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## DEVELOPMENT, FEASIBILITY, AND ACCEPTABILITY OF A BEHAVIORAL WEIGHT AND SYMPTOM MANAGEMENT INTERVENTION FOR BREAST CANCER SURVIVORS AND INTIMATE PARTNERS

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Author contribution

All authors contributed to the study conception and design. Material preparation, data collection and analysis were performed by CD, JW, RS, TS, and MP. The first draft of the manuscript was written by CD and all authors commented on previous versions of the manuscript. All authors read and approved the final manuscript.

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The Authors have no conflict of interest.

## Abstract

**Background**—Weight gain is common for breast cancer survivors and associated with disease progression, recurrence, and mortality. Traditional behavioral programs fail to address symptoms (i.e., pain, fatigue, distress) experienced by breast cancer survivors that may interfere with weight loss and fail to capitalize on the concordance in weight-related health behaviors of couples. This study aimed to develop and examine the feasibility and acceptability of a behavioral weight and symptom management intervention for breast cancer survivors and their intimate partners.

**Materials and Methods**—Interviews were conducted with N=14 couples with overweight/obesity to develop the intervention. Intervention feasibility and acceptability were examined through a single-arm pilot trial (N=12 couples). Patterns of change in intervention targets were examined for survivors and partners.

**Results**—Themes derived from interviews were used to develop the 12-session couple-based intervention, which included components from traditional behavioral weight management interventions, appetite awareness training, and cognitive and behavioral symptom management protocols. Couples also worked together to set goals, create plans for health behavior change, and adjust systemic and relationship barriers to weight loss. Examples were tailored to the experiences and symptom management needs of breast cancer survivors and partners. The intervention demonstrated feasibility (attrition: 8%; session completion: 88%) and acceptability (satisfaction). Survivors and partners experienced reductions in weight and improvements in physical activity, eating behaviors, emotional distress, and self-efficacy. Survivors evidenced improvements in fatigue and pain.

**Conclusions**—A behavioral weight and symptom management intervention for breast cancer survivors and partners is feasible, acceptable, and is potentially efficacious.

## Keywords

BREAST CANCER; WEIGHT MANAGEMENT; SYMPTOM MANAGEMENT; FEASIBILITY; ACCEPTABILITY; COUPLE

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## BACKGROUND

Weight gain is common for breast cancer survivors<sup>1,2</sup> and associated with disease progression, recurrence, and mortality.<sup>2,3</sup> Modest weight loss may decrease these risks.<sup>4</sup> However, few breast cancer survivors adhere to guidelines for healthy eating and physical activity,<sup>5,6</sup> key behaviors for weight loss and maintenance. This has led to recommendations for comprehensive cancer rehabilitation to include structured interventions to promote weight control and management.<sup>7–9</sup> Traditional weight management interventions target changes in diet and activity through lifestyle behavioral strategies.<sup>10</sup> Persistent pain,<sup>11</sup> fatigue,<sup>12</sup> and distress<sup>13</sup> may challenge survivors' abilities to engage in healthy eating and activity.<sup>14</sup> While prior interventions have independently addressed symptoms (e.g., distress,<sup>15</sup> pain<sup>16</sup>) or physical activity,<sup>17</sup> weight management interventions have not explicitly integrated behavioral symptom management strategies into their protocols.

Intimate partners often serve as survivors' primary supports.<sup>18</sup> Partners may experience increased fatigue and distress related to survivors' diagnoses and associated caregiving responsibilities, which may impact their own weight-related health behaviors.<sup>19</sup> Partners may also find weight management challenging due to their own health concerns and symptoms, which may be exacerbated by responsibilities and stress associated with their loved ones' cancer care.<sup>20</sup> Partners may, too, experience weight gain,<sup>19</sup> placing them at risk for overweight/obesity.

Cancer survivors and their intimate partners are likely to have interconnected health behaviors that challenge weight management. Behavioral weight loss interventions have typically been delivered to survivors and have not considered the shared health behaviors of survivors and partners. Behavior change can occur when couples work together to improve eating and activity.<sup>21</sup> Studies in the general population suggest that weight management interventions that include partners result in greater weight loss and maintenance.<sup>22</sup> Only one published trial has included family members-daughters-in a weight loss intervention for breast cancer survivors. The intervention resulted in significant improvements in weight and activity<sup>23</sup> and provides promising results for including family members in weight loss interventions. However, the relationship between mothers and daughters is quite different than that of breast cancer survivors and intimate partners, who often cohabitate, sharing in eating and physical activity practices. Targeting the shared weight-related behaviors of breast cancer survivors and their partners may be valuable.

The primary aims were to: 1) use information from stakeholders to develop an intervention for breast cancer survivors [body mass index (BMI)  $\geq 30$ ] and their intimate partners (BMI  $\geq 25$ ) providing instruction in behavioral weight management strategies and symptom (i.e., pain, fatigue, emotional distress) coping; and 2) pilot test the intervention to examine feasibility and acceptability. A secondary, exploratory aim was to examine change in intervention targets (e.g., weight, BMI, eating behavior, activity, symptoms) *for both* survivors and partners.

## MATERIALS AND METHODS

### Setting and Participants

Breast cancer survivors were recruited from a comprehensive cancer center. Eligibility criteria included: female gender; stage I-III breast cancer; BMI  $>30$ ; living with an intimate partner; age  $>21$  and  $<80$ ; and able to speak/read English. Interview participants were  $<5$  years from completion of primary cancer treatment; trial participants were  $<3$  years from treatment completion. Survivors provided permission to contact their intimate partners. Eligibility criteria for partners included: BMI  $>25$ ; age  $>21$  and  $<80$ ; and able to speak/read English. Exclusion criteria for all participants included: nonambulatory; major mental illness; residence  $>100$  miles from the research site; and inability to provide consent. Study procedures received institutional review board approval (Pro00063328, [Clinicaltrials.gov NCT02574507](https://clinicaltrials.gov/ct2/show/study/NCT02574507)). Participants completed written informed consent.

## Intervention Development Interviews

Individual and group interviews were conducted with N=14 couples ( $n=28$  unique individuals). Semi-structured interview guides were used. Topics included: 1) survivors' and partners' experiences with weight and symptom (i.e., pain, fatigue, distress) management; 2) intervention preferences; 3) factors influencing intervention participation; and 4) recommendations for intervention content. Interviews were 90 minutes, audio/video recorded, and transcribed verbatim. Participants were compensated \$20.

## Single-Arm Pilot Trial

A second, independent group of N=12 couples (N=24 unique individuals) participated in the single-arm pilot trial. Participants completed assessments at pretreatment, post-treatment (~18 weeks), and 3 months-post treatment. Assessments were conducted separately for survivors and partners, involved the completion of self-report measures and the 6-minute walk test (6MWT), and participants were weighed. Participants received \$20 per assessment (total=\$60/person).

## Study Measures

**Sociodemographic and medical variables**—Participants provided sociodemographic information (e.g., age, relationship length). Survivors provided information about their breast cancer diagnosis and treatments, and partners provided their medical history.

**Medical Comorbidity**—The Adult Comorbidity Evaluation 27 (ACE-27) assessed 27 common medical comorbidities among survivors via medical record abstraction.<sup>24</sup> Conditions were graded from 0 “none” to 3 “severe” based on the presence and severity of the condition; breast cancer diagnoses were excluded from scoring. Partners self-reported medical comorbidities.

**Feasibility, Acceptability and Satisfaction**—Feasibility was assessed by measuring treatment attrition and session attendance. The Treatment Acceptability Questionnaire (TAQ),<sup>25</sup> assessed participants' views of the intervention as acceptable, ethical, and effective. Total scores range from 6 to 42, with higher scores representing greater acceptability ( $\alpha=0.88$ ). The Client Satisfaction Questionnaire (CSQ)<sup>26</sup> asked participants to rate the quality and value of the program. Total scores range from 8 to 32; higher scores represent greater satisfaction ( $\alpha=0.92$ ). Participants completed two items specific to intervention content: “To what extent did this program help you better understand ways to manage your weight?” and “To what extent did this program help you to better understand ways to manage and cope with things like pain, fatigue, and distress?” Response options range from 1 “not at all helpful” to 4 “very helpful.”

**Weight and BMI**—Participants were weighed using an electronic scale. Height was obtained for BMI calculations ( $\text{kg}/\text{m}^2$ ).

**Eating Behavior**—The 21-item short form of the Three Factor Eating Questionnaire<sup>27</sup> assessed three domains of eating behavior: 1) cognitive restraint, 2) uncontrolled eating, and 3) emotional eating. Scores were calculated as the within domain average and range from 1

to 4. Higher scores represent greater cognitive restraint, uncontrolled eating, and emotional eating ( $\alpha=0.76-0.92$ ).

**Physical Activity**—The 6MWT provided an objective assessment of participants' abilities to exert effort in activity and was conducted following procedures outlined by the American Thoracic Society.<sup>28</sup> The total distance walked along an enclosed hallway over 6 minutes was obtained. The Stanford Leisure-Time Activity Categorical Item (L-Cat)<sup>29</sup> assessed physical activity. Participants selected the category best describing their activity level in the last month from 0 “inactive” to 5 “very active.”

**Symptom Severity & Interference**—The Brief Pain Inventory<sup>30</sup> assessed pain severity (average of worst, least, and average pain in the last week and current pain) and pain interference (average of seven items assessing the degree to which pain interfered with daily life in the last week). Higher scores indicate greater pain severity and interference ( $\alpha=0.85-0.95$ ). The 6-item PROMIS Fatigue Scale assessed fatigue in the last week.<sup>31</sup> Items were summed and converted to standardized T-scores, with higher T-scores representing greater fatigue ( $\alpha=0.97$ ). The 37-item short form of the Profile of Mood States<sup>32</sup> Total Mood Disturbance (TMD) assessed psychological distress in the last week by summing five subscales (tension, anger, depression, confusion, fatigue) and subtracting the vigor subscale. Higher scores represent greater mood disturbance ( $\alpha=0.91$ ).

**Self-efficacy for Weight and Symptom Management**—The Weight Efficacy Lifestyle Questionnaire-Short Form<sup>33</sup> is an 8-item measure of eating self-efficacy. Items are summed to create a total score ranging from 0 to 80. Higher scores indicate greater confidence in control of eating behavior ( $\alpha=0.95$ ). The 6-item Self-Efficacy for Managing Chronic Disease Scale<sup>34</sup> asks participants to rate their confidence in their ability to manage symptoms. Scores are computed as the average of the six items. Higher scores indicate greater confidence ( $\alpha=0.98$ ).

## DATA ANALYSIS

### Intervention Development Interviews

Interview transcripts were analyzed using thematic analysis to identify, analyze, and report themes and trends across data.<sup>35</sup> Prior to analysis, a preliminary codebook was developed with major content areas derived from the interview guide. Codes were applied using NVivo by two independent individuals to ensure similar understanding of codes and consistency in judgment. Discrepancies in data interpretation or code application were resolved as needed. The codebook was updated throughout to add data-driven codes, which were applied to previously coded text.<sup>35</sup> The codes were then sorted into themes.

### Single-Arm Pilot Trial

Descriptive statistics were computed for feasibility, acceptability, and satisfaction data. Recommendations for analyzing small sample pilot data were followed.<sup>36</sup> Mean differences in intervention targets and associated 95% confidence intervals from baseline to post-treatment and baseline to the 3 month follow-up were calculated for survivors and partners.

As this was a small pilot feasibility study, parametric test statistics and associated p-values are not reported. Effect sizes were computed using Hedges'  $g_{av}$  as recommended for repeated-measures designs with small samples.<sup>37</sup> Effect sizes are exploratory and should be interpreted cautiously.<sup>36</sup>

## RESULTS

### Intervention Development Interviews

Sixty breast cancer survivors were approached, and 41 were eligible; 34% ( $n=14$ ) participated with their intimate partner ( $n=14$ ). Reasons survivors provided for declining participation ( $n=27$ ) included: lack of time ( $n=8$ ); distance/transportation concerns ( $n=5$ ); not interested ( $n=7$ ); partner not interested ( $n=5$ ); and no reason given ( $n=2$ ). Interviews were scheduled to occur in groups. Due to cancellations/rescheduling, three couples completed individual interviews. The remaining 11 couples participated in four separate group interviews (2-3 couples/interview).

Survivors ( $n=14$ ) and partners ( $n=14$ ) were, on average, 56.4 ( $SD=6.65$ ) and 59.7 ( $SD=8.1$ ) years old, respectively. Survivors were  $M=27.2$  months ( $SD=7.4$ ) from diagnosis, and 57% were diagnosed with stage II cancer. 93% of couples were married and in their relationships for  $M=27.1$  years ( $SD=14.3$ ). The average BMIs were 33.1  $kg/m^2$  ( $SD=2.7$ ) and 30.6  $kg/m^2$  ( $SD=3.5$ ) for survivors and partners, respectively. 57% of partners endorsed  $>2$  health conditions and 29% endorsed pain-related conditions.

Themes derived from interviews are presented. Table 1 provides representative quotes and descriptions of how qualitative data informed the intervention.

1. *Difficulties with Weight Management Following Treatment Completion.* Survivors and partners indicated that changes in diet, mood (e.g., increased stress), and limitations in their ability to be physically active (e.g., due to their own or their partner's symptoms, time constraints) during the survivor's treatment contributed to weight gain. Weight loss following treatment was described as challenging for both members of a couple. Information provided spoke to the necessity of developing an intervention to promote weight loss that targeted both survivors and partners.
2. *Impact of Physical and Emotional Symptoms on Activity and Diet.* Participants endorsed pain, fatigue, and distress as common barriers to weight loss behaviors. For example, survivors acknowledged that neuropathy in their feet impacted their ability to use exercise machines and to feel safe when walking. Women receiving endocrine therapy described fatigue, joint stiffness, and pain as impacting their desire and ability to be active. Fatigue and low mood impacted participants' abilities to plan and cook nutritious meals. Some survivors also noted that their treatment-related side-effects (e.g., fatigue) impacted their ability to hold their partners accountable for their health behaviors (e.g., dietary choices). Partners described making food choices that were at times driven by their emotions and physical symptoms rather than hunger. Results guided the inclusion of strategies to help participants: 1) manage symptoms in the service of improving healthy

eating and activity; 2) increase awareness of activity (i.e., using a Fitbit) and eating behaviors (i.e., calorie tracking); and 3) learn how to exercise safely with treatment side effects and symptoms.

3. *Eating in Response to Non-Hunger Cues.* Factors unrelated to biological hunger, including emotions, situations (e.g., buffets), and time of day, impacted eating behaviors and food choices. Participants endorsed urges and cravings for foods high in calories, sugar, and fat, which they believed contributed to weight gain and difficulties with weight loss. Based on participants' feedback, the intervention included: 1) appetite awareness training;<sup>38</sup> 2) cognitive and behavioral strategies for managing eating triggers; and 3) tips for eating in specific situations (e.g., while on vacation).
4. *Relationship between Survivors' and Partners' Health.* Couples described conjoint sedentary behavior resulting from physical symptoms (e.g., pain, fatigue) experienced by one or both members of the couple. Couples also described shared eating habits following diagnosis and into survivorship, which contributed to weight gain. Strategies were introduced to help couples communicate about weight management behaviors and support one another in ways that did not involve food.
5. *Intervention Structure and Timing.* Participants were in support of a couple-based format and acknowledged potential benefits (e.g., accountability) of including one another in weight loss activities. Participants indicated value in initiating the program after completing treatment. The period following diagnosis and during treatment was described as a time with multiple competing demands and they would not have felt ready to receive weight management information. Participants were willing to participate in a program lasting several months. Couples stressed the importance of holding intervention sessions in a convenient location with free parking and described convenience as critical for retention. Based on feedback, the ~5-month intervention targeted couples following treatment completion. Intervention sessions were also intentionally held at a location with free/convenient parking.

## Intervention

A 12-session (90 minutes/session), in-person, couple-based intervention was developed (see Table 2). Sessions 1-6 occurred weekly, and sessions 7-12 occurred biweekly. The intervention included components from traditional behavioral weight management interventions (e.g., self-monitoring), appetite awareness training,<sup>38</sup> and cognitive and behavioral symptom management protocols. Informed by the Interdependence Model of Communal Coping and Behavior Change,<sup>39</sup> sessions focused on helping couples work together to create plans for health behavior change, work towards shared weight-related goals, and adjust systemic (e.g., buying unhealthy foods) and relationship (e.g., poor communication) barriers to weight loss. Examples were tailored to the experiences and symptom management needs of breast cancer survivors and their partners. Dietary and exercise recommendations and content were developed in conjunction with a licensed



dietician/nutritionist and an American College of Sports Medicine (ACSM)-certified clinical exercise physiologist.

The intervention was delivered by a clinical psychologist using a written therapist manual. Participants received a written patient manual. At the start of each session, participants were weighed and paper food diaries were reviewed along with homework assignments. Participants were given a Fitbit, and daily steps were reviewed at the start of each session. Couples were given the option to meet with an ACSM-certified clinical exercise physiologist for a consultation, which is offered at no cost as standard care through the comprehensive cancer center.

### Single-Arm Pilot Trial

156 breast cancer survivors received recruitment letters; 95 were eligible. Eighty-one declined participation [lack of time ( $n=26$ ); distance/transportation concerns ( $n=17$ ); family commitments ( $n=1$ ); financial concerns ( $n=2$ ); lack of interest ( $n=14$ ); health ( $n=1$ ); partner unavailable, too sick, or not interested ( $n=18$ ); and no reason given ( $n=2$ )]. Two deferred participation but were unable to be consented during the study enrollment period. Twelve survivors and their intimate partners ( $n=12$ ) consented.

Breast cancer survivors were female and partners were male; survivors were married to their participating partner. See Table 3 for participant baseline characteristics. Paired samples t-tests examined within couple variation at baseline. Survivors had significantly greater BMIs ( $M=38.57$  vs.  $31.53$ ,  $p=0.02$ ), were less active on the L-CAT ( $M=1.33$  vs.  $2.08$ ,  $p=0.04$ ), and were more likely to report emotional eating ( $M=2.50$  vs.  $1.70$ ,  $p=0.02$ ) than partners. Survivors also reported significantly greater pain interference ( $M=2.81$  vs.  $1.17$ ,  $p=0.02$ ), fatigue ( $M=57.03$  vs.  $46.35$ ,  $p<0.01$ ), and TMD ( $M=3.29$  vs.  $0.49$ ,  $p<0.01$ ) and lower symptom self-efficacy ( $M=6.13$  vs.  $8.32$ ,  $p<0.01$ ).

### Feasibility and Acceptability

The intervention was feasible, with participants completing 88% of scheduled intervention sessions. Notably, 83% ( $n=10$  couples) completed all 12 sessions. 92% of assessment visits were completed at each post-treatment time point. Participants found the intervention to be highly acceptable (TAQ:  $M=40.45$ ;  $SD=2.72$ ) and were satisfied with the treatment (CSQ:  $M=30.75$ ;  $SD=3.01$ ). The majority reported that the intervention was “quite” or “very helpful” in allowing them to better understand ways to manage weight (95%) and cope with symptoms (85%).

### Patterns of Change in Intervention Targets

Exploratory analyses examining change from pre- to post-treatment and pre-treatment to the 3-month follow-up are presented in Table 4. As the study was not powered to detect clinically meaningful effects, results should be interpreted cautiously.

### Survivors

Pre- to post-treatment reductions were found in weight and BMI, and were maintained 3-months post-treatment. Though changes were generally small ( $g_{av} < 0.5$ ), the average percent



change in weight from pre- to post-treatment was 6.0% ( $SD=6.0\%$ ) and from pre-treatment to the 3-month follow-up was 6.6% ( $SD=8.9\%$ ), falling within the 5-10% range in which clinical benefits are observed. Pre- to post-treatment improvements also were found in eating behaviors (cognitive restraint:  $g_{av}=0.65$ ; uncontrolled eating:  $g_{av}=0.58$ ; emotional eating:  $g_{av}=0.45$ ), physical activity (L-CAT:  $g_{av}=0.69$ ), symptoms (pain interference:  $g_{av}=0.49$ ; fatigue:  $g_{av}=0.76$ ; TMD:  $g_{av}=0.80$ ), and symptom self-efficacy ( $g_{av}=0.42$ ). Pre- to post-treatment changes in the 6MWT ( $g_{av}=0.12$ ) and weight self-efficacy ( $g_{av}=0.19$ ) were in the expected directions. Treatment targets improved from pre-treatment to the 3-month follow-up, with the exceptions of fatigue, TMD, and symptom self-efficacy, whose effects were smaller than those found from pre- to post-treatment.

## Partners

Reductions in weight and BMI were found from pre-treatment to post-treatment (weight:  $g_{av}=0.44$ ; BMI:  $g_{av}=0.59$ ) and pre-treatment to the 3-month follow-up (weight:  $g_{av}=0.47$ ; BMI:  $g_{av}=0.65$ ). The percent change in weight from pre- to post-treatment and pre-treatment to the 3-month follow-up were 6.3% ( $SD=3.9\%$ ) and 6.4% ( $SD=6.0\%$ ), respectively. Pre- to post-treatment improvements were found for eating behaviors (cognitive restraint:  $g_{av}=0.46$ ; uncontrolled eating:  $g_{av}=0.42$ ; emotional eating:  $g_{av}=0.34$ ) and activity (L-CAT:  $g_{av}=0.79$ ). With the exception of TMD, which improved slightly ( $g_{av}=0.25$ ), symptoms remained stable. Improvements were found for self-efficacy, with larger changes for weight ( $g_{av}=0.57$ ) than symptom ( $g_{av}=0.27$ ) self-efficacy. Treatment targets improved from pre-treatment to the 3-month follow-up, with the exception of the L-CAT, pain severity, and fatigue.

## DISCUSSION

The present study aimed to develop a behavioral weight management intervention for breast cancer survivors and partners that directly addressed physical and emotional symptoms that interfere with successful weight management. Weight management is a common challenge for individuals as they age. When faced with symptoms from comorbid medical conditions or cancer treatments (e.g., fatigue, persistent post-surgical pain, lymphedema, peripheral neuropathy), behaviors necessary for weight loss, including healthy eating and physical activity, become challenging. Qualitative data confirmed the impact of symptoms (e.g., pain, fatigue, emotional distress) on physical activity and healthy eating and pointed to the importance of including specific strategies (e.g., exercising safely with lymphedema or neuropathy, understanding cancer-related distress as an eating trigger) to assist survivors and partners with managing symptoms in the context of weight management.

The present study also targeted weight management behaviors for *both* breast cancer survivors *and* their intimate partners. Obesity risk is shared among members of a couple as evidenced by within couple concordance in BMI and adiposity<sup>40</sup> and obesity-promoting behaviors (e.g., sedentary behaviors,<sup>40</sup> dietary intake<sup>41</sup>). Family members are typically included in behavioral weight management interventions as supporters of change rather than targets of change. A “ripple” effect has been described where family members of individuals enrolled in weight management interventions also experience changes in weight and weight-related behaviors.<sup>42</sup> However, little is known about the impact that targeting both members

of a couple has on weight-related outcomes for breast cancer survivors and partners. By targeting both members of the couple, we hoped to facilitate greater *and* sustained weight loss and health behavior change.

Qualitative data pointed to couples working together to make dietary decisions and influencing one another's physical activity. Couples participating in the intervention were encouraged to create shared goals and find ways to support each other's goals. Helping to facilitate a supportive environment for couples to conjointly engage in health behavior change may have contributed to the high retention rates, high rates of intervention acceptability and satisfaction, and sustained weight loss.

Exploratory analyses suggested that both survivors and partners improved from baseline to both post-treatment time points on weight, BMI, eating behaviors, physical activity, emotional distress, and self-efficacy. Effect sizes ranged from small to large. While survivors evidenced improvements in physical symptom burden (i.e., pain, fatigue), partners did not. Not surprisingly, survivors experienced greater physical symptom burden at baseline than partners. Partners' lack of improvement may be a function of their overall low level of physical symptoms upon enrollment. For survivors, effects from pre-treatment to the 3-month follow-up were smaller for fatigue, emotional distress, and symptom self-efficacy than from pre- to post-treatment, and for partners, slight increases were seen in pain severity and fatigue at the 3-month follow-up. Ongoing booster sessions may be necessary for couples in which at least one member continues to experience high symptom burden following intervention completion. This study has several strengths including the use of a patient-oriented approach to intervention development, objective weight measurements, and high trial retention and session completion rates. There are limitations that warrant consideration. The small sample size and lack of a control arm limit our ability to draw conclusions from the exploratory effect size estimates. The majority Caucasian sample and recruitment of heterosexual couples limit generalizability. Future studies recruiting a more diverse group of cancer survivors and partners with overweight/obesity are necessary.

While trial participants found the intervention acceptable and retention was high, the accrual rate was 13%, which may further limit generalizability. Past work involving patient-caregiver/spouse dyads suggests that enrolling couples in research is often more difficult than enrolling individuals.<sup>17,43</sup> Primary reasons for non-participation included lack of time (31%) and distance/transportation (20%). The intervention required couples to attend 12 in-person, 90-minute sessions over ~5 months. Study sessions occurred on weekdays during working hours. Future work may benefit from using remote delivery (e.g., videoconferencing) methods and offering flexible appointment times. Further, a remote recruitment strategy (i.e., participants were sent recruitment letters and contacted via phone) was used. In-person recruitment may be more compelling.

## CONCLUSIONS

To our knowledge, this is one of the first studies to systematically develop a weight management intervention targeting both breast cancer survivors and their intimate partners that includes strategies to manage symptoms that often impact individuals' abilities

to engage in important weight loss and management behaviors, healthy eating and physical activity. The present study suggests that the developed couple-based intervention was acceptable, and once enrolled, retention was feasible. Exploratory examination of intervention targets suggests that the protocol may result in weight loss as well as improvements in physical activity, eating behaviors, emotional distress, and self-efficacy. For survivors, in particular, the intervention may improve physical symptoms. A randomized control trial to examine intervention efficacy is warranted. The in-person delivery of sessions, number of sessions (12), and timing of the intervention (weekday session occurring primarily during the work day) may have contributed to the low accrual rate. Future work should examine the use of remote delivery methods (e.g., videoconferencing) and the increased flexibility of appointment times for increasing intervention accessibility.

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**Table 1 - Themes derived from Individual and Group Interviews and Corresponding Intervention Components**

Themes	Representative Quotes	Corresponding Intervention Components
<p>1: Difficulties with weight management following treatment completion</p>	<p>Survivor: "I notice it's hard to lose weight... I just, it just seems like it's just hard. No matter what you give up... I just walk. I walk a lot and watch what I eat, you know, I really do but it just stays."                      Survivor: "I know what you mean because I was telling my husband, we joined the gym and I was going like three or four times a week and I was doing good and I wasn't losing not one single pound. I mean 30 minutes, 40 minutes, per day and didn't lose nothing... I was like this is terrible... there was no weight coming off. I'm like ok... Just give up. Forget it."                      Partner: "I'm going to suggest to Dr. XXXX, the oncologist, that there's a paper in this for him on the newly discovered belly fat effects of Tamoxifen in the spouse... The two changes I've noticed in terms of my stress handling, I eat more... A lot of junk food. I've been doing better but I've gained probably 15 to 20 pounds."</p>	<p>Included traditional behavioral weight management strategies (i.e., monitoring and tracking caloric intake, weighing at each session).                      Provided recommendations for daily caloric intake.                      Provided visual cues to help with understanding serving size (i.e., 4oz. chicken = 1 deck of cards).                      Provided a packet with calorie amounts for common foods by serving size.                      Focused on moderation and portion size rather than eliminating food groups from diet.                      Discussed the independent roles of diet and exercise in weight management.</p>
<p>2: Impact of Physical and Emotional Symptoms on Physical Activity/Exercise and Diet</p>	<p><b>Physical Activity/Exercise</b>                      Survivor: "We used to go hiking quite a bit and that, with the neuropathy I was really worried about because in the woods... on the trails there, they're covered in roots and stuff, and I was just so worried about tripping over that and falling, so still been afraid to do that but I'm close to wanting to start that."                      Survivor: "It's kind of hard to do stuff when your feet are numb and you're like going oh my. I remember he went walking with me and this is when I, we were biking and stuff and I was feeling really good and I just had a really bad day. My joints hurt and I'm like this is taking everything I got to take a step."                      Survivor: "...when I finished treatment I had this huge burst of energy and so I was walking two or three times a day for good walks, you know even before, even without him and then when I started my aromatase inhibitor I started having the joint pains and the feet pains and the exhaustion and so that definitely cut us back."  <b>Diet</b>                      Survivor: "But the fatigue is my biggest complaint. I'm so tired. I can stay in bed for days and then I feel bad, you know, I'm neglecting my family and I don't make dinner, and he's left to fend for himself, and he makes you know, pork and beans and hot dogs. It's about the only thing he knows how to cook."                      Survivor: "I saw [my spouse's] stress coming out and he's not a big sweet eater but he's a big candy eater so Mike and Ikes became his comfort measure... he would eat in private you know because he didn't want to make me sick... so a lot of times when that occurred there wasn't that accountability because I wouldn't be over there going, 'is that a baked potato on your plate? What's wrong with you?'"                      Survivor: "...never was that exhausted before in my life, and then you're like already having problems thinking and you're like what can I eat?... You're going to get whatever's the easiest, you know?... A bag of chips. Yay!"</p>	<p>Provided strategies for managing physical symptoms and emotional distress to help increase activity (e.g., activity pacing, relaxation training) and promote nutritious eating (e.g., cognitive restructuring, behavioral activation).                      Provided participants with a physical activity tracker to increase awareness of their current activity level.                      Participants were offered individual meetings with the cancer center's exercise physiologist; this is standard care.                      Included information about exercising safely with specific symptoms (e.g., lymphedema, neuropathy).                      Encouraged participants to track their eating behaviors (e.g., caloric intake, diet) on a daily basis along with notes about factors that may have triggered eating.</p>
<p>3: Eating in Response to Non-Hunger Cues</p>	<p>Survivor: "...I went on just like a foraging party because you know, my taste buds finally came back and I was like, 'Yes, I can have a cookie' and I can have all of this stuff and you know, but then after a little while it was like, okay now I need to go back to... normal eating..."                      Survivor: "...some of the things have been more of a habit rather than anything... They're just habit. 4 o'clock comes and I pour a glass of wine and get some junk food and then dinner comes and I'm not even hungry because I've been snacking... I plan healthy meals and decide at 4:30 hmmm pizza sounds good."                      Partner: "If I'm not doing anything at nighttime watching TV I just get up and get a little something and then get up and get a little something and eat a bowl of cereal before I go to bed and just being bored triggers my appetite."</p>	<p>Inclusion of strategies from Appetite Awareness Training to help participants learn to eat in response to internal, hunger cues.                      Discussion of common eating triggers (e.g., emotional, situational) and strategies to manage eating triggers.                      Included tips and suggestions for eating in special circumstances (e.g., on vacation, at a buffet, at someone's house)</p>
<p>4: Relationship between health behaviors of survivors and partners</p>	<p>Partner: "You know, she needed the support and I got support by seeing her do as well as she could possibly do through her treatment... So we stayed together and she wasn't into running marathons at that time so there was little or no exercise but you could still eat you know and that's a comforting thing for most anybody..."                      Survivor: "I think that's why I'm afraid to go to Weight Watcher's because you know, I'm the meal cooker so you know, I've never been raised or in a home or in a family where that you cook more than one meal and if you don't eat what I cook you go hungry... So I'm afraid that if I go to Weight Watcher's and I go on a diet I'm going to be putting him on a diet."</p>	<p>Included strategies to improve couple's communication.                      Included discussion of ways to support one another that did not involve food.</p>

Themes	Representative Quotes	Corresponding Intervention Components
<p>5: Intervention Format and Timing</p>	<p>Survivor: "...yeah I think in a couple format, I would enjoy that."                      Survivor: "If you had just talked to me... [in] the first few months going through this and everything about weight, eating healthy, I would have blown you off... I think timing is very important... So there's got to be a point of time where people have been able to digest it, they're through the hardest of it let's say."                      Survivor: "if you're going once every other week or once a month for six months, no, I mean that's not, I mean quite honestly to me that you're trading one series of appointments you used to have for another..."                      Survivor: "If there is this program like you are trying to start rather than your doctor or the nurse practitioner telling you, 'You need to be walking more,' but no, something about the accountability would have been... a motivating force for me to have done more. Otherwise no... I obviously opted not to do anything but I think if there was a reason aside from hearing it from a doctor visit for doing that and you know, a way to track it on a real day to day basis, I like that."</p>	<p>In-person intervention delivered to couples rather than to individuals or groups.                      Program targeted couples following treatment completion rather than newly diagnosed patients or those in the midst of treatment.                      Used a faded contact approach.                      An intervention lasting approximately 6 months would be acceptable.                      Intervention sessions were held in a location with convenient parking.                      Homework was assigned to be completed between each session, and homework was reviewed at the start of each session.</p>



Table 2 -

Session Outline

<p>Session 1: Introduction to the Program, Self-Monitoring, Relaxation 1</p>	<ul style="list-style-type: none"> <li>- Introduction and program rationale</li> <li>- Discuss couples working together to be partners in health and ways to support one another in managing weight and symptoms</li> <li>- Overview and rationale for self-monitoring</li> <li>- Relaxation 1: Progressive Muscle Relaxation</li> </ul>
<p>Session 2: Eating for Health, Making Decisions about Eating Behaviors, Relaxation 2</p>	<ul style="list-style-type: none"> <li>- Review the importance of weight management for survivors and partners</li> <li>- Discuss healthy eating and dietary recommendations</li> <li>- Complete Decisional Balance Exercise</li> <li>- Relaxation 2: Guided Imagery</li> </ul>
<p>Session 3: Increasing Physical Activity, Activity Pacing</p>	<ul style="list-style-type: none"> <li>- Provide exercise education, discuss ways to decrease sedentary behavior</li> <li>- Complete the exercise buddy agreement</li> <li>- Introduce the overactivity-cycle and activity-rest cycling as an alternative</li> </ul>
<p>Session 4: Planning Pleasant and Meaningful Activities; Relaxation 3</p>	<ul style="list-style-type: none"> <li>- Describe the rationale for planning pleasant and meaningful activities</li> <li>- Help couples identify individual and joint activities</li> <li>- Relaxation Part 3: Paced Breathing and Mini-Relaxation Practices</li> </ul>
<p>Session 5: Identifying &amp; replacing unhelpful thoughts</p>	<ul style="list-style-type: none"> <li>- Discuss the role of thoughts for weight management goals and wellbeing</li> <li>- Learn ways to recognize unhelpful thoughts (ABC model) and replace unhelpful thoughts (coping self-statements/thoughts)</li> </ul>
<p>Session 6: Refocusing &amp; Restructuring unhelpful thoughts, preparing for maintenance</p>	<ul style="list-style-type: none"> <li>- Learn to refocus and reframe unhelpful thoughts</li> <li>- Discuss a plan for entering maintenance phase of the program</li> <li>- Review progress in the program, including areas to continue to work on</li> <li>- Encourage participants to review their own progress on the "off weeks"</li> </ul>
<p>Session 7: Managing Emotional Eating Triggers</p>	<ul style="list-style-type: none"> <li>- Have participants identify individual and joint eating triggers</li> <li>- Discuss emotional triggers and strategies to manage them</li> <li>- Discuss social support and matching support needs with the appropriate support person for managing emotional triggers</li> </ul>
<p>Session 8: Managing Environmental Eating Triggers</p>	<ul style="list-style-type: none"> <li>- Discuss individual and joint environmental triggers and how changing the environment can help to modify food choices/portion size</li> <li>- Discuss changing patterns/habits to manage environmental triggers</li> <li>- Review the use of assertive communication for managing environmental triggers (specifically making requests and saying no)</li> </ul>
<p>Session 9: Appetite Awareness Training Rationale &amp; Appetite Monitoring</p>	<ul style="list-style-type: none"> <li>- Provide education about and rationale for appetite awareness training</li> <li>- Discuss eating in response to internal, appetite cues vs. other factors</li> <li>- Provide information about problems with ignoring hunger and fullness</li> <li>- Introduce the "What the Heck" response and tie it back to previously discussed skills (e.g., cognitive restructuring)</li> <li>- Introduce the Appetite Meter and discuss how to monitor appetite</li> </ul>
<p>Session 10: Managing Urges and Cravings &amp; Food Awareness Training</p>	<ul style="list-style-type: none"> <li>- Discuss and normalize the possibility for food cravings</li> <li>- Discuss strategies for managing urges and cravings, including time, distance, pleasant activities, relaxation, and urge surfing.</li> <li>- Discuss food awareness training strategies</li> </ul>
<p>Session 11: Engaging in valued behaviors and goal setting for the future</p>	<ul style="list-style-type: none"> <li>- Discuss the importance of living a valued life</li> <li>- Discuss the difference between values and goals and importance of setting value-congruent goals</li> <li>- Introduce the S.M.A.R.T. framework for goal setting</li> <li>- Identify individual and joint goals related to the program</li> </ul>
<p>Session 12: Maintaining Weight Loss &amp; Lifestyle Changes; Problem solving for relapse prevention</p>	<ul style="list-style-type: none"> <li>- Review progress and identify areas to continue to work on</li> <li>- Discuss continued self-monitoring for maintaining lifestyle changes</li> </ul>

- Discuss plans for maintenance  
- Normalize lapses; identify triggers for lapses, and create a plan for managing lapses, including using problem solving

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**Table 3 -**

**Sociodemographic and Medical Variables for Single-Arm Trial Participants**

	Survivor (N=12)		Partner (N=12)		Total (N=24)	
	Mean (SD)	% (n)	Mean (SD)	% (n)	Mean (SD)	% (n)
Age (years)	58.9 (10.9)		62.7 (10.4)		60.8 (10.6)	
Race						
African American		16.7% (2)		16.7% (2)		16.7% (4)
Caucasian/White		83.3% (10)		83.3% (10)		83.3% (24)
Ethnicity						
Non-Hispanic		100% (12)		91.7% (11)		95.8% (23)
Hispanic		0% (0)		0% (0)		0% (0)
Not reported		0% (0)		8.3% (1)		4.2% (1)
Education						
High school diploma/GED		25.0% (3)		16.7% (2)		20.8% (5)
Some college		41.7% (5)		8.3% (1)		25.0% (6)
Bachelor's degree		25.0% (3)		66.7% (8)		45.8% (11)
Master's degree		8.3% (1)		8.3% (1)		8.3% (2)
Employment status						
Employed, full or part time		58.3% (7)		58.3% (7)		58.3% (14)
Retired		33.3% (4)		41.7% (5)		37.5% (9)
On disability		8.3% (1)		0.0% (0)		4.2% (1)
Married		100% (12)		100% (12)		100% (24)
Length of relationship (years)	30.9 (12.8)		31.9 (13.3)		31.4 (12.7)	
Household size (people)	2.9 (1.9)		3.0 (1.9)		3.0 (1.7)	
Time since diagnosis (months)	20.6 (10.4)					
Cancer Stage						

	Survivor (N=12)		Partner (N=12)		Total (N=24)	
	Mean (SD)	% (n)	Mean (SD)	% (n)	Mean (SD)	% (n)
I		41.7% (5)				
II		33.3% (4)				
III		25.0% (3)				
Cancer treatments (%)						
Chemotherapy		66.7% (8)				
Radiation		66.7% (8)				
Hormonal Therapy		91.7% (11)				
Surgery (Mastectomy)		50.0% (6)				
Surgery (Lumpectomy)		63.6% (7)				
Comorbidities (ACE-27)						
None		16.7% (2)				
Mild		16.7% (2)				
Moderate		50.0% (6)				
Severe		16.7% (2)				
Specific Comorbidities						
Hypertension		75.0% (9)		33.3% (4)		54.2% (13)
Heart Disease		8.3% (1)		33.3% (4)		20.8% (5)
Rheumatoid Arthritis		8.3% (1)		8.3% (1)		8.3% (2)
Osteoarthritis		25.0% (3)		16.7% (1)		20.8% (5)
Diabetes		25.0% (3)		50.0% (6)		37.5% (9)
Sciatica		8.3% (1)		0.0% (0)		4.2% (1)
Pulmonary issues		33.3% (4)		16.7% (2)		25.0% (6)
Other Cancers		33.3% (4)		16.7% (2)		25.0% (6)

Note- GED: Tests of General Educational Development; ACE-27: Adult Comorbidity Evaluation 27

**Table 4 -** Change in variables of interest over time for breast cancer survivors and partners

	Baseline to Post-treatment			Baseline to 3 month Follow-up		
	Mean Difference (SD)	95% CI	Hedge's g	Mean Difference (SD)	95% CI	Hedge's g
<b>Breast Cancer Survivors (N=12)</b>						
Weight (pounds)	10.95 (11.03)	(3.06, 18.83)	0.17	12.48 (16.00)	(1.04, 23.93)	0.19
Body Mass Index (kg/m <sup>2</sup> )	1.97 (2.06)	(0.50, 3.44)	0.22	2.18 (2.87)	(0.13, 4.23)	0.24
Eating Behavior						
Cognitive Restraint	-0.48 (0.47)	(-0.80, -0.17)	0.65	-0.53 (0.45)	(-0.83, -0.23)	0.71
Uncontrolled Eating	0.36 (0.52)	(0.01, 0.71)	0.58	0.33 (0.47)	(0.01, 0.65)	0.47
Emotional Eating	0.39 (0.76)	(-0.11, 0.90)	0.45	0.52 (0.72)	(0.03, 1.00)	0.61
Physical Activity						
Six Min. Walk Test (ft)	-65.10 (77.03)	(-124.30, -5.89)	0.12	-135.65 (87.90)	(-209.13, -62.16)	0.32
Stanford L-CAT	-0.91 (0.83)	(-1.47, -0.35)	0.69	-1.00 (1.73)	(-2.16, 1.64)	0.73
Pain						
Severity	0.04 (0.97)	(-0.62, 0.69)	0.02	0.30 (1.33)	(-0.60, 1.19)	0.18
Interference	1.00 (1.87)	(-0.25, 2.26)	0.49	1.04 (2.34)	(0.53, 2.62)	0.49
Fatigue	7.34 (9.18)	(1.17, 13.51)	0.76	6.52 (8.30)	(0.94, 12.10)	0.64
Emotional Distress (TMD)	2.21 (2.39)	(0.61, 3.82)	0.80	1.84 (2.02)	(0.48, 3.20)	0.65
Symptom self-efficacy	-1.02 (1.83)	(-2.25, 0.21)	0.42	-0.53 (1.35)	(-1.44, 0.37)	0.23
Weight self-efficacy	-10.6 (20.14)	(-25.01, 3.81)	0.19	-10.40 (23.43)	(-27.16, 6.36)	0.40
<b>Intimate Partners (N=12)</b>						
Weight (pounds)	14.55 (9.43)	(7.80, 21.30)	0.44	15.18 (14.98)	(4.46, 25.90)	0.47
Body Mass Index (kg/m <sup>2</sup> )	2.03 (1.30)	(1.10, 2.96)	0.59	2.14 (2.05)	(0.67, 3.61)	0.65
Eating Behavior						
Cognitive Restraint	-0.28 (0.73)	(-0.81, 0.24)	0.46	-0.44 (0.62)	(-0.86, -0.03)	0.90
Uncontrolled Eating	0.27 (0.34)	(0.02, 0.51)	0.42	0.34 (0.27)	(0.17, 0.52)	0.63
Emotional Eating	0.27 (0.65)	(-0.20, 0.73)	0.34	0.41 (0.54)	(0.05, 0.77)	0.62
Physical Activity						
Six Min. Walk Test (ft)	-59.00 (123.70)	(-147.49, 29.49)	0.11	-61.40 (137.80)	(-167.33, 44.52)	0.14

	Baseline to Post-treatment			Baseline to 3 month Follow-up		
	Mean Difference (SD)	95% CI	Hedge's g	Mean Difference (SD)	95% CI	Hedge's g
Stanford L-CAT	-1.30 (1.77)	(-2.56, -0.04)	0.79	-0.36 (1.43)	(-1.33, 0.60)	0.26
Pain						
Severity	-0.23 (0.67)	(-0.71, 0.26)	0.10	0.29 (1.59)	(-0.87, 1.26)	0.11
Interference	-0.21 (0.85)	(-0.82, 0.39)	0.09	0.16 (0.61)	(-0.25, 0.56)	0.07
Fatigue	0.93 (4.32)	(-2.16, 4.02)	0.09	-0.05 (6.83)	(-4.64, 4.53)	0.01
Emotional Distress (TMD)	0.70 (1.85)	(-0.63, 2.02)	0.25	0.72 (1.71)	(-0.43, 1.87)	0.33
Symptom self-efficacy	-0.40 (1.85)	(-1.23, 0.92)	0.27	-0.52 (1.09)	(-1.25, 0.22)	0.36
Weight self-efficacy	-13.00 (14.94)	(-23.69, -2.31)	0.57	-13.64 (11.16)	(-21.13, -6.14)	0.61

Note-L-CAT: Leisure Time Activity Categorical Item; TMD: Total Mood Disturbance