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EDITORIAL

Mind/body interventions for hot flashes

Millions of women in the United States experience hot flashes (HFs), and many find their lives significantly disrupted as a result of this and other menopause-related symptoms, including sleep and mood disturbance. Since the publication of the results of the Women's Health Initiative in July 2002,¹ there has been a dramatic shift in the way in which the medical community prescribes hormones, and a significant decline in the use of hormone therapy both in the United States and worldwide.²⁻⁴ In addition, there has been an increasing trend toward the use (and availability) of complementary and alternative medicine (CAM) treatments, and these are commonly used by women to treat menopausal symptoms.^{5,6} Although CAM nutritional and herbal therapeutics are generally perceived to be safer than prescription medications and allow the user to feel more in control of her own health,⁷ with a paucity of evidence supporting the safety, quality, and efficacy of these products, there is a growing need for safe and proven options for symptomatic women who choose not to use hormones.

In this issue of *Menopause*, Carmody et al⁸ report results from an uncontrolled feasibility study to test whether a nonpharmacologic, behavioral (mind/body) intervention commonly used to cope with stress could influence HFs. The first question to ask is: why is the ability to cope with stress important for the study of HFs?

A stress response is triggered when a person perceives that she is in danger (either a physical or psychological threat) and that she does not have the resources to cope with that situation. Stress-coping ability involves developing the perception that one has the adaptive resources to handle the stressor. Previous research has established a relationship between stress and HFs.^{9,10} Women who seek medical advice or report distress from HFs appear to have lower stress-coping abilities than women without HFs.¹¹ Cognitive variables such as negative/catastrophic thoughts or negative self-image negatively affect the experience of vasomotor symptoms.^{9,10} Finally, a sense of

increased control has been shown to correlate with less distress and discomfort during HFs.¹²

Carmody et al assessed whether a mindfulness-based stress reduction (MBSR) program would be acceptable to women for management of HFs and to evaluate MBSR's impact on HFs. Key elements of the MBSR group program include mindfulness meditation and cognitive/educational skills designed to develop more resources for responding positively (adaptively) to stressful situations, such as HF at an inopportune moment. Mindfulness is described as "a state of sustained attention to physical sensations, perceptions ... thoughts" that allows the individual to have an awareness of, without reacting to, a given situation. Participants attended eight weekly 2½-hour sessions in which they received training in mindfulness through body scan meditation, breath-focused meditation, and mindful stretching exercises. They were instructed to practice these techniques at home for 45 minutes a day, record the amount of their home practice, and record the number of HFs on daily log forms. Carmody et al report an improvement on several quality-of-life (QOL) measures and a 40% reduction in median HF severity. The authors conclude that these results provide preliminary positive evidence of the feasibility and efficacy of MBSR for managing HFs. While the feasibility of providing MBSR to menopausal women was clearly demonstrated, the efficacy of MBSR on HFs is not so clear. First, because only 11 of the 18 consenting participants completed all the outcome measures, a rather large percentage of participants (40% or 7/18) had missing data. It is possible that these participants did not respond as dramatically to the MBSR program as those participants who completed all outcome questionnaires. In addition, without inclusion of a comparison group, it is difficult to interpret the reported 40% reduction in HFs; participants may simply report reduced HFs from the natural progression of HFs over time. As such, any conclusions regarding the efficacy of MBSR on incidence and severity of HFs are premature. Furthermore, we

wonder whether women with poorer QOL scores at baseline also reported the highest incidence or severity of HFs? We are also curious whether the women who reported the most improvement in QOL also indicated the greatest reduction in HFs? Given that others have shown a relationship between stress and HFs^{9,10} and that there are many individual and cultural factors that play a role in QOL,¹³ these two additional statistical analyses would have been enlightening and served to guide future research studies.

Nevertheless, results from this small pilot study are intriguing and confirm findings from other studies.^{14,15} Specifically, behavioral approaches that use relaxation techniques can optimize coping and directly affect the experience of HFs. In a more recent study, Nedstrand et al¹⁶ compared the effects of “applied relaxation” (AR) to estrogen therapy in a 12-week randomized, prospective study of women self-reporting moderate to severe HFs. Women randomized to the AR group ($n = 15$) were taught relaxation skills, including progressive muscle relaxation, body relaxation without muscle tension, self-instructed relaxation, and “rapid” relaxation techniques to be used as a coping technique for handling sudden unanticipated HFs. There was a mean decrease in HFs of 77%, which persisted until the 6-month follow-up assessment. Women randomized to the estrogen treatment group ($n = 15$) experienced a 90% reduction in incidence of HFs. Both groups reported improved mood on self-report scales. In summary, we agree with the conclusion of Carmody and colleagues that future research is warranted.

FUTURE STUDIES OF MIND/BODY INTERVENTIONS ON HFs

However, the question remains: what are the critical elements in the study design and conduct of clinical trials of mind/body interventions on HFs? Despite these encouraging findings, very few of the above-noted studies included a comparison or control group. Controlled studies are required to evaluate the efficacy of these treatments. However, does one strive to employ a placebo-controlled trial of mind/body interventions, akin to the design used in the study of herbal therapeutics? CAM studies of herbal therapeutics have shown that there is a large placebo effect in this patient population⁵; therefore, we believe that it is critical to blind individuals assessing outcomes of individual patient treatment assignments and to mask intervention from study participants. Some have suggested that it is impossible to use blinding or masking techniques in any mind/body

clinical trials.¹⁷ Not only do we disagree, but we recently conducted a clinical trial to study the effects of the relaxation response in healthy young adults. By designing this study as a comparison between two different stress management techniques, we were able to blind the data collectors and mask the intervention from the study participants.¹⁸ We advocate use of these techniques to tease out the impact of the placebo effect on outcome.

Nevertheless, we recognize that there may be instances in which blinding and masking are not available or feasible. Under those circumstances, we strongly advocate that investigators use objective outcome measures. In the studies above, distress and QOL, as well as the incidence and severity of HFs, were assessed by study participants' self-report. This is an established method to evaluate “subjective” HFs. However, it is also possible to measure physiologic or “objective” HFs using sternal skin conductance. This method of evaluation has been validated and shown to correlate highly with patients' self-reported HFs in a laboratory setting.¹⁹ However, as Carmody and colleagues point out, the concordance between subjective and objective HFs can be quite variable in ambulatory settings. If participants in a given study are going to be aware that they are receiving the active intervention or the control, then we advocate including both objective and subjective HF measures.

A final and less controversial issue centers on the selection of an appropriate comparison group. Does one compare mind/body approaches to usual care, or should one strive for a comparison group that receives equal attention? In our above-mentioned study, the active intervention and the comparison groups both received equal contact time with the intervention leader and listened to an audiotape of an identical duration. Thus, although the content of the programs differed, the attention and study requirements, as well as contact with the provider of both groups, were equal. In consideration of the large placebo effect previously shown in studies of HFs, we believe that an adequate comparison group should have equivalent attention.

In conclusion, group-based mind/body interventions have four basic components: social support, relaxation techniques, cognitive/coping skills, and educational information. Whether one or all of these constituent attributes influence outcomes, we conclude that mind/body/behavioral medicine interventions hold great potential for managing HFs. Given the multifaceted nature of this type of intervention, there are many questions to be asked and answered in future studies. Although we believe that the various

mind/body approaches have a common physiologic underpinning (relaxation response),¹⁷ are there subtle differences across the different methods used to elicit the relaxation response, eg, MBSR versus AR versus transcendental meditation? What are the mechanisms of action? Can we develop measurable outcomes (biological markers) that can determine who is eliciting the relaxation response and thus more effectively evaluate the efficacy of these interventions? Last, can we identify which individuals would benefit more from one method over another? We advocate for the careful design and conduct of future studies to increase our understanding of the many factors that play a role, so that there can be more effective options made available to women seeking relief from HFs.

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