Menopause: The Journal of The North American Menopause Society
Vol. 21, No. 4, pp. 339-346
DOI: 10.1097/gme.0b013e31829e4baa

Efficacy of yoga for vasomotor symptoms: a randomized controlled trial

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Abstract

Objective: This study aims to determine the efficacy of yoga in alleviating vasomotor symptoms (VMS) frequency and bother.

Methods: This study was a three-by-two factorial, randomized controlled trial. Eligible women were randomized to yoga (n = 107), exercise (n = 106), or usual activity (n = 142), and were simultaneously randomized to a double-blind comparison of ω-3 fatty acid (n = 177) or placebo (n = 178) capsules. Yoga intervention consisted of 12 weekly 90-minute yoga classes with daily home practice. Primary outcomes were VMS frequency and bother assessed by daily diaries at baseline, 6 weeks, and 12 weeks. Secondary outcomes included insomnia symptoms (Insomnia Severity Index) at baseline and 12 weeks.

Results: Among 249 randomized women, 237 (95%) completed 12-week assessments. The mean baseline VMS frequency was 7.4 per day (95% CI, 6.6 to 8.1) in the yoga group and 8.0 per day (95% CI, 7.3 to 8.7) in the usual activity group. Intent-to-treat analyses included all participants with response data (n = 237). There was no difference between intervention groups in the change in VMS frequency from baseline to 6 and 12 weeks (mean difference [yoga − usual activity] from baseline at 6 wk, −0.3 [95% CI, −1.1 to 0.5]; mean difference [yoga − usual activity] from baseline at 12 wk, −0.3 [95% CI, −1.2 to 0.6]; $P = 0.119$ across both time points). Results were similar for VMS bother. At week 12, yoga was associated with an improvement in insomnia symptoms (mean difference [yoga − usual activity] in the change in Insomnia Severity Index, 1.3 [95% CI, −2.5 to −0.1]; $P = 0.007$).

Conclusions: Among healthy women, 12 weeks of yoga class plus home practice, compared with usual activity, do not improve VMS frequency or bother but reduce insomnia symptoms.

Key Words: Clinical Trials Network – Vasomotor symptoms – Yoga – Meditation – Menopause – Hot flashes.

Received April 8, 2013; revised and accepted May 29, 2013.

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Parts of this manuscript were presented at the annual meeting of The North American Menopause Society on October 7, 2012, in Orlando, FL.

Funding/support: This study was funded by the National Institutes of Health as a cooperative agreement issued by the National Institute on Aging, Eunice Kennedy Shriver National Institute of Child Health and Human Development, National Center for Complementary and Alternative Medicine, Office of Research on Women's Health, and grants U01AG032656, U01AG032659, U01AG032669, U01AG032682, U01AG032699, and U01AG032700 from the National Institute on Aging. At Indiana University, the project was partly funded by the Indiana Clinical and Translational Sciences Institute, grant UL1RR02571 from the National Institutes of Health, National Center for Research Resources, and Clinical and Translational Sciences Award.

Clinical trial registration: NCT01178892 (ClinicalTrials.gov).

Financial disclosure/conflicts of interest: K.M.N. has received research support from Integrated Diagnostics Inc L.A.L. is a consultant to a Data Monitoring Committee for Ariosa Diagnostics. E.W.F. has received research support from Forest Laboratories Inc and Bionovo Inc L.S.C. has served as a consultant to Noven Pharmaceuticals and has received research support from Astra-Zeneca Pharmaceuticals, Bristol-Myers Squibb, Cephalon Inc, GlaxoSmithKline, Ortho-McNeil Janssen, Pfizer Inc, and Sunovion Pharmaceuticals Inc H.J. has received grant support from Cephalon/Teva, is on the advisory board for Noven, and has done consulting for Sunovion. K.E.E. is a consultant to a Data Monitoring Committee for Merck, Sharp, and Dohme. All other authors have no direct conflicts of interest or financial disclosures relevant to this manuscript.

Supplemental digital content is available for this article. Direct URL citations appear in the printed text and are provided in the HTML and PDF versions of this article on the journal's Web site (www.menopause.org).

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Hormonal agents have been the predominant therapy for menopausal vasomotor symptoms (VMS; hot flashes plus night sweats), but their use decreased substantially with shifts in our understanding of risks and benefits identified in the Women's Health Initiative.[1-3] However, no other treatments have Food and Drug Administration approval for VMS. Alternatives to hormone therapy have been explored. To date, selective serotonin reuptake inhibitors have demonstrated modest efficacy for the relief of menopause symptoms,[4] whereas the search for mind-body therapies,[5] herbal treatments,[6] and supplements to lessen menopause symptoms continues, with limited success.

Yoga is a mind-body therapy that includes stretching, poses requiring balance and core strength, deep breathing, and meditation.[7] In 2007, 6.1% of the adult US population reported practicing yoga,[8] and women are almost four times as likely to practice yoga than men.[9] Population-based surveys indicate that some women use yoga in an attempt to manage their menopause symptoms.[10,11] Yoga has been investigated as a therapy for VMS, but studies to date have been limited in size or methodology, and results have been mixed.[12-17] We evaluated the efficacy of a yoga program designed to reduce the frequency and bother of VMS.

The rationale for evaluating yoga was based on hypothesized physiologic changes that occur with menopause (or estrogen withdrawal).[18] Menopause is associated with a narrowing in the range of core body temperatures at which physiologic responses to induce cooling or heating occur.[19] These changes seem to be regulated by central noradrenergic neurotransmitters and sympathetic nervous system (SNS) regulation, specifically an increase in norepinephrine.[18,20,21] The hypothesis that central noradrenergic neurotransmitters and SNS regulation affect VMS is supported by clinical and anecdotal reports linking psychological stress and SNS regulation and VMS.[22-25] Yoga may decrease autonomic arousal through changes in the levels of circulating neurotransmitters and hormones.[26] These changes would reduce SNS activation, which has been implicated in VMS etiology. Behavioral interventions can impact both SNS and parasympathetic nervous system functioning and stress reactivity,[27-30] raising the possibility that yoga might decrease menopausal VMS through its impact on these finely balanced systems.

METHODS

Study design

Details about the MsFLASH (Menopause Strategies: Finding Lasting Answers for Symptoms and Health) Network, its study design, and its protocols have been published.[31,32] This study was a multisite, three-by-two factorial, randomized controlled trial. Eligible women were randomized to 12 weeks of yoga, exercise, or usual activity, and simultaneously randomized to 1.8 g/day ω-3 fish oil capsules (ethyl eicosapentaenoic acid, 1275 mg; docosahexaenoic acid, 300 mg) or placebo capsules. The factorial design was motivated by our desire for all participants to receive some intervention and hence have an expectancy of benefit (although participants taking pills knew that they could be on either placebo or ω-3s) and to reduce costs. No head-to-head comparisons between yoga and exercise were planned. Interactions between behavioral interventions and ω-3 fatty acids were hypothesized to be improbable. This report describes the results of the yoga intervention compared with usual activity; results for the exercise and ω-3 comparisons are reported separately. The study was approved by the Institutional Review Boards at each clinical site and by the Data Coordinating Center. All participants provided a written informed consent form.

Yoga intervention

No single standardized yoga practice could be identified as being most appropriate for the relief of menopause symptoms. Investigators (K.J.S. and C.B.-L.) worked with expert yoga instructors and consultants from the National Center for Complementary and Alternative Medicine to create a program that emphasized the practice of "cooling" breathing exercises and three groups of poses (asanas) believed to be useful for relieving VMS.[12,33] We sequenced poses according to the principles of viniyoga[34] to promote safety.

Class content

Yoga instruction was provided during 12 weekly 90-minute classes. Each class included breathing exercises, 11 to 13 poses (restorative, inverted, lateral bends, twists, forward bends, and counter poses), and deep relaxation featuring Yoga Nidra (a meditative practice). Three different sequences of poses were used to increase variety and to maintain participant interest. Women joined class as they were recruited. Before her first class, each woman met with the instructor for 30 minutes to discuss health concerns and to learn the breathing exercises.

Home practice

Home practice included breathing, poses, and Yoga Nidra. Participants were given written instructions, a DVD with the three sequences of poses, a CD for Yoga Nidra, and supplies (bolster, strap, blanket, and mat). Participants were instructed to practice at home for 20 minutes for each day that they did not attend class, alternating poses one day with Yoga Nidra the next day.

Classes were offered twice weekly. Yoga instructors had at least 5 years of teaching experience and 500 hours of training. Yoga consultants conducted 2-day trainings at each study site. Instructors were taught to strictly adhere to the protocol. A research staff member attended every yoga class and completed a yoga protocol adherence log. Investigators (K.J.S. and C.B.-L.) were in weekly contact with the instructors via e-mail to discuss class experiences, adverse events (AEs), adherence, and other questions.

Usual activity comparison group

Women in the usual activity group were instructed to follow their usual routine and were asked not to engage in yoga or not to change their exercise routines. At study end, they were offered their choice of a 3-hour yoga workshop or a 1-month gym membership.

Eligibility, screening, randomization, and blinding

The trial was conducted at three MsFLASH sites: Indianapolis, Oakland, and Seattle. Participants were recruited from February 2011 through January 2012, primarily by mass mailings to age-eligible women, using purchased lists and health plan enrollment files. Eligible women were aged 40 to 62 years; were in the menopausal transition or in postmenopause or had hysterectomy with follicle-stimulating hormone levels higher than 20 mIU/mL and estradiol levels of 50 pg/mL or less; and were in generally good health. The VMS eligibility criteria were as follows: 14 or more hot flashes/night sweats per week recorded on daily VMS diaries for 3 weeks; VMS rated as bothersome or severe on four or more occasions per week; and VMS frequency on week 3 did not decrease greater than 50% from the average weekly levels on weeks 1 and 2. Exclusion criteria included the following: body mass index (BMI) higher than 37 kg/m^2; use of hormonal contraceptives or hormones in the past month; use of prescription or over-the-counter treatments for VMS in the past month; unstable medical conditions; current use of one of the study interventions or related activity (ie, yoga, tai chi, qi gong, meditation, regular exercise, ω-3 fatty acid supplements, or frequent consumption of fish); contraindications to exercise (eg, physical limitations), yoga, or ω-3 (eg, allergy to soy or fish); or a major depressive episode in the past 3 months.

Data collection

After telephone screening, the women completed a 2-week VMS diary and a questionnaire. Those who remained eligible attended an in-person visit that included a blood draw, physical measures, and an additional baseline questionnaire. After that visit, the women completed the week 3 VMS diary. They returned to the clinic for a final determination of eligibility and randomization.

Randomization was conducted in a secure Web-based database, maintained at the MsFLASH Data Coordinating Center, using a dynamic randomization algorithm to maintain comparability between study groups with respect to clinical site. For the behavioral interventions, a 3:3:4 (yoga/exercise/control) allocation was used to improve the power for intervention versus control contrasts while reducing costs. Local access to information on assignment to yoga, exercise, or usual activity was limited to site staff involved in intervention delivery to ensure masking of data collectors. Equal allocation was used for ω-3 and placebo treatments.

Follow-up

During week 2, participants were contacted by study staff blinded to ω-3 assignment to encourage compliance and to evaluate tolerance to the study capsules. During intervention weeks 6 and 12, participants completed 7-day VMS diaries. All other baseline measurements were repeated either during week 12 or at the week 12 clinic visit. Participants were compensated US$50 for their time and effort after each clinic visit, for a possible total of US$150.

Measurements

The primary outcomes were VMS frequency and bother based on daily diaries[4] in which participants entered the number of VMS they had experienced upon awakening (for nighttime symptoms) and before going to sleep (for daytime symptoms). They rated VMS bother for each day on a scale from 1 to 4 (1, none; 2, a little; 3, moderately; 4, a lot).

The secondary outcomes were subjective sleep quality and sleep disturbances (Pittsburgh Sleep Quality Index [PSQI]),[35] insomnia symptoms (Insomnia Severity Index [ISI]),[36] depressive symptoms (Patient Health Questionnaire-8 [PHQ-8] depression domains),[37] and anxiety (Generalized Anxiety Disorder-7 [GAD-7]).[38]

AEs were assessed using a self-reported questionnaire listing 15 common AEs related to yoga, physical activity, and ω-3 fatty acids. Participants were instructed to call the study nurse to report any potential AEs during the study. Newly emergent AEs were identified by comparing AE reports during treatment to baseline reports.

Statistical analysis

Baseline characteristics were compared between treatment groups using t tests or χ^2 tests. The primary intent-to-treat analysis included all randomized participants with response data, which were collected regardless of intervention adherence. Among 249 women who were randomized, 237 (95.2%) provided week 12 response data (Fig. 1).

Baseline VMS frequency was calculated as the mean of the daily totals reported for the first two screening weeks. VMS frequencies on weeks 6 and 12 were calculated as the mean of the daily frequencies for those weeks. Baseline, week 6, and week 12 bother were also defined as the means of the daily ratings. A categorical variable indicating clinical VMS improvement was defined as a 50% or more decrease in VMS frequency at 12 weeks from baseline.

Intervention arm contrasts were computed as Wald statistics from linear regression models summarizing VMS frequency or bother on or during weeks 6 and 12 as a function of randomization assignment, adjusted for clinical site, visit (week 6 or 12), ω-3 intervention assignment, and baseline outcome value. Natural logarithmic transformations were applied to hot flash frequencies to accommodate modeling assumptions. Robust standard errors were calculated via generalized estimating equations to account for correlations between repeated measures from each participant.

Variables hypothesized a priori to modify treatment response on VMS frequency included prior experience with yoga and/or meditation, depressive symptoms (PHQ-8 continuous score), anxiety (GAD-7 continuous score), BMI (<25, 25 to <30, and ≥30 kg/m^2), and race (African American, white). Tests for interaction between these variables and treatment assignment were performed within the linear regression model.

Secondary analyses also applied linear regression to model changes in the measures of subjective sleep quality and sleep disturbances (PSQI[35]), insomnia symptoms (ISI[36]), depressive

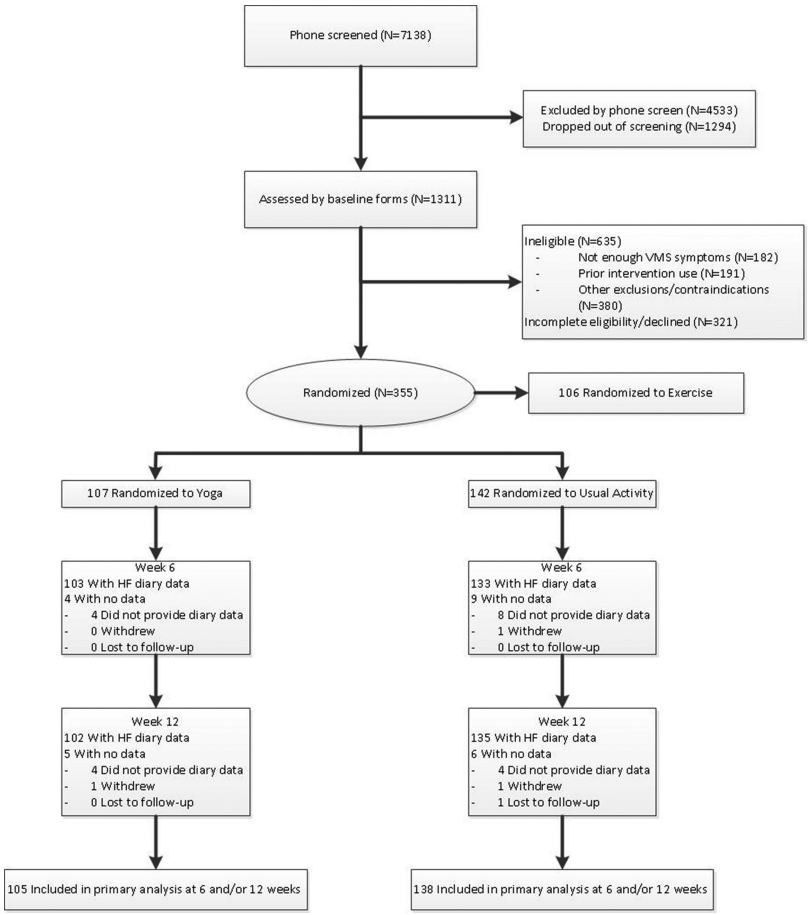

FIG. 1. Participant recruitment. VMS, vasomotor symptoms.

symptoms (PHQ-8[37]), and anxiety (GAD-7[38]) as a function of treatment assignment, following an approach similar to that used with primary analyses. Incidence of newly emergent AEs was compared between groups using Fisher's exact test.

Multiple comparisons determined our choice of *P* values that would be considered statistically significant. A two-sided *P* value less than 0.025 was considered statistically significant for the two primary outcomes. For the four outcomes examined as secondary analyses, a *P* value less than 0.0125 was considered statistically significant. Analyses were conducted using SAS version 9.2 (SAS Institute, Cary, NC).

A sample of 112 yoga participants and 150 usual activity participants was planned to provide 90% power to detect a mean difference of 1.9 VMS/day (reduction) between groups (a 0.49-SD reduction in VMS per day), based on the variability observed in preliminary data from the first 97 participants enrolled in the MsFLASH escitalopram trial.[4] This calculation was based on a *t* test with a two-sided significance level of 0.025 to account for two primary outcomes (VMS frequency and VMS bother), allowing for a 10% loss to follow-up in both arms and an extra 10% in the exercise arm to address the potential for increased variability in outcomes owing to differing adherence to the intervention.

RESULTS

Among 249 women, 107 were randomly assigned to receive yoga and 142 were assigned to usual activity (Fig. 1). There were no significant differences in baseline characteristics between the two intervention groups. The mean age of participants was 54 years, 63% were white, most were postmenopausal and well educated, their mean BMI was 27 kg/m^2, and a few were smokers (Table 1). Follow-up rates among the intervention and usual activity groups were 96% and 95% at 6 weeks, and 94% and 95% at 12 weeks, respectively, with no differences between groups.

VMS frequency and bother

The mean baseline VMS frequency was 7.4 per day (95% CI, 6.6 to 8.1) in the yoga group and 8.0 per day (95% CI, 7.3 to 8.7) in the usual activity group, with a range of 2.1 to 21.4 VMS/day (Table 2). Yoga did not significantly reduce the frequency of VMS relative to usual activity, adjusted for site, visit (week 6 or 12), ω-3 capsule assignment, or baseline VMS frequency (Fig. 2). In the yoga group, the mean hot flash frequency on week 12 decreased to 4.6 VMS/day (95% CI, 3.9 to 5.3), a 35% decrease or a mean of 2.9 fewer VMS per day compared with baseline. The placebo group decreased to

TABLE 1. *Baseline demographic and clinical characteristics by intervention arm: yoga versus usual activity*

	Yoga (n = 107)	Usual activity (n = 142)
Age at screening, mean (SD), y	54.3 (3.9)	54.2 (3.5)
Age at screening, n (%)		
<50 y	7 (6.5)	10 (7.0)
50-54 y	50 (46.7)	69 (48.6)
55-59 y	39 (36.4)	51 (35.9)
≥60 y	11 (10.3)	12 (8.5)
Race, n (%)		
White	68 (63.6)	90 (63.4)
African American	25 (23.4)	41 (28.9)
Other	14 (13.1)	11 (7.7)
Clinical center, n (%)		
Indianapolis	36 (33.6)	48 (33.8)
Oakland	33 (30.8)	44 (31.0)
Seattle	38 (35.5)	50 (35.2)
Education, n (%)		
High school diploma/GED or less	7 (6.5)	8 (5.6)
School/training after high school	31 (29.0)	40 (28.2)
College graduate	69 (64.5)	94 (66.2)
Employment status, n (%)		
Retired or no employment	14 (13.1)	18 (12.7)
Full time	60 (56.1)	91 (64.1)
Part time	17 (15.9)	17 (12.0)
Homemaker	4 (3.7)	7 (4.9)
Other	11 (10.3)	9 (6.3)
Married/living with partner, n (%)	73 (68.2)	97 (68.3)
Smoking, n (%)		
Never	73 (68.2)	89 (62.7)
Past	25 (23.4)	36 (25.4)
Current	8 (7.5)	16 (11.3)
Alcohol use, n (%)		
0 drinks/wk	45 (42.1)	51 (35.9)
1 to <7 drinks/wk	48 (44.9)	62 (43.7)
≥7 drinks/wk	14 (13.1)	27 (19.0)
BMI, mean (SD), kg/m^2	27.1 (4.6)	26.9 (4.6)
BMI, n (%)		
<25 kg/m^2	39 (36.4)	49 (34.5)
25-29 kg/m^2	39 (36.4)	59 (41.5)
≥30 kg/m^2	29 (27.1)	34 (23.9)
Menopause status, n (%)		
Postmenopause	80 (74.8)	116 (81.7)
Late transition	24 (22.4)	23 (16.2)
Early transition	3 (2.8)	3 (2.1)
Hysterectomy, n (%)	17 (15.9)	22 (15.5)
Bilateral oophorectomy, n (%)	8 (7.5)	13 (9.2)
Self-reported health, n (%)		
Excellent	18 (16.8)	24 (16.9)
Very good	45 (42.1)	70 (49.3)
Good	39 (36.4)	40 (28.2)
Fair	5 (4.7)	8 (5.6)
Depression score (PHQ-8), mean (SD)	4.0 (3.6)	4.1 (3.6)
Depression score, n (%)		
No depression (0-4)	65 (60.7)	91 (64.1)
Mild depression (5-9)	32 (29.9)	38 (26.8)
Moderate to severe depression (≥10)	9 (8.4)	11 (7.7)
Anxiety score (GAD-7), mean (SD)	3.2 (3.8)	3.0 (3.0)
Anxiety score, n (%)		
No anxiety (0-4)	78 (72.9)	105 (73.9)
Mild anxiety (5-9)	21 (19.6)	30 (21.1)
Moderate to severe anxiety (≥10)	8 (7.5)	7 (4.9)

BMI, body mass index; PHQ-8, Patient Health Questionnaire-8; GAD-7, Generalized Anxiety Disorder-7.

5.4 VMS/day (95% CI, 4.8 to 6.1), a 27% decrease or a mean of 2.6 fewer VMS per day. The mean difference between yoga and usual activity in the reduction of VMS from baseline to weeks 6 and 12 was −0.3 VMS/day (6 wk: 95% CI, −1.1 to 0.5; 12 wk: 95% CI, −1.2 to 0.6; overall $P = 0.119$). The mean baseline rating for VMS bother was 2.9 (95% CI, 2.8 to 3.0) in the yoga group and 3.0 (95% CI, 2.9 to 3.1) in the usual activity group (Table 2). There were no statistically significant differences in the change in VMS bother between baseline and 6 and 12 weeks when comparing yoga to usual activity (overall $P = 0.417$).

There were no statistically significant interactions between treatment effects and baseline characteristics on VMS frequency, including prior participation in yoga or meditation ($P = 0.67$), depressive symptoms ($P = 0.44$), BMI (<25, 25 to <30, and ≥30 kg/m^2; $P = 0.37$), or race ($P = 0.48$; Table, Supplemental Digital Content 1, http://links.lww.com/MENO/A60).

Secondary outcomes

Clinical improvement in VMS at week 12 (≥50% decrease from baseline in VMS frequency) occurred at a similar rate between the yoga group and the usual care group (36% and 30%, respectively; $P = 0.31$). The yoga intervention significantly improved insomnia symptoms but had no significant impact on anxiety, sleep quality, or depressive symptoms (Table 2). The mean change in ISI score between baseline and 12 weeks was −4.4 for the yoga intervention and −3.1 for usual activity ($P = 0.007$).

Among women assigned to yoga, 68% reported at the end of the trial that yoga helped relieve their menopause symptoms with minimal adverse effects, 66% reported being satisfied with their hot flash relief, and 87% said they would like to continue practicing yoga.

Intervention adherence

Participants attended 8.5 (3.5) [mean (SD)] sessions of the 12 scheduled yoga sessions (ranging from 0 to 13). Women practiced at home 4.1 (2.3) times per week. On average, women did poses 2.6 (1.1) times per week and Yoga Nidra 2.3 (1.2) times per week. Results were not altered when analyses were limited to women who were 80% adherent (attended at least 80% of the yoga classes).

Adverse events

Newly emergent AEs were reported by 33.7% in the yoga group and by 39.3% in the usual activity group ($P = 0.41$). There were no differences in emergent AEs between groups at any time point, including muscle aches and strains (6.7% in the yoga group and 10.3% in the usual activity group), low back pain (4.2% in the yoga group and 3.1% in the usual activity group), or changes in strength or sensation in the arms or legs (5.5% in the yoga group and 8.9% in the usual activity group). There were no reported serious AEs. Tolerability of treatment was high; no participants stopped the intervention because of AEs.

DISCUSSION

Based on the intent-to-treat analysis of this randomized controlled trial, we found that a 12-week program of yoga had no effect on VMS frequency or bother when compared with usual activity. VMS decreased equally in the yoga and usual activity groups over 12 weeks of intervention. Secondary

TABLE 2. *Changes in primary and secondary outcomes by intervention arm: yoga versus usual activity*

	Yoga		Usual activity		Difference	
	n	Mean (95% CI)	n	Mean (95% CI)	Mean (95% CI)	*P*
Primary outcomes						
Hot flashes per day[a]						0.119[b]
Baseline	107	7.4 (6.6 to 8.1)	142	8.0 (7.3 to 8.7)	−0.6 (−1.7 to 0.4)	
Week 6 to baseline	103	−2.3 (−2.9 to −1.6)	133	−2.0 (−2.5 to −1.4)	−0.3 (−1.1 to 0.5)	
Week 12 to baseline	102	−2.9 (−3.6 to −2.2)	135	−2.6 (−3.2 to −2.0)	−0.3 (−1.2 to 0.6)	
Bother (1-4)						0.417[b]
Baseline	107	2.9 (2.8 to 3.0)	142	3.0 (2.9 to 3.1)	−0.1 (−0.3 to 0.0)	
Week 6 to baseline	101	−0.4 (−0.5 to −0.3)	132	−0.4 (−0.5 to −0.3)	0.0 (−0.1 to 0.2)	
Week 12 to baseline	100	−0.6 (−0.7 to −0.4)	133	−0.5 (−0.6 to −0.4)	0.0 (−0.2 to 0.1)	
Secondary outcomes						
ISI sleep						0.007[c]
Baseline	106	11.8 (10.8 to 12.8)	140	12.2 (11.4 to 13.1)	−0.4 (−1.8 to 0.9)	
Week 12 to baseline	99	−4.4 (−5.4 to −3.4)	130	−3.1 (−3.9 to −2.4)	−1.3 (−2.5 to −0.1)	
PSQI sleep						0.049[c]
Baseline	102	7.7 (7.1 to 8.4)	139	8.4 (7.8 to 8.9)	−0.7 (−1.5 to 0.2)	
Week 12 to baseline	95	−2.1 (−2.7 to −1.4)	131	−1.6 (−2.1 to −1.1)	−0.5 (−1.2 to 0.3)	
Depression (PHQ-8)						0.028[c]
Baseline	106	4.0 (3.3 to 4.7)	140	4.1 (3.5 to 4.6)	−0.1 (−1.0 to 0.8)	
Week 12 to baseline	99	−0.8 (−1.5 to −0.1)	133	0.1 (−0.5 to 0.7)	−0.9 (−1.8 to 0.1)	
Anxiety (GAD-7)						0.182[c]
Baseline	107	3.2 (2.5 to 3.9)	142	3.0 (2.5 to 3.5)	0.2 (−0.7 to 1.1)	
Week 12 to baseline	101	−0.7 (−1.5 to 0.0)	135	−0.1 (−0.7 to 0.4)	−0.6 (−1.5 to 0.3)	

ISI, Insomnia Severity Index; PSQI, Pittsburgh Sleep Quality Index; PHQ-8, Patient Health Questionnaire-8; GAD-7, Generalized Anxiety Disorder-7.
[a]Hot flash frequency values were log-transformed for modeling.
[b]*P* values from contrasts comparing yoga with usual activity in a repeated-measures linear model of outcome as a function of intervention arm, clinical center, visit (week 6 or 12), ω-3 intervention assignment, and baseline outcome value. $P < 0.025$ was considered statistically significant to account for the two primary outcome comparisons of interest.
[c]*P* values from contrasts comparing yoga with usual activity in a linear model of outcome as a function of intervention arm, clinical center, ω-3 intervention assignment, and baseline outcome value. $P < 0.0125$ was considered statistically significant to account for the four secondary outcome comparisons of interest.

analyses found no difference in clinical improvement in VMS frequency but demonstrated that the yoga intervention improved insomnia symptoms.

Reports from three previous trials of the effects of yoga practice on menopause symptoms are generally consistent with our VMS results. Elavsky and McAuley[39] studied 4 months of Iyengar yoga, walking, or usual activity (n = 164). There were no significant between-group differences in VMS at 4 months. Positive affect increased in both walking and yoga groups compared with the control group. In a trial conducted by Afonso et al,[16] 61 postmenopausal women aged 50 to 65 years who had insomnia were randomized to biweekly 1-hour yoga classes, biweekly passive stretching, or usual care. They found that, compared with usual care, women assigned to yoga had significant improvement in the Kupperman Menopause Index, Insomnia Severity Index, Menopause-Specific Quality of Life Questionnaire, and Inventory of Stress Symptoms for Adults; hot flash frequency was not measured.[16] However, given the extremely high withdrawal rate (23% overall and 63% in the yoga group), these results must be viewed cautiously.[40] A yoga intervention that included breathing practices, sun salutation, and cyclic meditation was compared with simple physical exercises (both 1 h/d and 5 d/wk for 8 wk) in a randomized controlled trial of 120 women aged 40 to 55 years who had follicle-stimulating hormone levels of 15 mIU/mL or more. At 8 weeks, there were no significant group differences in the change in daytime hot flashes, night sweats, or disturbed sleep. However, yoga resulted in a significant improvement in Greene Climacteric Scale vasomotor subscale scores.[15] In contrast, two small nonrandomized yoga studies comparing VMS symptoms before and after yoga intervention reported that yoga reduced VMS frequency, severity, and bother,[12] as well as severity of menopause-related symptoms, hot flash daily interference, sleep efficiency, sleep disturbances, and sleep quality.[14] Interpretation of the results of these two studies is limited by the lack of a randomized controlled trial design.

We found that yoga modestly reduced insomnia symptoms, which are common among women during the menopausal transition[41-50] and can prompt women to seek therapy.[51,52]

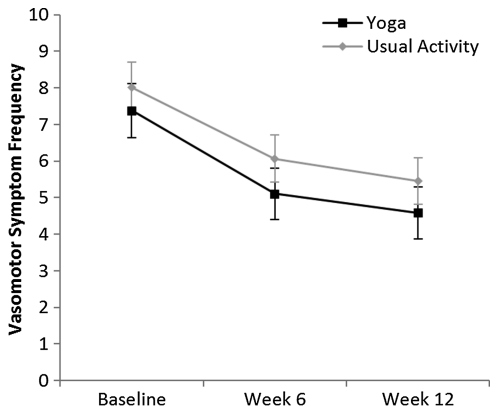

FIG. 2. Frequency of vasomotor symptoms over time, by intervention arm, at baseline, on week 6, and on week 12. Data are presented as mean (standard error).

Although our findings also suggest beneficial effects of yoga on sleep quality and depressive symptoms, these differences did not reach the level of significance required in our analyses of the four secondary outcomes. In general, these findings are consistent with numerous other studies that have found yoga to exert beneficial effects on insomnia,[16,53-56] sleep disturbances,[55,56] and depressive symptoms.[13,57-59]

Several limitations are noteworthy. Although this was a community-based sample, the participants may be a select group motivated to seek treatment; thus, our results may not be generalizable to all women. We examined several potential moderating factors for treatment response, but other factors probably exist. The overall effect was modest for all outcomes. The 12-week treatment interval was brief, but data indicate that this interval is sufficient to determine the long-term efficacy of nonhormonal treatments.[60,61] Although participants kept a home practice log, short of videotaping their practice at home it was impossible to know if their home practice was of equal intensity to the yoga class. We also cannot rule out the possibility that other yoga approaches might decrease menopause symptoms. Finally, the "dose" of yoga required to have an effect—including effects on the physiologic parameters of sympathetic/parasympathetic tone—is not known. Studies in which frequency and dose are carefully regulated would be required to answer this question.

Study strengths include adherence to the state-of-the-science randomized trial design, the design and strict standardization of the yoga intervention, the large sample size, the inclusion of perimenopausal and postmenopausal women, reasonable adherence to therapy, the prospective assessment of VMS, and the low dropout rate. The low rates of AEs provide reassurance that similar yoga programs are safe for midlife women.

CONCLUSIONS

In this randomized controlled trial, we find that yoga has no effect on VMS frequency or bother. However, yoga modestly improves insomnia symptoms—another menopause symptom important to midlife women. Future trials designed to determine the dose of yoga required to detect meaningful effects on insomnia symptoms, subjective sleep quality, and depressive symptoms are warranted.

Acknowledgments: The MsFLASH Network was established under a National Institutes of Health cooperative agreement to conduct studies on the efficacy of treatments for the management of menopausal VMS. The studies are sponsored by the National Institute on Aging, in collaboration with the Eunice Kennedy Shriver National Institute of Child Health and Development, National Center for Complementary and Alternative Medicine, and Office of Research on Women's Health.

The network sites that participated in this study were as follows: Seattle, WA (Group Health Research Institute; principal investigators: K.M.N. and S.D.R.); Indianapolis, IN (Indiana University; principal investigators: J.S.C. and L.A.L.); and Oakland, CA (Kaiser Permanente Division of Research; principal investigators: B.S. and B.C.). The Data Coordinating Center of the network is based at the Fred Hutchinson Cancer Research Center (principal investigators: A.Z.L. and G.L.A.; chairperson: K.E.E., University of Minnesota).

Other investigators of the MsFLASH Network who contributed to this study include L.S.C. and H.J. (Massachusetts General Hospital), and E.W.F. (University of Pennsylvania).

We thank D. Lee Alekel, PhD (program officer, Division of Extramural Research, National Center for Complementary and Alternative Medicine) for review of the yoga protocol and critical review of the manuscript. We thank Robin Rothenberg for her many contributions to the design and implementation of the yoga intervention.

K.A.G. had full access to all data in the study and takes responsibility for the integrity of the data and the accuracy of data analysis. All authors made substantial contributions to the study and this manuscript. None was compensated for manuscript preparation. The National Institutes of Health had no role in the collection, analysis, and interpretation of the data. The National Institutes of Health staff critically reviewed the study protocol and drafts of the manuscript before journal submission. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.

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