Cognitive-Behavioral Intervention for Hot Flashes

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Purpose/Objectives: To pilot test the acceptability of a DVD platform to deliver a newly created cognitive-behavioral hot flash intervention and estimate the efficacy of the new intervention.

Design: Nonrandomized pretest, post-test design.

Setting: Midwestern and southeastern outpatient cancer clinics serving urban and rural areas.

Sample: 40 participants from two sites completed the study.

Methods: After completing preintervention assessments, participants watched a DVD of the intervention, practiced the intervention for one week, and then completed postintervention assessments. Data were collected with a brief interview, questionnaires, objective hot flash monitoring, and wrist actigraphy.

Main Research Variables: Hot flash occurrence, severity, bother, mood disturbance, affect, hot flash disruption, and sleep disturbance.

Findings: The DVD was a feasible and acceptable method for intervention delivery. Although participants expressed difficulty in applying the intervention in certain situations, they also described benefits that included shorter hot flash duration (not measured in this study). Paired t tests showed significant but minor decreases in worst hot flash severity, worst hot flash bother, mood, and disruption of daily activities.

Conclusions: The DVD was an acceptable way to deliver the intervention. However, the intervention will need to be improved before being tested in a larger study.

Implications for Nursing: A cognitive-behavioral intervention may be a useful adjunct or alternative to current hot flash treatments. Findings will be used to modify the intervention and data collection methods before undertaking a larger study.

Key Points . . .

- Hot flashes are frequent, severe, and bothersome and may be associated with mood disturbances, negative affect, disruptions in daily life, and sleep disturbance.
- Cognitive-behavioral interventions have been shown to be useful for treating a variety of symptoms.
- Interventions that do not prevent hot flashes but help mitigate hot flash severity and bother may be acceptable and useful for women with or at high risk for breast cancer.

Hot flashes are distressing symptoms. Women with a history of breast cancer often experience frequent, severe, and bothersome hot flashes that negatively impact related outcomes, including mood, affect, daily activities, and sleep (Carpenter, Andrykowski, Cordova, et al., 1998; Carpenter, Elam, et al., 2004; Carpenter, Johnson, Wagner, & Andrykowski, 2002; Couzi, Helzlsouer, & Fetting, 1995; Love, Nguyen, Nguyen, Nguyen, & Havighurst, 1999; Savard et al., 2004; Stein, Jacobsen, Hann, Greenberg, & Lyman, 2000; Thomas, 2003). In addition, women at high risk for breast cancer may experience hot flashes because they cannot take estrogen preparations for relief of hot flashes or as a side effect of breast cancer preventive agents (Agnusdei, Liu-Leage, & Augendre-Ferrante, 1999). For both groups, interventions are needed to diminish hot flashes and improve related outcomes.

Although pharmacologic therapies are used widely for managing hot flashes and related outcomes (mood, affect, daily activities, and sleep), they are not appropriate or effective for all women. For example, many breast cancer survivors are not interested in medications. In one survey, 40% of 74 postmenopausal breast cancer survivors with hot flashes reported an interest in behavioral treatments, whereas only 26% reported an interest in pharmacologic treatments for hot flashes (Carpenter, Andrykowski, Cordova, et al., 1998). In addition, hot flash treatments such as paroxetine may place women at risk for drug-drug interactions. Paroxetine inhibits cytochrome P450 (CYP2D6) enzymes involved in metabolizing tamoxifen

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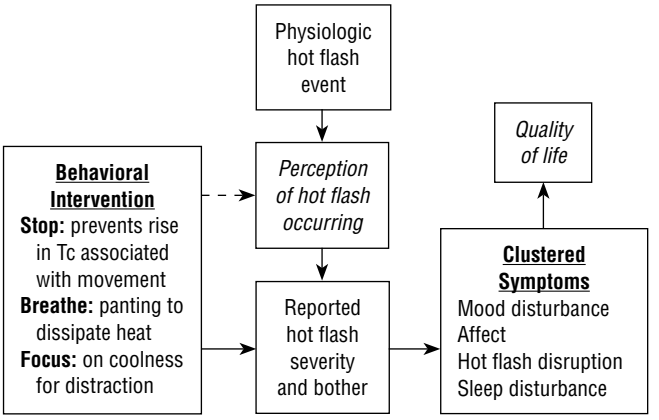
and lowers concentrations of the potent metabolite endoxifen (Stearns, Beebe, Iyengar, & Dube, 2003; Stearns, Johnson, et al., 2003). Finally, pharmacologic treatments may not afford complete relief of hot flashes. Most studies show a reduction of only one to two hot flashes per day with treatment (for a review, see Nelson et al., 2006). Thus, interventions that can be used in lieu of or in addition to standard pharmacologic treatments are needed.

Cognitive-behavioral interventions have been shown to be useful alternatives or adjuncts to pharmacologic therapies for managing a variety of symptoms (for a review, see Redd, Montgomery, & DuHamel, 2001). Relaxation training and paced respiration (e.g., slow, deep breathing) are two cognitive-behavioral interventions that effectively decrease hot flashes (for a review, see Carpenter, 2005c). However, relaxation and paced respiration protocols that have been evaluated to date are time consuming and resource intensive. For example, existing interventions require as many as 12 one-hour teaching sessions over a 4- to 12-week period as well as access to trained interventionists (Freedman & Woodward, 1992; Ganz et al., 2000; Germaine & Freedman, 1984; Irvin, Domar, Clark, Zuttermeister, & Friedman, 1996; Irvin, Friedman, & Domar, 1995; Stevenson & Delprato, 1983; Wijma, Melin, Nedstrand, & Hammar, 1997).

A simpler, streamlined intervention that easily can be disseminated and implemented into standard clinical practice is needed. For example, rather than in-person teaching sessions, an intervention could be disseminated easily using a DVD platform. This format is capable of delivering audio and video, is viewable using a computer or DVD player, is inexpensive to mass market, and can be disseminated easily via postal mail or the Internet. Drawbacks to using a DVD include the one-way nature of instruction and limited opportunity for participants to ask questions. The purposes of this study were to determine acceptability of a DVD intervention delivery platform and to pilot test the efficacy of a new cognitive-behavioral intervention.

Conceptual Model

A conceptual model created to guide the study is depicted in Figure 1. One premise of the model is that hot flashes are physiologic events as well as reported events. First, hot flashes are well-described physiologic occurrences that result in a heat dissipation response. Prior to a hot flash, core body temperature begins to rise by more than 0.1ºC (Carpenter, Gilchrist, Chen, Gautam, & Freedman, 2004; Freedman & Krell, 1999) and an inspiratory sigh is released (Woodward, Greville, & Freedman, 1995). During a hot flash, sweating and peripheral vasodilation increase sternal skin conductance (Carpenter, Gilchrist, et al.; Freedman, Norton, Woodward, & Cornelissen, 1995), heart rate increases (Kronenberg, 1990; Kronenberg, Cote, Linkie, Dyrenfurth, & Downey, 1984), metabolic rate increases (Carpenter, Gilchrist, et al.; Freedman, 1998), and blood pH decreases slightly (Aktan, Kaleli, & Sungurtekin, 1998). Each of these parameters, including core body temperature, returns to pre–hot flash levels as the hot flash dissipates. In addition, a hot flash is a perceived event that can be rated by women in terms of severity and bother (Carpenter et al., 2002; Finck, Barton, Loprinzi, Quella, & Sloan, 1998). Severity and bother are subjective ratings of how intense and how distressing (or bothersome) hot flashes



Tc—core body temperature

Note. The dotted line depicts the point at which the intervention was applied by the participant. Italicized concepts were not measured in the study.

Figure 1. Conceptual Model

are and may be defined individually by each woman in terms of how hot she becomes during the flash, how much she perspires, or how long the hot flash lasts (Carpenter et al., 2002; Finck et al.).

A second premise of the model is that hot flashes can have a negative impact on mood, affect, daily activities, and sleep—all of which can adversely affect quality of life (Carpenter, Andrykowski, Cordova, et al., 1998; Carpenter, Elam, et al., 2004; Carpenter et al., 2002; Couzi et al., 1995; Love et al., 1999; Savard et al., 2004; Stein et al., 2000; Thomas, 2003). Alleviating hot flashes may help improve other related outcomes.

In the model, the cognitive-behavioral intervention is aimed at reported hot flash severity and bother. Because the intervention was used after women perceived a hot flash as occurring (e.g., physiologic event of the hot flash already under way), it was not expected to alter the physiologic occurrence of hot flashes.

Methods

Setting

This study was conducted at two sites, one in the midwest and another in the southeastern United States. Both sites were affiliated with National Cancer Institute–designated cancer centers serving urban and rural populations.

Design

The study was completed in two parts. Part I involved creating a DVD for intervention delivery at two study sites, a process that is not the focus of this article. Part II involved pilot testing the intervention using a quasi-experimental, pretest to post-test design.

Intervention

The intervention included one cognitive activity (distraction) and two behaviors (remain still, breathe). The behaviors were aimed at facilitating the drop in core body temperature that occurs after a hot flash (Carpenter, Gilchrist, et al., 2004; Freedman, 1998). The first behavior that the women were

taught was to remain still during the hot flash rather than increasing their movement by removing clothes, fanning themselves, or walking around. The rationale for this behavior change is based on findings that activity and exercise increase core body temperature (Brenner, Shek, Zamecnik, & Shephard, 1998; Guyton & Hall, 2000), which may inhibit the drop in core temperature following a hot flash and exacerbate hot flash severity and bother. The second behavior that the women were taught was open-mouth breathing at a rate slightly faster than normal (e.g., modified panting), a common behavioral response in animals to dissipate body heat. Women were taught to part their lips slightly and increase their breathing rate. Third, to take women's minds off feelings of heat and perspiration, they were taught to use a distraction technique that involved focusing on the sensation of coolness that occurrs on the palate during open-mouth breathing.

The DVD consisted of video clips demonstrating the intervention during three situations: resting at home, during housework, and in a work environment. A cartoon depicted the proposed physiologic mechanism of action on core body temperature. A voice-over and on-screen text boxes repeated instructions to "stop, breathe, and focus" to help women remember how to use the behavioral intervention. Women were taught to use the stop-breathe-focus intervention as soon as a hot flash was perceived. They were instructed to stop using the intervention if they felt lightheaded and to avoid using the intervention while driving or during other activities requiring concentration to ensure safety.

Sample

Women diagnosed with any stage of breast cancer or at high risk for the disease were included. All women were older than 21 years, were having hot flashes as demonstrated by sternal skin conductance monitoring, and were able to provide informed consent. Forty-nine women were recruited (26 women at site 1 and 23 women at site 2), with 40 completing all aspects of the study.

Procedures

The study was approved by the institutional review boards and the cancer center scientific review committees at each study site. Potential participants were recruited using an institutional review board–approved recruitment database or with the assistance of physician coinvestigators. Women were approached in person in the clinics or via telephone. Interested women were screened for eligibility and, if eligible, were scheduled for their first study session. Informed consent was obtained from all participants. Throughout the study, a research assistant met with participants at the cancer centers, the women's homes, or the women's workplaces to decrease patient travel. All procedures were performed by the research assistant.

Prior to the intervention, women wore a hot flash monitor for two 24-hour sessions, wore a wrist actigraph for seven nights, and completed a set of questionnaires. The intervention then was delivered by a research assistant via laptop computer. Women were instructed to practice using the intervention for one week. At the end of the week, women had the option of watching the DVD again (e.g., a "booster" intervention session). Postintervention data collection then commenced. Women wore a hot flash monitor for two 24-hour sessions, wore a wrist actigraph for seven nights, and completed a set of questionnaires. Women were compensated $40 for their time and effort in completing the study.

Measurements

Sample description information was obtained from questionnaires completed before the intervention. Data collected included demographics, menopausal status, and breast cancer-related disease and treatment information (when applicable).

Intervention acceptability: The researchers assessed for this outcome in three ways. First, they asked women to track how many times the intervention was used. Following intervention delivery, women were instructed to press a button on the hot flash monitor (or wrist actigraph) each time the intervention was used. No other data on intervention use were collected. Second, women were asked to complete a questionnaire assessing their attitudes about the DVD delivery platform (six items) and the intervention (eight items). Women rated each item on a five-point scale as strongly agree, agree, neutral, disagree, or strongly disagree. Responses to items were examined individually; a total score was not calculated. Third, women at one study site responded to an open-ended question asking for general comments and suggestions for changing the DVD video, audio, or intervention itself. Responses were tape-recorded, transcribed verbatim, and entered into an electronic format for coding and sorting.

Physiologic hot flashes: This symptom was measured using the **Biolog® 3991 sternal skin conductance monitor** (Morro Bay, CA). The method has been described previously as a feasible, accurate way to assess physiologic hot flashes (Carpenter, 2005a; Carpenter, Andrykowski, Freedman, & Munn, 1999; Carpenter, Gautam, Freedman, & Andrykowski, 2001; Carpenter, Gilchrist, et al., 2004; Carpenter, Monahan, & Azzouz, 2004). Participants received instructions on the use and care of the monitor and wore it for 24 hours at a time. Following completion of each monitoring session, data were downloaded and analyzed using previously published procedures (Carpenter, 2005a; Carpenter et al., 1999, 2001; Carpenter, Gilchrist, et al.; Carpenter, Monahan, et al.). The number of physiologically documented (objective) hot flashes was summed for the two 24-hour periods preintervention and for the two 24-hour periods postintervention.

Hot flash severity and bother: These outcomes were assessed using numeric rating scales (Carpenter, 2005b). Participants rated overall severity in the past week and worst severity in the past week on 0- to 10-point numeric rating scales anchored by not at all and extremely severe. Overall bother in the past week and worst bother in the past week were assessed similarly.

Related outcomes: Additional outcomes were assessed pre- and postintervention using questionnaires and wrist actigraphy. Mood disturbance was assessed using the **Center for Epidemiologic Studies–Depression Scale (CES-D)** and the **Profile of Mood States–Short Form (POMS-SF)**. The CES-D is a 20-item self-report assessing presence and severity of depressive symptoms during the prior week (Radloff, 1977). Respondents rated each item on a four-point scale. After four positively worded items were reverse scored, responses were summed to obtain total scores ranging from 0–60 (higher scores indicated higher depressive symptoms). Psychometrics of the CES-D have been examined extensively, and the scale has been used widely in research, including the authors' own

breast cancer research (Carpenter, Andrykowski, Wilson, et al., 1998). The POMS-SF is a measure of current (during the prior week) mood disturbance consisting of 37 items (Shacham, 1983) from the original 65-item POMS (McNair, Lorr, & Droppelman, 1981). A total mood disturbance score is computed, with higher scores indicating higher mood disturbance. Psychometrics among patients with cancer suggest that the reliability and validity of the POMS-SF is equal to the full-length version (Carpenter et al., 2002; Curran, Andrykowski, & Studts, 1995).

Affect was assessed using the **Positive and Negative Affect Scale,** a 20-adjective list of feelings and emotions that yields positive and negative subscales (Watson, Clark, & Tellegen, 1988). Participants rated each item from 1 (very slightly or not at all) to 5 (extremely) to indicate feelings during the prior week. Subscales scores were calculated, with higher scores indicating higher positive affect and higher negative affect. Cronbach's alphas in prior research among patients with cancer have been 0.89 or higher (Carpenter et al., 2002; Koller et al., 1996).

Hot flash disruption was evaluated using the **Hot Flash Related Daily Interference Scale (HFRDIS).** This 10-item scale measures the degree that hot flashes interfere with nine daily life activities; the 10th item measures the degree to which hot flashes interfere with overall quality of life (Carpenter, 2001). The scale was modeled after items on the Brief Pain Inventory (Daut, Cleeland, & Flanery, 1983), which assess the degree that pain interferes with seven similar activities. Participants rated the degree to which hot flashes have interfered with each item during the previous week using a 0 (do not interfere) to 10 (completely interfere) scale. A total and mean score were computed as the sum and average of items, respectively. Psychometrics have been reported previously and found to be acceptable (Carpenter, 2001).

Sleep disturbance was assessed using the **Pittsburgh Sleep Quality Index (PSQI)** and wrist actigraphy. PSQI items use varying response categories that include recording usual bed time, usual wake time, number of actual hours slept, number of minutes to fall asleep, and Likert scales. The 19-item scale yields a global score, with higher scores indicating poorer sleep quality and higher sleep disturbance (Buysse et al., 1991; Buysse, Reynolds, Monk, Berman, & Kupfer, 1989). Psychometrics support reliability and validity among women with breast cancer (Beck, Schwartz, Towsley, Dudley, & Barsevick, 2004; Carpenter & Andrykowski, 1998; Carter, 2002; Carter & Chang, 2000; Fortner, Stepanski, Wang, Kasprowicz, & Durrence, 2002; Stein, Chartier, & Walker, 1993).

The wrist **Actiwatch®** (Mini Mitter, Bend, OR) contains an accelerometer that measures kinetic energy or motion during the daytime and nighttime (Berger, 1998; Berger & Farr, 1999; Berger & Higginbotham, 2000). The device measures 1" x 1" x 0.25," weighs 0.75 ounces, is worn on the nondominant wrist, and resembles a regular wristwatch. Data were downloaded to a personal computer, and software was used to quantify total sleep time (hours, minutes) and wake after sleep onset (percent). The Actiwatch was worn for one week preintervention and one week postintervention. Total sleep times were calculated as the mean number of hours and minutes slept per night during each week. Percent wake after sleep onset was calculated similarly as the average percentage of time spent awake during each week. Actigraphs are used widely among patients with cancer as valid, objective measures of sleep (Ancoli-Israel et al., 2003; de Souza et al., 2003; Littner et al., 2003; Miaskowski & Lee, 1999; Shinkoda et al., 1998). To help interpret Actiwatch data, nightly bedtime was recorded as the time subjects turned the lights off and daily wake time as the time their feet touched the floor in the morning.

Data Analysis

Data analysis proceeded in three steps. First, chi-square and t tests were used to compare participants' demographics, menopausal status, and disease and treatment characteristics across study sites. Because participant characteristics did not differ by study site ($p > 0.07$), participants were combined into one sample for the analysis. Second, intervention acceptability was evaluated by examining frequencies of intervention use, percentages of agreement or disagreement with each acceptability item, and open-ended responses. Responses to the open-ended item on the acceptability scale were transferred to an electronic format, where they were coded and sorted by the research assistant who was present when participants responded to the open-ended item. The codes and sorting were verified by a second research assistant. Disagreements were resolved through discussion. The principal investigator created categories for the various codes to further group the responses that were agreed upon by the research assistant. Finally, to evaluate efficacy, paired t tests were used to compare pre- and postintervention data for hot flashes and other outcomes. Paired t tests were calculated using the entire sample ($N = 40$) and for a subset of women identified as having the worst hot flash severity ($n = 25$, i.e., women who rated worst hot flash severity during the past week as 7 or higher).

Data on intervention use were not available for the analysis. Although participants were not instructed to press the buttons on the hot flash monitor or wrist actigraph until after watching the DVD (e.g., postintervention), preintervention "accidental" button presses occurred and their cause could not be determined. As a result, the postintervention button presses were considered inaccurate because they could have been accidental or intentional.

Results

Sample

Forty women, 22 from site 1 and 18 from site 2, met inclusion criteria and completed all weeks of study. Participants were African American (25%) or Caucasian (75%), were married or partnered (60%), were employed full- or part-time (75%), were an average of 54.42 years old (SD = 8.10), and had a median of 16 years of education (range = 12–20 years). Participants were postmenopausal (93%) or perimenopausal (7%). Thirty-nine were breast cancer survivors, and one was at high risk for breast cancer. The survivors were three months to 10 years following diagnosis ($\bar{X} = 3.45$ years, SD = 2.49) with a similar time following completion of treatment ($\bar{X} = 2.93$ years, SD = 2.19). Treatments included surgery alone (7%), surgery plus radiation (41%), surgery plus chemotherapy (13%), or surgery, radiation, and chemotherapy (39%). Most reported the presence of at least one non–breast cancer comorbid condition (65%), and most were taking a selective estrogen receptor modulator or aromatase inhibitor (80%).

Acceptability

Acceptability data from the feedback questionnaire are found in Table 1. Feedback on the DVD and intervention was generally positive. Feedback suggested that the intervention was more helpful during the daytime rather than at night.

Acceptability data from the open-ended item were grouped into five categories related to intervention components, intervention use, efficacy for hot flashes, importance of related outcomes, and general comments (see Table 2). The category "intervention use" included comments describing specific situations when the intervention was difficult or embarrassing to use. Women described difficulty using the intervention at night, either because they fell asleep while using it or they were not awake enough to be able to concentrate on doing the intervention as instructed. In addition, the "efficacy for hot flashes" category included comments that women thought the intervention decreased hot flash duration. Because the researchers did not measure hot flash duration, no data were available to validate the women's comments.

Efficacy

Efficacy results are presented in Table 3 for the entire sample and for the subset of 25 women who rated their hot flashes as worst everity (i.e., 7 or higher). Results from the entire sample indicated that the intervention significantly decreased (improved) worst severity, worst bother, HFRDIS total, and HFRDIS average. However, changes were comparable to about a 10% decrease in hot flash severity, bother, or disruption. A nonsignificant but consistent trend was found for all scores to improve postintervention, with the exception of objective hot flash frequency, which remained the same. Similarly, results for the subset with worst hot flash severity indicated that compared to preintervention, postintervention severity, bother, and HFRDIS average decreased by about 10%. No change was found in any other related outcomes, with the exception of a statistically significant improvement in CES-D scores among the subset with worst hot flash severity.

Table 1. Participant Feedback on the DVD Delivery Platform and the Intervention

Response	Agree (%)	Neutral (%)	Disagree (%)
DVD delivery platform			
1. Could see the video clearly	100	–	–
2. The video took too much time.	–	–	100
3. Enjoyed watching the video	65	33	2
4. Prefer an in-person demonstration	5	35	60
5. Would like a copy of the video	21	28	51
6. Hard to pay attention to the video	2	3	95
Intervention			
1. Taught other people	44	15	41
2. Difficult to use	7	5	88
3. Forgot to use	5	15	80
4. Embarrassing to use around other people	25	15	60
5. Helped during the day	68	23	9
6. Helped at night	45	23	32
7. Prefer different treatment	22	43	35
8. Continue using intervention	93	–	7

N = 40

Discussion

This pilot study provided preliminary information on a newly created behavioral intervention for hot flashes using a DVD intervention delivery platform. Overall, the DVD was an accepted and feasible intervention delivery method. Although statistically significant improvement in hot flash parameters was seen, changes were equal to about a 10% change. The 10% reduction in hot flashes did affect related outcomes, with HFRDI improving in all participants and CES-D scores improving in the subset that reported the worst hot flash severity. Given those results, the current intervention would need to be improved significantly before additional testing would be warranted.

Acceptability of the DVD as a method for intervention delivery was favorable, suggesting that the delivery platform would be appropriate to use in future studies. Although the researchers provided participants with a laptop to view the DVD, market research statistics suggest that a majority of Americans own a DVD player. As of 2003, almost 61 million DVD players had been sold with an estimated 43 million American households owning at least one DVD player (Audio Revolution, 2003). DVD players can be purchased for cars and homes and are included on many personal computers. Thus, most future study participants are likely to own a DVD player to use when viewing the intervention.

Acceptability of the intervention itself also was favorable, with most participants indicating that they planned to continue using the intervention. Responses to open-ended questions included suggestions for modifying the intervention in a future study. For example, suggestions for using the intervention in situations that might prove embarrassing for study participants could be included in a future version of the DVD. This and other barriers would need to be addressed before testing a subsequent iteration of the intervention. Responses to the open-ended question also indicated that the intervention might be effective in decreasing the duration of hot flashes, a variable that was not measured in this study. Duration could be measured using subjective reports because measuring duration objectively with sternal skin conductance monitoring is not possible. In addition, responses indicating that nearly half of the participants taught someone else the intervention suggest that strategies should be used to control diffusion of the intervention between treatment and control groups in a future study.

Several findings were consistent with the theoretical model. First, as predicted, the intervention did not affect physiologic hot flashes because it was aimed at alleviating hot flash severity and bother rather than the occurrence of the hot flash. However, in contrast to the present study's findings, two other studies investigating cognitive-behavioral hot flash interventions have shown benefit in preventing the physiologic occurrence of hot flashes. Freedman and Woodward (1992) randomized 33 healthy women to receive training in paced respiration, progressive muscle relaxation without breathing instruction, or alpha encephalographic biofeedback training during six- or eight-week sessions. Physiologically documented hot flashes decreased significantly from baseline

Table 2. Participant Feedback on the Intervention

Category	Description	Sample Comments
Intervention components	Pros and cons of stopping, breathing, and focusing	Sometimes it was easier to go back to sleep than do the breathing. It gave me something to do so that I was less focused on the hot flash.
Intervention use	Pros and cons of using the intervention	I fell asleep before I had really finished. I used it during class. I thought it was difficult to use in a lot of normal, everyday situations, such as work. I just had to find ways to excuse myself [to use it in front of others].
Efficacy for hot flashes	Usefulness of the intervention for hot flash distress, duration, frequency, and severity	Not necessarily reduce the distress of the entire hot flash . . . it reduced the distress of the peak. It seems like [hot flash] might be shorter [duration]. It made it shorter and less intense. I thought, oh God, this is an intense one; then I started doing my breathing, and it just brought it right down.
Importance of related outcomes	Importance of sleep and hot flash disruption	It is the sleep that is killing every one of us. Even [my son] likes it much better.
General comments	General comments about study and disseminating study information	We don't want to take medication. How do you dispense this? Can you get on *Oprah* [national television talk show]? I did show it to a couple of people.

N = 22

to post-treatment only in the paced respiration group (n = 11, $p < 0.02$). Later work by Freedman, Woodward, Brown, Javiad, and Pandey (1995) compared paced respiration (n = 13) to alpha electroencephalogram biofeedback using similar procedures with similar results. Results from the latter study also suggested that relief may have been caused by changes in the pattern of heat loss over 24 hours rather than a simple reduction in hot flashes. Whether the present study's intervention resulted in similar changes in patterns of heat loss is unknown and could be studied in future research.

Table 3. Intervention Efficacy on Hot Flashes and Related Outcomes (Paired T Tests)

	All Cases (N = 40)					Subset of Cases (N = 25)[a]				
	Preintervention		Postintervention			Preintervention		Postintervention		
Outcome	$\bar{X}$	SD	$\bar{X}$	SD	p	$\bar{X}$	SD	$\bar{X}$	SD	p
Physiologic hot flashes (Biolog®)	18.03	15.22	18.54	15.30	0.751	17.83	13.98	17.04	13.00	0.64
Reported hot flash severity and bother										
Overall severity in the past week	5.60	1.94	5.50	1.90	0.604	6.72	1.23	6.46	1.25	0.352
Overall bother in the past week	5.66	2.25	5.46	2.32	0.414	6.80	1.36	6.48	1.81	0.311
Worst severity in the past week	**7.18**	**2.02**	**6.54**	**2.10**	**0.003**	**8.44**	**0.97**	**7.60**	**1.42**	**0.001**
Worst bother in the past week	**6.79**	**2.36**	**6.19**	**2.48**	**0.012**	**8.10**	**1.34**	**7.30**	**1.94**	**0.009**
Mood disturbance										
CES-D	10.65	8.38	9.40	7.88	0.107	**10.96**	**8.67**	**8.32**	**7.64**	**0.005**
POMS-SF-TMD	36.13	21.62	33.40	18.12	0.182	37.56	24.12	32.96	20.30	0.089
Affect										
PANAS-positive affect	33.75	7.56	33.78	7.56	0.979	34.08	8.65	34.72	8.12	0.634
PANAS-negative affect	13.70	4.55	12.85	4.12	0.092	13.88	5.41	12.88	4.88	0.131
Hot flash disruption										
HFRDIS total	**29.78**	**21.19**	**23.25**	**19.81**	**0.005**	**36.00**	**22.33**	**27.12**	**21.63**	**0.002**
HFRDIS average	**3.30**	**2.35**	**2.58**	**2.20**	**0.005**	**4.00**	**2.48**	**3.01**	**2.40**	**0.002**
Sleep disturbance										
PSQI global	9.15	3.89	8.68	3.65	0.2	9.08	3.69	8.84	3.50	0.507
Actiwatch sleep time (hours:minutes)[b]	6:09	1:13	6:12	0:53	0.7	5:58	1:19	6:02	0:51	0.759
Actiwatch percent wake after sleep onset[b]	15.79	9.89	14.71	4.89	0.494	16.66	12.48	14.39	5.12	0.395

[a] Women with worst hot flash severity ratings $\geq$ 7 on a 0- to 10-point numeric rating scale.

[b] n = 35 for all cases analysis, n = 20 for subset of cases analysis.

CES-D—Center for Epidemiologic Studies–Depression Scale; HFRDIS—Hot Flash Related Daily Interference Scale; PANAS—Positive and Negative Affect Scale; POMS-SF-TMD—Profile of Mood States–Short Form total mood disturbance score; PSQI—Pittsburgh Sleep Quality Index

In addition, as predicted by the conceptual model, because the researchers saw only minimal improvement in hot flash severity and bother, improvement occurred in hot flash–related disruption in daily activities but not in affect or sleep. Although depressive symptoms improved significantly among the subset of women with the worst hot flash severity (e.g., the group most likely to benefit from the intervention), the change was minimal and possibly not clinically meaningful.

Limitations

First, because the study had an unblinded, single-group design, positive findings might be the result of a placebo effect. The reduction in worst hot flash severity and bother was comparable to the placebo effect seen in prior studies (for a review, see Sloan et al., 2001). Second, the sample size was small. However, this was a pilot study and not meant to be definitive. Third, the researchers encountered difficulty in quantifying frequency of intervention use and, therefore, the variable was not included in the analyses. Although the researchers assume that those who received the most benefit were those who used the intervention most consistently or most frequently, the hypothesis cannot be evaluated using the study data.

Implications for Practice

Although the intervention will need further refinement before it is ready for additional testing and use in clinical practice, the present research broadly suggests that other interventions could be developed and disseminated via a DVD platform. Because the researchers found the DVD intervention to be acceptable and feasible for teaching women with or at high risk for breast cancer how to manage their hot flashes, a DVD likely would be acceptable and feasible for teaching patients how to manage other symptoms. Nurses who routinely teach patients behavioral techniques for managing various cancer-related symptoms are urged to consider using a DVD for intervention delivery. Use of a DVD may result in less one-to-one time needed for patient teaching and subsequent cost savings.

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