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### **Description of an Audio-Based Paced Respiration Intervention for Vasomotor Symptoms**

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### Abstract

Millions of women experience menopause-related hot flashes or flushes that may have a negative effect on their quality of life. Hormone therapy is an effective treatment, however, it may be contraindicated or unacceptable for some women based on previous health complications or an undesirable risk-benefit ratio. Side effects and the unacceptability of hormone therapy have created a need for behavioral interventions to reduce hot flashes. A variety of complex, multimodal behavioral, relaxation-based interventions have been studied with women (n = 88) and showed generally favorable results. However, currently extensive resource commitments reduce the translation of these interventions into standard care. Slow, deep breathing is a common component in most interventions and may be the active ingredient leading to reduced hot flashes. This article describes the content of an audio-based program designed to teach paced breathing to reduce hot flashes. Intervention content was based on skills training theory and music entrainment. The audio intervention provides an efficient way to deliver a breathing intervention that may be beneficial to other clinical populations.

### **Keywords**

entrainment, music medicine, hot flashes, paced respiration

For millions of menopausal women, hot flashes or flushes (eg. vasomotor symptoms) are frequent, severe, bothersome events that interfere with daily life.<sup>1-5</sup> Hot flashes are experienced as sudden rushes of heat and sweating, most commonly felt in the upper chest, neck and face. Hot flashes have been associated with mood disturbance, negative affect, and sleep disturbance.<sup>6-11</sup> Although hormone therapy is an effective treatment, it is contraindicated for women with breast and other estrogen-dependent cancers<sup>12,13</sup> and is no longer acceptable to others because of changes in its risk-benefit ratio.14-20 Estimates indicate that up to 60% of women discontinued hormone therapy after publication of the Women's Health Initiative findings in 2002.<sup>21,22</sup> Other nonhormonal pharmaceutical treatments have shown mixed efficacy and some side effects such as somnolence, nausea, and dizziness frequently lead to discontinuation of these medications.23

The physiological causes of hot flashes are unclear. A widely accepted hypothesis is that hot flashes are a marker of increased sympathetic activation likely triggered by the estrogen withdrawal that occurs at menopause and resulting changes in other hormones and neurotransmitters acting both peripherally and centrally.<sup>24</sup> Evidence for increased sympathetic activation comes from measurable physiological increases in sweating, heart rate, and metabolic rate that occur with each hot flash.

### Current Behavioral Interventions for Hot Flash Management

Concerns about hormone therapy and side effect profiles of other pharmaceutical-based hot flash treatments have created a need for behavioral interventions to reduce hot flashes and associated menopausal symptoms. A variety of multicomponent behavioral and relaxation-based interventions have been evaluated for hot flashes, but these tend to involve a significant time commitment. Specifically, a review using PubMed and PsychInfo search engines returned 21 English-language reports (see Table 1) describing various multicomponent interventions targeting hot flashes. Intervention examples include relaxation associated with yoga,<sup>25-29</sup> relaxation-based cognitive-behavioral

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Author, Date	Intervention	Daily Practice	# of Sessions	Session Duration	Duration of Intervention
Alder et al 2000 <sup>31</sup>	Education, cognitive-behavioral intervention with relaxation and breathing	Not specified	7	1.5 hours	7 weeks
Booth-Laforce et al 2007 <sup>25</sup>	Hatha yoga with breathing practice during first 15 minutes of warm up	15 minutes	10	75 minutes	10 weeks
Carmody et al 2006 <sup>38</sup>	Mindfulness-based stress reduction (MBSR)	45 minutes 6 days/week	8	2.5 hours	8 weeks
Carmody 2011 <sup>39</sup>	MBSR	45 min/6 days week	8	2.5 hours + I all-day class	8 weeks
Carson et al 2009 <sup>26</sup>	Yoga of awareness program	Encouraged daily practice	8	2 hours	8 weeks
Cohen et al 2007 <sup>27</sup>	Restorative yoga	60 minutes	8	1.5 hours	8 weeks
Elavsky et al 2007 <sup>28</sup>	lyengar yoga	Practice encouraged	16	1.5	8 weeks
Elkins 2007 <sup>37</sup>	Hypnosis with suggestions for relaxation and mental imagery for coolness	Not specified	4	45 minutes	4 weeks
Freedman et al 1992 <sup>44</sup>	Paced respiration at 6-8 cycles/min	Not specified	8	l hour	16 weeks
Freedman et al 1995 <sup>58</sup>	Paced respiration 6-8 cycles/min	Not specified	8	l hour	16 weeks
Ganz et al <sup>32</sup>	Comprehensive Menopausal Assessment Intervention	Not specified	2	45 minutes- 1.5 hours	4 months
Germaine et al 1984 <sup>40</sup>	Progressive muscle relaxation with breath work	2×/day	6	Not specified	6 weeks
Hunter et al 2009 <sup>33</sup>	Cognitive–behavioral Intervention	Encouraged with CD	6	1.5 hours	6 weeks
Irvin et al 1996 <sup>41</sup> Keefer and Blanchard 2005 <sup>34</sup>	Relaxation and diaphragmatic breathing Psychoeducational program cognitive restructuring with paced respiration	20 min/day everyday Not specified	3 8	l hour 1.5 hours	7 weeks 8 weeks
Manocha et al 2007 <sup>29</sup>	Sahaja yoga meditation	15 minutes 2×/day	16	Not specified	8 weeks
Mann 2012 <sup>30</sup>	Group cognitive-behavioral therapy with paced breathing	2-5 minutes throughout day	6	1.5 hours	6 weeks
Stevenson and Delprato 1983 <sup>35</sup>	Psychoeducational program with PMR and breathing training	Not specified	10	l hour	12 weeks
Wijma et al 1997 <sup>42</sup>	Applied relaxation with breathing training	Weeks 1-6: at home practice 2×/day Weeks 7-12: practice 15-20 minutes daily	12	l hour	12 weeks
Zaborowska et al 2007 <sup>43</sup>	Applied relaxation	Daily practice	12	l hour	12 weeks

Table I. Multicomponent Relaxation-Based Behavioral Hot Flash Therapies.

or psychoeducational interventions,<sup>30-36</sup> hypnosis incorporating deep relaxation and suggestions of coolness,<sup>37</sup> mindfulness-based stress reduction,<sup>38,39</sup> relaxation paired with paced respiration,<sup>40-42</sup> and relaxation paired with acupuncture and medications.<sup>43</sup>

One barrier to the integration of such behavioral interventions into standard care is the extensive resource (time and personnel) commitment required (see Table 1). Multicomponent interventions average 9 weekly sessions (range 3-16 weeks) led by an interventionist. The average intervener contact time is 13 hours (range 3-30 hours). Finally, participants are asked to practice intervention content from 15 to 60 minutes/day (average 30 minutes daily practice). Thus, due to intervention complexity, delivery, and extensive time commitment for both interventionists and patients current interventions have low potential for translation to standard care.

A potential alternative to complex, multicomponent interventions is a single component paced respiration intervention, which is a common component of the behavioral interventions described above. According to one small study, laboratory-based training in paced respiration at 6 to 8 breaths/min may be the only component that is needed to reduce hot flashes.<sup>44</sup>

However, there were no large-scale, translational studies testing paced respiration.<sup>45</sup> We received funding from the National Institutes of Health to conduct the first large-scale study of a more simplified, audio-based paced respiration intervention women could use at home.

### An Audio-Based Paced Respiration Training Intervention

*Rationale for intervention.* Paced respiration is hypothesized to minimize hot flashes by decreasing sympathetic activation. Paced respiration or slow deep diaphragmatic breathing has been shown to be beneficial in decreasing thermal pain and postoperative pain<sup>46</sup> and symptoms of motion sickness.<sup>47</sup> Long-term benefits of twice a day practice and implementation during a hot flash may be a reduction in central sympathetic activation.

The research team included a PhD music therapist, PhD nurse researcher with expertise in behavioral oncology and women's health specifically hot flashes, and a composer with a Doctorate in Musical Arts (DMA) specializing in computer music and music theory. We created and tested an audio-based, at-home training and practice intervention program for menopausal women who experience daily hot flashes. Specifically, we were interested in an acceptable and easily disseminated intervention that did not require the time and resource commitments of previous studies. The intervention was designed to teach slow deep breathing (paced respiration) to apply at the time of a hot flash and practice twice daily through the use of 2, 15-minute tracks of instrumental music designed to be consistent with prior intervention studies. The music was composed specifically for this study to encourage slow breathing through rhythmic entrainment and harmonic and melodic phrases that cued and shaped desired muscle movements and targeted breath rate.

### Theory of Music Entrainment for Paced Respiration

Music structures slow deep breathing via entrainment. Entrainment is a biological process that involves synchrony of internal rhythms (breathing) with an external stimuli or sound sources (music).<sup>48,49</sup> Many studies document the immediate and strong coordination of motor responses to an auditory rhythm such as a metronome and/or music by way of rhythmic entrainment, which stabilizes and optimizes movements so they are more efficient.<sup>50-55</sup> Rhythmic auditory stimulation (RAS), an intervention based on rhythmic entrainment, is indicated in the rehabilitation of movements that are intrinsically rhythmical.<sup>56</sup> We were interested in the breath depth, which is similar to RAS, as well as the breath rate. Therefore, additional musical elements, such as melodic and harmonic phrases, and dynamics, were used to cue and simulate the shape of the desired breathing rate and depth.<sup>56</sup>

## Process of Development and Decisions About Composing the Music

The theory of music entrainment for paced respiration guided our search for music. Acceptable criteria included music that was structured and consistent to cue breathing depth at the target rate (6-8 breaths/min) but had enough variability musically to be interesting and maintain focus of attention. We first looked for published music recordings in popular book and music stores and on the Internet. Music used for relaxation frequently uses a slow steady tempo (60-80 beats/min) that structures breathing, but music for entrainment requires variations in tempo for entrainment to occur.<sup>49</sup> Due to the difficulties finding music that was consistent with entrainment theory and potential costs and time needed to resolve copyright issues, we decided to commission two original compositions for the purpose of this study.

The music was composed electronically using Reason v.3.5 by Propellerhead, a professional grade software package for musical composition and arranging.<sup>57</sup> Reason provides an array of virtual instruments and digital effects used to mimic most instrumental timbres or create new synthesized sounds and textures. Electronic composition was considered a time and cost-effective approach to composing the amount of music necessary for the project compared to using live instrumental performances that required rehearsal time and recording studio space.

The overall musical style chosen for each composition arose from an effort to achieve a balance of "easy listening" versus "continually engaging" as well as consistency with entrainment theory. Familiar musical idioms from popular music such as drumbeats in four-four time and simple melodic refrains created a listening situation approachable to a vast majority of potential listeners. To keep the listener's attention in a relatively focused state necessary for the entrainment process, the music incorporated a sophisticated structure and a highly varied timbre palette commonly found in contemporary classical and popular music.

### Mapping Breath to Musical Structure (The Breath Metronome)

The structure of both pieces of music was built around a lowfrequency bass line that is clearly heard throughout the entirety of the music, without any significant variation in timbre, register, or rhythmic placement. From a musical standpoint, this aspect of the music is quite conventional: a moving bass line that acts as an anchor for changes in harmony. The bass line, or breath metronome, is heard by the listener as a repeating pattern of two tones: one higher than the other, with each tone falling exactly on the beat. The pattern was designed to be highly obvious and predictable after only a few repetitions. A crucial aspect of the breath metronome is that the high-low pattern corresponds exactly to the strong-weak accent pattern felt in the four-four meter, which is continually articulated by a drumbeat. This allows the breath metronome to be followed intuitively with minimal effort. The goal is for the listener to naturally associate the inhale-exhale cycle of the breathing with the continual alternating high-low, strong-weak patterns contained in the breath metronome. Because the rate of breath is analogous to tempo, it is possible to accurately measure the exact number of breaths taken and the rate at which they occur

by the listener's progress through the music and the speed of the breath metronome.

The entrainment process works by gradually slowing the breath metronome until the tempo corresponding to the target breath rate is reached. In order to for the listener to comfortably reach the desired breathing rate each piece begins with a brief (1-2 minutes) musical introduction designed to transition the listener to the main section of the music, which focuses on the target breath rate. At this point, the music continues for 15 minutes at the target rate. The first music track ("Transcendence I") is a training track that starts at an average respiration rate (16 bpm) and reaches a target rate of 12 breaths/min. The second track ("Transcendence II") is an advanced level pacedbreathing that started at 12 breaths/min and slowed to the target 7 breaths/min rate, which is consistent with previous intervention studies targeting 6 to 8 breaths/min.44,58 This rate is maintained for 15 minutes, which has been shown to be an effective rate and duration of paced respiration.

### Content of the Intervention

The Breathe for Hot Flashes intervention included two main components: a CD with an instruction track with printed liner notes reinforcing audio instructions and the 2 tracks of originally composed music. The instruction track contained the rationale and specific orientation to paced respiration. While entrainment is often a preconscious process, it was necessary to provide additional structure and expectations to encourage the women to use the CD to meet the recommended dosage  $(2\times/day practice and implementation during hot flashes)$ . The instruction track also provided standardization in delivery and assisted in establishing treatment fidelity.

The instruction track and corresponding printed instructions followed the guidelines for skills training interventions including operationalizing the skill and providing a rationale for the skills as well as the structure, format, timing, and expectations.<sup>59</sup> The descriptions contained in the instructional track provided opportunities for practice, feedback, and coaching that helped strengthen the skill acquisition.

Specifically, the instruction track contained information about the purpose of the intervention program, a basic explanation of why hot flashes occur, and how slow deep breathing was hypothesized to decrease hot flashes. The instructions then provided recommendations about how to create an environment that would facilitate practice. Proper posture and paced respiration technique were described next. Additional steps included time for practice and suggested activities to measure proficiency. The paced respiration practice during the instruction track included the "breath metronome" that was embedded in the musical compositions. This provided an opportunity for women to actually practice breathing with the metronome, while it was distinct from the rest of the musical composition. Eighty-eight women randomized to the "Breathe for Hot Flashes intervention"  $(N = 218)^{60}$  were instructed to listen to the CD, starting with "Transcendence I" and moving to "Transcendence II" when comfortable, and practice for

15 minutes twice daily and to apply the breathing at the onset of each hot flash. Finally, the instructions included contraindications for listening to the music and/or practicing the slow, deep breathing (ie, while driving). The liner notes included a transcript of the audio instructions as well as illustrations to reinforce the introduced concepts. Primary outcomes of hot flash frequency, severity, and bother were measured in all participants at baseline, week 8, and week 16.<sup>60</sup>

### Conclusions and Recommendations for Future Interventions

While many theoretical and practical issues were dealt with prior to intervention delivery, there were issues that arose that we did not anticipate. Many of these issues dealt with the preconceived notion of the purpose of the intervention, specifically the combination of music and paced respiration. The music contained on the CD was designed to structure paced respirations while maintaining a level of arousal that discouraged sleep. Some study participants voiced displeasure because they said the variety within the musical compositions was distracting and that they were not experiencing a deep relaxation. This required an explanation about the purpose of the music to structure breathing for the entire 15-minute period as opposed to relaxation.

Another issue was our inaccurate belief that women might need practice to learn paced respiration. The CD contained 2 tracks of music, one at a slightly higher rate than the target goal, because we anticipated that women might need to gradually learn to lower their breath rate. Instead, most women were able to quickly learn to slow deep breath at the target rate. For example, within 2 weeks, 51% of women were able to accurately demonstrate paced respiration at 6 to 8 breaths/min and sustained for 15 minutes. By 8 weeks, this rose to 84%.<sup>61</sup> Thus, we found that the first track of music was not truly necessary for women's learning.

The final issue is related to the inability of hearing the lowfrequency tones that comprised the breath metronome, and this occurred in 2 instances: (1) low playback speaker quality and (2) low-frequency hearing loss. The low-frequency tones were imperceptible when the music was played back on some commercially available speakers, specifically computer speakers. This required raising the frequencies (or pitches) of the breath metronome. However, women who experienced lowfrequency hearing loss were still unable to hear the breath metronome, excluding them from study participation.

### Modality

Previous behavioral interventions have focused on in-person and laboratory- or clinic-based delivery that require multiple hours and visits. This format is intuitively more expensive than a home- and CD-based intervention. A CD intervention with audio and print instructions also allows easy standardization of intervention delivery. However, the CD was not as acceptable as a DVD format in terms of understandable instructions, level of difficulty, difficulty in paying attention, and length of time needed to learn the breathing.<sup>61</sup> Future interventions may need to include a multimedia format with more explicit visual instructions. Either CD or DVD could be incorporated within one of the clinic-based, multimodal interventions mentioned earlier as some patients may need the support of a professional. With quickly advancing technology, the program could be easily disseminated via the Internet to translate to a wider audience regardless of location or time constraints.

### Future Research

While the current trial did not find paced respiration efficacious for hot flashes related to estrogen depletion,<sup>60</sup> the music compositions functioned as intended by structuring practice time and teaching paced respirations. However, other populations experiencing hot flashes as a result of diseases or treatments may benefit. For example, this intervention might be helpful for individuals experiencing hot flashes due to carcinoid syndrome, systemic mast cell disease, pheochromocytoma, medullary carcinoma of the thyroid, pancreatic islet cell tumors, renal cell carcinoma, neurological or spinal cord injury, or flushing reaction related to alcohol, drugs, or food additives.<sup>62</sup> Future research could also focus on testing the intervention in other populations where paced respiration may be beneficial for health outcomes. For example, hospitalized patients can be taught to use paced respiration to reduce anxiety during procedures or extended hospitalizations. The intervention could also be incorporated into other more intensive cognitive-based programs, particularly as a method for structuring at home practice.

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