amongst secondary endpoints.

Comorbidity

At baseline 14 participants received a diagnosis of either current Major Depressive Disorder or current Dysthymia. Anxiety disorders diagnoses were also common and included Generalized Anxiety Disorder and Panic Disorder with/without Agoraphobia. Prevalence of comorbid conditions are shown in Table 4.

CAPS

Initial average pre-treatment CAPS score at screening for the Intervention Group was 56.3 (SD=12.3). After completion of the SKY intervention this group displayed significant declines on CAPS, reducing to a mean of 42.1, SD=18.2 ($t(13)=3.19$, 95% CI 4.6 to 23.7, $p<0.01$) at a 6-week follow-up. This was further significantly decreased at 6-month follow-up to 26.2, SD=14.8 ($t(13)=3.59$, 95% CI 6.4 to 25.5 $p<0.01$, when compared to 6-week post-intervention

Table 1: Mean age of subjects and test scores at Baseline.

Characteristics at Baseline	Intervention Group (n=14)	Wait-List Control (n=11)	P
	Mean (Standard Deviation)		
Age (years)	58.5 (3.8)	58.4 (4.8)	0.94
CAPS	56.3 (12.3)	56.6 (18.7)	0.96
CES-D	24.7 (13.6)	29.1 (9.2)	0.39
PCLM-17	53.0 (13.8)	53.1 (12.7)	0.99
WHOQoL	85.8 (10.0)	82.4 (8.7)	0.38
AUDIT-Total Alcohol consumption Alcohol dependence Alcohol related problems	12.1 (6.0) 7.4 (3.1) 1.4 (1.6) 3.4 (2.5)	14.9 (10.3) 7.7 (4.2) 2.6 (3.7) 4.5 (4.0)	0.41 0.80 0.25 0.40

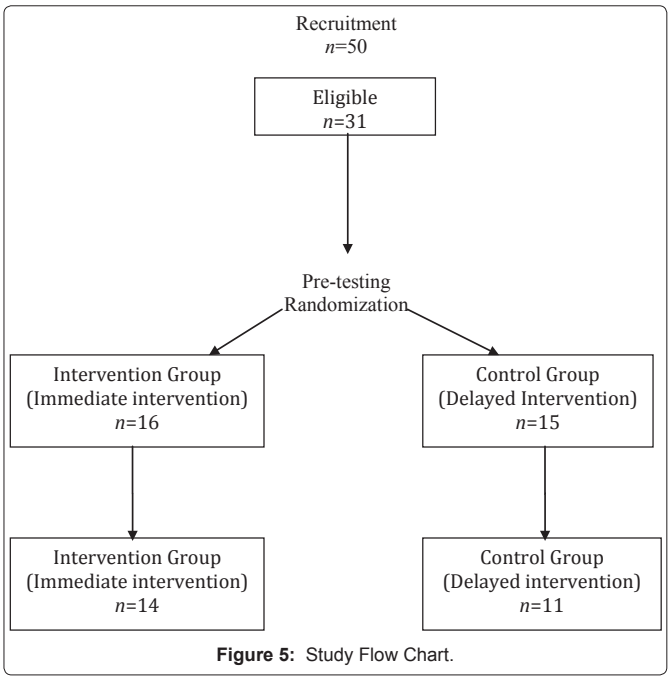

Figure 5: Study Flow Chart.

results). A one-way repeated measures ANOVA revealed these gradual declines were significant, Wilks's $\lambda=.11$, $F(2,12)=50.84$, $p<.00$, partial $\eta^2=.89$. The Control Group received a CAPS evaluation at similar time periods with the inclusion of a second pre-intervention assessment immediately before receiving treatment. At baseline, their average CAPS score was 56.6 (SD=18.7), which did not change in the later pre-testing (time 2) assessment (M=56.6, SD=18.9). Changes in CAPS scores from the second pre-testing (time 2) to the 6-week post-intervention assessment revealed a significant difference, $t(10)=3.80$, 95% CI 10.7 to 41.1, $p < .00$. An LOCF was performed for three participants whereby 6-week scores were carried forward to 6-month post-intervention evaluations. At 6-months, no significant change was noted from 6-week assessments ($t(10)=0.00$, 95% CI -14.3 to 14.3, $p=1.00$). Amongst all evaluation periods overall, changes in the Control Group's average CAPS scores were significant, Wilks's $\lambda=.33$, $F(3,8)=5.50$, $p=.02$, partial $\eta^2=.67$. Within group CAPS assessments are displayed in Table 2.

Despite both groups having significant changes in CAPS scores overall, they displayed different patterns after completing the SKY course as outlined above. As a result, the authors addressed this finding by completing between group analyses amongst the various time periods. Comparing initial baseline CAPS scores, no significant difference was found between the Treatment and Control groups, $t(23)=-.06$, 95% CI -13.2 to 12.5, $p=.96$. Being assessed on this scale again 6-weeks after, when the Intervention Group had already completed the intervention and just before the Control Group began, significant changes were noted amongst the scores ($t(23)=-1.94$, 95% CI -29.9 to 1.0, $p=.06$). A two-way ANOVA demonstrated there was a significant interaction between the time of assessment and group amongst initial baseline results and the second evaluation, Wilks's $=.83$, $F(1,23)=4.761$, $p=.04$, partial $\eta^2=.17$ (Table 5). An analysis of covariance was conducted to determine whether post-treatment (6-week and 6-month) scores between the Treatment and Control groups differed after controlling for ratings at the initial pre-treatment. A preliminary analysis evaluating the homogeneity-of-slopes assumption indicated that the relationship between pre-treatment

Table 2: CAPS outcomes at assessment periods.

Time of Assessment Group	Pre-intervention (Time 1)	Pre-intervention (Time 2)	6-weeks post intervention	6-months post intervention	F	P
	Mean (Standard Deviation)					
Intervention Group (n=14)	56.3 (12.3)	n/a	42.1 (18.2)	26.2 (14.8)	50.84*	0.00
Wait-list Control (n=11)	56.6 (18.7)	56.6 (18.9)	30.7 (25.9)	30.7 (27.8)	5.50*	0.02

*Significant at 0.05 level

scores and the dependent variable (group assigned) did not differ significantly as a function of the independent variable, $F(1,21)=0.21$, MSE=337.26, $p=.65$, partial $\eta^2= .01$. The ANCOVA was not significant for either post-intervention periods (6 weeks: $F(1,22)=2.60$, MSE=325.2, $p=.12$; 6 months: $F(1,22)=0.30$, MSE=376.5, $p=.59$), suggesting improvement in CAPS evaluations did not differ based on the group assigned. This result was confirmed when independent-samples t-tests did not demonstrate any significant findings when comparing the two groups on their 6-week (Treatment: M=42.1, SD=18.2, Control: M=30.7, SD=25.9, $t(23)=1.29$, 95% CI -6.8 to 29.7, $p=.21$) and 6-month (Treatment: M=26.2, SD=14.8, Control: M=30.7, SD=27.8, $t(14.43)=-0.49$, 95% CI 9.3 to -24.3, $p=.63$) post-intervention evaluations.

CES-D

With a LOCF analysis performed for one drop out who did not complete the CES-D post-intervention assessment, significant reductions were demonstrated in the Intervention Group from baseline (M=24.7, SD=13.6), declining to M=16.8, SD=7.1 ($t(13)=3.45$; 95% 3.0 to 12.9, $p < .00$) at the end of the intervention. A paired-samples correlation revealed that scores at a follow-up assessment approximately one-month after completing the course were strongly correlated to those at the end of the intervention ($r(11)= .85$, $p<.01$), the participant with no immediate CES-D post-assessment being omitted. This corresponds to the significant reduction revealed when comparing baseline evaluations to follow-up (Table 3). The Control Group's average CES-D score was 29.1 (SD=9.2) at the initial evaluation with one participant not completing the assessment at this time, compared to 29.5 (SD=9.7) at the second pre-treatment testing period with all participants. To analyze the effect of the intervention, an analysis of the second pre-intervention results with those reported at the end of the course was conducted and revealed an insignificant change, $t(10)=0.68$, 95% CI -5.0 to 9.4, $p=.52$). Follow-up scores were weakly correlated to scores at the end of the intervention, $r(9)=.24$, $p=.48$. Significant discrepancies were recognized between the second pre-intervention evaluation and follow-up results however, $t(10)=2.78$, 95% CI 1.8 to 15.9, $p=.02$, as demonstrated in Table 3.

There was a significant interaction between the time of assessment and group on the CES-D measure, Wilks's $\lambda=0.72$, $F(1,22)=8.76$, $p=.01$, partial $\eta^2= .28$, represented in Table 5. This table displays that no difference was noted between the two groups in their initial baseline scores, however there was a distinction when comparing the Intervention Group's post-intervention results to those reported by the Control Group just before they received the SKY course. The Intervention and Control groups did not significantly differ in their reported follow-up scores (Treatment: M=16.9, SD=10.5; Control: M=20.7, SD=8.8, $t(23)=-0.98$, 95% CI -12.1 to 4.3, $p=.34$).

PCLM-17

Average PCLM-17 scores in the Intervention Group significantly decreased from 53.0 (SD=13.8) at baseline to 32.1 (SD=6.8) immediately upon course completion, $t(13)=7.43$, 95% CI 14.8 to 26.9, $p < .00$. A paired-samples t-test revealed that there was no significant decline from this group's scores at the end of the course to the follow-up assessment approximately 1-month after completing the intervention, $t(13)=-1.68$, 95% CI -7.8 to 1.0, $p=.12$. There was a moderately strong correlation identified for PCLM-17 results between these two time periods, $r(12)= .76$, $p < .00$. In the Control Group, an insignificant reduction from M=51.2, SD=12.2 to M=50.8, SD=6.9 ($t(10)=0.10$, 95% CI -7.5 to 8.2, $p=.92$) was noted from pre-intervention Time 1 to Time 2. Comparing Time 2 evaluations to those immediately after the course was completed revealed no significant changes, $t(10)=.10$, 95% CI -7.5 to 8.2, $p=.92$. Similar to the outcomes witnessed in the Treatment Group, assessing the Control Group's post-intervention scores with those reported at a later follow-up demonstrated a significant result, $t(10)=5.1$, 95% CI 7.2 to 18.6, $p < .00$, having a moderately strong correlation as well, $r(9)= .74$, $p=.01$. An analysis of average PCLM-17 immediately before the SKY intervention compared to follow-up demonstrated a significant difference, $t(10)=3.35$, 95% CI 4.4 to 22.1, $p < .00$ (Table 3).

Table 3: Difference in secondary outcome measures for Intervention and Control groups.

Group	Scale	Pre-intervention scores*	Post-intervention scores**	P
		Mean (Standard Deviation)		
Intervention Group (n=14)	CES-D	24.7 (13.6)	16.9 (10.5)	.003***
	PLCM-17	53.0 (13.8)	35.6 (11.4)	.000***
	WHOQoL	85.8 (10.0)	88.6 (8.2)	.177
	AUDIT - Total	12.1 (6.0)	9.8 (5.2)	.208
Waitlist Control (n=11)	CES-D	29.5 (9.7)	20.7 (8.8)	.019***
	PLCM-17	51.2 (12.2)	37.9 (12.1)	.007***
	WHOQoL	85.1 (7.0)	84.8 (22.0)	.967
	AUDIT - Total	11.8 (7.8)	11.0 (7.1)	.314

*Time 2 pre-intervention scores were used for comparison for the waitlist Control Group to demonstrate how each group responded to their respective interventions.
**Post-treatment scores utilized were approximately 1-month after each group completed the intervention.
***Significant at 0.05 level

Table 4: Prevalence of comorbid conditions amongst Intervention and Control groups, with PTSD as primary diagnosis.

Comorbidity	Number (%) of participants		P
	Intervention group	Control group	
Depression	3 (21)	4 (36)	0.66
Dysthymia	3 (21)	4 (36)	0.66
Suicidality*	2 (14)	2 (14)	0.84
Panic	4 (29)	1 (9)	0.34
Agoraphobia	9 (64)	6 (55)	0.70
Substance Abuse (other than alcohol)	0 (0)	0 (0)	1.00
GAD (Generalized Anxiety Disorder)	10 (72)	8 (73)	1.00
ADD (Attention Deficit Disorder)	3 (21)	1 (9)	0.60
Anxiety	5 (36)	8 (73)	0.11

*suicidality present in any severity

As Table 5 displays, between groups there was no difference noted with initial assessments on the PCLM-17, however once the Treatment Group received the intervention their scores significantly differed from the Control Group's when assessed again (both 6 weeks after the initial evaluation). This was represented in the significant finding reported between time of assessment and group using a two-way ANOVA, Wilks's λ=0.59, $F(1,23)=15.8$, $p < .00$, partial $\eta^2= .41$. After the Control Group received the intervention, there were no significant changes between group averages at follow-up (Treatment: M=35.6, SD=11.4; Control: M=37.9, SD=12.1; $t(23)=-0.50$, 95% CI -12.1 to 7.4, $p=.62$).

WHOQoL

No significant result was noted in the Treatment Group from baseline to follow-up evaluations that occurred approximately one-month after completing the SKY course, $t(13)=-1.43$, 95% -7.0 to 1.4, $p=.18$ (Table 3). A LOCF analysis was performed for one participant in the Control group from baseline Time 1 to Time 2, and to a post-intervention assessment. Another LOCF analysis was conducted for an additional participant in the Control group, whereby the score at Time 2 pre-treatment assessment was carried over to their post-intervention evaluation. The Control Group did not display any significant changes between pre-treatment Time 1 and Time 2 scores, (Time 1: M=82.4, SD=8.7; Time 2: M=85.1, SD=7.0; $t(10)= -1.31$, 95% CI -7.4 to 1.9, $p=.22$), nor from Time 2 to post-intervention as seen in Table 3, $t(10)=0.04$, 95% CI -14.1 to 14.7, $p=.97$).

There was no significant interaction between time of assessment and group when comparing initial baseline to follow-up scores between the groups, Wilks's λ=0.86, $F(1,23)=3.7$, $p=.98$, $\eta^2 < .00$. This was confirmed by finding no significant differences when comparing the Treatment and Control groups between baseline QoL scores with QoL 6-weeks later (after the Treatment Group completed the intervention) as demonstrated in Table 5. The final comparison between post-assessment scores between the two groups was insignificant as well, (Treatment: M=88.6, SD=5.2; Control: M=11.0, SD=7.1, $t(23)=0.59$, 95% CI -9.4 to 16.9, $p=.56$.

Table 5: Between group analyses, revealing the effect of the intervention. Initial baseline scores (T1) were compared to those reported at the second evaluation (T2). T2 was 1-month post-treatment for the Intervention group, and immediately prior to starting treatment for the Control group. Independent-samples t-tests and two-way ANOVAS were conducted.

Scale *Time*	Intervention Group (n=14)	Wait-list Control (n=11)	P (t-test)	P (ANOVA)
CAPS				
Pre-treatment T1	56.3 (12.3)	56.6 (18.7)	.96	.04*
1-month evaluation T2	42.1 (18.2)		.06*	
Pre-treatment T2		56.6 (18.9)		
CES-D				
Pre-treatment T1	24.7 (13.6)	29.1 (9.2)**	.38	.01*
1-month evaluation T2	16.9 (10.5)		.01*	
Pre-treatment T2		29.9 (10.2)**		
PCLM-17				
Pre-treatment T1	53.0 (13.8)	53.1 (12.7)	.99	.00*
1-month evaluation T2	35.6 (11.4)		.00*	
Pre-treatment T2		51.2 (12.2)		
WHOQoL				
Pre-treatment T1	85.8 (10.0)	82.4 (8.7)	.38	.98
1-month evaluation T2	88.6 (8.2)		.27	
Pre-treatment T2		85.1 (7.0)		
AUDIT – Total				
Pre-treatment T1	12.1 (6.0)	14.9 (10.3)	.44	.76
1-month evaluation T2	19.8 (5.2)		.44	
Pre-treatment T2		11.8 (7.8)		

*Significant at 0.05 level

**One patient in the Control Group did not complete a pre-treatment Time 1 CES-D assessment, and was therefore omitted within this data.

Audit

All but one subject in the study were heavy drinkers, consuming the equivalent of more than 6 shots of hard liquor in addition to numerous glasses of beer daily. Participants were asked to reduce their drinking by half during the yoga course. Complete abstinence was not advised due to concerns about potential withdrawal symptoms. A paired-samples t-test revealed that the Treatment Group had an insignificant mean decline in scores from pre-treatment (M=12.1, SD=6.0) to follow-up (M=9.8, SD=5.2), $t(13)=1.33$, 95% CI -1.5 to 6.2, $p=.21$. For the Control Group, an LOCF analysis was undertaken with one participant whereby the baseline Time 1 score was carried over to pre-intervention Time 2. Between Time 1 and Time 2 pre-treatment results, a significant reduction was revealed (Time 1: M=14.9, SD=10.3; Time 2: M=11.8, SD=7.8; $t(10)=2.42$, 95% CI 0.2 to 5.9, $p=.04$). Mean scores did not significantly decline from the second pre-intervention to follow-up however, as displayed in Table 3.

A comparison between initial Treatment and Control mean scores showed no significant results, $t(15.16)=-0.79$, 95% 95% CI -10.2 to 4.7, $p=.44$, similar to a between group analysis of scores reported 6-weeks later, $t(23)=-0.78$, 95% CI -7.4 to 3.4, $p=.44$ (Table 5). This finding was confirmed with an insignificant difference amongst the time of assessment and group through a two-way ANOVA, Wilks's λ=1.00, $F(1,23)=0.10$, p=.75, $\eta^2 < .00$. Evaluating follow-up scores approximately one month after each group received the intervention revealed no significant change between the two groups, (Treatment: M=19.8, SD=5.2; Control: M=11.0, SD=7.1; $t(12.16)=-0.79$, 95% CI -6.3 to 3.9, p=.64).

Risks and adverse reactions

There was minimal identified risk from yoga breathing and related practices. Two participants with severe COPD and dyspnea who were unable to perform breathing practices withdrew from the study as the yoga breathing technique exacerbated their respiratory difficulties. No other adverse reactions were recorded.

However, due to the re-experiencing symptomatology inherent in PTSD, some participants reported transient mild psychological discomfort in the form of fleeting images from the past while they were engaged in yoga breathing. Thus, although some minimal emotional discomfort did occur, participants were protected from more severe reactions, presumably by the effects of the slow breath practices and potentially by reducing sympathetic activity and possibly improving emotion regulation.

Discussion

The modified SKY program provided significant changes for participants completing the treatment in this population with severe PTSD, suggesting it could be considered an important additional treatment option in chronic PTSD sufferers. Changes were noted for both groups on the CAPS as well as the CES-D and PCLM-17, but there were no significant changes after completion of the SKY intervention for WHOQoL or AUDIT-Total scores. Data showing that the CAPS, CES-D and PCLM-17 scores were significantly reduced within both groups, yet statistically similar with one another at follow-up assessments, infers that the beneficial effect of the adapted SKY course did not diminish once treatment was received. From baseline, the effect size (ES) of the difference in CAPS scores 6-weeks

after initiating treatment was 0.90 for the Intervention Group and 1.2 for the Control. The effect size of the difference in CAPS scores from baseline to 6-months was 2.9 and 0.88 for the Intervention and Control group respectively. A large ES is 0.8 or above, moderate ES is 0.5, weak ES is 0.3 or less. Typically, effect sizes for antidepressant trial are in the 0.5 range [70].

Limitations of this study include the small sample size, the impossibility of blinding subjects to the intervention, and the use of a wait-list control as opposed to an active control. Although the sample size was small, the magnitude and consistency of improvements resulted in findings that are potentially clinically applicable. While the participants are representative of male Australian veterans with chronic PTSD, larger studies with more diverse populations are needed in order to extrapolate these findings to a more general population.

One issue in multi-component interventions involves the difficulty of proving which components are responsible for the outcome, for example, yoga practices, psychoeducation, group processes, or expectations. Keeping in mind that the subjects had a 30-year history of treatment resistant disabling PTSD which had not responded to individual or group therapy, it is less likely that the response to this intervention could be attributed to the small amount of time used for group processes (total of 105 minutes during five-day22-hour program) or psychoeducation (total of 30 minutes during the 5-day program). Moreover, the long history of failed treatment attempts would more likely result in negative rather than positive expectations. Despite the small number of subjects, the large effect size resulted in statistically significant results. However, the methodological limitations warrant additional study using larger numbers of subjects and active controls. Given that poor prognosis for PTSD has been linked to its degree of chronicity [71], comorbidity with anxiety disorders and alcohol/substance dependence [72], current results suggest a potentially better outcome in other populations with less chronic PTSD, less alcohol/substance abuse and less comorbidity with anxiety disorders.

Overall, quality of life did not improve significantly as measured by the total score of the WHOQoL. However, this may be partly due to the fact that many items explore aspects of physical health, living conditions, finances, work capacity, and access to health care that would not be expected to change in response to this intervention. In addition, it is remarkable that several participants articulated concerns about the subsequent consequences involving disability pensions as a result of their self-reported improvement, despite repeated reassurance of confidentiality. This suggested that participants may have downgraded their actual improvement because of concerns related to losing their disability benefits. Such under reporting of symptom improvement raises the possibility that the intervention may have been even more effective than was indicated by the changes in test results.

Further limitations of the current study are the lack of blinding participants and instructors as well as the absence of an equivalent active control intervention. Although this study attempted to dissect whether the intervention utilized was advantageous, both groups did receive treatment making these results difficult to diffuse. These methodological challenges are inherent in studies of either yoga interventions or psychotherapy in which it is impossible to have an apparently identical placebo control or blinding of subjects. While the possibility exists that symptoms improved merely by participating in an organized therapy setting, this explanation is improbable considering that the study population suffered from PTSD symptoms for over 30 years despite a variety of previous therapeutic interventions including individual and group therapies.

Although regular reminders by phone were administered, a challenge to the maintenance of the improvement was the failure of participants to commit to practicing yoga regularly and attending the follow-up sessions offered. Additionally, as the initial yoga instructors were unable to travel regularly to Brisbane, a local yoga teacher who had not been involved in teaching the SKY Course held the follow-up sessions. The sustained improvement, despite the change of teacher, implies that the maintained improvement was attributable to the treatment intervention and not the specific instructors.

Yoga breath interventions can be safely integrated with concurrent psychotherapy and pharmacotherapy [73]. The current study supports these findings as there were no concerning interactions reported between pharmacotherapy and yoga practice, despite all subjects simultaneously undergoing pharmacotherapy. One area of caution is with individuals diagnosed with Bipolar II Disorder, for whom forceful or rapid yoga breathing can have stimulating effects, which can trigger manic states. Such reactions have been observed in several cases by the authors (RP Brown and PL Gerbarg). Furthermore, such rapid breathing can increase the rate of lithium excretion and thus lower serum lithium levels [54]. Therefore it is advised that individuals with bipolar disorder not engage in rapid breathing practices and that lithium levels be monitored if such patients engage in rapid yoga breathing.

Ultimately, adapting and disseminating multi-component yoga programs to veterans can be challenging. As preliminary studies suggest yoga based therapies to be helpful for PTSD along with other mental conditions, the particular intervention used in this study was designed for military veterans and as such, the authors were hopeful that the treatment would prove beneficial to this population. In this study population of chronically disabled veterans being given yoga treatment 30 years after their military service, the 22-hour intensive course was probably responsible for inducing the noted positive changes in both groups that participated. This suggests that training health care providers, chaplains, and military personnel to administer core practices, such as the intervention described here, should be considered and made available. This would make widespread use of such practices feasible and sustainable within military health care systems.

Conclusions

The results of this randomized, single-blind, wait-list controlled trial indicate that participation in a 5-day multi-component Sudarshan Kriya Yoga course adapted for veterans significantly improved scores at 6 weeks on standardized measures of PTSD (CAPS) in Australian Vietnam Veterans with chronic PTSD. Participants were encouraged to do daily yoga practice at home for 20-30 minutes in the morning and 10-20 minutes in the afternoon. They were offered group sessions once a week for one month and once a month thereafter. Further improvements in measures of PTSD were evident at 6-month follow-up based on CAPS scores. These positive responses occurred in these subjects despite having 30-year histories of treatment-resistant severe PTSD, alcohol abuse, and dependence on disability status. Early intervention could therefore be even more effective in preventing chronic PTSD and in reducing chronic disability and co-morbid substance abuse. Multi-component mind-body interventions that emphasize specific yoga breath techniques geared towards veterans

suffering from PTSD may offer a valuable adjunctive tool in the treatment of these very ill patients.

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Conflicts of Interest

Dr. Janis Carter receives payment for treating veterans including for MCYI programs. She has no conflicts of interests. For Dr. Patricia L. Gerbarg no competing financial interests exist. Dr. Richard P. Brown received no financial remuneration for teaching or promoting SKY courses or for any services to the AOLF or the IAHV other than reimbursement for travel expenses. No competing financial interests exist. For Dr. Robert S. Ware no competing financial interests exist. For Ms. Christina D'Ambrosio no competing financial interests exist. For Ms. Mihaela Dirlea no competing financial interests exist. For Dr. Monica Vermani no competing financial interests exist. For Dr. Martin A. Katzman no competing financial interests exist. None of the authors have any current affiliation with AOLF or IAHV. For Ms. Leena Anand no competing financial interests exist.

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