



Current opinion

Feasibility and acceptability of restorative yoga for treatment of hot flushes: A pilot trial

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Abstract

Objective: To determine the feasibility and acceptability of a restorative yoga intervention for the treatment of hot flushes in postmenopausal women.

Methods: A pilot trial in 14 postmenopausal women experiencing ≥ 4 moderate to severe hot flushes per day or ≥ 30 moderate to severe hot flushes per week. The intervention consisted of eight restorative yoga poses taught in a 3-h introductory session and 8 weekly 90-min sessions. Feasibility was measured by recruitment rates, subject retention and adherence. Acceptability was assessed by subject interview and questionnaires. Efficacy measures included change in frequency and severity of hot flushes as recorded on a 7-day diary.

Results: Recruitment was accomplished as planned. The majority of study subjects (93%) completed the trial. Of those who completed the trial, 92% attended seven or more of the eight yoga sessions. The majority of the subjects were satisfied with the study and 75% continued to practice yoga 3 months after the study. Mean number of hot flushes per week decreased by 30.8% (95% CI 15.6–45.9%) and mean hot flush score decreased 34.2% (95% CI 16.0–52.5%) from baseline to week 8. No adverse events were observed.

Conclusions: This pilot trial demonstrates that it is feasible to teach restorative yoga to middle-aged women without prior yoga experience. The high rates of subject retention and satisfaction suggest that yoga is an acceptable intervention in this population. Our results indicate that a larger, randomized controlled trial to explore the efficacy of restorative yoga for treatment of menopausal symptoms would be safe and feasible.

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1. Introduction

Today, there are over 36 million American women between the ages of 45 and 65 [1]. As they pass through menopause, approximately two-thirds will experience hot flushes [2]. Though hormone therapy is a very effective treatment for hot flushes, clinical trials have raised concerns about its safety [3–6]. Several other treatments for hot flushes have been proven effective in clinical trials, including progestins, clonidine, gabapentin and selective serotonin reuptake inhibitors. However, most are only modestly effective, and all are associated with side effects [7]. In search of alternatives to traditional pharmacologic therapies, women have tried a variety of herbal preparations and nutritional supplements, including soy, black cohosh, dong quai, Vitamin E and red clover. However, systematic reviews of randomized controlled trials of botanical supplements found most were ineffective for relief of vasomotor symptoms [8–10].

The mechanism of hot flushes is not fully understood, but there is significant evidence that increased sympathetic nervous system activity plays an important role [11–13]. Yoga is an ancient healing technique that involves controlled breathing, postures and meditation. Physiologic studies have shown that yoga increases heart rate variability and decreases oxygen consumption, heart rate and blood pressure, all indicative of decreased sympathetic nervous system activity [14–16]. Small trials using relaxation techniques related to yoga, such as meditation and controlled breathing, have found significant improvements in hot flushes [17,18]. However, it is not clear whether yoga will have similar efficacy, which yoga postures should be used and whether an intervention can be easily taught to postmenopausal women without prior yoga experience. Given these preliminary data and questions, we convened a panel of expert yoga teachers to develop an intervention designed to relieve hot flushes and conducted a pilot trial of an 8-week restorative yoga intervention to evaluate the feasibility, acceptability and preliminary efficacy of restorative yoga as a treatment for hot flushes and other menopausal symptoms.

2. Materials and methods

This uncontrolled pilot study enrolled 14 postmenopausal women who participated in an 8-week

restorative yoga intervention. The study was conducted at the University of California, San Francisco.

2.1. Subjects

Subjects were postmenopausal women aged 40–65 years old who experienced ≥ 4 moderate to severe hot flushes per day or ≥ 30 moderate to severe hot flushes per week. Women who used selective estrogen receptor modulators or aromatase inhibitors within 3 months of study enrollment were excluded from the study. Women were also ineligible if they used pharmacologic, complimentary or alternative medical treatments for menopausal symptoms within 4 weeks of enrollment. Potential subjects were not excluded based on level of physical activity or fitness. We aimed to enroll 12–15 subjects in 12 weeks. Subjects were recruited using advertisements in local newspapers, primary care clinics and gynecology clinics. We also contacted women who had previously inquired about studies of hot flush therapies and had given permission to be contacted for new studies. Two research assistants conducted the telephone screening and one research nurse conducted the screening visits.

2.2. Study protocol

2.2.1. Design

After initial telephone screening, women attended a screening visit to confirm eligibility. Those who were eligible and wished to participate had an enrollment visit where they provided a medical and medication history, completed baseline questionnaires on menopausal symptoms and were given instructions on completion of a 7-day hot flush diary. Women recorded the time and severity of each hot flush in the diary. Severity was graded as mild, moderate or severe on a scale of 1–3 [19]. The questionnaires were repeated at week 8 of the yoga intervention. The hot flush diary was repeated at week 4 and week 8. Subjects completed a follow-up questionnaire 3 months after the final yoga session to assess whether they continued to practice yoga. The study protocol was approved by the Institutional Review Board at the University of California, San Francisco. All subjects provided written informed consent prior to enrollment in the study.

2.2.2. Yoga intervention

The yoga intervention was designed by two expert, certified yoga instructors with extensive experience working with peri- and postmenopausal women, each of whom have published books on the use of yoga for menopausal symptoms [20,21]. The yoga instructors agreed that the most appropriate postures for relief of hot flushes in peri- and postmenopausal women are derived from restorative yoga, a branch of yoga that focuses on deep relaxation and uses props to provide total body support. All subjects attended a 3-h introductory workshop that reviewed the eight postures included in the yoga intervention (*Balasana* (Child's Pose), *Adho Mukha Svanasana* (Downward Facing Dog), *Baddha Konasana* (Seated Bound Angle Pose), *Upavistha Konasana* (Seated Wide Angle Pose), *Viparita Karani* (Supported Legs Up the Wall), *Setu Bandha Sarvangasana* (Supported Bridge Pose), *Supta Baddha Konasana* (Supported Lying Down Bound Angle Pose) and *Savasana* (Corpse Pose)). Subjects then attended eight weekly 90-min yoga sessions that were taught by two certified yoga teachers. Subjects were also asked to practice at home for 1 h at least three times per week and were given a log to record the amount of time and types of postures they practiced.

2.2.3. Questionnaires

The Menopause-Specific Quality of Life is a validated 29-item questionnaire that uses an 8-point Likert scale to rate the severity of symptoms in four domains—vasomotor, physical, psychosocial and sexual [22]. Each question is scored 1–8, with higher scores indicating more severe symptoms. Domain-specific scores are calculated as the mean score for all questions in that domain, yielding scores from 1–8. The summary score is calculated as the mean of the four domain-specific scores [23]. The Insomnia Severity Index is a validated 7-item questionnaire that uses a 5-point Likert scale [24]. Questions are scored 0–4 points each for a summary score of 0–28, with higher scores indicating more significant sleep disturbance. The Menopausal Symptom Questionnaire consists of six questions about common menopausal symptoms. The questions use a 5-point Likert scale to rate the symptoms over the prior month. Improvement for each symptom was defined as a decrease of at least one level on the Likert scale.

2.3. Statistical analysis

All women with any outcome measurements were included in the analysis. The primary feasibility outcome was the time required to recruit 12–15 subjects. Secondary feasibility outcomes included the number of telephone screens and screening visits, subject retention and adherence to the study protocol. Acceptability was evaluated with questionnaires and an interview during the final visit. The primary efficacy outcome was the change in frequency of hot flushes from baseline to the end of the 8-week training period as recorded in the 7-day hot flush diary. Secondary efficacy outcomes included change in hot flush frequency at 4 weeks, change in hot flush score (derived as number of hot flushes each day multiplied by the severity graded as 1–3) at 4 and 8 weeks and change in score on the Menopause-Specific Quality of Life, Insomnia Severity Index and Menopause Symptom Questionnaire. Continuous variables were summarized using the mean, standard deviation and 95% confidence intervals. Changes from baseline to post-intervention in continuous outcome variables were analyzed using Student's paired *t*-test with a level of significance of $\alpha=0.05$, two-tailed. All data analysis was performed using SAS software (Version 9.0).

3. Results

3.1. Subjects and recruitment

Fourteen subjects were recruited in 9 weeks, yielding a recruitment rate of 1.6 subjects per week. One hundred fourteen women completed telephone screening, 23 women attended screening visits and 14 women enrolled. The main reasons for ineligibility were insufficient number of hot flushes and the use of exclusionary medications. Among the women who were eligible for the study but declined to participate, the main reasons were scheduling conflicts and desire to use a different hot flush treatment. The baseline characteristics of the subjects are shown in Table 1. The mean age of study subjects was 57.6 (S.D. 3.1) years, mean weight was 73.2 (S.D. 11.1) kg, mean BMI was 27.8 (S.D. 4.3) and 10 of 13 (76.9%) were White.

Table 1
Baseline characteristics of the participants

Characteristic	N=13
Age, years (mean \pm S.D.)	57.6 \pm 3.1
Race/ethnicity, n (%)	
White	10 (76.9%)
Black	2 (15.4%)
Multiethnic/mixed race	1 (7.7%)
BMI (mean \pm S.D.)	27.8 \pm 4.3
Tobacco use, n (%)	
Never smoker	5 (38.5%)
Former smoker	8 (51.5%)
Current smoker	0 (0%)
Alcohol use, n (%)	
None in past 30 days	2 (15.4%)
1–3 times in past 30 days	8 (61.5)
3–4 days per week	1 (7.7%)
Every day	2 (15.4%)
History of hysterectomy, n (%)	2 (15.4%)
History of oophorectomy, n (%)	2 (15.4%)

S.D., standard deviation, BMI, Body Mass Index.

3.2. Retention and adherence

Of the 14 subjects enrolled in the trial, 1 discontinued participation after 4 weeks and did not complete any outcome measures due to progression of an illness that began prior to enrollment in the trial. The remaining 13 subjects completed outcome measures at weeks 4 and 8. One woman completed questionnaires at week 8 but did not complete her hot flush diary within the specified time and this diary was excluded from the analysis. Twelve subjects completed the 3-month follow-up questionnaire. Of the 13 women who completed the trial, 12 (92.3%) attended seven or more of the eight yoga sessions. Adherence to home practice ranged from 77 to 308 minutes per week with a mean home practice time of 170 (S.D. 85) minutes per week. Feedback from the subjects and yoga instructors suggested that aids, such as photographs of the subjects in the poses or an audio or video guide, could improve home practice.

3.3. Subject satisfaction

The majority (92.3%) of the subjects felt that the study met their expectations. Two (15.4%) of the

subjects felt that the yoga postures were difficult and three (23.1%) of the subjects felt it would be difficult to continue to practice yoga after the study ended. Feedback from the final interviews was positive, with the majority of women stating they enjoyed learning yoga and were satisfied with the study. When asked to select the most bothersome part of the study, “taking time to practice yoga at home” was the most common choice, selected by five subjects (38.5%). On the 3-month follow-up questionnaires, 75.0% of subjects reported they continued to practice yoga. All of these women practiced the postures they learned during the study, and 44.4% had learned new postures following the study. No adverse events occurred during the trial.

3.4. Hot flushes

Changes in hot flushes are shown in Table 2. The mean frequency of hot flushes at baseline was 59.7 (S.D. 22.6) per week. At week 4 the frequency of hot flushes decreased 14.6 (S.D. 13.7) from baseline (-28% ; $p=0.0006$); at week 8 frequency decreased 17.2 (S.D. 13.8) from baseline (-30.8% ; $p<0.001$). The percent change in hot flush frequency following the yoga intervention ranged from -68.1 to $+10.6\%$.

The mean hot flush score was 99.9 (S.D. 33.8) at baseline and decreased by 29.6% (S.D. 32.2%) at week 4 ($p=0.006$) and 34.2% (S.D. 28.8) at week 8 ($p=0.002$). The percent change in hot flush score following the yoga intervention ranged from -74.2 to $+17.2\%$.

3.5. Other menopausal symptoms

Changes in questionnaire scores are shown in Table 2. Mean summary scores on the Menopause-specific Quality of Life questionnaire decreased from 4.4 (S.D. 1.5) at baseline to 3.3 (S.D. 1.3) at week 8 ($p=0.09$). The majority of the improvement occurred in the vasomotor ($p=0.06$) and physical ($p=0.05$) domains of the questionnaire. Scores on the Insomnia Severity Index improved from 14.0 (S.D. 6.3) at baseline to 10.4 (S.D. 5.2) at week 8 ($p=0.02$). On the Menopausal Symptom Questionnaire, 69% of subjects had improvement in hot flushes, 46% had improvement in sleep and 46% had improvement in “aches and pains”.

Table 2
Changes in hot flashes and menopausal symptom scores

Measure	Baseline	Week 4	Week 8 ^a	<i>p</i> value*	Percent change
Number of hot flashes per week	59.7 ± 22.6	45.1 ± 28.2	43.8 ± 24.5	0.001	–31%
Hot Flash Score	99.9 ± 33.8	74.4 ± 55.9	70.3 ± 46.5	0.007	–34%
MENQOL Summary Score	4.4 ± 1.5		3.3 ± 1.3	0.09	–16%
Vasomotor domain	6.1 ± 1.4		4.5 ± 2.0	0.06	–21%
Physical domain	4.1 ± 1.8		3.1 ± 1.4	0.05	–18%
Psychosocial domain	4.0 ± 1.9		3.0 ± 1.7	0.13	–11%
Sexual domain	3.3 ± 2.0		2.7 ± 1.6	0.35	0%
Insomnia Severity Index	14.0 ± 6.3		10.4 ± 5.2	0.02	–20%

Values are given as means ± standard deviations or mean percentage change.

* Refers to the comparison of baseline to week 8 measurements.

^a n = 12 for week 8 Number of hot flashes per week and Hot Flash Score, n = 13 for week 8 questionnaire scores.

4. Discussion

Despite the existence of effective pharmacologic therapies for hot flashes, many women avoid treatment due to contraindications or concerns about adverse effects. We hypothesized that restorative yoga may be a safe and acceptable behavioral treatment for menopausal symptoms. For this pilot trial, we consulted expert yoga instructors to develop an intervention for postmenopausal women with little or no prior yoga experience. As hot flashes may be due to increased sympathetic nervous system activity, the panel recommended using restorative yoga. Restorative yoga emphasizes gentle, supported poses and deep relaxation, and it is believed to reduce sympathetic activity. To ensure the intervention was generalizable, the panel selected poses that could be performed by women with a wide range of body types, flexibility and fitness levels. The majority (69%) of women in our study were overweight or obese, most had never done yoga and many had arthritis or prior injuries that limited their physical activity. However, subjects were able to perform the sequence of poses using simple, standard modifications from the instructors if needed.

The reasonable amount of time and resources required to recruit the study subjects suggests that a larger, randomized trial of the intervention is feasible. In addition, we had excellent retention of study subjects and high rates of subject satisfaction. The majority of subjects felt the yoga postures were not difficult to learn and continued to practice yoga three months after the study had ended. Attendance of the yoga classes was excellent but adherence to home practice varied. Prac-

tice aids, such as photographs of the subjects in the poses or an audio or video guide might improve home practice.

Hot flush frequency was significantly improved at weeks 4 and 8 of the yoga intervention, with reductions of 28% and 30% respectively. Decreases in hot flush severity were demonstrated by the significant reduction in hot flush score and improvements in scores on the Menopause-Specific Quality of Life vasomotor domain and the Menopausal Symptom Questionnaire hot flush question. Questionnaires also showed improvements in sleep, musculoskeletal symptoms and quality of life. These improvements might be the result of decreased sympathetic tone, which is thought to play a role in menopausal hot flashes. Hot flashes appear to be due to a narrowing of the thermoregulatory null zone such that small increases in core body temperature result in vasodilation and sweating [25]. This abnormality in thermoregulation may be due to decreasing estrogen levels associated with menopause that alter central nervous system adrenergic neurotransmission. This theory is supported by studies that show systemic administration of yohimbe, an alpha 2-adrenergic antagonist that increases norepinephrine release, provokes hot flashes and administration of clonidine, an alpha 2-adrenergic agonist that decreases norepinephrine release, reduces the frequency of hot flashes [11,13].

Our study was not adequately powered to examine changes in markers of sympathetic tone. However, in a recent systematic review of published trials of yoga and yoga-based interventions, 85% of eligible studies found evidence that yoga reduced sympathetic activity [26]. Measures of sympathetic activity in these studies

included heart rate, respiratory rate, cortisol and catecholamine levels, renin activity, skin conductance, heart rate variability and baroreflex sensitivity. Trials measuring blood pressure also suggest that regular yoga practice decreases sympathetic activation. Of 12 randomized controlled trials, 9 (75%) found significant reductions in blood pressure in the yoga versus control groups [26].

The clinical significance of our results is difficult to interpret given the uncontrolled design of this pilot study. The reduction in menopausal symptoms that we observed may have been due to factors other than the yoga intervention. The placebo effect in trials of pharmacologic therapies for hot flushes has varied widely and the approximately 30% reduction in hot flush frequency observed in this study could be consistent with a placebo effect [27]. However, the placebo effect for behavioral interventions such as yoga may be smaller than that observed in drug trials. In prior studies of non-pharmacologic therapies for hot flushes, groups given behavioral control interventions consisting of muscle relaxation, biofeedback, or reading showed no significant improvement in hot flushes [17,18,28]. It is also possible that increased home practice might improve the efficacy of the yoga intervention.

5. Conclusions

This pilot trial demonstrates that it is feasible to recruit women with hot flushes for a trial of yoga and teach restorative yoga to middle-aged women without prior yoga experience. The excellent subject retention, adherence and satisfaction suggest that a larger trial is feasible. Preliminary data demonstrating significant improvements in measures of hot flush frequency and severity, quality of life and sleep quality following the restorative yoga intervention need to be confirmed in a larger, randomized controlled trial.

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