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A Pilot Study of a Mental Silence Form of Meditation for Women in Perimenopause

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Abstract Menopausal symptoms often feature or are worsened by psychological and psychosomatic factors. As there is limited research into the potential role of psychological interventions, especially meditation, for the treatment of these symptoms the current study adopted an AB case series design with a follow-up phase. Fourteen women who were experiencing hot flashes and other menopausal symptoms and receiving no treatment for them attended meditation classes twice weekly for 8 weeks and practiced daily at home. A mental silence orientated technique of meditation called Sahaja Yoga (SYM) was taught. The Hot Flash Diary, Kupperman Index, MENQOL, Greene's Climacteric Scale and STAI, were administered at baseline, mid treatment (4 weeks), post-treatment (8 weeks) and at 8 weeks follow-up. Substantial improvements in all measures occurred at post treatment. Changes in vasomotor symptoms, especially hot flashes, were most prominent as a significant decrease of 67% at post-treatment and 57% at follow-up ($\chi^2 = 11.7$, $p < .003$) were noted and Kupperman's Index score decreased by 58% at post-treatment and 40% at follow-up ($\chi^2 = 11.7$, $p < .005$). All other symptom measures improved substantially from baseline to post-treatment, non-parametric analysis indicating that most of these changes were significant. These findings tentatively suggest that menopausal symptoms, especially vasomotor symptoms, and particularly hot flashes, might be substantially improved by using meditation.

Keywords Meditation · Hot flashes · Menopausal symptoms · Menopause · Mental silence · Sahaja Yoga · Behavior therapy

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A total of 70% of women experience symptoms during perimenopause (MacKinlay & Jeffreys, 1974), a period which begins a few years prior to cessation of menstruation and continues for some years afterwards, typically lasting about 5 years. The most commonly-experienced menopausal symptom is the hot flash, which can occur unexpected and randomly. Hot flashes can be detrimental to quality of life (Daly et al., 1993), are sometimes overwhelming, and can affect social life, ability to work, sleep patterns, and general perception of health (Greendale, Lee, & Arriola, 1999; Roberts, Chambers, Blake, & Webber, 1992; Stein, Jacobsen, Hann, Greenberg, & Lyman, 2000).

Women with severe menopausal symptoms often seek pharmacological management. The most widely-used strategy is hormone replacement therapy (HRT). This is effective, but many women are concerned about its potential side effects (Hill, Weiss, & La Croix, 2000), which can be short term, such as PV bleeding, or long term, such as an increased risk of certain cancers. Recent revisions to menopausal management guidelines (Women's Health Initiative Investigators, 2002) and associated media attention has led to increased consumer interest in more 'natural' options. For instance, a North American Menopause Society survey (1997) of women aged 45–60 found

that 80% of respondents had used nonprescription therapies to manage short-term disturbances or prevent long-term consequences of menopause. Interest seems particularly strong among women in whom HRT is contraindicated, such as those with a history of breast cancer (Newton, Buist, Keenan, Anderson, & LaCroix, 2002).

Simple lifestyle changes directed at modifying the physiological environment can be effective. There is evidence that regular exercise (Ivarsson, Spetz, & Hammar, 1998), elimination of smoking (Starapoli, Flaws, Bush, & Moulton, 1998), and avoiding stress (Gannon, Hansel, & Goodwin, 1987; Swartzman, Edelberg, & Kermann, 1990) can reduce the impact of hot flashes. One study even reported that hot flashes ceased immediately following exposure to cold (Casper & Yen, 1985), implying that hot flashes may be linked to irregular hypothalamic regulation of core body temperature. Consequently, strategies such as taking cold drinks, reducing the intake of spicy foods, and providing room air circulation may be effective.

Complementary and alternative therapies include herbs, vitamin and nutritional supplements, and behavior therapies (Barton, Loprinzi, & Ko, 2002; Kronenberg & Fugh-Berman, 2002). Behavioral therapies are particularly attractive to both consumers and clinicians as they are non-invasive and do not involve the consumption of exogenous agents. As part of a preliminary assessment for an interventional study (described in further detail below), Hunter and Liao (1995) surveyed menopausal women who were seeking help for menopausal symptoms, and found that 60% of respondents preferred psychological treatment to HRT. Their reasons included wanting to avoid the side effects of HRT and use natural options while at the same time gaining broader skills in managing stress and enhancing self-efficacy.

Previous psychological treatments studied have included breathing exercises, relaxation (Freedman & Woodward, 1992; Wijma, Melin, Nedstrand, & Hammar, 1997), cognitive behavioral therapy (Hunter & Liao, 1996), biofeedback, hypnosis (Younus, Simpson, Collins, & Wang, 2003) and mindfulness meditation (Carmody, Crawford, & Churchill, 2006). These studies are summarized for the reader (see Table 1). In summary, change in average hot flash frequency was quite variable, ranging from 35% to 70%, and the degree and scope of changes in ancillary symptoms also varied considerably.

Of particular relevance is the preliminary study by Carmody in which mindfulness based stress reduction (MBSR) was taught to 15 women. Participants experienced a reduction of approximately 40% in the frequency of hot flashes. Mindfulness meditation is a technique of meditation that involves observation of thoughts and feelings, a kind of meta-cognitive process, with the aim of making the

Table 1 Review of behavioral therapy trials for menopausal symptoms

Author (year)	Design	*N*	Duration (weeks)	Main intervention	% Change in frequency of HF at end of intervention	Other measures
Stevenson and Delprato (1983)	SCD	4	12	Multicomponent	70	
Germaine and Freedman (1984)	RCT	12	6	Progressive muscle relaxation	54	
Freedman and Woodward (1992)	RCT	33	8	Paced respiration	39	
Hunter and Liao (1995)	NRT	61	6–8	Cognitive behavioral therapy	50	Mood; anxiety
Irvin, Domar, Clark, Zuttermeister, and Friedman, (1996)	RCT	33	10	Relaxation response	35*	STAI; profile of mood states; hot flash intensity
Wijma et al. (1997)	SCD	6	12	Applied relaxation	56	Kupperman Index; Symptom Check List 50
Younos et al. (2003)	SCD	14	4	Hypnosis	65	Quality of Life Questionnaire-C30, Brief Fatigue Inventory
Carmody et al. (2006)	RCT	15	7	Mindfulness	34	MENQOL; hot flash-related daily interference scale, women's health initiative insomnia rating scale, Symptom Check List 90R, perceived stress scale

Note: *Nonsignificant; HF, Hot flash; SCD, Single case design; RCT, Randomized control trial; NRT, Non-randomized trial; STAI, State Trait Anxiety Inventory; MENQOL Menopause Specific Quality of Life Questionnaire

practitioner calmer and less likely to engage in negative thinking when faced with stressful events. MBSR includes coaching in certain mental attitudes and beliefs about the relationship between thoughts, feelings the mind and sense of self and other exercises (Kabbat-Zinn, 1990). Questions remain as to whether or not mindfulness is a meditation technique, a relaxation method or a more complex form of behavioral therapy. While meditation and relaxation are overtly similar researchers such as Manocha, Marks, Kenchington, Peters, and Salome (2002) provide empirical evidence for a distinction between "classical" meditation (with its emphasis on the mental silence experience), and meditation as a method of relaxation and generic stress management strategies. A separate assessment of the clinical potential of mental silence orientated meditation is therefore warranted.

This exploratory study examined the effects of SYM as a management strategy for menopausal symptoms, particularly hot flashes using a "classical" definition of meditation which features a state of 'mental silence' or 'thoughtless awareness' (Devi, 1997). Sahaja Yoga is a technique that emphasizes the importance of this classical approach and practitioners describe experiencing the state of mental silence as a key part of the meditative experience. It can be characterized by the following features: Elimination of unnecessary, especially negative thought activity; focusing attention effortlessly on the 'present moment' experience; and remaining alert and aware (sometimes more aware, but not hyperactive) and in full control of one's faculties.

Method

A single cohort prospective, observational interventional study using an AB design with a follow-up phase with assessments at baseline, weeks 4, 8, and 16 was utilized.

Participants

Fourteen women with menopausal symptoms were enrolled into a specifically-designed, 8-week-long instructional program conducted at the Sydney Menopause Centre, Royal Hospital for Women, Sydney, Australia.

Referrals were made by clinical staff at the Sydney Menopause Centre of individuals who were attending the center for assessment and treatment of menopausal symptoms. Inclusion/exclusion criteria for this trial were: last menstrual period over 6 months prior; no other treatment, alternative or conventional, for menopausal symptoms for the past 8 weeks; no history of breast cancer; age between 40 and 60; no history of significant psychological or physical illness; nonsmoker; and less than two standard alcohol drinks per day. Subjects did not have a surgically/medically induced menopause; or unwillingness to comply with treatment guidelines of the study. Participants experienced a minimum of five hot flashes a day, as measured by a hot flash diary.

Eighteen women originally agreed to be contacted by the researcher. Four women were excluded because they were unable to make the necessary commitment to attend classes. Fourteen women gave informed consent and four women dropped out before the end of the intervention phase of the study and one woman was lost to follow-up. Mean age was 55 years. Thirteen of the subjects were either married or in defacto relationships.

The study was approved by the South Eastern Area Health Service Ethics Committee.

Procedure and Measures

The meditation group attended the Sydney Menopause Centre two evenings per week for 8 weeks where they received structured classes on the practice of SYM. The technique is based on a "classical" understanding of meditation and uses a simple series of silent affirmations based on a traditional understanding of yogic psychophysiology.

The instructor was a health professional with expertise in SYM instruction. Each instructional session lasted one and a half hours. All participants began the program simultaneously. Instructional audiotapes were given, as well as written guidelines on how to cultivate the meditation experience.

Each class began with an attendance role, followed by a brief instructional talk on the principles of meditation to be learned that day (focused on methodology such as breathing techniques, attentional focusing skills and designed to enhance the experience of mental silence), a question-and-answer session on any difficulties participants were experiencing, two guided meditation sessions separated by a short break, and a second, brief question time.

Participants were introduced to the idea that most menopausal symptoms could be spontaneously corrected by the practice of regular meditation. The idea that the state of mental silence was the crucial therapeutic component of the experience was impressed upon them.

During meditation subjects were encouraged to sit quietly in a chair or in a comfortable position that facilitated their meditation experience. The instructional sessions were specifically focused on helping participants achieve the experience of "mental silence" and each week informal feedback was sought by instructors regarding each participants' progress with regard to this. They were encouraged

to practice the techniques that they learned at home for 15 min twice each day.

Measures

At the first visit and at weeks 4, 8, and 16, participants completed a battery of self-report questionnaires and a hot flash diary:

- The Flash Count Diary requires that subjects tally each hot flash as it occurred throughout a 7-day period (Sloan et al., 2001).
- The Kupperman Index of Menopausal Symptoms, the oldest menopausal self-report instrument, is a validated menopause-specific symptom measure (Kupperman, Blatt, Wiesbader, & Filler, 1953; Kupperman, Wetchler, & Blatt, 1959) that focuses primarily on symptomatic relief.
- The Menopause Specific Quality of Life Questionnaire (MENQOL) is a validated questionnaire assessing the impact of menopausal symptoms on quality of life and is designed to detect changes as a result of treatment (Hilditch et al., 1996).
- The State Trait Anxiety Inventory (STAI) has been widely used in a variety of research settings and is one of the most popular assessment tools used in research into meditation (Spielberger, Gorsuch, & Lushene, 1968).
- The Greene's Climacteric Scale is a self-report scale measuring the severity of three common types of menopausal symptoms: psychological, somatic, and vasomotor (Greene, 1998).

Statistical Analysis

The most conservative approach in the handling of missing values was taken, with no attempt being made to estimate missing values, and each analysis used all available scores.

Non-parametric analysis was the most appropriate way to handle the data because of the small sample size. These results are presented in Table 2. Response rates were compared between pre-intervention, post-intervention, and at follow-up to determine any change in hot flash frequency. To facilitate discussion in this paper as well as comparison with other studies Table 3 summarizes the percentage change for each measure, between baseline and post-intervention and baseline and follow-up.

Results

Vasomotor Symptoms

There was a clear improvement in vasomotor symptoms, particularly hot flashes. Hot flash frequency is best assessed by determining responder rate, with a reduction of 50% or more regarded as a positive response (MacLennan, Lester, & Moore, 2001). Eight out of ten participants exhibited a positive response, and this response was maintained at 16 weeks follow-up. By post-treatment, hot flash frequency was an average 67% below baseline, and at follow-up it was still 57% below baseline. Non-parametric analysis of hot flash frequency across the entire study showed that the changes were significant.

Table 2 Non-parametric repeated measures Friedman test

Measure	*N*	Baseline Mean rank	Post-treatment Mean rank	Follow-up Mean rank	Friedman χ^2 (2df)	*p*
Hot flash frequency	10	2.89	1.50	1.61	11.7	.003
Kupperman Index	8	2.88	1.31	1.81	10.5	.005
Greene Climacteric Scale						
Vasomotor	9	2.89	1.33	1.78	14.9	.001
Somatic	9	2.50	1.28	2.22	8.9	.012
Anxiety	9	2.67	1.22	2.11	10.1	.006
Psychometric	9	2.56	1.22	2.22	9.2	.010
Depression	9	2.33	1.50	2.17	4.7	.097
MENQOL						
Vasomotor	9	2.28	1.72	2.00	1.5	.469
Psychosocial	9	2.33	1.11	2.56	10.9	.004
Physical	8	2.50	1.75	1.75	3.0	.223
Sexual	9	2.56	1.56	1.89	7.0	.030
STAI-state	10	2.50	1.80	1.70	4.0	.135
STAI-trait	10	2.50	1.60	1.90	4.4	.110

Note: MENQOl, Menopause Specific Quality of Life Questionnaire; STAI, State Trait Anxiety Inventory

Table 3 Descriptive summary of changes, baseline to post-intervention, to follow-up

Measure	Post-intervention % Change	Follow-up % Change
Hot flush frequency	67.2	56.2
Kupperman Index	58.2	40.4
Greene Climacteric Scale		
Vasomotor	71.1	52.4
Somatic	80.8	29.3
Anxiety	77.5	32.9
Psychometric	74.3	21.4
Depression	69.1	2.1
MENQOL		
Vasomotor	46.7	46.7
Psychosocial	45.9	37.2
Physical	53.0	31.7
Sexual	56.2	33.3
STAI-state	25.8	26.6
STAI-trait	26.4	23.0

Note: MENQOl, Menopause Specific Quality of Life Questionnaire; STAI, State Trait Anxiety Inventory

The Kupperman Index fell to a level 58% below baseline, with only some loss of benefit at the follow-up assessment, (compared to Wijma et al. (1997) average 43% reduction in severity scores, which was however maintained at follow-up). Non-parametric analysis showed the changes in the Kupperman's Index to be significant.

Similarly, the vasomotor subscale of Greene's Climacteric Scale improved an average 71% post-treatment. At follow-up, scores returned to 53% below that of baseline. Analysis of this subscale showed these changes to be significant. The MENQOL's vasomotor subscale scores were 53% better at post-treatment, and remained unchanged at follow-up however on statistical analysis these changes were not significant.

Informal feedback from participants indicated most subjects did not continue meditating with the same intensity after cessation of the program.

Other Symptoms and QOL Domains

Non-vasomotor symptom scores did not change as impressively. For instance, the Psychometric and Depression subscales of the Greene's Climacteric Scale and the Physical subscale of the MENQOL, despite their impressive changes at post-intervention were not maintained at follow-up. Consequently, analysis showed that these changes were not significant across the full duration of the study.

Discussion

Notwithstanding the obvious limitations of this small, uncontrolled trial those participants who completed the program and were followed up appeared to experience substantial improvements in a wide range of symptomatology. The most remarkable response was related to vasomotor symptoms, particularly hot flashes. Analysis by either frequency or responder rate indicated that the improvement was both statistically and clinically significant and more or less sustained even at the follow-up phase. There was no significant change in frequency in the follow-up phase, indicating that, even without professional supervision and formal classes, participants were able to maintain the health advantage that they achieved in the formal phase of the treatment program.

Clinically significant improvements also occurred in a number of the other measures, many of which were also statistically significant. The Kupperman Index, the Vasomotor, Somatic and Anxiety subscales of the Greene's Climacteric Scale, the Psychosocial and Sexual subscales of the MENQOL all exhibited statistically significant changes across the entire assessment period. This is not to say that the other changes seen in the other scales, such as in both state and trait subscales of the STAI or the vasomotor subscale of the MENQOL, were negligible. In fact Table 3 shows that the changes in these measures were substantial however the power of the analysis is limited by the small sample size. More fine grained analysis, say, between baseline and post-intervention, was deemed inappropriate given the small sample size and exploratory nature of the study.

The loss of benefit indicated in some of the scales at follow-up may be explained by reduced compliance in the follow-up phase. By the same token, this also suggests that even partial compliance with the treatment program may be sufficient to maintain some benefits.

The improvements reported here compare favorably with previous studies (see summary Table 1) suggesting that the SYM approach may be more effective than a simple relaxation approach, but may not necessarily be more effective than multimodal approaches.

The mechanism of the menopausal hot flash is not yet fully understood although a neuroendocrine pathway is thought to have a primary role (Barton et al., 2002). It has been proposed that a psychophysiological, neuroendocrine pathway exists in which estrogen withdrawal leads to a decrease in endorphin and catecholamine levels, which culminates in increased hypothalamic norepinephrine and serotonin release. The change in these two factors then lowers the set point in the thermoregulatory nucleus of the brain: heat loss mechanisms are triggered and consequent increases in peripheral blood flow remove heat

from the body, producing both a hot flash and associated vasomotor phenomena (Shanafelt, Barton, Adjei, & Loprinzi, 2002).

Consequently, SYM may be helpful in mitigating the experience of hot flashes via a number of possible pathways. Studies in the area have implicated the stress response via reduction in physiological arousal (Panjwani, Gupta, Singh, Selvamurthy, & Rai, 1995), creation of a change in the levels of circulating stress hormones (Panjwani et al., 1995) or in reductions in cortisol releasing factor (Harte, Eifert, & Smith, 1995). However, Swartzman et al. (1990) in a study on stress-induced hot flashes, suggested simple reduction in arousal may not be the only explanation. Using objective measurements, these researchers found menopausal women exposed to various experimental stressors experienced more frequent and more distressing symptoms, but the additional hot flashes did not occur during stress and were not associated with elevated sympathetic arousal. This suggests the effects may be mediated by a slower neuroendocrine pathway other than the sympathoadrenal axis which supports the stress response. For example, stress and, inversely, stress reduction may alter hypothalamic release of estrogen, which in turn changes the firing threshold of hypothalamic thermoregulatory neurons. The negative emotions of stress are processed in the limbic system, and some experiments involving stimulation of the hippocampus have been shown to change thermosensitivity of preoptic neurons (Shanafelt et al., 2002). This might explain why stress potentiates rather than precipitates hot flashes and why meditation might be effective not only in reducing the severity of hot flashes but also preventing them.

From a psychobehavioral perspective Borkovec et al. (1987), and many others have found that CBT leads to a reduction in the physiological and psychological elements of anxiety in normal populations and clinical populations. However, in the present study, more robust effects were observed in scales assessing physical symptoms rather than psychological ones. This suggests that SYM's primary effect was via alteration of physiological function rather than cognition and that the significant changes in psychological measures may be a consequence secondary to changes in physiological activity.

The small sample size in the current study means small, but real, treatment effects may not have been identified. This may explain why some changes in psychological measures, such as that seen in the vasomotor scale of the MENQOL, failed to reach significance in the non-parametric analysis despite their impressive numerical changes and the clinical improvements that they imply. Further studies using larger samples are needed to more fully explore this.

Of the14 participants for whom baseline measures were taken, only 10 continued with the study. Selection bias may, therefore, have inflated the apparent effect of the intervention. Selection bias is especially important in studies such as this which involve intense commitment from participants and hence considerable expectation of benefit as well as selection through attrition of those that are experiencing positive outcomes. On the other hand, our drop out rate is similar to that seen in many other lifestyle modification studies, and similar rates would probably be seen in real life. Furthermore, while the drop-out phenomenon introduces bias by selecting for those most motivated, or those experiencing most benefit, it also allows researchers to look at the efficacy of such treatments in those participants most likely to try them in the community.

The absence of a control group makes it difficult to identify the magnitude of nonspecific factors, such as the placebo effect, expectancy, demand, practice effect, and regression to the mean. It is well recognized that these phenomena can have potent effects in psychophysiological symptoms such as the vasomotor phenomena associated with the perimenopause; for example, flashing responds to suggestions of improvement (Clayden, Bell, & Pollard, 1974). A number of reviews have suggested that placebo effect can be substantial for vasomotor symptoms (Shanafelt et al., 2002). MacLennan et al. (2001) systematic review of estrogen versus placebo effects for the management of menopausal symptoms found that, while HRT was clearly more effective than placebo, subjects in the placebo groups experienced up to 50% improvement in hot flash frequency from baseline to the end of the study.

In our study, the responder rate was 80%, and the mean reduction in hot flashes was 67%. This suggests that the observed effect is unlikely to be due to placebo or other nonspecific factors alone. The fact that hot flashes, compared with affective phenomena such as anxiety or depression, improved to a greater degree supports the idea that the observed effect is not simply due to a change in subjective perception. Similarly, while it is possible that participants may have experienced an unrelated, spontaneous improvement as part of the condition's natural history, the usual time span for such regression to the mean is several years, whereas the improvements in this study occurred over several weeks and were maintained for some months afterwards.

The improvements in the psychological dimensions are consistent with effect magnitudes seen in studies using CBT or other psychotherapy, although our intervention did not include any formal counseling. A number of studies clearly suggest that meditation can have an effect similar to (West, 1987) or greater than (Manocha et al., 2002) that of other behavioral techniques. There is also some evidence to

suggest that the effect of meditation, and some other behavior therapies, extends beyond subjective experience and into the physical parameters of illness itself (Manocha et al., 2002).

Carmody et al.'s (2006) study which used mindfulness meditation reported similar levels of completion by participants but considerably smaller effects on hot flash frequency (35% at the end of the intervention period and 45% at the follow-up phase). The apparently larger response observed in our study may be due to the fundamental differences between the two approaches vis a vis the emphasis on mental silence in the SYM technique versus the emphasis on mental observation in the MBSR. The comparative effects of these two approaches warrant further investigation.

Admittedly, the heuristic nature of this study has its limitations. But its value is significant because, first, it suggests that a potent effect may be available from an easily learned behavioral method. Second, this method is concerned with a relatively unique idea that the meditative "state of consciousness" is responsible for its therapeutic effect. Third, no other behavioral method has explicitly connected this notion with health outcomes and yet the apparent magnitude of effect is one of the largest so far reported in the literature. Fourth, other RCTs of the same method suggest that this conceptual approach to meditation, unlike other approaches, is yielding evidence of specific effects. Therefore this study is not only significant to clinicians looking for promising behavioral therapies but will also be useful to those researchers looking for ways to understand and study meditation.

In conclusion, this preliminary assessment of meditation for menopausal hot flashes and other menopausal symptoms showed SYM has demonstrated promising effects. These effects seem comparable if not possibly greater than that seen in studies of other behavior therapies. Further investigation is needed using RCT methodology with adequate sample size and proper strategies to control for non-specific effects associated with behavior therapies to determine whether or not these effects are real and specific to this particular intervention. As demand from consumers for information on non-pharmacological approaches to controlling menopausal symptoms increases, the imperative for such exploration grows.

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