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Motivational Interviewing to Promote Physical Activity in Breast Cancer Survivors

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by

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Dedication

Venturing on the path less traveled has characterized my personal journey over the past 12 years. Luckily, it has not been a lonely one, and I take this opportunity to extend my sincere gratitude to my constant companions and guides.

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Abstract

Despite documented health benefits, most breast cancer survivors (BCS) do not meet physical activity (PA) guidelines. Hence, evaluating diverse intervention approaches to promote PA in BCS is imperative. Motivational Interviewing (MI) offers a non-prescriptive, client-centered approach to PA promotion that has not been adequately evaluated in BCS. In this randomized-controlled trial, 66 Stage 0-IIIa BCS within three years post-treatment, insufficiently active and contemplating increasing PA were randomly assigned to a MI intervention or an active control condition. The MI intervention implemented motivational and behavior change strategies consistent with MI principles. The active control condition provided education and prescriptive recommendations on diet, PA, and stress management. Participants completed two in-person and one phone-based sessions over 4 weeks. Outcomes were assessed at baseline, 6-week, and 12-week follow-up. The primary outcome was efficacy of the MI intervention to promote PA. Contrary to the hypothesis that the MI intervention would be superior, PA improvements were evident for both groups, with 60% of all participants meeting PA guidelines at 12-week follow-up. Secondary outcomes involved intervention effects on depressive symptoms, fatigue, vigor, and aerobic fitness. Contrary to hypotheses, improvements in secondary outcomes were evident for both groups. Exploratory moderation analyses yielded no group differences in PA outcomes based on baseline activity level, perceived stress, age, or body mass index. Exploratory mediation

analyses indicated that the relationships between group assignment and change in secondary outcomes were not mediated by change in PA. In analyses of the combined sample, higher baseline aerobic fitness predicted greater improvement in PA over time. Overall, results suggest that diverse intervention approaches can help promote PA in BCS. Future research should evaluate long-term maintenance of gains and theoretical mechanisms of the intervention effect.

Introduction

Over the past 20 years, innovations in breast cancer early detection, effective treatment, and supportive care have greatly increased breast cancer patients' likelihood of long-term survival. Currently, there are approximately 2.4 million breast cancer survivors in the United States (Ries et al., 2008). Breast cancer survivors face many challenges, including increased risk for emotional, cognitive, and physical symptoms that are detrimental to quality of life; recurrent and/or secondary cancers; and adverse long-term health effects (e.g., Demark-Wahnefried, Aziz, Rowland, & Pinto, 2005; Stein, Syrjala, & Andrykowski, 2008). Positive changes in health behaviors, such as increasing physical activity, may help breast cancer survivors optimize their health-related outcomes. The cancer survivorship stage has been conceptualized as a "teachable moment" during which motivation to make healthy behavior changes, such as increasing physical activity, may be enhanced (Demark-Wahnefried et al., 2005). To date, the majority of interventions to promote physical activity among breast cancer survivors have involved pre-planned, supervised, exercise regimens that are time- and resource-intensive and may have limited potential for long-term maintenance and dissemination. Motivational interventions may address these limitations; however, they have received relatively less attention. The present study developed and examined the efficacy of a Motivational Interviewing-based intervention to promote physical activity among early-stage breast cancer survivors who

are three months to three years post-treatment, are insufficiently active, and are contemplating increasing their level of activity.

Physical Activity and Breast Cancer Survivorship

Physical activity is a modifiable health-behavior associated with improved psychological well-being (e.g., less depression, reduced anxiety), physical well-being (e.g., reduced fatigue, improved sleep) and functional well-being (e.g., improved aerobic fitness) among breast cancer survivors (Courneya, 2003; Ferrer, Huedo-Medina, Johnson, Ryan, & Pescatello, 2011; Irwin, 2009; Knobf, Musanti, & Dorward, 2007; McNeely, Campbell, Rowe, Klassen, Mackey, & Courneya, 2006; Speck, Courneya, Masse, Duval, & Schmitz, 2010). Additionally, a meta-analysis including data from 12,108 breast cancer patients suggests that higher levels of post-treatment physical activity are associated with a 24% reduction in risk of breast cancer recurrence, 34% reduction in the risk of breast cancer death, and 41% reduction in risk of all-cause mortality (Ibrahim & Al-Homaidh, 2011). Of note, risk reduction has been demonstrated in survivors engaging in as little as one to three hours of weekly moderate-intensity exercise (Holmes, Chen, Feskanich, Kroenke, & Colditz, 2005).

The American Cancer Society (ACS) supports the physical activity recommendations specific for cancer survivors by an expert panel convened by the American College of Sports Medicine (Rock et al., 2012). These guidelines recommend that cancer survivors engage in 150 minutes of moderate-to-strenuous physical activity or 75 minutes of strenuous physical activity per week (Schmitz et al., 2010). However, a population-based study of cancer survivors indicates that 63% of breast cancer survivors are not meeting these recommendations (Blanchard, Courneya, & Stein, 2008). In

response, researchers have developed interventions to promote physical activity among cancer survivors and have evaluated their efficacy (Galvao & Newton, 2005; McNeely et al., 2006; Schmitz, Holtzman, Courneya, Masse, Duval, & Kane, 2005).

Physical activity is defined as any bodily movement that is produced by the contraction of skeletal muscle and that increases energy expenditure (U.S. Department of Health and Human Services, 1996). Physical activity is a broad category that encompasses activities that vary in type, intensity, and purpose. Exercise is a subcategory of physical activity that involves planned, structured, and repetitive bodily movement that is performed for the purpose of improving or maintaining physical fitness (U.S. Department of Health and Human Services, 1996). The research literature includes interventions that target the promotion of the broader category of physical activity (which may or may not include exercise) as well as those that target the promotion of the subcategory of exercise among cancer patients and survivors.

A systematic review and meta-analysis evaluating 82 randomized controlled trials of physical activity in cancer survivors during and after treatment, in which the majority of studies (86%) focused on breast cancer survivors, found that physical activity interventions delivered after treatment (e.g., survivorship stage) had positive effects on physical activity level, aerobic fitness, upper and lower body strength, lean body mass, vigor/vitality, fatigue, overall quality of life, and mood disturbance (Schmitz et al., 2005; Speck et al., 2010). Similarly, a systematic review and meta-analysis of 14 randomized controlled trials examining exercise interventions for breast cancer patients (8 trials) and survivors (6 trials) found positive outcomes for quality of life, aerobic fitness, physical functioning, and fatigue (McNeely et al., 2006). Both review articles noted that the

majority of studies (over 75%) involved a supervised, pre-planned, exercise intervention. Although the specific exercise prescriptions varied broadly, the majority (over 80%) included aerobic exercise with or without resistance training (McNeely et al., 2006; Schmitz et al., 2005; Speck et al., 2010).

As these data indicate, existing interventions to promote physical activity in breast cancer survivors predominantly involve pre-planned, supervised exercise programs that are time- and resource-intensive and extrinsically impose specific physical activity regimens (Irwin, 2009). However, prescriptive and supervised exercise programs may have limited potential for widespread dissemination and long-term adoption of behavior change. In fact, an evaluation of the rate of uptake of supervised exercise programs indicated that 56% of cancer patients on treatment and 63% of those post-treatment agreed to enroll in an intervention program; however, only half of patients approached both enrolled and completed the program (Maddocks, Mockett, & Wilcock, 2009).

Why are breast cancer survivors not participating in supervised, prescriptive exercise programs in larger numbers? Research suggests that part of the reason is that many survivors find supervised, prescriptive exercise programs inconvenient. For instance, the most common reason why survivors refused to participate in an exercise program is that they are impractical and require a substantial time commitment (Maddocks, Mockett, & Wilcock, 2008). Additionally, some survivors find supervised exercise programs unappealing. To illustrate, a recent survey study of the physical activity preferences of 307 cancer survivors (breast, prostate, colorectal, or lung) indicated that the majority prefer unsupervised exercise (57%); in fact, over 80% prefer walking or recreational exercises (Jones and Courneya, 2002). Finally, cancer survivors

have unique and varied preferences for the setting (e.g., gym vs. home) and timing (e.g., morning vs. evening) of physical activity (Jones and Courneya, 2002). In conjunction, these data suggest that a "one-size fits all" model of exercise interventions for cancer survivors may have limited uptake.

Alternatively, cancer survivors may benefit from a more individualized and flexible approach to promoting physical activity (which may or may not include exercise) that focuses on enhancing their motivation to increase their level of activity and takes into consideration their interests, preferences, and needs. In fact, research on the health benefits of physical activity specifically indicates that regular, moderate-intensity physical activity of any type can improve health and well-being; in other words, health benefits are not restricted to structured exercise regimens or strenuous intensity activities (Haskell et al., 2007; U.S. Department of Health and Human Services, 1996).

An Alternate Model: Motivational Interviewing

An alternate model, derived from Self-determination Theory (SDT), holds that lasting behavior change occurs when an individual's psychological needs for autonomy, competence, and relatedness are met (Ryan & Deci, 2000). From this perspective, attempts to promote physical activity should foster intrinsic motivation, offer supportive guidance, and emphasize individual choice. Motivational Interviewing (MI), which is a client-centered, empathic, directive, counseling style that is consistent with SDT, may to be ideally suited to promoting physical activity in breast cancer survivors (Markland, Ryan, Tobin, & Rollnick, 2005; Milne, Wallman, Guilfoyle, Gordon, & Courneya, 2008).

The developers of MI define it as "a directive, client-centered counseling style for eliciting behavior change by helping clients to explore and resolve ambivalence" and

enhance intrinsic motivation for change (Miller and Rollnick, 2002, p. 22). The counseling style is client-centered, but it is also directive: the counselor acts as a guide who intentionally focuses on and pursues the central goals of (1) resolving ambivalence towards change in the service of enhancing intrinsic motivation for change and (2) strengthening commitment to change. MI is based on three principles that are conceptualized as the "spirit" of MI: collaboration, evocation, and autonomy (Miller and Rollnick, 2002). Collaboration (vs. confrontation) refers to the partnership and joint-decision making roles of therapist and the client within an MI environment, which is supportive rather than coercive. Evocation (vs. education) reminds therapists to evoke from clients their own resources and intrinsic motivations for change. Autonomy (vs. authority) refers to client's prerogative to make their own choices (e.g., whether or not and how much to change); the therapist facilitates the client's own choices.

The "spirit" of MI is reflected in four core clinical principles that are meant to guide therapist conduct: express empathy, develop discrepancy, roll with resistance, and support self-efficacy (Miller and Rollnick, 2002). Expressing empathy involves listening to clients and truly understanding them and their ambivalence, without judgment. Developing the discrepancy between the client's behavior and important personal goals or values is an important component of motivating change. Rolling with resistance reminds a therapist to refrain from opposing client resistance; rather, respond with empathy and consider the need to shift strategies. Supporting self-efficacy involves affirming and believing in the client's ability to change.

These core clinical principles of MI are reflected in its core clinical skills: open-ended questions, affirmations, reflective listening, and summarizing (Miller and Rollnick,

2002). Open-ended questions encourage longer, more informative responses. Affirmations are verbal statements of appreciation or positive reinforcement; these must be sincere. Reflective listening involves reflecting back to clients the meaning/feelings behind what they have just said. Summary statements are used to link different pieces of information or to transition to a new task or direction. These clinical skills are applied with the purpose of eliciting client "change talk", which are client-generated self-motivational statements reflecting desire, perceived ability, need, readiness, reasons, or commitment to change (Miller and Rollnick, 2002). Change talk is the key to transitioning from ambivalence to commitment to change. From a practical perspective, MI offers several strategies that are congruent with core clinical principles and core clinical skills and can help guide the MI session, for example: importance and confidence rulers, the decisional balance exercise, and the values sort card (Miller and Rollnick, 2002; Rollnick, Miller, and Butler, 2008).

From a theoretical perspective, it is important to note that MI is a clinical style that developed from clinical practice. Miller acknowledges that MI is conceptually related to Rogerian client-centered therapy, Festinger's cognitive dissonance, and Bem's self-perception theory (Miller and Rose, 2009). Additionally, the Transtheoretical Model of Change (TTM; Prochaska and DiClemente, 1983) has been proposed as a helpful contextual framework for MI. According to the TTM, the process of behavior change involves several Stages of Change (precontemplation, contemplation, preparation, action, maintenance), each of which is reflective of a different degree of motivational readiness for change. Conceptually, MI may be most helpful to individuals in the contemplation stage, which is characterized by ambivalence towards change (DiClemente and

Velazques, 2002). Most recently, Self-Determination Theory (SDT; Ryan and Deci, 2000) has been proposed as a coherent theoretical framework for MI (Markland, Ryan, Tobin, and Rollnick, 2005; Vansteenkiste and Sheldon, 2006). SDT holds that lasting behavior change occurs when an individual's psychological needs for autonomy, competence, and relatedness are met. From this perspective, attempts to promote behavior change should foster intrinsic motivation, offer supportive guidance, and emphasize individual choice – all of which are reflective of MI principles (Markland et al., 2005; Vansteenkiste and Sheldon, 2006).

From the perspective of clinical practice, MI was originally developed for use with individuals with alcohol abuse problems. However, it has since been applied to a variety of health-related behaviors, including smoking cessation, HIV prevention, and physical activity (Burke, Arkowitz, and Menchola, 2003; Hettema et al., 2005).

Motivational Interviewing and Physical Activity Promotion

MI interventions for physical activity offer an alternative to prescriptive programs. Specifically, a person's unique behavioral preferences and goals are respected; ambivalence towards behavior change is explored and resolved; self-efficacy is supported; and intrinsic motivation for physical activity is maximized. This combination of factors is expected to offer an advantage in terms of the adoption and maintenance of regular physical activity. MI has only been applied to physical activity promotion within the last 15 years. Two recent meta-analyses evaluating the efficacy of controlled clinical trials of MI interventions across a variety of health-related behaviors included a sub-analysis of "diet and exercise" interventions (Burke et al., 2003; Hettema et al., 2005). Unfortunately, these meta-analyses offer limited insight into the efficacy of MI

interventions specifically designed to promote physical activity. For instance, the Burke et al. (2003) meta-analysis examined four "diet and exercise" MI interventions and concluded that they yield a medium effect size (d = .0.53). However, only one of the cited studies intervened on exercise and reported change in exercise as a primary outcome. Similarly, the Hettema et al. (2005) meta-analysis reported "encouraging effects" of MI interventions for "diet and exercise"; however, the four studies cited were all primarily dietary interventions.

Since existing meta-analyses offer little evidence for or against the efficacy of MI interventions to promote physical activity, conclusions must be drawn from analyzing individual studies. There are six published studies involving a MI intervention for physical activity promotion. Two studies targeted community-based samples (Bennett, Young, Nail, Winters-Stone, and Hanson, 2008; Harland, White, Drinkwater, Chinn, Farr, and Howel, 1999). Three studies targeted patient populations, including diabetes, chronic heart failure, and cancer (Bennett, Lyons, Winters-Ston, Nail, and Scherer, 2007; Brodie and Inoue, 2005; Jackson, Asimakopoulou, and Scammell, 2007). One study targeted individuals with at least one medical risk factor (obesity, hypertension, or hypercholesterolemia) for coronary heart disease (Hardcastle, Taylor, Bailey, and Castle, 2008). Several features of these studies are reviewed and summarized below, including: study design and characteristics, control group characteristics, intervention design (delivery format, and intervention intensity), interventionist training and treatment fidelity, intervention content, follow-up periods, and main outcomes.

All six studies were randomized controlled trials, which represents a strength because it balances most confounding factors and increases confidence in the validity of

the intervention effect. Most studies (four) assigned participants to an intervention or a control condition. One study included five conditions: control, one session of MI, one session of MI + gym vouchers, six sessions of MI, and six sessions + gym vouchers (Harland et al., 1999). Another study included three conditions: standard care (nurse-delivered information on physical activity), MI, and MI + standard treatment (Brodie and Inoue, 2005). Sample sizes ranged from 34 to 523 individuals. Most studies (four) had small samples of 34-60 participants, two of which were from the U.S. and two from the U.K. Two studies had large sample sizes of 334 and 523 individuals; both from the U.K. All studies included predominantly Caucasian individuals.

The control conditions of most (four) studies can be characterized as no-treatment controls: they received written information materials, usually in the form of a brochure that was also made available to those in the intervention group. The two remaining studies had control groups that received brief or minimal information on physical activity from a health care practitioner (Bennett et al., 2008; Brodie and Inoue, 2005); hence, they did not account for time and attention effects.

There was wide variability in the delivery format and intensity of the interventions. Most interventions (four) were delivered in-person. One intervention was delivered via telephone only (Bennett et al., 2008) and another included both an in-person and a telephone delivery component (Bennett et al., 2007). Of the five studies including in-person sessions, most (four) were delivered in a health-care setting; only one was delivered in participants' homes (Brodie and Inoue, 2005). The intensity of an intervention was evaluated based on the number of contact sessions and the duration of sessions. Across studies, the number of contact sessions ranged from one to eight

sessions. Most interventions included three to eight contact sessions; only two included a single-session (Harland et al., 1999; Jackson et al., 2007). Contact sessions ranged anywhere from 15-60 minutes in duration, with half the studies having sessions lasting an average of 20-30 minutes. The single-session interventions had the longest duration (one lasted 40 minutes and the other 60 minutes).

Although all studies mentioned that the interventionists were trained in MI, they provided few to no details about the quality of the training or about the interventionist's expertise in MI. In two studies from the same research group, the interventionist had 14-16 hours of training; in another study eight hours of training were provided; one study mentioned interventionists completed a specific training course; and two studies did not provide training details. Across studies, there is not enough information to judge whether or not interventionists were sufficiently and adequately trained in MI intervention delivery.

Treatment fidelity was rarely evaluated in the studies reviewed. Only one study (Bennett et al., 2008) formally evaluated treatment fidelity by having an external MI expert code a random sample of four intervention recordings following the empirically-validated Motivational Interviewing Treatment Integrity (MITI) coding manual (Moyers, Martin, Manuel, Hendrickson, & Miller, 2005; Pierson et al., 2007); evaluation results were favorable. An additional two studies informally explored treatment fidelity by having the MI trainer, throughout the course of the intervention period, review an unspecified number of intervention recordings and discuss issues of intervention implementation (Bennett et al., 2007; Hardcastle et al., 2008).

Across studies, the MI interventions exclusively implemented MI specific strategies to promote physical activity. All studies noted that the content of the intervention was tailored to the unique needs of the individuals, was guided by MI principles, and employed MI core clinical skills. All studies offered minimal to no description of the specific goals of the MI session(s), the range of topics discussed with participants, or the type of MI-specific clinical strategies used. No studies mentioned the use of a semi-formal or formal manual to guide intervention delivery. Hence, from an intervention content perspective, there is very little information to guide future studies on MI interventions for physical activity.

The follow-up periods in these studies ranged from six weeks to 12 months. Most (four) studies assessed follow-up physical activity immediately post-intervention. One study included a mid-intervention and a post-intervention assessment of physical activity (Bennett et al., 2007). Another study included an immediately post-intervention and a long-term follow-up assessment of physical activity at 12 months post-intervention (Harland et al., 1999).

In all studies, a main outcome of interest was change in physical activity from baseline to post-intervention follow-up in the MI-intervention group compared to the control group. All studies assessed physical activity exclusively via self-report measures. All studies noted no significant baseline difference in physical activity between those in the control and intervention groups. The majority of studies (five) reported results favoring the MI-based interventions: compared to controls, those receiving the MI intervention reported a statistically significant increase in physical activity at post-intervention follow-up (five out of six studies). Only one study did not report a

significant post-intervention increase in physical activity (Bennett et al., 2008). Upon closer examination, it is evident that this study differed from all others in that it did not include any in-person sessions; instead, the intervention was exclusively telephone-based.

As the review of the literature on MI to promote physical activity illustrates, there is considerable variability in the design and implementation of these interventions. In light of this variability, the virtual consensus on the efficacy of MI-based interventions for the promotion of physical activity is compelling. The evidence offers strong support for the development and evaluation of MI-based interventions to promote physical activity among patient populations, including cancer survivors.

Motivational Interviewing to Promote Physical Activity in Cancer Survivors

As indicated above, only one randomized-controlled trial has tested the efficacy of an MI intervention for increasing physical activity in cancer survivors (Bennett et al., 2007). The study sample ($N = 56$) consisted of survivors of several different forms of cancer, including breast cancer, who ranged from six months to 17 years since end of cancer treatment. The MI intervention included one in-person session and three telephone sessions conducted two weeks, two months, and four and a half months after the initial session. Results indicate that, relative to a time and attention control group, the MI intervention group significantly increased their level of physical activity from pre- to post-intervention. While this study offers preliminary evidence in support of the efficacy of an MI intervention to promote physical activity in breast cancer survivors, it has several methodological limitations that diminish confidence in its findings and raises questions regarding the generalizability of results. Specifically, the study included a small and heterogeneous sample with regard to cancer type and span of survivorship, it

did not capitalize on the "teachable moment" that is proximal to the end of cancer treatment, and it did not include an active control group. The present study will address these methodological limitations.

The Current Study: Overview, Aims, and Hypotheses

A randomized controlled trial design was used to test the efficacy of a brief MI-based intervention to promote physical activity among early-stage breast cancer survivors. Recent breast cancer survivors, from three months up to three years post-treatment, were targeted in order to capitalize on the "teachable moment" that may occur following treatment and during which motivation for health behavior change may be enhanced. Additionally, the study targeted survivors who were insufficiently active, yet were contemplating increasing their level of physical activity. The main outcome of interest was change in physical activity. The secondary outcomes of interest were changes in depressive symptoms, fatigue, vigor, and aerobic fitness, all variables that are consistently associated with change in physical activity. Specific aims and hypotheses follow.

Specific Aim 1: To evaluate the efficacy of a brief MI intervention, relative to an active control intervention (healthy lifestyle counseling), to promote physical activity among early stage breast cancer survivors who are insufficiently active and are contemplating increasing their physical activity. ***Hypothesis 1a***: The MI intervention group, but not the control group, is expected to report a significant increase in physical activity from baseline to the 6-week follow-up. ***Hypothesis 1b***: For the MI intervention group, the increase in physical activity from baseline to 6-week follow-up will be maintained at the 12-week follow-up.

Specific Aim 2: To examine the impact of the MI intervention on depressive symptoms, fatigue, vigor, and aerobic fitness. ***Hypothesis 2a***: The MI intervention group, but not the control group, is expected to report a significant decrease in depressive symptoms from baseline to the 12-week follow-up. ***Hypothesis 2b***: The MI intervention group, but not the control group, is expected to report a significant decrease in fatigue from baseline to the 12-week follow-up. ***Hypothesis 2c***: The MI intervention group, but not the control group, is expected to report a significant increase in vigor from baseline to the 12-week follow-up. ***Hypothesis 2d***: The MI intervention group, but not the control group, is expected to report a significant increase in aerobic fitness from baseline to the 12-week follow-up.

Specific Aim 3: To explore, via mediational analyses, whether the degree of change in physical activity explains the expected benefits of the MI intervention on depressive symptoms, fatigue, vigor, and aerobic fitness at the 12-week follow-up.

Specific Aim 4: To explore whether baseline activity level and baseline perceived stress are moderators of group differences in change in physical activity over time.

Methods

Power Analysis

A power analysis was conducted using GPower software, specifying power of 0.80 at alpha $\leq .05$ (two-tailed) to detect a small-to-medium group x time interaction effect (main outcome of interest) in a repeated-measures design. Results suggested a total sample size of 52 participants. Accounting for a projected 20% attrition rate, 66 breast cancer survivors were enrolled in the study. A small-to-medium effect size was selected because it is the best estimate offered by recent meta-analyses of MI-based interventions to promote "diet and exercise" (Burke et al., 2003; Hettema et al., 2005). Additionally, the only existing study of an MI-based intervention to promote physical activity among cancer survivors reported a medium ($d = .55$) effect size (Bennett et al., 2007).

Procedures

Focus group. Focus groups were conducted with eight breast cancer survivors in order to obtain their feedback about the proposed study. Of these women, 50% were familiar with research indicating the regular physical activity is associated with improved quality of life among breast cancer survivors. Half the women reported that they currently engaged in weekly, regular physical activity. Of these, all women reported walking as part of their exercise routine; additionally, at least one woman reported engaging in yoga, bicycling, aerobic exercise classes, or strength training. The reported duration of physical activity ranged from 80-450 minutes per week. Of the women who did not report

engaging in weekly, regular physical activity, all expressed an interest in increasing their activity level. All of them identified lack of the time, and two pointed out lack of motivation, as the main barriers to engaging in regular physical activity. When asked to imagine the strongest motivator for increasing their level of activity, two women were not sure, one woman mentioned her health, and one mentioned convenience. All of the insufficiently active women expressed an interest in learning more about, and potentially participating in, a program to promote physical activity.

Responses to a brief description of the MI intervention were all favorable. The women indicated that the program "made sense", would be a "good introduction to exercise", and sounds "reasonable because we all *know* we should do it, but *how to get there* and be *motivated* to do it is key". When presented with options regarding the number of intervention sessions and the time in-between sessions, the majority reported that the time commitment of two in-person sessions spaced one week apart and one phone booster session seemed appropriate and not cumbersome; however, one woman expressed an interest in weekly sessions. All women reported that offering a menu of options for increasing physical activity was more appealing than a prescription for activity. In summary, among insufficiently active breast cancer survivors, responses to the proposed intervention were favorable.

Pilot study. The study was approved by the Institutional Review Board at the University of South Florida (see original approval letter in Appendix A). Prior to the initiation of a randomized controlled trial, a pilot study was conducted to examine the acceptability and feasibility of the proposed MI intervention. Three breast cancer survivors took part in the pilot study. Eligibility screening, recruitment, and MI

intervention procedures were conducted as outlined below. Pilot study participants were interviewed at the end of each study session in order to gather feedback on the helpfulness of the intervention, acceptability of the pre-intervention assessment, comfort level with the intervention setting/context, and acceptability of the time commitment involved (see Appendix B for feedback guide). Based on participant feedback, study procedures were modified as appropriate.

Eligibility. Eligibility criteria were: a) $\geq$ 18 years of age; b) capable of speaking and reading English); c) diagnosed with stage 0-IIIa breast cancer; d) no current clinical evidence of breast cancer; e) surgically treated for breast cancer; f) completed chemotherapy and/or radiotherapy at least three months but no more than three years prior; g) physically able to exercise as measured by the Physical Activity Readiness Questionnaire-Revised (Thomas, Reading, & Shephard, 1992); h) currently insufficiently active, meaning engaging in 0 minutes of moderate or strenuous intensity physical activity as measured by the Godin Leisure Time Exercise Questionnaire (Godin & Shepard, 1985); and i) contemplating increasing physical activity as measured by the Exercise Stages of Change – Short Form (Marcus, Selby, Niaura, & Rossi, 1992). Additionally, in order to support the statement in the informed consent form of this being a study of a program to promote either physical activity or a healthy lifestyle, one item assessing stage of change for adopting a healthy diet was included among the eligibility questions.

Recruitment. Following medical chart review for initial eligibility, potential participants were mailed a letter describing a study to promote a healthier lifestyle among breast cancer survivors. The letter indicated that within the next two weeks a research

coordinator would make contact via telephone to provide additional information and included a toll-free number to opt-out. Patients who did not opt-out within two weeks were contacted to learn more about the study, determine interest, and confirm eligibility. It was emphasized that participants would be randomly assigned to either a program to promote physical activity or a program to promote a healthy lifestyle. Interested and eligible participants who verbally agreed to participate in the study were scheduled for the baseline assessment and intervention session.

Baseline assessment and randomization. During the first study visit, participants reviewed and signed an informed consent form prior to completing the baseline assessment of demographic, clinical and anthropometric information, along with physical activity, diet, fatigue, depressive symptoms, perceived stress, vigor, and aerobic fitness. Participants were then randomized 1:1 to the MI intervention or the healthy lifestyle control condition via an automated web-based system. Randomization was stratified according to whether or not the participant was receiving adjuvant hormonal therapy for breast cancer.

Intervention sessions 1-3. Participants completed two in-person sessions (Sessions 1 and 2) and one booster phone session (Session 3) of the MI or the healthy lifestyle (control) intervention. Sessions 1 and 2 were spaced one week apart and sessions 2 and 3 were spaced two weeks apart. Session 1 was conducted immediately after baseline assessment and randomization and lasted approximately 60 minutes. Session 2 took place one week later and lasted approximately 45-60 minutes. Session 3 occurred two weeks later (four weeks post-baseline) and lasted approximately 10-15- minutes.

Follow-up. Participants completed a 6-week follow-up assessment of all self-report measures via mail. Participants also completed a 12-week in-person follow-up assessment that was identical to baseline assessment and was conducted by research assistants who were blinded to randomization.

Interventionist training. Both the MI intervention and the healthy lifestyle control were conducted by a single interventionist. The interventionist completed 16 hours of MI training with an experienced MI trainer certified by the Motivational Interviewing Network of Trainers. Additionally, the interventionist completed several hours of self-training in MI by reviewing the book *Building Motivational Interviewing Skills: A Practitioner's Workbook* (Rosengren, 2009) and watching the videotape training series *Motivational Interviewing: Professional Training Series* (Miller, Rollnick, & Moyers, 1998).

MI intervention. The MI intervention was designed to be consistent with the spirit and principles of MI, as outlined by its developers. Since MI is a client-centered, directive, counseling *style*, it is not appropriate to fully manualize its delivery. However, in order to ensure consistency in intervention delivery across sessions/participants, a semi-structured MI-based intervention protocol was developed to guide intervention delivery. The protocol was modeled after an existing MI intervention manual (Catley, Goggin, Kennedy, & Resnicow; personal communication) and was tailored for the purposes of this study in consultation with an MI expert certified by the Motivational Interviewing Network of Trainers (Dr. Mariann Suarez, Department of Psychiatry and Behavioral Sciences, University of South Florida). The intervention upholds the four core MI principles: expressing empathy, developing discrepancy, rolling with resistance, and

supporting self-efficacy. Specific therapeutic techniques that are in line with these principles were used as needed, including: open-ended questions, affirmation, reframing, reflective listening, importance and confidence rulers, values sort exercise, and summarizing. A summary of the content of each intervention session follows; for full details on each session please refer to Appendices B-D.

Session 1. First, the interventionist provided a brief overview of the purpose of the session. Knowledge about the benefits of exercise for breast cancer survivors was assessed, additional information on this topic was provided, and participants' reactions to this information were discussed. Next, participants were asked to review a typical day. A discussion of the role of physical activity during a typical day, or lack thereof, ensued. The interventionist acknowledged the challenges of incorporating regular physical activity into a busy schedule. Then, the interventionist elicited "change talk" by assessing perceptions of the importance of physical activity and confidence in one's ability to engage in physical activity. Additionally, the good things vs. not so good things about engaging in regular physical activity were explored. Another technique for generating "change talk", the Values Clarification exercise, was used to help participants explore how engaging in physical activity relates to their core values and goals in life. The interventionist then summarized the stated reasons for change vs. the reasons not to change and queried participants on their preferred next step. If participants expressed commitment to change and interest in exploring ways to initiate change, a *collaborative* discussion ensued to establish personalized and realistic physical activity goals. On the other hand, if participants did not express interest in changing level of activity, the interventionist proposed to resume the discussion during session 2. The session ended by

prompting participants to summarize the discussion and reinforcing their level of engagement during the session (see Appendix C). Finally, an appointment for session 2 was scheduled.

Session 2. First, the interventionist provided a succinct review of the prior week's collaborative discussion. Session 2 involved two possible tracks: one for participants who set physical activity goals during session 1 and another for those who did not. If physical activity goals were set during session 1, adherence was evaluated. Depending on level of adherence to goals, the discussion focused on reinforcement and validation or problem-solving barriers. Goal satisfaction was discussed, along with the potential need to re-formulate goals. If physical activity goals were not set during session 1, the discussion focused on resolving ambivalence and reviewing reasons for change until participants expressed readiness to set physical activity goals. Then, barriers to goal attainment were problem-solved. The session ended by prompting participants to summarize the session and reinforcing their level of engagement (see Appendix D). Finally, an appointment for phone-based booster session 3 was scheduled.

Session 3. The third session was a booster conducted via telephone. The degree to which participants did or did not attain their physical activity goals was reviewed. As needed, motivations for change discussed in sessions 1 and 2 were re-visited, barriers to goal attainment were problem-solved, satisfaction with established goals was evaluated and goals were either reinforced or re-formulated, progress made thus far was validated and encouragement was provided for the future (see Appendix E).

Healthy lifestyle counseling. To control for time and attention, the study also featured a healthy lifestyle counseling condition that covered material on physical

activity, nutrition, and stress management. The protocol was developed in consultation with a nutritionist from the Moffitt Cancer Center and is based on the ACS healthy lifestyle guidelines (ACS, 2006), the U.S. Department of Health & Human Services physical activity recommendations for adults (U.S. Department of Health & Human Services, 2008), and an overview of behavioral and cognitive stress management techniques. Session 1 reviewed body mass index (BMI), provided information on BMI and cancer risk, reviewed physical activity and nutrition guidelines and recommendations for cancer survivors, and prescribed specific lifestyle modifications. Session 2 provided general information on the stress response, stress and cancer, diaphragmatic breathing for stress management, and stress management tips for cancer survivors. Session 3 reviewed physical activity and dietary habits and provided additional prescriptive advice on lifestyle modifications. For more details, see Appendices F-H.

Compensation. Participants were compensated $25 for their time and travel at baseline and at the 12-week follow-up assessment.

Intervention credibility. Intervention credibility was assessed using a self-report measure adapted from previous research (Jacobsen, Meade, Stein, Chirikos, Small, & Ruckdeschel, 2002; see Appendix I). This measure was included in the 6-week follow-up assessment packet that participants completed via mail. Participants rated the following on a seven-point scale (0 = not at all to 6 = extremely): the perceived effectiveness of the assigned intervention in promoting physical activity, the perceived effectiveness of the assigned intervention in promoting a healthy lifestyle, the perceived skill and competency of the interventionist, and the perceived importance of making the assigned intervention

available to other breast cancer survivors. These data were used to confirm the expected equivalence of both intervention conditions with regard to credibility.

Treatment integrity. A random sample of 10% of the MI sessions was reviewed by a certified MI trainer (Dr. Mariann Suarez) and assessed for treatment integrity. Random selection was performed by a random number generator. Treatment integrity was evaluated with the Motivational Interviewing Treatment Integrity (MITI) manual, version 3.1.1, which is an empirically-validated behavioral coding system that evaluates competency in implementing MI (Moyers, Martin, Manuel, Miller, & Ernst, 2010). The MITI has two components: Global Scores and Behavior Counts. This study focused on assessment of the Global Score, which is a 5-point (1= low adherence to MI, 5 = high adherence to MI) holistic rating, representative of the entire interaction, that is assessed for each of the following global dimensions: evocation, collaboration, autonomy/support, direction, and empathy. A summary Global Spirit Rating is computed by averaging the scores for evocation, collaboration, and autonomy/support. Based on expert opinion, an average of 4 on Global Scores and Global Spirit Rating represents the threshold for competency in MI (Moyers et al., 2010).

Measures

Demographic data. Demographic data obtained at baseline via a self-report questionnaire included: age, sex, race/ethnicity, marital status, employment status, income, education, use of hormonal therapy, and menopausal status (see Appendix J).

Clinical characteristics. Clinical characteristics, including disease stage, date of diagnosis, treatment regimen, date of last treatment, and use of hormonal therapy were assessed via medical chart review (see Appendix K).

Anthropometric data. Anthropometric data, specifically height and weight, were obtained at baseline and 12-week follow-up via standardized procedures. An electronic scale was used to assess weight in pounds. Height was measured in feet and inches using a measuring ruler, marked in 1/16 inch segments, that was affixed to a wall. Participants were asked to take off their shoes during weight and height assessments. Height and weight data was used to calculate BMI using a standard formula.

Readiness for physical activity. Readiness for physical activity was evaluated as part of the study eligibility assessment using the Physical Activity Readiness Questionnaire (PAR-Q; Thomas, Reading, & Shephard, 1992). The PAR-Q is a seven-item self-report measure that assesses potential risks of engaging in moderate to strenuous physical activity based on responses to specific health history questions. "No" responses to all seven items indicate none/low and a "yes" response to at least one item indicates possible risk for medical complications as a result of moderate to strenuous physical activity. Individuals who responded "yes" to at least one item were deemed ineligible for this study (see Appendix L).

Stages of change for physical activity. As part of the study eligibility assessment, a modified version of the Exercise Stages of Change-Short Form (Marcus, Selby, Niaura, & Rossi, 1992) was used to assess stage of change for physical activity. The modification involved replacing all mentions of "exercise" in the instructions and text with the term "physical activity". This brief self-report measure assessed the degree to which individuals engage or plan to engage in regular physical activity. Those who responded that they do not engage in regular physical activity, but intend to in the next

six months, were classified as "contemplators" based on the Stages of Change model and were deemed eligible to participate in the study (see Appendix M).

Stages of change for diet. In order to support the statement in the informed consent form of this being a study of a program to promote either physical activity or a healthy lifestyle among breast cancer survivors, the eligibility assessment also included one question related to stages of change for healthy eating. Specifically, one question assessed the degree to which individuals adopt or plan to adopt a healthy diet (see Appendix M). Answers had no bearing on eligibility.

Physical activity. Leisure-time physical activity was assessed with a modified version of the Godin Leisure-Time Exercise Questionnaire (LTEQ; Godin & Shephard, 1985). The LTEQ has adequate psychometric properties, including test-retest reliability and concurrent and criterion validity (Pereira et al., 1997). The original version assesses past-week frequency of strenuous, moderate, and mild exercise >15 minutes in duration. The modified version used in this and prior studies (e.g. Andrykowski, Beacham, & Jacobsen, 2007) assessed frequency plus duration (in minutes) of strenuous, moderate, and mild activity, thus allowing for calculation of total minutes of physical activity in the past week (see Appendix N). Responses on the LTEQ were used to compute units of weekly metabolic equivalents (METS) by using a modified version of the formula proposed by its developers that has been used in prior research (Andrykowski et al., 2007): total METS = (total minutes of strenuous exercise/15 x 9) + (total minutes of moderate exercise/15 x 5) + (total minutes of mild exercise/15 x 3). Additionally, responses were used to estimate the proportion of breast cancer survivors who met recommended physical activity guidelines of ≥150 minutes of moderate or ≥ 75 minutes

of strenuous activity, or a combination, per week (Rock et al., 2012; Schmitz et al., 2010).

During the study eligibility assessment, the LTEQ was administered via the telephone. Eligible participants were those deemed insufficiently active based on the absence (0 minutes) of moderate or strenuous intensity activity in the past week (Pate, O'Neill, & Lobelo, 2008).

Diet. In order to support the statement in the informed consent form of this being a study of a program to promote either physical activity or a healthy lifestyle among breast cancer survivors, dietary habits were assessed with the All-Day Fruit and Vegetable Screener (Thompson et al., 2002). This self-report food frequency screener assesses adherence to a diet rich in fruits and vegetables. Specifically, using the 1992 USDA Food Guide Pyramid definition of "serving", the screener records the number of servings and serving sizes, over the past month, of 10 categories of fruits and vegetables. A complex scoring algorithm is computes the estimated total daily number of fruit and vegetable servings (Thompson et al., 2002). Among women, the All-Day Screener correlates at 0.51 with a 24-hour dietary recall assessment (Thompson et al., 2002). Hence, the All-Day Screener is deemed to an adequate estimate of median fruit and vegetable intake (see Appendix O).

Fatigue. The Fatigue Symptom Inventory (FSI; Hann et al., 1998) was used to assess self-reports of the frequency and severity of fatigue, as well as its perceived interference with quality of life. Frequency is assessed as the number of days (0-7) in the past week that participants felt fatigued and the average daily duration of fatigue (0=none of the day to 10=the entire day). Severity involves assessing the most, least, and average fatigue experienced in the past week, as well as current fatigue, using an 11-point scale

(0=not at all fatigued to 10=as fatigued as I could be). Fatigue interference involves assessing, using an 11-point scale (0-no interference to 10=extreme interference) the extent to which fatigue in the past week was perceived to interfere with general activity, ability to bathe and dress, normal work activity, concentration, social relations, enjoyment of life, and mood. Previous research has demonstrated the reliability (e.g., internal consistency reliability = .90) and validity of the FSI with cancer patients (Hann et al., 1998; Hann, Denniston, & Baker, 2000). Analyses in this study focused on the fatigue interference scores (see Appendix P). In this study, internal consistency reliabilities for the FSI were good for all three assessment points, with alphas ranging from .81 to .88.

Depressive symptoms. The Center for Epidemiologic Studies-Depression Scale (CES-D; Radloff, 1977) was used to assess depressive symptoms in the past week. This self-report 20-item measure assesses common clinical symptoms of depression that are not confounded with health-related symptoms typically present in patient populations (see Appendix Q). Responses are recorded on a scale ranging from 0 (rarely or none of the time) to 3 (most or all of the time). A cut-off score of 16 is used to identify the presence of clinically significant symptoms of depression (Radloff, 1977). The psychometric properties of the CES-D are strong: internal consistency reliability ranges from .85 in community samples to .90 in psychiatric samples, test-retest reliability ranges from .51 to .67 in 2- to 8-week intervals, and concurrent validity is well established (Radloff, 1977; Roberts & Vernon, 1983; Weissman, Sholomkas, Pottenger, Prusoff, & Locke, 1977). In this study, internal consistency reliabilities for the CES-D were excellent for all three assessment points, with alphas ranging from .95 to .96.

Vigor. The Profile of Mood States-Vigor subscale (POMS-V; McNair, Lorr, & Droppelman, 1981) was used to assess the mood state of vigor-activity over the past

week. This self-report 8-item measure assesses, on a five-point scale ranging from "not at all" to "extremely", the degree to which respondents have felt lively, active, energetic, cheerful, alert, and full of pep (see Appendix R). The POMS, including the vigor subscale, has excellent psychometric properties (McNair et al., 1971). The POMS-V has been used before with breast cancer patients and demonstrated excellent internal consistency reliability (e.g., Tamagawa et al., 2013). In this study, internal consistency reliabilities for the POMS-Vigor were excellent for all three assessment points, with alphas ranging from .93 to .95.

Perceived stress. The Perceived Stress Scale (PSS; Cohen, Kamarck, & Mermelstein, 1981) was used to appraise stress level over the past week. This self-report 10-item measure asks respondents to rate, on a five-point scale ranging from "never" to "very often", how frequently they felt overloaded/stressed in a general sense, not related to any particular event (see Appendix S). The PSS has excellent psychometric properties (Cohen and Williamson, 1988) and has been used before in breast cancer patients with evidence for good internal consistency reliability (e.g., Golden-Kreutz et al., 2005). In this study, internal consistency reliabilities for the PSS were good for all three assessment points, with alphas ranging from .82 to .83.

Aerobic fitness. The 6-minute walk test (6MWT; American Thoracic Society Committee, 2002) provided an objective assessment of cardiopulmonary functional capacity (i.e. aerobic fitness). The test measures the distance a person can cover while walking quickly on a flat surface for 6 minutes. A review of the various measures of functional status found that the 6MWT is preferred due to its easy administration, good patient tolerance, and concordance with activities of daily living (Solway, Brooks,

Lacasse, & Thomas, 2001). Additionally, it offers strong evidence of reliability and validity (American Thoracic Society Committee; 2002; Solway et al., 2001). Although there are no criteria for meaningful clinical change in cancer patients, prior research suggests 54 meters as meaningful change in patients with cardiopulmonary diseases (Rasekaba, Lee, Naughton, Williams, & Holland, 2009), 50 meters in geriatric populations with mobility disabilities (Perera, Mody, Woodman, & Studenski, 2006), and 45 meters in chronic heart failure patients (Shoemaker, Curtis, Vangsnes, & Dickinson, 2012).

The test was performed by a research assistant, using standardized instructions, in an indoor hallway that is long, straight, and flat. The start and turnaround points were clearly marked with small orange traffic cones. Participants were instructed to walk the course for 6 minutes, exerting their best effort. The test was stopped at any time if participants complained of any of the following: chest pain, intolerable dyspnea, leg cramps, staggering, diaphoresis, or pale or ashen appearance (American Thoracic Society Committee, 2002). Research assistants recorded the number of laps and distance travelled, as well as adverse events (see Appendix T).

Statistical Analyses

Descriptive statistics (i.e., means and standard deviations) were calculated to summarize demographic, clinical, and anthropometric characteristics. Successful randomization was verified by conducting t-tests and chi-square analyses to evaluate intervention vs. control group differences for age, BMI, race/ethnicity, marital status, income, education, type since diagnosis, type since treatment completion, stage of disease, type of treatment, and use of hormonal therapy. Variables that differed

significantly ($p < .05$) between groups were included as covariates in all subsequent analyses. Group differences in intervention credibility ratings were examined using ANOVA.

Hierarchical linear modeling (HLM) was used to examine group differences in change in physical activity (hypotheses 1a and 1b), depressive symptoms (hypothesis 2a), fatigue (hypothesis 2b) and vigor (hypothesis 2c) over the 12-week follow-up period. Compared to a traditional repeated-measures ANOVA approach, HLM more accurately estimates rates of change (Raudenbush and Bryk, 2002). HLM also offers the flexibility of modeling both linear and non-linear time trajectories. Additionally, in a longitudinal design, HLM uses available data to estimate missing data for outcome variables, thus maximizing power (Raudenbush and Bryk, 2002). In this study, the Level 1 model represents repeated assessments of the outcome variables (i.e., baseline, 6-week, 12-week follow-up) that are nested within participants. Growth curve modeling was used to analyze individual change over time on each outcome variable. Group (intervention vs. control) was added as a Level 2 predictor of both initial status (i.e., intercept) and pattern of change over time (i.e., slope) for each outcome variable. The slope is of primary interest in that it reflects variability in change over time as a function of group (i.e., group x time interaction). To examine specific aim 4, the proposed moderator variables baseline activity level (a categorical variable dichotomizing the sample into sedentary vs. insufficiently active at baseline) and baseline perceived stress were added to the Level 2 model examining change in physical activity outcomes.

As an adjunct to HLM analyses, ANCOVAs were conducted to examine mean-level group differences in each of the outcome variables (physical activity, depressive

symptoms, fatigue, and vigor) at each follow-up assessment, controlling for baseline values. In addition exploratory moderator analyses were conducted with the following variables: baseline age, baseline BMI, and baseline activity level (a categorical variable dichotomizing the sample into sedentary vs. insufficiently active at baseline).

To examine change in aerobic fitness over time (hypothesis 2d), a 2 (condition: control or intervention) X 2 (time: baseline, 12-weeks) repeated measures ANOVA was performed, with condition as the between-subjects variable, time as the within-subjects variable, and aerobic fitness (distance covered in the 6MWT) as the dependent variable. As an adjunct to repeated measures analyses, ANCOVAs were conducted to examine mean-level group differences in aerobic fitness, controlling for baseline values. Additionally, exploratory analyses were conducted to examine group differences in meaningful clinical change in distance walked.

The exploratory mediational models that are the focus of specific aim 3 were conducted using the nonparametric bootstrapping procedures recommended by Shrout and Bolger (2002) using the SPSS macros developed by Preacher and Hayes (2004). Bootstrapping involves repeatedly and randomly "resampling" the data with replacement and computing the indirect effect in each resample. Over many bootstrap resamples an estimate of the sampling distribution of the indirect effect is generated and can be examined empirically using percentile confidence intervals. If zero does not lie within the estimated 95% confidence intervals of the true indirect effect, the indirect effect is deemed significantly different from zero at $p < .05$ (Shrout & Bolger, 2002; Preacher & Hayes, 2004). The bootstrapping approach offers several advantages over both the Baron and Kenny causal steps approach to mediation and the Sobel test for indirect effects,

including increased power, decreased likelihood of Type I and Type II errors, and it does not assume that the sampling distribution of the indirect effect is normal (Shrout & Bolger, 2002; Preacher & Hayes, 2004). Hence, bootstrapping offers a more accurate empirical test of the indirect effect and is the preferred method for meditational analyses (Fritz & MacKinnon, 2007; Preacher & Hayes, 2004; Shrout & Bolger, 2002). Consistent with emerging consensus, the indirect effect was evaluated regardless of whether or not a significant total effect was observed (Hayes, 2009; Shrout & Bolger, 2002; Zhao, Lynch, & Chen, 2010).

Results

Participants

Recruitment and attrition. A total of 513 breast cancer survivors were screened to determine eligibility (see Figure 1). Of these, 68 were excluded after a preliminary medical record review because they did not meet eligibility criteria for stage of cancer and/or type of treatment. The remaining 445 breast cancer survivors were mailed a recruitment letter prior to telephone contact. One hundred nine women could not be reached by telephone. Of the women contacted via telephone, 157 declined to participate and 110 did not meet full eligibility criteria for the study. The remaining 69 breast cancer survivors agreed to participate in the study (30.5% participation rate); 3 were recruited for the pilot study and 66 were enrolled in the randomized trial. There were no significant differences between those who declined and agreed to participate in the study in terms of age, stage of diagnosis, or type of treatment (*p*s > .05).

Of those who consented to participate in the randomized trial, 8 (12.1%) completed only the baseline assessment, 15 (22.7%) completed baseline and only one follow-up assessment, and 43 (65.2%) completed all three assessments. Attrition rates did not differ between the intervention and control groups [$\chi^2(3, N = 66) = 0.85, p = .84$]. There were no significant differences in the demographic, clinical, or anthropometric characteristics, physical activity, depressive symptom, or fatigue profile of participants

who completed the baseline assessment only relative to those who completed the baseline and at least one additional follow-up assessment (*p*s > .05).

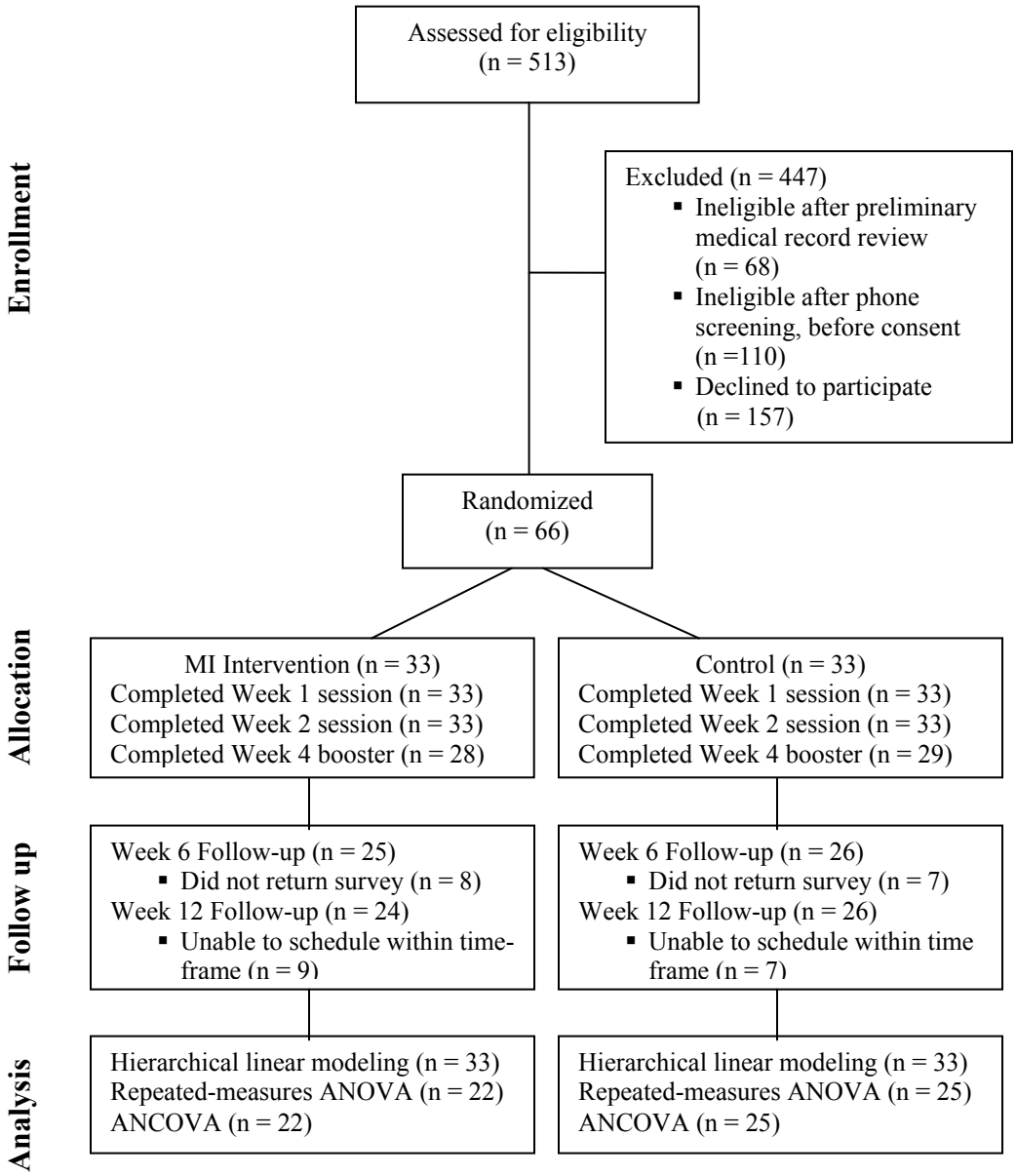

Figure 1. Flow diagram of breast cancer survivors' enrollment and progress through a RCT of a MI-based intervention to promote physical activity.

Sample characteristics. Table 1 summarizes demographic, anthropometric, and clinical characteristics of intervention and control group participants at the baseline assessment. Overall, participants ranged from 40 to 74 years old (M = 56, SD = 8.57). Most were Caucasian (83%), not Hispanic (89%), married (62%), had completed at least some college education (85%), and had a gross annual income greater than $40,000 (68%). Participants' BMI ranged from 18.9 to 49.2 (M = 28.6, SD = 6.52). Approximately 29% had a BMI < 25 (normal weight), 33% had a BMI of 25-29.9 (overweight), and 38% had a BMI > 30 (obese). There were no statistically significant differences between the intervention and control groups on these demographic or anthropometric characteristics (ps > .05).

The sample included Stage 0 (21%), Stage I (38%), Stage II (36%), and Stage IIIa (4.5%) breast cancer survivors who were an average of 27.5 (SD = 7.38) months since diagnosis and 22.4 (SD = 7.32) months since treatment completion. Type of treatment received varied, with 24% receiving surgery only, 17% receiving surgery and chemotherapy, 35% receiving surgery and radiation, and 24% receiving all three forms of treatment. While there were no group differences in time since diagnosis, time since treatment completion, type of treatment received or hormone therapy status, there was a significantly greater proportion of survivors diagnosed with Stage 0 breast cancer in the control condition (see Table 1).

Table 1.

Participant Demographic and Clinical Characteristics

	Intervention		Control			
	M	*SD*	*M*	*SD*	*t*	*p*
Age	55.2	8.72	57.1	8.43	0.91	.37
Body mass index	29.47	7.18	27.79	5.78	-1.05	.30
Time since diagnosis (months)	27.48	6.78	27.73	8.04	0.13	.90
Time since treatment (months)	22.45	6.47	22.42	8.17	-0.02	.99
	n	*%*	*n*	*%*	χ^2	*p*
Race					4.16	.25
Caucasian	28	84.8	27	81.8		
African American	4	12.1	3	9.1		
Asian	1	3.0	0	0		
More than one race	0	0	3	9.1		
Ethnicity					1.44	.23
Hispanic	2	6.1	5	15.2		
Non-Hispanic	31	93.9	28	84.8		
Marital Status					3.51	.48
Never married	6	18.2	2	6.1		
Currently married	19	57.6	22	66.7		
Separated or Divorced	5	15.2	7	21.2		
Widowed	3	9.1	2	6.1		
Education					1.78	.78
High school	4	12.1	6	18.2		
Some college	7	21.2	9	27.3		
College graduate	13	39.4	11	33.3		
Graduate degree	9	27.3	7	21.2		
Annual Income					.03	.86
< $40,000	10	31.3	11	33.3		
> $40,000	22	68.8	22	66.7		
Stage at diagnosis					9.75	.01*
Stage 0	3	9.1	11	33.3		
Stage I	18	54.5	7	21.2		
Stage II or IIIa[a]	12	36.4	15	45.5		
Treatment					4.41	.22
Surgery only	5	15.2	11	33.3		
Surgery and Chemotherapy	7	21.2	4	12.1		
Surgery and Radiation	14	42.4	9	27.3		
Surgery, Chemotherapy, and Radiation	7	21.2	9	27.3		
Hormone Therapy (Yes)	23	69.7	19	57.6	1.05	.31

[a]Stages II and IIIa were combined due to low frequency of stage IIIa (n = 3) diagnosis

Intervention Credibility

Group differences on intervention credibility were evaluated using ANOVA. As expected, effectiveness ratings for dietary improvement were significantly higher in the control group ($M = 5.15$, $SD = 0.88$) than in the intervention group ($M = 3.40$, $SD = 1.73$), $F(1, 49) = 21.02$, $p < .001$. Unexpectedly, effectiveness ratings for physical activity improvement were also significantly higher in the control group ($M = 5.00$, $SD = 1.17$) than in the intervention group ($M = 4.12$, $SD = 1.57$), $F(1, 49) = 5.34$, $p = .03$. However, ratings in both groups were generally favorable, with means exceeding the midpoint (3) on seven-point (1 to 7) rating scales. There were no group differences in the perceived skill and competency of the interventionist [control $M = 5.65$, $SD = 0.85$; intervention $M = 5.72$, $SD = 1.02$; $F(1, 49) = 0.06$, $p = .80$] or the perceived importance of making the program delivered available to other breast cancer survivors [control $M = 5.54$, $SD = 1.07$; intervention $M = 5.44$, $SD = 1.08$; $F(1, 49) = 0.11$, $p = .75$]

Treatment Integrity

A random sample of 10% of MI sessions 1 and 2 were assessed for treatment integrity using the Motivational Interviewing Treatment Integrity (MITI) manual, version 3.1.1 (Moyers et al., 2010). The Global Scores for evocation, collaboration, autonomy/support, direction and empathy ranged from 4.8-5 (5 = highest possible rating). The Global Spirit Rating of 5 exceeds the threshold for competency in MI, indicating the intervention was implemented in accordance with MI spirit and principles.

Table 2.

Descriptive Statistics of Predictor and Outcome Variables

Outcomes	Baseline *M (SD)*	6-week *M (SD)*	12-week *M (SD)*
Physical Activity (METS)			
Intervention	15.88 (16.45)	64.52 (47.04)	59.47 (46.97)
Control	18.33 (15.12)	77.50 (92.71)	66.49 (49.20)
Total Minutes - Any Activity			
Intervention			167.29
Control	79.39 (82.27)	195.80 (133.45)	(111.47)
	91.67 (75.55)	213.27 (222.55)	188.46
			(133.11)
Total Minutes - Moderate Activity			
Intervention	0	109.20 (109.78)	83.33 (88.25)
Control	0	90.00 (98.10)	85.00 (65.13)
Total Minutes - Strenuous Activity			
Intervention	0	27.00 (67.14)	37.29 (79.32)
Control	0	57.11 (127.48)	43.65 (69.48)
Aerobic Fitness (6MWT, meters)			
Intervention	414.92 (81.19)	--	495.90 (99.72)
Control	426.52 (86.86)		461.81 (88.47)
Depressive Symptoms (CES-D)			
Intervention	9.84 (6.78)	8.79 (6.90)	7.78 (6.38)
Control	11.48 (6.40)	9.38 (7.04)	10.15 (9.10)
Fatigue Interference (FSI)			
Intervention	11.03 (12.73)	5.36 (6.95)	7.67 (10.71)
Control	14.00 (15.89)	11.88 (13.25)	8.31 (13.68)
Vigor (POMS-V)			
Intervention	18.39 (5.76)	18.44 (6.44)	19.67 (7.57)
Control	18.09 (7.48)	20.81 (6.30)	21.73 (6.68)
Perceived Stress (PSS)			
Intervention	11.29 (5.76)	9.63 (4.79)	7.50 (5.06)
Control	13.26 (4.15)	10.92 (4.92)	8.90 (4.22)
Body Mass Index			
Intervention	29.47 (7.18)	--	28.77 (6.78)
Control	27.79 (5.78)		27.12 (5.96)
Fruit and Vegetable Consumption			
Intervention	4.40 (3.94)	3.88 (3.37)	4.41 (4.95)
Control	2.89 (1.78)	4.35 (2.84)	4.41 (2.95)

Analyses for Intervention vs. Control Group Effects on Outcomes

Physical Activity Outcomes

Descriptive data. Mean METS at baseline and 6- and 12-week follow-up are presented in Table 2. There were no group differences in baseline METS, $t(64) = 0.63$, $p = .53$. Per eligibility criteria, none of the study participants met physical activity guidelines at baseline. At 6-week follow-up, 72% of those in the intervention group and 54% of those in the control group met physical activity recommendations (≥150 of moderate or ≥75 minutes of strenuous intensity activity, or a combination, per week); the difference in proportions was not statistically significant, $\chi^2(1, N = 51) = 1.80$, $p = .18$. At 12-week follow-up, 54% of those in the intervention group and 65% of those in the control group met physical activity guidelines; the difference in proportions was not statistically significant, $\chi^2(1, N = 50) = 0.65$, $p = .42$.

Intervention effect on pattern of change over time. HLM was conducted to test hypothesis 1a and 1b (see Table 3). Prior to specifying the models of interest, an unconditional model with no predictors was examined to assess the appropriateness of modeling both inter- and intra-individual predictors of change in METS. The ICC was .20, suggesting that 20% of the variability in change in physical activity is due to inter-individuals differences and 80% to intra-individual differences, thus supporting the examination of both classes of predictors.

Table 3.

Physical Activity – HLM estimates of pattern of change over time

	Unconditional Model	Quadratic Growth Model	Group as Predictor Model	Planned Moderator Model
Fixed Effects Coefficient				
Intercept	45.96**	17.10**	18.24**	-1.01
Group			-2.47	0.41
Stage			0.08	0.63
Perceived Stress				0.15
Activity Level				22.61**
Linear Slope		76.08**	55.56**	49.40
Group			-16.81	-15.38
Stage			25.14	23.61
Perceived Stress				-1.02
Activity Level				10.94
Quadratic Slope		-27.51**	-14.98	-16.11
Group			6.37	6.81
Stage			-13.61	-12.62
Perceived Stress				0.94
Activity Level				-0.82
Random Effects Variance				
Level-1 error	2390.43	161.59	169.85	121.71
Intercept	613.57	85.71**	83.62**	39.33**
Linear Slope		15882.31**	15920.81**	16829.09**
Quadratic Slope		3628.89**	3605.54**	3809.68**
Covariance				
Int-Linear Slope		572.01	569.30	435.64
Int-Quadratic Slope		-216.75	-213.16	-178.57
Indicators of Fit				
-2LL (# of parameters)	1799.63 (2)	1613.31 (7)	1578.23 (7)	1523.22 (7)
AIC	1803.63	1627.31	1592.23	1537.22
BIC	1809.87	1649.14	1614.06	1559.05

*$p < .05$, **$p < .01$

First, to describe the pattern of change in METS over time, a Level 1 model was specified where both the intercept and slopes for linear and quadratic trends were allowed to vary randomly. Results indicated that both the linear ($p < .001$) and quadratic trends ($p = .002$) were significant. Specifically, a positive linear trend from baseline to 6-week follow-up indicated an initial increase in activity level from baseline to 6-weeks, while a negative quadratic trend indicated a subsequent decrease in activity level from 6- to 12-weeks follow-up. The statistically significant variance components of the slopes point to inter-individual differences in the pattern of change in physical activity ($ps < .001$), which further supports examination of Level 2 predictors.

Second, to examine whether change in physical activity varies by group assignment, a Level 2 model specifying group as a predictor of intercept and slopes (i.e., group x time interaction) was evaluated. Stage at diagnosis was included as a covariate in the model. Results did not support group x time effects on change in physical activity (linear $p = 0.87$, quadratic $p = 0.76$). That is, the pattern of change over time in physical activity was not significantly different for survivors in the intervention or control groups; consequently, hypotheses 1a and 1b were not supported. See Figure 2 for a depiction of the average pattern of change in physical activity for the intervention and control groups.

Intervention effect on mean change over time. As an adjunct to HLM analyses, an ANCOVA was conducted to examine mean-level group differences in METS at each follow-up assessment, controlling for baseline status and stage at diagnosis. The results confirm the findings from HLM; there were no group differences in METS at 6-week ($F(1, 47) = 0.001$, $p = .97$, $\eta^2 = < .01$) or 12-week follow-up ($F(1, 46) = 0.44$, $p = .55$, $\eta^2 = .01$).

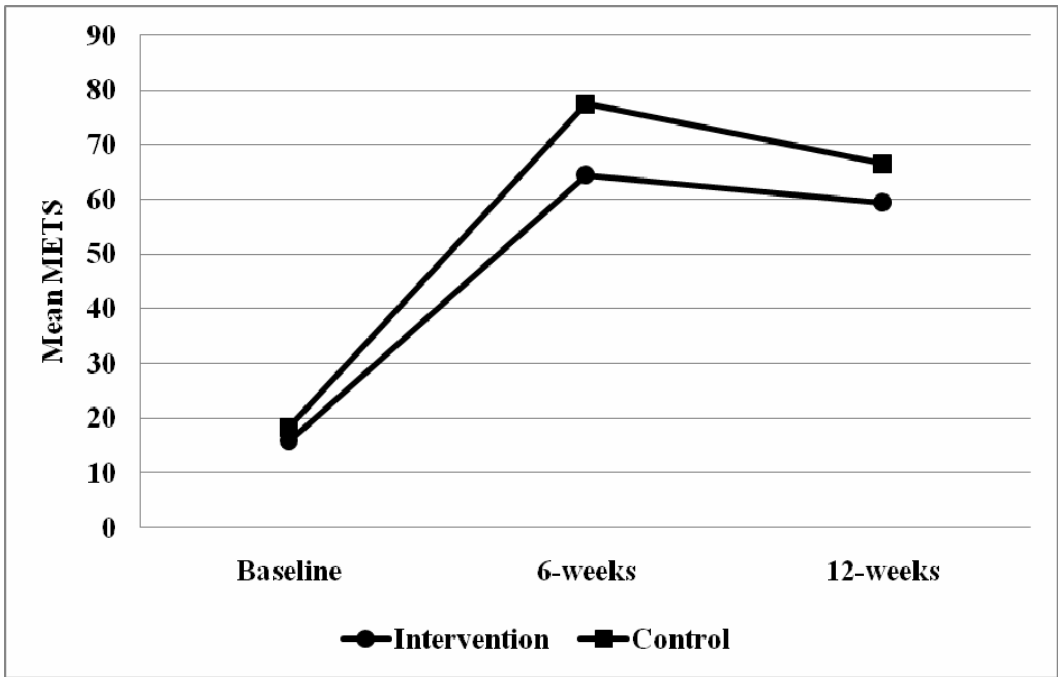

Figure 2. Average pattern of change in physical activity for the intervention and control groups.

Moderator analyses. Planned moderator analyses were performed via HLM to address specific aim 4 (see Table 3). Results indicated that neither baseline perceived stress (linear $p = 0.73$, quadratic $p = 0.56$) nor baseline activity level categorized as sedentary vs. insufficiently active (linear $p = 0.34$, quadratic $p = 0.61$) were significant moderators of group differences in change in physical activity over time. Exploratory moderator analyses were also conducted with baseline age and baseline BMI; no statistically significant group differences in physical activity outcomes were noted based on subgroup status ($ps < .05$).

Depressive Symptom Outcomes

Descriptive data. Descriptive data for depressive symptoms at baseline and 6- and 12-week follow-up are presented in Table 2. There were no group differences in baseline depressive symptoms, $t(63) = 1.00$, $p = .32$. Across groups and assessment time-points, mean depressive symptom scores were well below the cut-off score of 16 that would be indicative of clinically significant symptoms of depression.

Intervention effect on pattern of change over time. HLM was conducted to test hypothesis 2a (see Table 4). Prior to specifying the models of interest, an unconditional model with no predictors was examined to assess the appropriateness of modeling both inter- and intra-individual predictors of change in depressive symptoms. The ICC was .70, suggesting that 70% of the variability in change in depressive symptoms is due to inter-individuals differences and 30% to intra-individual differences, thus supporting the examination of both classes of predictors.

First, to describe the pattern of change in depressive symptoms over time, Level 1 models of both linear and quadratic change were evaluated. Results indicated that both the linear ($p = .02$) and quadratic ($p = .04$) trends were significant. Specifically, a negative linear trend from baseline to 6-week follow-up indicated an initial decrease in depressive symptoms from baseline to 6-weeks, while a positive quadratic trend indicated a subsequent increase in depressive symptoms from 6- to 12-weeks follow-up. Although the variance components of the slopes were not statistically significant ($ps > .05$), suggesting the absence of individual variation in the pattern of change in depressive symptoms, a Level 2 model specifying group as a predictor of intercept and slopes (i.e., group x time interaction) was evaluated in the interest of hypothesis testing.

Table 4.

Depressive Symptoms – HLM estimates of pattern of change over time

	Unconditional Model	Quadratic Growth Model	Group as Predictor Model
Fixed Effects Coefficient			
Intercept	9.95**	10.64**	11.99**
Group			-1.61
Stage			-0.44
Linear Slope		-2.43*	5.17**
Group			-0.25
Stage			2.44*
Quadratic Slope		0.99*	2.31**
Group			-0.04
Stage			-1.12
Random Effects Variance			
Level-1 error	14.79	6.80	6.53
Intercept	36.25**	36.34**	37.06**
Linear Slope		12.77	12.37
Quadratic Slope		0.51	0.46
Covariance			
Int-Linear Slope		-2.73	-2.82
Int-Quadratic Slope		0.13	0.13
Indicators of Fit			
-2LL (# of parameters)	1029.58 (2)	1009.82 (7)	994.85 (7)
AIC	1033.58	1023.82	1008.85
BIC	1039.78	1045.52	1030.55

*$p < .05$, **$p < .01$

Results did not support group x time effects on change in depressive symptoms (linear $p = 0.90$, quadratic $p = 0.97$). That is, the pattern of change over time in depressive symptoms was not significantly different for survivors in the intervention or control groups; consequently, hypothesis 2a was not supported. See Figure 3 for a depiction of the average pattern of change in depressive symptoms for the intervention and control groups.

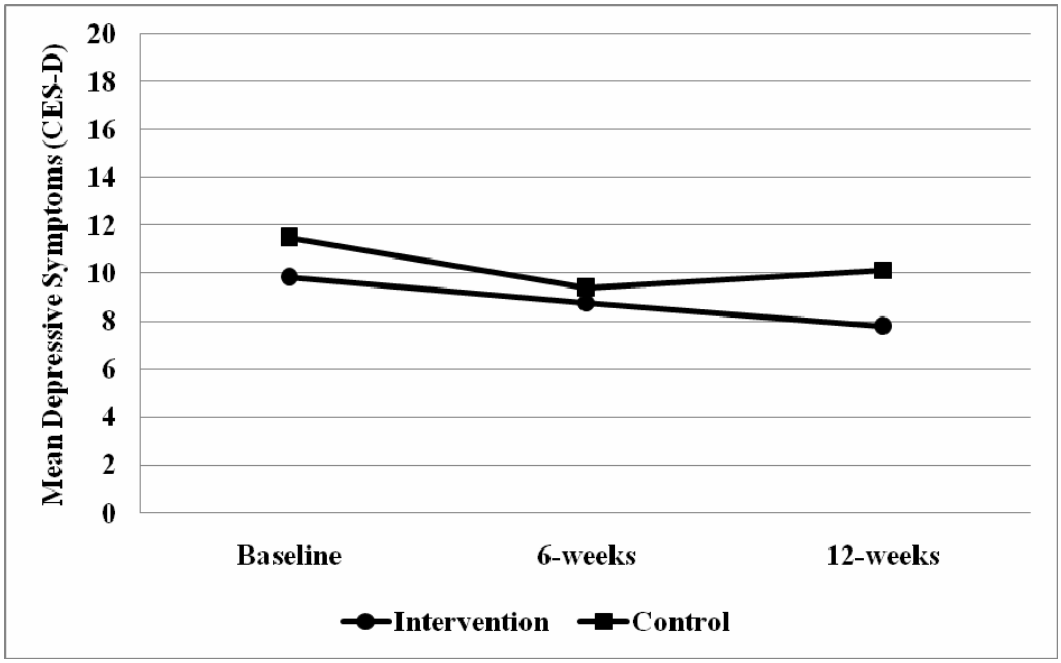

Figure 3. Average pattern of change in depressive symptoms for the intervention and control groups.

Intervention effect on mean change over time. As an adjunct to HLM analyses, an ANCOVA was conducted to examine mean-level group differences in depressive symptoms at each follow-up assessment, controlling for baseline status and stage at diagnosis. The results confirmed the findings from HLM; there were no group differences

in depressive symptoms at 6-week ($F(1, 45) = 0.08$, $p = .77$, $\eta^2 = < .01$) or 12-week follow-up ($F(1, 44) = 0.18$, $p = .67$, $\eta^2 = < .01$).

Exploratory mediation analyses. Exploratory mediation analyses were performed to address specific aim 3 and examine whether change in physical activity mediates the association between group assignment and depressive symptoms at 12-week follow-up. The model included group assignment as the independent variable, change in physical activity from baseline to 12-week follow-up as the mediator, depressive symptoms at 12-week follow-up as the dependent variable, and both depressive symptoms at baseline and stage at diagnosis as covariates. The indirect effect was not statistically significant (indirect effect = 0.30, *SE* = 0.85, bias corrected 95% CI = [-1.34, 2.17]), indicating that change in physical activity did not mediate the relationship between group assignment and depressive symptoms at 12-week follow-up.

Fatigue Outcomes

Descriptive data. Descriptive data for fatigue interference at baseline and 6- and 12-week follow-up are presented in Table 2. There were no group differences in baseline fatigue interference, $t(64) = 0.83$, $p = .40$.

Intervention effect on pattern of change over time. HLM was conducted to test hypothesis 2b (see Table 5). Prior to specifying the models of interest, an unconditional model with no predictors was examined to assess the appropriateness of modeling both inter- and intra-individual predictors of change in fatigue interference. The ICC was .60, suggesting that 60% of the variability in change in fatigue interference was due to inter-individuals differences and 40% to intra-individual differences, thus supporting the examination of both classes of predictors.

Table 5.

Fatigue Interference – HLM estimates of pattern of change over time

	Unconditional Model	Linear Growth Model	Quadratic Growth Model	Group as Predictor Model
Fixed Effects Coefficient				
Intercept	10.29**	12.20**	12.51**	12.17**
Group				-4.18
Stage				1.72
Linear Slope		-2.27**	-4.76	-2.54
Group				0.52
Stage				0.01
Quadratic Slope			-1.26	
Random Effects Variance				
Level-1 error	67.06	58.68	49.02	58.84
Intercept	101.48**	129.90**	157.38**	129.39**
Linear Slope		3.59	100.00 *	4.61**
Quadratic Slope			14.64	
Covariance				
Int-Linear Slope		-16.78	-101.05	
Int-Quadratic Slope			38.92	
Indicators of Fit				
-2LL (# of parameters)	1265.43 (2)	1254.83 (4)	1245.66 (7)	1241.17 (4)
AIC	1269.43	1262.83	1259.66	1255.17
BIC	1275.65	1275.27	1281.44	1276.95

*$p < .05$, **$p < .01$

First, to describe the pattern of change in fatigue interference over time, Level 1 models of both linear and quadratic change were evaluated. An evaluation of fit indicators suggested that the model with only a linear trend was a better fit to the data. Specifically, a significant negative linear trend from baseline to 12-week follow-up indicated that fatigue interference decreases over time (p = .004). Although the variance component of the slope was not statistically significant, suggesting the absence of individual variation in the pattern of change in fatigue interference, a Level 2 model specifying group as a predictor of intercept and slope (i.e., group x time interaction) was evaluated in the interest of hypothesis testing. Results did not support group x time effects on change in fatigue interference (p = .99). That is, the pattern of change over time in fatigue interference was not significantly different for survivors in the intervention or control groups; consequently, hypothesis 2b was not supported. See Figure 4 for a depiction of the average pattern of change in fatigue interference for the intervention and control groups.

Intervention effect on mean change over time. As an adjunct to HLM analyses, an ANCOVA was conducted to examine mean-level group differences in fatigue interference at each follow-up assessment, controlling for baseline status. The results partially differ from findings using HLM, since at 6-week follow-up fatigue interference was significantly lower in the intervention group relative to the control group, $F(1, 46) = 4.78$, $p = .03$, $\eta^2 = .06$. However, consistent with findings from HLM, there were no group differences at 12-week follow-up, $F(1, 46) = 0.002$, $p = .97$, $\eta^2 < .01$.

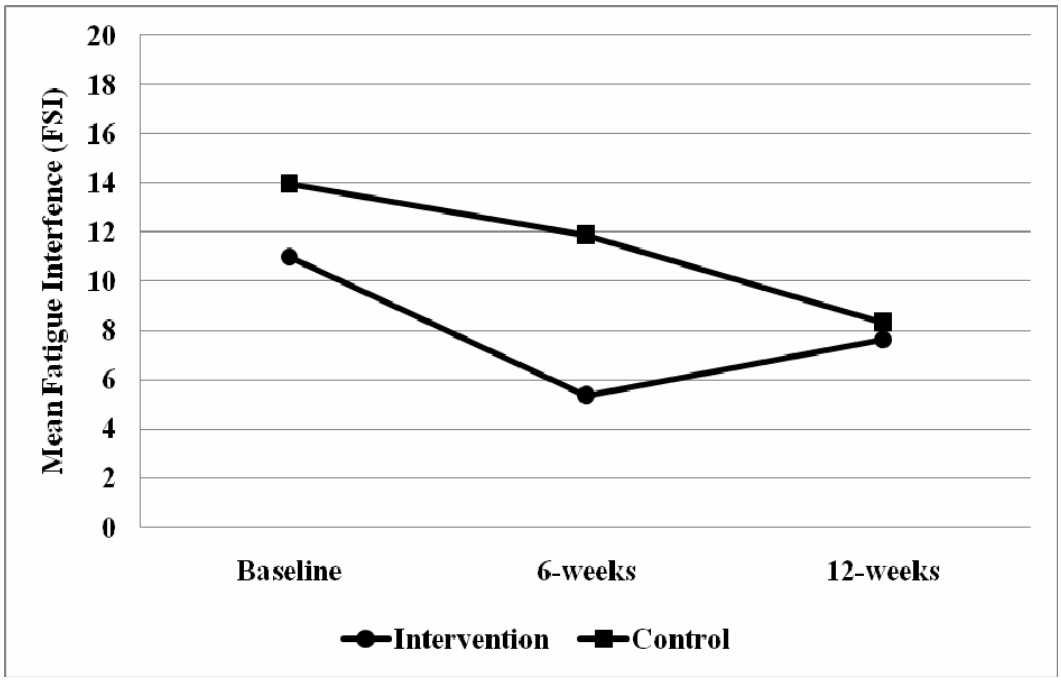

Figure 4. Average pattern of change in fatigue interference for the intervention and control groups.

Exploratory mediation analyses. Exploratory mediation analyses were performed to address specific aim 3 and examine whether change in physical activity mediates the association between group assignment and fatigue interference at 12-week follow-up. The model included group assignment as the independent variable, change in physical activity from baseline to 12-week follow-up as the mediator, fatigue interference at 12-week follow-up as the dependent variable, and both fatigue interference at baseline and stage at diagnosis as covariates. The indirect effect was not statistically significant (indirect effect = -0.32, *SE* = 0.59, bias corrected 95% CI = [-2.26, 0.45]), indicating that change in physical activity did not mediate the relationship between group assignment and fatigue interference at 12-week follow-up.

Since the ANCOVA results suggest group differences in fatigue interference at 6-week follow-up, an additional meditational model was examined with group assignment as the independent variable, change in physical activity from baseline to 6-week follow-up as the mediator, fatigue interference at 6-week follow-up as the dependent variable, and both fatigue interference at baseline and stage at diagnosis as covariates. The indirect effect was not statistically significant (indirect effect = .03, *SE* = .51, bias corrected 95% CI = [−1.46, 0.87]), indicating that change in physical activity did not mediate the relationship between group assignment and fatigue interference at 6-week follow-up.

Vigor Outcomes

Descriptive data. Descriptive data for vigor at baseline and 6- and 12-week follow-up are presented in Table 2. There were no group differences in baseline vigor, $t(64) = -0.18$, $p = .85$.

Intervention effect on pattern of change over time. HLM was conducted to test hypothesis 2c (see Table 6). Prior to specifying the models of interest, an unconditional model with no predictors was examined to assess the appropriateness of modeling both inter- and intra-individual predictors of change in vigor. The ICC was .60, suggesting that 60% of the variability in change in fatigue interference was due to inter-individuals differences and 40% to intra-individual differences, thus supporting the examination of both classes of predictors.

First, to describe the pattern of change in vigor over time, Level 1 models of both linear and quadratic change were evaluated. An evaluation of fit indicators suggested that the model with only a linear trend was a better fit to the data. Specifically, a significant positive linear trend from baseline to 12-week follow-up indicated that vigor

increases over time (p = .02). The statistically significant variance components of the slope point to inter-individual differences in the pattern of change in vigor (p = .002), which further supports examination of Level 2 predictors.

Table 6.

Vigor - HLM estimates of pattern of change over time

	Unconditional Model	Linear Growth Model	Quadratic Growth Model	Group as Predictor Model
Fixed Effects Coefficient				
Intercept	2.38**	2.28**	2.28**	2.44**
Group				0.04
Stage				-0.15
Linear Slope		0.12*	0.13	0.17
Group				-0.16
Stage				0.02
Quadratic Slope			-0.01	
Random Effects Variance				
Level-1 error	0.24	0.18	0.41	0.17
Intercept	0.48**	0.49**	0.52**	0.50**
Linear Slope		0.05**	0.15	0.06**
Quadratic Slope			0.01	
Covariance				
Int-Linear Slope		-0.03	-0.10	
Int-Quadratic Slope			0.04	
Indicators of Fit				
-2LL (# of parameters)	353.64 (2)	346.93 (4)	351.83 (7)	353.44 (4)
AIC	357.64	354.93	365.83	367.44
BIC	363.88	367.40	387.66	389.27

*p < .05, **p < .01

Second, to examine whether change in vigor varies by group assignment, a Level 2 model specifying group as a predictor of intercept and slope (i.e., group x time interaction) was evaluated. Results did not support group x time effects on change in vigor (linear $p = .14$). That is, the pattern of change over time in vigor was not significantly different for survivors in the intervention or control groups; consequently, hypothesis 2c was not supported. See Figure 5 for a depiction of the average pattern of change in vigor for the intervention and control groups.

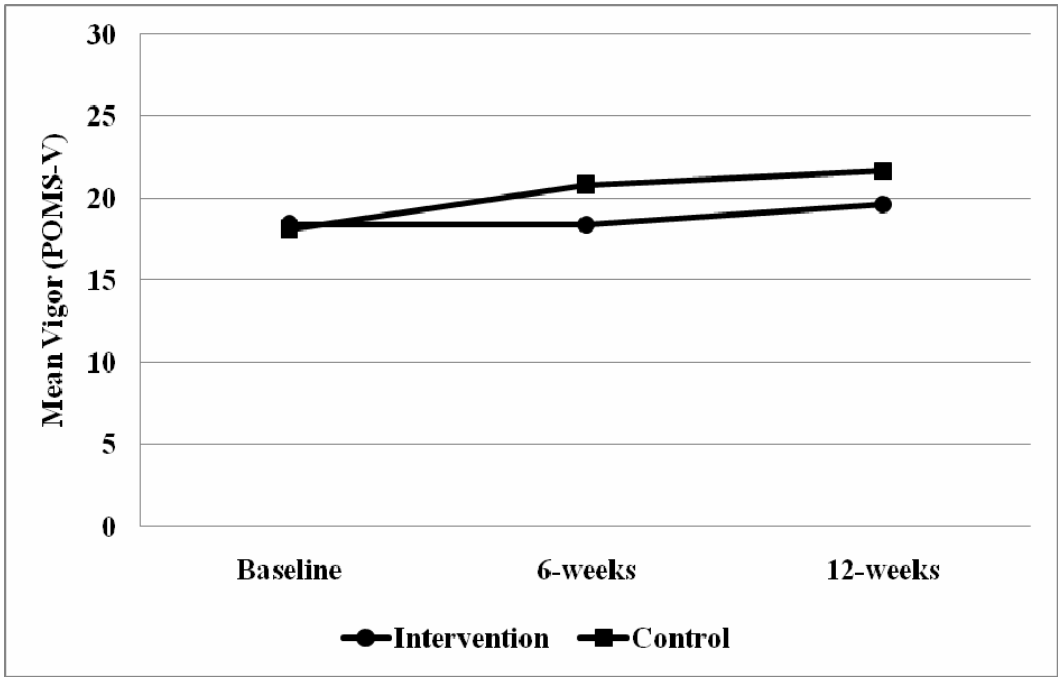

Figure 5. Average pattern of change in vigor for the intervention and control groups.

Intervention effect on mean change over time. As an adjunct to HLM analyses, an ANCOVA was conducted to examine mean-level group differences in vigor at each follow-up assessment, controlling for baseline status and stage at diagnosis. The results confirm the findings from HLM; there were no group differences in vigor at 6-week ($F(1, 47) = 1.66$, $p = .20$, $\eta^2 = .02$) or 12-week follow-up ($F(1, 46) = 1.08$, $p = .30$, $\eta^2 = .01$).

Exploratory mediation analyses. Exploratory mediation analyses were performed to address specific aim 3 and examine whether change in physical activity mediates the association between group assignment and vigor at 12-week follow-up. The model included group assignment as the independent variable, change in physical activity from baseline to 12-week follow-up as the mediator, vigor at 12-week follow-up as the dependent variable, and both vigor at baseline and stage at diagnosis as covariates. The indirect effect was not statistically significant (indirect effect = -0.32, *SE* = 0.59, bias corrected 95% CI = [-2.26, 0.45]), indicating that change in physical activity did not mediate the relationship between group assignment and vigor at 12-week follow-up.

Aerobic Fitness Outcomes

Descriptive statistics. Descriptive data for aerobic fitness (6MWT) at baseline and 12-week follow-up are presented in Table 2. There were no group differences in aerobic fitness at baseline, $t(64) = .56$, $p = .58$.

Meaningful change. In the absence of criteria for meaningful clinical change in the 6MWT for cancer patients or survivors, an evaluation was conducted using a criterion derived from a sample of patients with cardiopulmonary diseases (e.g., COPD) and involves a change in walking distance of 54 meters (Rasekaba et al., 2009). Accordingly, participants were categorized based on whether or not they met criteria for meaningful change. The proportion of survivors meeting criteria for meaningful change was 20% in the control group and 45.5% in the MI group; however, this difference was not statistically significant [$\chi^2(1, N = 47) = 3.49$, $p = .06$].

Intervention effect on pattern of change over time. A repeated-measures ANCOVA, controlling for stage at diagnosis, was conducted to test hypothesis 2d. There

was a significant main effect for time, with both the control and intervention group exhibiting improved aerobic fitness at 12-week follow-up relative to baseline, $F(1, 44) = 28.46$, $p < .001$, $\eta^2 = .40$. However, there was no main effect for group ($F(1, 44) = 2.11$, $p = .15$, $\eta^2 = .02$) or group x time interaction ($F(1, 44) = 2.48$, $p = .12$, $\eta^2 = .05$). That is, the pattern of change over time in aerobic fitness was not significantly different for the sample as a whole or differentially for survivors in the intervention group versus the control group; consequently, hypothesis 2d was not supported. See Figure 6 for a depiction of the average pattern of change in aerobic fitness for the intervention and control groups.

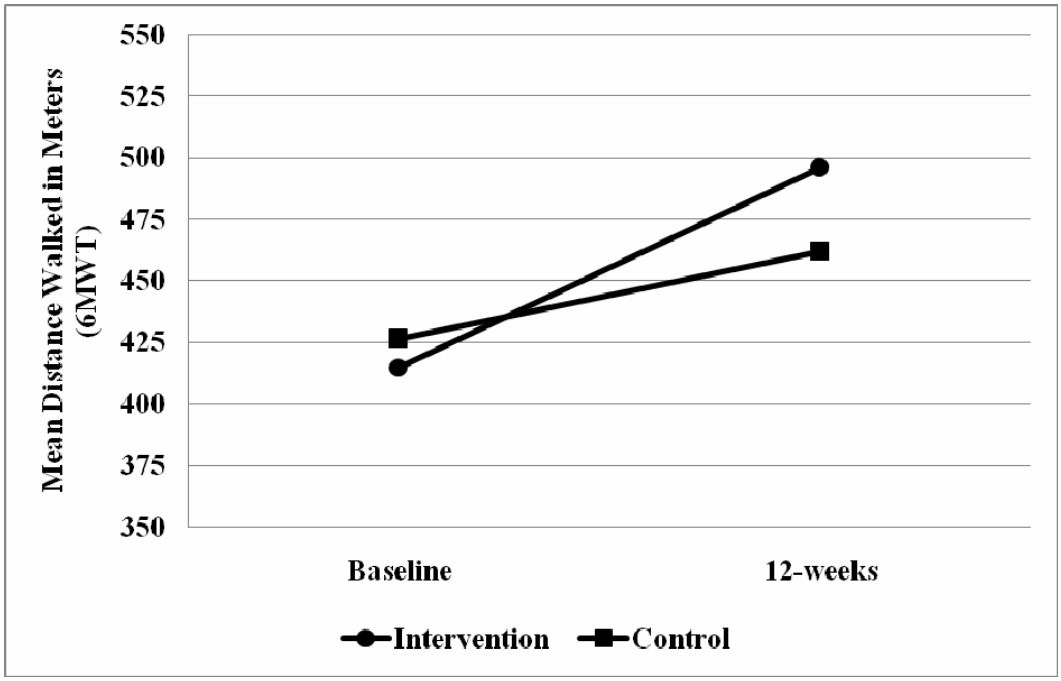

Figure 6. Average pattern of change in aerobic fitness for the intervention and control groups.

Intervention effect on mean change over time. As an adjunct to repeated-measures analysis, an ANCOVA was conducted to examine mean-level group differences in aerobic fitness at the 12-week follow-up assessment, controlling for baseline status and stage at diagnosis. The results indicated there were no group differences in aerobic fitness at 12-week follow-up, $F(1, 43) = 2.89$, $p = .09$, $\eta^2 = .03$.

Exploratory mediation analyses. Exploratory mediation analyses were performed to address specific aim 3 and examine whether change in physical activity mediates the association between group assignment and aerobic fitness at 12-week follow-up. The model included group assignment as the independent variable, change in physical activity from baseline to 12-week follow-up as the mediator, aerobic fitness at 12-week follow-up as the dependent variable, and both aerobic fitness at baseline and stage at diagnosis as covariates. The indirect effect was not statistically significant (indirect effect = -2.79, *SE* = 5.42, bias corrected 95% CI = [-23.90, 3.06]), indicating that change in physical activity did not mediate the relationship between group randomization and aerobic fitness at 12-week follow-up.

Analyses for Overall Effects on Physical Activity Outcomes

While there was no evidence for intervention effects on physical activity, the data suggest an overall effect of time for physical activity. To investigate this effect further, data were combined to examine predictors of change over time in physical activity. The following variables were examined as potential predictors: baseline activity level (sedentary vs. insufficiently active), BMI, age, depressive symptoms, fatigue, and fitness. As a first step, correlational analyses were conducted to determine the association of these potential predictor variables at baseline with physical activity (METS) at 6- and 12-

weeks follow-up (see Table 7). No variables were significantly correlated with METS at 6-week follow-up. However, baseline activity level, BMI, and aerobic fitness were associated with METS at 12-week follow-up (*p*s < .05).

Table 7.

Correlations of Potential Predictor Variables and METS at 6- and 12-weeks Follow-up

Values at Baseline	6-weeks METS	12-weeks METS
Age	-.08	-.18
BMI	-.12	-.39**
Activity Level (Sedentary vs. Insufficiently Active)	.14	.35*
Aerobic Fitness	.24	.55***
Depressive Symptoms	-.02	.18
Fatigue Interference	.12	.27
Fatigue Severity	-.01	.18

*$p < .05$, **$p < .01$, ***$p < .001$

The predictive value of these variables was further examined in a hierarchical linear regression model. The dependent variable in these analyses was METS at 12-weeks follow-up. In step 1, group assignment, stage, and baseline METS where entered as predictors; in step 2, baseline activity level (sedentary vs. insufficiently active), BMI, and aerobic fitness were entered as predictors. Results (Table 8) indicate that baseline aerobic fitness was a significant predictor of physical activity at 12-weeks follow-up ($p = .01$). Specifically, breast cancers survivors who exhibited higher levels of aerobic fitness at baseline reported greater increase in physical activity at the 12-week follow-up.

Baseline BMI and baseline activity level (sedentary vs. insufficiently active) were not significant predictors of change in physical activity at follow-up ($p = .27$).

Table 8.

Predictive Model of Change in Physical Activity from Baseline to 12-week Follow-up

Predictor	β	R^2	ΔR^2	*p*
Step 1		.26		.003
Stage	-.09			
Group	-.06			
Baseline METS	.50***			
Step 2		.45	.19	<.001
Baseline Activity Level	.04			
Baseline BMI	-.10			
Baseline Aerobic Fitness	.40**			

Note. $F(6, 43) = 5.85$, $p < .001$

*$p < .05$, **$p < .01$, ***$p < .001$

Discussion

A growing body of evidence supports the positive impact of physical activity interventions on health outcomes in breast cancer survivors (McNeely et al., 2006; Pekmezi & Demark-Wahnefried, 2011; Schmitz et al., 2005; Speck et al., 2010). Most physical activity interventions evaluated in the literature to date adopt a prescriptive style and are time and resource intensive, which may limit their sustainability and potential for dissemination (Irwin, 2009). An alternative, more flexible approach to behavior change involves enhancing breast cancer survivor's motivation for physical activity while incorporating their individual interests, preferences, and needs. Motivational Interviewing, a client-centered, empathic, counseling style offers a helpful clinical framework for promoting behavior change in a distinctly non-prescriptive and individualized style (Markland et al., 2005; Miller & Rollnick, 2002; Milne et al., 2008). The primary goal of this randomized-controlled trial was to evaluate the efficacy of a MI-based intervention to promote physical activity among insufficiently active breast cancer survivors. Survivors who were within 3 months to 3 years post-treatment, insufficiently active, and contemplating increasing their level of physical activity were randomly assigned to the MI-based intervention or a healthy lifestyle counseling control condition.

The primary hypothesis was that the MI group, but not the control group, would report improvements in physical activity across the follow-up assessment period. Contrary to predictions, both the intervention and control groups exhibited improved

physical activity levels over time. In fact, survivors in both groups reported remarkable improvements in physical activity levels following this brief intervention. Specifically, the overall sample engaged in 0 minutes of weekly moderate and strenuous physical activity at baseline (per eligibility requirements) and a weekly average of 84 minutes of moderate and 41 minutes of strenuous activity 12-weeks later. Similarly, at baseline none of the breast cancer survivors in the overall sample met recommended physical activity guidelines of ≥150 minutes of moderate or ≥ 75 minutes of strenuous activity, or a combination, per week; however, 60% met or exceeded these guidelines 12-weeks later. While the long-term maintenance of these gains is unknown, the overall pattern and rate of improvement is promising. It is especially encouraging to note such improvement in physical activity levels in a sample of survivors who were in the "contemplation" stage of readiness for change (per eligibility requirements), which is arguably a more relevant and challenging target for intervention than being in the "preparation" or "action" stages of readiness.

Secondary hypotheses involved intervention effects on improvements over time for depressive symptoms, fatigue interference, vigor, and aerobic fitness. Again, contrary to predictions, results generally showed that both the intervention and control groups experienced improvements over time in depressive symptoms, fatigue interference, vigor, and aerobic fitness. Although at baseline survivors reported low levels of depressive symptoms and fatigue interference, as well as moderate levels of vigor, further improvements in these areas following participation in a physical activity or healthy lifestyle intervention may help optimize long-term psychosocial well-being. One exception to the pattern of no group differences is that, relative to controls, the MI group

reported significantly less fatigue interference at 6-week follow-up. While this group difference is in the expected direction, it was not evident at 12-week follow-up and it was not observed in the hierarchical linear models. Consequently, it is difficult to draw conclusions based on this isolated finding. Additionally, a trend was noted in which those in the MI group , relative to those in the control group, were more likely to meet criteria for meaningful change in aerobic fitness. While this trend is intriguing, it is difficult to interpret in the absence of meaningful clinical change criteria specific to cancer survivors.

In the absence of expected group differences in change in physical activity, several moderating variables were explored to determine whether subgroups of survivors may have differentially benefited from the MI intervention. Overall, the pattern of no group differences in change in physical activity was maintained regardless of breast cancer survivors' baseline status on activity level (sedentary vs. insufficiently active), perceived stress, BMI, or age. Mediational models were also explored to determine whether the relationships between group assignment and change in depressive symptoms, fatigue interference, vigor, and aerobic fitness were mediated by change in physical activity. None of the meditational models was supported, which is consistent with the similar pattern of change in physical activity observed in both the MI and control group participants.

In the absence of an overall or moderated effect of the MI intervention on change in physical activity, the MI and control groups were combined and overall predictors of change in activity were examined. Baseline aerobic fitness was identified as a unique predictor of change in physical activity, with breast cancer survivors exhibiting higher

levels of fitness at baseline reporting greater improvement in physical activity over time. This suggests that survivors with lower levels of fitness prior to initiating a physical activity program may benefit from additional support. Perhaps being less fit results in greater physical discomfort (e.g., respiratory distress, pain) when initiating a physical activity routine, which may result in discouragement and discontinuation. Educating less fit survivors about the possibility of physical discomfort, its relative duration, and relevant coping strategies may help them overcome this barrier.

Methodological features and theoretical considerations may serve to explain why hypotheses in this study were generally not supported. Relevant methodological factors include: stringent eligibility criteria, intervention intensity, comparison to an active control group, and intervention credibility. The eligibility criteria for this study were more stringent than most prior trials of physical activity, which have typically adopted a "take all comers" approach to recruitment. Specifically, a review of trials from 2005-2009 noted that less than half (43%) exclude participation in a physical activity intervention based on current activity level (Speck et al., 2010). Additionally, most prior studies have not implemented a need-based approach to recruitment (Speck et al., 2010). The inclusion in prior trials of participants who may already be adequately physically active and those who may be further along in their readiness for change in physical activity may have biased results in favor of the interventions being tested (Pekmezi & Dehmark-Wahnefried, 2011; Speck et al., 2010). In contrast, this study exclusively recruited insufficiently active "contemplators" of physical activity change; that is, those with the lowest performance and highest need for improvement in physical activity.

In terms of intervention intensity, most prior studies (both non-MI and MI-based) involved intervention delivery over the course of at minimum 5 weeks, and more typically over 12 weeks (Speck et al., 2010). In contrast, this study implemented a brief intervention of 3 sessions over a period of 4 weeks. It is possible that a more intensive intervention protocol including more frequent contacts over a longer period of time may have produced more favorable outcomes in the MI group. However, the fact that breast cancer survivors in both groups improved their physical activity level, on average, after participation in a brief intervention speaks to the potential for a relatively modest investment in resources to have a positive impact on the overall health status of breast cancer survivors.

The use of an active control condition is arguably the most meaningful methodological distinction between this study and prior RCTs of both non-MI and MI-based interventions to promote physical activity in cancer survivors. Most non-MI intervention studies have compared a prescriptive, supervised exercise program to a usual care or waitlist group that receives no specific guidance on physical activity change (for reviews, see Pekmezi & Dehmark-Wahnefried, 2011; Schmitz, 2005; Speck et al., 2010). Similarly, the only prior trial of a MI-based physical activity intervention for cancer survivors used a time and attention control condition that did not include content specific to physical activity promotion (Bennett et al., 2007). Thus, the positive outcomes for physical activity change in both types of trials are not surprising, since the likelihood of spontaneous uptake of physical activity in the absence of an intervention is relatively low and many survivors reduce their level of activity after treatment (Blanchard et al., 2008; Irwin, 2009). In contrast, the active control condition in this study included psycho-

education about physical activity guidelines and prescription of a specific physical activity routine. Thus, the present study design is a much more stringent evaluation of the efficacy of MI for physical activity promotion than is typical in the literature.

The higher degree of perceived credibility of the control condition for physical activity promotion certainly contradicts expectations prior to data collection. One possible explanation is that the prescriptive style of the control condition was better aligned with potential expectations of the type of supportive services commonly encountered within a medical setting. Another possibility is that, by targeting multiple behavior change areas (i.e., physical activity, nutrition, and stress management), the control intervention may have inspired greater confidence in the likelihood of overall behavior change. The literature offers conflicting evidence for this hypothesis, as some studies suggest multiple behavior change is more challenging, while other studies suggest that change in one behavior may function as a "gateway" for change in other behaviors (Noar, Chabot, & Zimmerman, 2008; Prochaska, Spring, & Nigg, 2008).

Theoretical considerations may also help explain the pattern of results. It is important to recall that MI was developed based on clinical practice, not theory (Miller & Rollnick, 2002). However, MI has been conceptualized as a good fit for the tenets of Self-determination Theory, which posits that *long-term* behavior change is motivated by a sense of autonomy, competency, and relatedness (Markland et al., 2005; Vansteenkiste & Sheldon, 2006). Thus, it is possible that the MI-based intervention is not well-matched to an evaluation of *short-term* change in physical activity. Perhaps the impact of MI on behavior change is more accurately evaluated during examination of longer-term change in outcomes. Another pertinent consideration is that enhancing motivation for change

may be conceptualized as a necessary, but not a sufficient, precursor to successful behavior change. Anecdotally, several survivors reported various practical and knowledge-based barriers to regular physical activity, despite high level of motivation. It is possible that, while the MI-based intervention addressed motivation for change, the control intervention may have more directly addressed barriers to regular physical activity.

The clinical implications of this study are noteworthy. First, the overwhelming majority of breast cancer survivors queried indicated that a program promoting physical activity change or healthy lifestyle change should be more readily and broadly available to cancer survivors. The opinions of this sample of survivors are thus aligned with the Institute of Medicine's (IOM) recommendation that cancer survivors be provided with survivorship care plans that incorporate recommendations about preventive practices that help optimize well-being (IOM, 2006). Additionally, the positive outcomes observed for both the MI-based and healthy lifestyle counseling interventions suggests that behavior change interventions may be flexibly delivered in a variety of formats and styles. Moreover, this study suggests that positive change in physical activity is feasible with implementation of a relatively brief intervention requiring a modest investment of resources. In an era of increasing concerns over the cost-benefit ratio of interventions in healthcare settings, a brief intervention to promote physical activity may help meet the needs of both patients and healthcare delivery environments.

Several limitations to this study must be acknowledged. The sample only included breast cancer survivors with early stage disease and within three years of end of treatment; therefore, findings may not be generalizable to long-term survivors, survivors

of other types of cancer, and those with more advanced disease. The demographic characteristics of the sample were generally representative of the patient population at Moffitt Cancer Center, which is largely White, educated, and socioeconomically stable; hence, findings may not generalize to a more demographically diverse sample. Moreover, the study did not assess level of physical activity prior to breast cancer diagnosis, a variable that may have predicted differential intervention effects (e.g., the control intervention may have been more effective among survivors who were active prior to diagnosis) or differential patterns of outcomes in the combined sample (e.g., more marked improvement among those active prior to diagnosis). Retention proved challenging, with 12% of participants lost to follow-up after the baseline assessment and only 65% completing all three assessment points. While the lost to follow-up rate is comparable to that of prior trials (Speck et al., 2010) and did not differ on variables measured, there may have been important differences on unmeasured variables between those who completed the study and those lost to follow-up. From a measurement perspective, while the use of retrospective, self-report surveys of physical activity is standard in the literature (for reviews, see Speck et al., 2010; Schmitz et al., 2005), it does raise concerns about recall bias and positive impression management. Statistically, multiple comparisons using both hierarchical linear modeling and analysis of covariance increases the likelihood of chance findings; however, results from both types of analyses converged for the most part. Finally, theoretical constructs that may act as mechanisms of change in the MI-based intervention (e.g., self-efficacy for physical activity) were not evaluated, as the primary goal of this study was to determine the efficacy of the MI intervention.

Despite these limitations and challenges, several strengths of this study are noteworthy. The design ensured needs-based enrollment in the trial by restricting study eligibility to those who were insufficiently active and contemplating increasing physical activity. Treatment integrity was evaluated, which is essential to ensuring that the MI-based intervention did, in fact, reflect the spirit of MI. The in-person study assessments were conducted by research assistants who were blinded to randomization, thus decreasing the likelihood of experimenter bias. Furthermore, the comparison to an active control is a methodological strength of this study, as it ensures that any effect of the MI-based intervention is, in fact, due to the unique contribution of the MI counseling style and not to common factors. Finally, by examining mediating pathways and moderators of change in the context of a longitudinal design, this study responds to the call for research on more descriptive and complex models of health behavior change in cancer survivors (Park & Gaffey, 2007).

Future research is necessary to clarify questions raised by the study findings. First, the study raises questions about how meaningful the improvements in physical activity, depressive symptoms, fatigue interference, vigor, and aerobic fitness observed in both the MI and healthy lifestyle counseling groups really are. Might improvements in these outcomes have occurred over time independent of receiving an MI intervention or a healthy lifestyle intervention? A study implementing a three group design comparing the MI intervention to an active and a classic waitlist control conditions would help address this question. Second, this longitudinal study's follow-up time frame was limited to three months. While the pattern of improvement in physical activity change during this time period is encouraging, it is imperative to evaluate long-term maintenance of gains (e.g., 6

month, 12 month follow-ups). Relevant questions include whether there are critical periods during which an intervention "booster" session may positively impact maintenance of gains. Third, while this study attempted to target a sample of survivors with low motivation and high need for physical activity change, recruitment and retention challenges were notable. More research is needed to determine the most effective strategy for targeted outreach to cancer survivors who would benefit the most from lifestyle changes. For instance, it is important to determine how to most efficiently identify and recruit these patients within healthcare delivery settings and to identify strategies that may help improve retention.

Additional research is also needed to improve the quality of the evidence-base regarding the benefits of physical activity promotion among cancer survivors. One challenge that has been repeatedly cited in the literature (Speck et al., 2010; Park & Gaffey, 2007) involves heterogeneity in measurement methods. Arriving at a consensus about standardized measures of outcomes of interest would help facilitate cross-trial comparisons and conclusions. In addition, trials with larger samples are necessary to maximize power and help instill confidence in the stability of findings. Finally, more work is needed to help identify effective venues for dissemination of sustainable, evidence-based health promotion programming that meets the unique needs of survivors of breast and other types of cancer.

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Appendices

Appendix A: IRB Approval Letter

USF
UNIVERSITY OF
SOUTH FLORIDA

DIVISION OF RESEARCH INTEGRITY AND COMPLIANC
Institutional Review Boards, FWA No. 0000166
12901 Bruce B. Downs Blvd., MDC035 • Tampa, FL 33612-475
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July 29, 2010

Paul Jacobsen, PhD
H Lee Moffitt Cancer Center
MRC-PSY

RE: **Expedited Approval** for Initial Review
IRB#: Pro00001278
Title: Motivational Interviewing to Promote Physical Activity in Breast Cancer Survivors

Dear Dr. Jacobsen,

On 7/28/2010 the Institutional Review Board (IRB) reviewed and **APPROVED** the above referenced protocol**.** Please note that your approval for this study will expire on 7/28/2011.

Approved Items:
Protocol Document(s):
Study Protocol

Consent/Assent Document(s):
Adult Informed Consent with Authorization.pdf

It was the determination of the IRB that your study qualified for expedited review which includes activities that (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more of the categories outlined below. The IRB may review research through the expedited review procedure authorized by 45CFR46.110 and 21 CFR 56.110. The research proposed in this study is categorized under the following expedited review category:

(5) Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis).

(6) Collection of data from voice, video, digital, or image recordings made for research purposes.

(7) Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

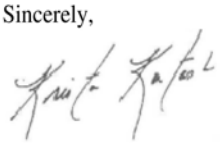
Please note, the informed consent/assent documents are valid during the period indicated by the official, IRB-Approval stamp located on the form. Valid consent must be documented on a copy of the most recently IRB-approved consent form.

Your study qualifies for a waiver of the requirement for signed authorization as outlined in the HIPAA Privacy Rule regulations at 45 CFR 164.512(i) which states that an IRB may approve a waiver or alteration of the authorization requirement provided that the following criteria are met (1) the PHI use or disclosure involves no more than a minimal risk to the privacy of individuals; (2) the research could not practicably be conducted without the requested waiver or alteration; and (3) the research could not practicably be conducted without access to and use of the PHI.

As the principal investigator of this study, it is your responsibility to conduct this study in accordance with IRB policies and procedures and as approved by the IRB. Any changes to the approved research must be submitted to the IRB for review and approval by an amendment.

We appreciate your dedication to the ethical conduct of human subject research at the University of South Florida and your continued commitment to human research protections. If you have any questions regarding this matter, please call 813-974-9343.

Sincerely,



Krista Kutash, PhD, Chairperson
USF Institutional Review Board

Cc: Anna Davis, USF IRB Professional Staff

Appendix B: Pilot-testing Feedback Guide

1. What are your thoughts on the time commitment for this program? As a reminder, the program involves 2 in-person visits and 1 phone session. Is it feasible? Why or why not?

2. What are your thoughts on the assessment that you completed before starting the program? As a reminder, the assessment involved completing the questionnaires, measuring your height and weight, and walking along a long hallway for 6 minutes.

3. Do you believe this program could be helpful in the promotion of physical activity among breast cancer survivors? Why or why not?

4. Think about the setting in which the program took place (Moffitt, Survivorship Clinic, consult room). Did you find the setting comfortable? Why or why not?

5. Can you think of anything that could be improved about this program, in order to make it more helpful to breast cancer survivors?

Appendix C: MI Protocol Week 1

MI PROTOCOL – WEEK 1

BEFORE SESSION: 30 minutes

I. Questionnaire Packet

II. Height and Weight Assessment

III. 6 Minute Walk Test

SESSION 1: 60-75 minutes

I. Greeting and Overview

II. Review Typical Day

III. Importance of PA for BCS – use Elicit-Provide-Elicit

IV. Elicit Change Talk

- **1. Importance Ruler**
- **2. Confidence Ruler**
- **3. Good Things vs. Not so Good Things**
- **4. Values Clarification**
- **5. Looking Forward and Backward**

IV. Overall Summary

V. Set Goals and Personal Plan

- **1. Goal Setting Worksheet**
- **2. Implementation Intentions**

VI. Wrap-Up

- **1. Global Summary**
- **2. Set next appointment**

I. GREETING AND OVERVIEW

→ *Thank you for coming in today and for completing all of the study assessments. If it's okay with you, I was hoping to provide you with a brief overview of today's meeting. Does that sound okay?*

→*One of the main things that this program offers is help with improving your overall health by incorporating more physical activity into your life. Our discussion will be collaborative and will focus on your unique needs and challenges. Does that sound okay?*

II. REVIEW TYPICAL DAY

→ *If it's okay with you, I'd like to spend the next 5-10 minutes going over your typical day – say yesterday – from beginning to end. Let's start at the beginning…when did you get up?*

(As needed, probe with "what happened?" or "how did you feel?")

Create a rough outline of client's day/schedule in the space below. Summarize in a reflective way.

→ *It seems that you have quite a busy day. Currently, how does physical activity fit or not fit into your daily schedule? (Make notes on barriers to PA)*

Use reflective listening and paraphrase.

III. IMPORTANCE OF PA FOR BCS – USE ELICIT-PROVIDE-ELICIT

→ *If it's okay with you, I'd like to find out a little bit more about what you know about the importance of physical activity for the overall health of a breast cancer survivor, such as yourself. Tell me what you know about the recommended weekly amount of physical activity for breast cancer survivors.*

Use reflective listening and paraphrase.

Discuss additional reasons why exercise is important and clarify guidelines:

→ *If it's okay with you, I'd like to discuss some (additional) reasons why physical activity is important for breast cancer survivors.*

AND/OR

→ *If it's okay with you, I'd like to clarify what the most up-to-date recommended physical activity guidelines for breast cancer survivors indicate.*

→ *I wonder, what are your thoughts on this information? What do you make of all this?*

Use reflective listening and paraphrase. Clarify as needed.

IV. ELICIT CHANGE TALK

→ *We've had a discussion about why it's important for breast cancer survivors to engage in physical activity. If it's ok with you, I'd like to switch gears and talk about how important it is for <u>you</u>, specifically, to engage in physical activity.*

1. IMPORTANCE RULER

→ *On a scale from 0-10, where 0 is not at all important and 10 is extremely important, how important would you say it is for you to exercise?*

→ *So you feel it is at least a little important (1-3)/somewhat important (4-7)/very important (8-10). Why are you at (stated #) and not a (lower # -- avoid zero, be flexible)?*

Reflect and paraphrase. Focus on "reasons for change" that client expresses.

IF the stated important level is less than 8…

→ *What would it take to get your importance level up to a (add 3-5 points to stated #)?*

Reflect and paraphrase.

2. CONFIDENCE RULER

→ *Many people find that although regular physical activity is at least somewhat important to them, they may or may not be confident in their ability to engage in activity. If it's okay with you, I'd like to get a sense for your confidence in your ability to engage in physical activity.*

→ *On a scale from 0 to 10, where 0 is not confident at all and 10 is extremely confident, how confident would you say you are that if you decided to engage in regular physical activity, you could do it?*

→ *So you feel it at least a little bit confident (1-3)/somewhat confident (4-7)/very confident (8-10). Why are you at (stated #) and not (lower # -- avoid zero, be flexible)?*

Reflect and paraphrase. Focus on "strengths" that client expresses.

IF the stated confidence level is less than 8…

→ *What would it take to get your confidence level up to a (add 3-5 points to stated #)?*

Use reflective listening and summarizing and reinforce the participant's efforts.

3. GOOD THINGS vs. NOT SO GOOD THINGS about PA

→ *Let's talk a little about the good things and the not so good things about physical activity. First, tell me about the not-so good side of engaging in regular physical activity. What are the downsides? What don't you like about it?*

Use reflective listening and paraphrase or summarize.

→ *Now, what are some of the good things about regular physical activity?*

(If necessary, probe further) *When you have been regularly active in the past, what have you liked about it? Even if you haven't been regularly active in the past, what do you imagine you might like about it?*

Summarize the not so good things and the good things in "you" language; be succinct.

4. VALUES CLARIFICATION

→ *Now I'd like to talk to you a little about some of the things that you value most in life. For this part, I would like to look at this Values Clarification Card, which is yours to keep. I would like you to just take a moment to think about the things in your life that are most important to you.*

LIST OF VALUES	
Healthy	**Happy**
Safe	**Productive**
Comfortable (pain free)	**Helpful**
Financially Independent	**Knowledgeable**
Good parent	**Attractive**
Good spouse/partner	**Disciplined**
Good community member	**Responsible**
Strong	**In control**
On top of things	**Respected**
Competent	**Athletic**
Spiritual	**Not Hypocritical**
Passionate	**Energetic**
Faithful, Religious	**Considerate**
Successful	**Youthful**
Popular	**Independent**
Other_____	

→ *The list in front of you shows a few traits/values/characteristics that are important to some people. Pick the 2 or 3 characteristics that are most important to you. Please feel free to add to this list if there are any other values that are important to you.*

→*Tell me, why are these traits/values that you have chosen important to you? How, if at all, is regular physical activity related to these values?*

Use OARS (open-ended questions, affirmations, reflective listening, summarizing) as needed/appropriate.

IF PARTICIPANT DOES NOT MAKE THE CONNECTION BETWEEN HEALTH AND CORE VALUES: Use one or more of these prompts.

→ *Think about the things in your life that are important to you. How, if it at all, would regular physical activity affect the things that are important to you?*

Proceed to ask the other questions in relation to what they have said here.
Use OARS as needed.

→ *I'm curious (name of participant), what connection, if any, do you see between regular physical activity and your ability to live out (name specific values or goals endorsed)?*

Use OARS as needed.

5. LOOKING FORWARD AND BACKWARD

→ *Suppose you continue as you have been, without changing, without engaging in regular physical activity. What do you imagine would happen to your ability to live out (name specific values or goals endorsed)?*

Use OARS as needed.

→ *If you were successful in engaging in regular physical activity, how would things be different? What would be the impact on your ability to live out (name specific values or goals endorsed)?*

Use OARS as needed.

IV. PROVIDE OVERALL SUMMARY OF DISCUSSION

→ *So on the one hand, you have mentioned several reasons why engaging in regular physical activity has been a challenge and may not be the best thing right now (state the reasons)*

→*On the other hand, you have mentioned several reasons why it would be important to change (state the reasons)*

Summarize the most important not so good things about engaging in regular physical activity, and then follow with a summary of the good things/positive reasons for engaging in regular physical activity and the core values/goals associated with regular physical activity.

→*Does that sound about right? Any additional thoughts?*

V. SET GOALS AND PERSONAL PLAN

→ *I am wondering, given what we've talked about, where you would like to go from here. What do you think our next step should be?*

Use reflective listening and paraphrase

→ *Would you be interested in working together on a plan, or perhaps setting some goals related to increasing your level of activity today, or perhaps at our next meeting? It is entirely up to you.*

IF NOT READY TO SET GOALS → Empathize with the challenges of initiating behavior change, then move on to WRAP-UP

IF READY TO SET GOALS → Move on to GOAL SETTING WORKSHEET

1. GOAL SETTING WORKSHEET

Give participant worksheet to review/complete

→ *Remember that you are the best judge of what will be best for you. If it's okay, I'd like for you to think of a goal you could set for yourself for the next week concerning your level of physical activity? Remember the goal should be clear, realistic, not too much or too little. Think of something that suits you and your lifestyle best. What are you thoughts about a goal?*

Reinforce appropriate goals

IF clients are having trouble coming up with goals, ASK:

→ *Some women with breast cancer have benefited from these types of activities.*

Present menu of physical activity options.

→ *Which, if any, o these activities might be of interest to you?*

Use OARS as needed.

→ *What are some of the things you will need to do to achieve this goal? Think of specific steps or actions and specific times when you might do them.* **Use OARS as needed.**

	Specific Action	When?
1.		
2.		
3.		
4.		
5.		

2. IMPLEMENTATION INTENTIONS

→ *Think about the next 7 days. When would be a good time for you to (specific action)? Be as specific as possible. Where would you do (specific action)? With whom would you do (specific action)?*

Follow the same line of questioning for each of the specific actions listed above.

Summarize Implementation Intentions.

VI. WRAP-UP

1. GLOBAL SUMMARY

→ *Before we end, I'd like to take a moment to hear what, if anything, you got out of today's session.* **Allow participant to summarize.**

→ *Good, I'm glad you found that helpful.*

2. SET NEXT APPOINTMENT

→ *Thank you very much _____ (name) for all your time and effort today. The next session takes place next week, in-person, here at Moffitt. This next session will be shorter, lasting 30-45 minutes. If it's okay with you, let's schedule our next visit for _____.*

Give participant appointment card.

→ *Thank you again for your time today and I look forward to seeing you soon! Have a good evening/day/morning!*

Appendix D: MI Protocol Week 2

MI PROTOCOL – WEEK 2

SESSION 2: 45-60 minutes

IF GOALS NOT SET LAST SESSION	**IF GOALS SET LAST SESSION**
I-A. Greeting and Overview	**I-B. Greeting and Overview**
II-A. Review of Last Session	**II-B. Review of Last Session**
III-A. Set Goals and Personal Plan	**III-B. Review Adherence to Goals**
1. Goal Setting Worksheet	**1. If at least some adherence**
2. Implementation Intentions	**2. If no adherence**
IV-A. Explore Barriers	**IV-B. Evaluate Need for Goal Adjustment**
V-A. Wrap-Up	**V-B. Wrap-up**
1. Global Summary	**1. Global Summary**
2. Set next appointment	**2. Set net appointment**

Note: This script has two tracks to follow, depending on whether participant did or did not set goals the previous week. Make note of this and choose appropriate track. Sections I. (Greeting and Overview) and V. (Wrap-up) are the same regardless of which track participants fall into.

I-A & B. GREETING AND OVERVIEW

→ *Thank you for coming in today, it's nice to see you again. If it's okay with you, I was hoping to start our discussion today by briefly reviewing our discussion during our last meting. Does that sound okay?*

→ *As you know, this program offers help with improving your overall health by means of incorporating more physical activity into your life. In our discussion last week we went over your typical day, we reviewed the pros and cons of incorporating physical activity to your daily life, and we discussed how increasing your level of activity relates to your core values and goals in life.*

II-A. REVIEW LAST SESSION

→ *Tell me a little bit about what you specifically recall about your discussion last week.*

Use OARS as needed as participant recollects the discussion from last week. Focus on eliciting and reinforcing participant-initiated "change talk"

→ *That's very much what I remember from our discussion. Would it be okay if I reviewed a few additional details that I recall from our meeting?*

During our discussion, you mentioned several reasons why engaging in regular physical activity has been a challenge and may not be the best thing right now (state the reasons). However, also mentioned several reasons why it would be important to change (state the reasons).

→ *Last week, you mentioned that the next step for you would be to (insert participant's stated next step from last week). What are your thoughts, today, about your next step?*

Use reflective listening and paraphrase.

IF PARTICIPANT IS READY TO SET GOALS → GO TO NEXT SECTION

IF PARTICIPANT IS AMBIVALENT → use OARS to continue to explore/discuss this ambivalence. Focus on "change talk" and relating physical activity to core values/goals.

II-B. REVIEW LAST SESSION

→ *Tell me a little bit about what you specifically recall about your discussion last week.*

Use OARS as needed as participant recollects the discussion from last week.

→ *That's very much what I remember from our discussion. Would it be okay if I reviewed a few additional details that I recall from our meeting?*

During our discussion, you mentioned several reasons why engaging in regular physical activity has been a challenge and may not be the best thing right now (state the reasons). However, also mentioned several reasons why it would be important to change (state the reasons). We also worked together on some goals for yourself.

III-A. SET GOALS AND PERSONAL PLAN

→ *Okay, since you are interested in moving forward by exploring ways to increase your level of activity, would it be okay if we work together on setting some goals for yourself?*

1. GOAL SETTING WORKSHEET

Give participant worksheet to review/complete

→ *Remember that you are the best judge of what will be best for you. If it's okay, I'd like for you to think of a goal you could set for yourself for the next week concerning your level of physical activity? Remember the goal should be clear, realistic, not too much or too little. Think of something that suits you and your lifestyle best. What are you thoughts about a goal?*

Reinforce appropriate goals

IF clients are having trouble coming up with goals, ASK:

→ *Some women with breast cancer have benefited from these types of activities.*

Present menu of physical activity options.

→ *Which, if any, o these activities might be of interest to you?*

Use OARS as needed.

→ *What are some of the things you will need to do to achieve this goal? Think of specific steps or actions and specific times when you might do them.* **Use OARS as needed.**

	Specific Action	When?
1.		
2.		
3.		

2. IMPLEMENTATION INTENTIONS

→ *Think about the next 7 days. When would be a good time for you to (specific action)? Be as specific as possible. Where would you do (specific action)? With whom would you do (specific action)?*

Follow the same line of questioning for each of the specific actions listed above.

Summarize Implementation Intentions.

III-B. REVIEW ADHERENCE TO GOALS

→*I have a copy of your Goal Worksheet right here. If it's okay with you, I would like to get a sense for your experience with the goals you set for yourself.*

1. IF AT LEAST SOME ADHERENCE TO GOALS:

To praise and encourage adherence to goals, and reinforce their importance for the participant, consider using any combination of the following prompts:

→ *That's great! It sounds like you've had a positive experience with (some or all) of your goals.*

→ *What motivated you to take the steps necessary to meet these goals?*

→ *Tell me a little bit about your activity routine. What have you enjoyed the most about it?*

→ *What has been the most difficult thing about sticking to your goals?*

→ *How do you overcome these potential obstacles to achieving your activity goals?*

Use reflective listening and paraphrase.

2. IF NO ADHERENCE TO GOALS:

→ *It sounds like you are having difficulty meeting these physical activity goals has been challenging. I wonder, what are your thoughts on this?*

Use reflective listening and paraphrase

To further explore difficulty adhering to goals consider using any combination of the following prompts:

→ *During our initial meeting, you identified the following as important values (list out values). How, if it at all, might increasing your level of physical activity impact your ability to live up to these values (name specific values)?*

→ *Over the past 3 weeks, what types of thoughts did you have, if any, about making steps towards your physical activity goals?*

→ *What kinds of obstacles make it difficult for you to achieve your activity goals?*

→ *I wonder, what kind of strategies do you think might help you overcome these obstacles to achieving your physical activity goals?* **With permission, suggest strategies as needed.**

→ *Are there other strategies that you can think of can help you overcome the obstacles you just described (refer to obstacles mentioned by participant)?*

Use reflective listening and paraphrase

IV-A. EXPLORE BARRIERS

→ *If it's okay with you, I'd like us to take a closer look at the Goals Worksheet. Ask yourself – are there any barriers I can think of that would get in the way of my ability to meet these goals?*

Use OARS as needed.

→ *Let me see if I understand correctly. You think that (mention barrier) might get in the way of (mention goals). Also…**REPEAT AS MANY TIMES AS NEEDED.***

Does that sound about right?

→ *You know yourself best and what would best help you tackle these barriers. What might you do to prevent (mention barrier) from getting in the way with (mention goal)?* ***REPEAT AS MANY TIMES AS NEEDED.***

Use reflective listening and paraphrase.

IF participant was able to generate ways to address barriers:

→ *Those are some excellent ideas!*

Provide additional affirmation as needed.

IF participant was NOT able to generate ways to address barriers:

→ *With your permission, I have some suggestions for way to address the barriers you mention. Would it be okay if I offered some suggestions?* **LIST OPTIONS.** *Do any of those suggestions sound applicable to your situation and needs?*

→ *I'm glad you found some of those suggestions helpful. Can you think of any other strategies you can use to prevent (mention barriers) from getting in the way of (mention goal)?* **Summarize the discussion.**

IV-B. EVALUATE NEED FOR GOAL ADJUSTMENT

→ *Given what we've talked about, on a scale from 1 to 10, with 1 being not at all and 10 being extremely, how satisfied are you with your list of physical activity goals?*

→ *So you feel at least a little satisfied (1-3)/somewhat satisfied (4-7)/very satisfied (8-10) with your physical activity goals. Why are you at (stated #) and not (lower # -- avoid zero, be flexible)?* **Reflect and paraphrase**

→ *What would it take to get your satisfaction level up to a (add 3-5 points to stated level)?* **Reflect and paraphrase**

→ *What, if any, adjustments would you like to make to your physical activity goals?*

If NO ADJUSTMENTS: **Move on to Wrap-Up**

If YES TO ADJUSTMENTS:

→ *(Summarize adjustments described). What, if any, ideas do you have that may help you accomplish your revised set of goals?*

→ ***If some ideas:*** *As you think about your ideas/plans, is there anything you are particularly worried or concerned about? Tell me about it.* **Use reflective listening and paraphrase. Problem-solve as needed.**

→***If no:*** *There are a number of strategies or tips that some people find helpful. If it's okay with you, we could discuss some of these together.* **With permission, offer suggestions.**

V-A & B. WRAP-UP

1. GLOBAL SUMMARY

→ *Before we end, I'd like to take a moment to hear what, if anything, you got out of today's session.* **Allow participant to summarize.**

→ *Good, I'm glad you found that helpful.*

2. SET NEXT APPOINTMENT

→ *Thank you very much _____ (name) for all your time and effort today. The next session takes place in two weeks, over the phone. This next session will be shorter, lasting 15-20 minutes. During the week of (insert week), when would it be a good time to chat over the phone?*

→ *Let's schedule our phone session for _____.*

Give participant appointment card.

→ *Thank you again for your time today and I look forward to talking with you soon! Have a good evening/day/morning!*

MI PROTOCOL – WEEK 4

SESSION 3: 10-15 minutes

I. Greeting and Evaluate if Good Time to Talk

II. Evaluate Adherence to Goals

1. **If at least SOME adherence to goals**

2. **If NO adherence to goals**

III. Evaluate Satisfaction with Goals

IV. Evaluate Need for Adjustment to Goals

V. Wrap-Up

1. **Brief Encouragement/Validation**

2. **Set next appointment**

Note: This is a phone session. The goal is to review progress and problem-solve barriers or adjust goals, as needed.

I. GREETING and EVALUATE IF GOOD TIME TO TALK

→ *Hello Mrs. _____. This is ____ calling from Moffitt Cancer Center to follow-up on the health promotion program you are participating in. How are you? (Exchange pleasantries). During our initial meeting you indicated that today, at this time, would be a good time to talk for about 20 minutes. Is this still a good time?*

IF <u>GOOD TIME</u> TO TALK:

→ *Great! I'd like to remind you that, with your permission, this phone-call will be recorded for quality purposes.* **Continue with the rest of the interview**

IF <u>BAD TIME</u> TO TALK:

→ *Perhaps we can arrange for a more convenient time for us to speak. What would be good time for you within the next 2-3 days? (Set up a time for a follow-up call).*

→ *Okay, so we're all set to resume this phone-call on (date) at (time). I look forward to speaking with you then. Have a nice day!*

II. EVALUATE ADHERENCE TO GOALS

☺ *If it's okay with you, I'd like to spend a few minutes reviewing what we talked about in our meeting 3 weeks ago. If you recall, we talked about (Review topics discussed and the participant's exercise goals). If it's okay with you, I would like to get a sense for your experience with the goals you set for yourself.*

<u>IF AT LEAST SOME ADHERENCE TO GOALS</u>:

To praise and encourage adherence to goals, and reinforce their importance for the participant, consider using any combination of the following prompts:

→*That's great! It sounds like you've had a positive experience with (some or all) of your physical activity goals.*

→*What motivated you to take the steps necessary to meet these goals?*

→*Tell me a little bit about your activity routine. What have you enjoyed the most about it?*

→*What has been the most difficult thing about sticking to your physical activity goals?*

→*How do you overcome these potential obstacles to achieving your physical activity goals?*

Use reflective listening. Provide extensive affirmations to support behavior change.

<u>IF NO ADHERENCE TO GOALS</u>:

→*It sounds like you are having difficulty meeting the physical activity goals you set for yourself. I wonder, what are your thoughts on this?* **Use reflective listening and paraphrase**

To further explore difficulty adhering to goals consider using any combination of the following prompts:

→*During our initial meeting, you identified the following as important values (list out values). How, if it at all, might physical activity impact your ability to live up to these values?*

→ *Over the past 3 weeks, what types of thoughts did you have, if any, about making steps towards your physical activity goals?*

→*What kinds of obstacles make it difficult for you to achieve your physical activity goals?*

→*I wonder, what kind of strategies do you think might help you overcome these obstacles to achieving your physical activity goals?* **With permission, suggest strategies as needed.**

→ *Are there other strategies that you can think of can help you overcome the obstacles you just described (refer to obstacles mentioned by participant).*

Use reflective listening and paraphrase

III. EVALUATE SATISFACTION WITH GOALS

☺ *Given what we've talked about, on a scale from 1 to 10, with 1 being not at all and 10 being extremely, how satisfied are you with your list of physical activity goals?*

☺ *So you feel at least a little satisfied (1-3)/somewhat satisfied (4-7)/very satisfied (8-10) with your physical activity goals. Tell me what account for your satisfaction? Why are you at (stated number) and not 0?* **Reflect and paraphrase.**

☺ *What would it take to get your satisfaction level up to a (add 3-5 points to stated level)?* **Reflect and paraphrase.**

IV. EVALUATE NEED FOR ADJUSTMENT TO GOALS

→ *What, if any, adjustments would you like to make to your physical activity goals?*

If NO ADJUSTMENTS: **Move on to Wrap-Up**

If YES TO ADJUSTMENTS:

→ *(Summarize adjustments described). What, if any, ideas do you have that may help you accomplish your revised set of goals?*

→ ***If some ideas:*** *As you think about your ideas/plans, is there anything you are particularly worried or concerned about? Tell me about it.* **Use reflective listening and paraphrase. Problem-solve as needed.**

→***If no:*** *There are a number of strategies or tips that some people find helpful. If it's okay with you, we could discuss some of these together.* **With permission, offer suggestions.**

V. WRAP-UP

IF AT LEAST SOME ADHERENCE TO GOALS:

→ *I'm glad that you have been able to meet the goals you set for yourself and I encourage you to keep up the good work. I understand how much effort and commitment it takes on your part to meet your goals, and I admire your success.*

IF NO ADHERENCE TO GOALS:

→ *I'm glad we had this opportunity to discuss your goals and come up with some strategies to help you meet them. I understand how much effort and commitment it takes on your part to meet these goals, and I admire your determination to move forward.*

REMINDER ABOUT 12-WEEK FOLLOW-UP

→ *Thank you very much _____ (participant name) for your time today. The next time we meet will be in 6 weeks, at Moffitt, where we will complete the same assessment you did during our first meeting. We will also review your progress and obtain your feedback about this program. If it's okay with you, let's schedule our follow-up meeting for _____. I will be giving you an appointment reminder call a couple of days before the scheduled meeting. I look forward to seeing you then! Have a good evening/day/morning!*

Appendix F: Healthy Lifestyle Counseling Protocol Week 1

HEALTHY LIFESTYLE COUNSELING PROTOCOL – WEEK 1

BEFORE SESSION: 30 minutes

I. Questionnaires Packet

II. Height and Weight Assessment

III. 6 Minute Walk Test

SESSION 1: 60 minutes

I. Greeting and Overview

NUTRITION

II. Review Food Consumed in Typical Day

III. Balanced Diet recommendations from ACS and CDC

IV. Information on Calorie-counting and Portion-control

V. Set Prescriptive Goals for Improving Diet

PHYSICAL ACTIVITY

VI. Review Physical Activity in Typical Day

VII. Physical Activity recommendations for Cancer Survivors from ACS

VIII. Review Sample Activities and Calories-burned

IX. Set Prescriptive Goals for Increasing Physical Activity

WRAP-UP

VI. Provide overview of material to be covered in next session and set next appointment

HEALTHY LIFESTYLE COUNSELING PROTOCOL – WEEK 2

SESSION 1: 45 minutes

I. Greeting and Overview

II. Review of Last Session

1. Explore Barriers

2. Offer Prescriptive Solutions

STRESS-MANAGEMENT

III. Review Major Sources of Stress

IV. Provide Information on Stress and Health

V. Review Stress-management Techniques

VI. Set Prescriptive Goals for Stress-Management

WRAP-UP

VII. Set next appointment

HEALTHY LIFESTYLE COUNSELING PROTOCOL – WEEK 4

SESSION 3: 10-15 minutes

I. Greeting and Evaluate if Good Time to Talk

II. Review Meals of previous day, Physical Activity of past week, Stress level of past week

III. Evaluate Barriers to Healthy Lifestyle

IV. Offer Prescriptive Solutions or Tips to Top 3 Barriers

V. Wrap-Up

Appendix I: Intervention Credibility Questionnaire

ICQ

Please answer the following questions:

1. How effective do you think the program you received as part of this study will be in promoting ***[if intervention]*** *greater physical activity* ***[OR if control]*** *a healthy diet*?

□	□	□	□	□	□	□
0	1	2	3	4	5	6
Not at all effective						**Extremely effective**

2. How skillful and knowledgeable do you consider the person who explained the program to you?

□	□	□	□	□	□	□
0	1	2	3	4	5	6
Not at all skillful						**Extremely skillful**

3. How important do you think it is that we made this program available to other breast cancer survivors?

□	□	□	□	□	□	□
0	1	2	3	4	5	6
Not at all important						**Extremely important**

APPENDIX J: Background Information Form

1. Today's date: _____/_____/_____ (month/day/year)
2. Birth date: _____/_____/_____ (month/day/year)
3. Age: _____
4. Please identify your ethnic group (check one)

   ___ 1 Hispanic or Latino

   ___ 2 Not Hispanic or Latino

5. Please identify your race (check one)

   _____1 White
   _____2 Asian
   _____3 Black or African American
   _____4 American Indian or Alaska Native
   _____5 Native Hawaiian or Pacific Islander
   _____6 More than one race

6. Marital status (check one):

   _____1 Never Married
   _____2 Currently Married
   _____3 Separated
   _____4 Divorced
   _____5 Widowed

7. Level of school completed (check one):

   _____1 Less than 7th grade
   _____2 Junior High School (7th, 8th, & 9th grade)
   _____3 Partial High School (10th or 11th grade)
   _____4 High School Graduate (12th grade)
   _____5 Partial college of specialized training
   _____6 College or University graduate
   _____7 Graduate or professional degree

8. Current employment situation (check all that apply):

   _____1 Full time at job
   _____2 Part time at job
   _____3 On leave with pay
   _____4 On leave without pay
   _____5 Disabled
   _____6 Seeking work
   _____7 Retired
   _____8 Homemaker
   _____9 Student

9. Which category best describes your usual occupation? If not currently employed, which category best describes your LAST job? (check one):

_____1 Professional (e.g., teachers, nurses, lawyers, physicians, & engineers)

_____2 Manager/Administrator (e.g., sales managers)

_____3 Clerical (e.g., secretaries, clerks or mail carriers)

_____4 Sales (e.g., sales persons, agents & brokers)

_____5 Service (e.g., police, cooks, waitress, or hairdressers)

_____6 Skilled Crafts, Repairer (e.g., carpenters)

_____7 Equipment or Vehicle Operator (e.g., truck drivers)

_____8 Laborer (e.g., maintenance factory workers)

_____9 Farmer (e.g., owners, managers, operators or tenants)

_____10 Member of the military

_____11 Homemaker (with no job outside the home)

_____12 Other (describe)_____

10. Approximate annual gross income for your household: (check one number) (Remember, your information will remain completely confidential)

_____ 1 Less than $ 10,000

_____ 2 $10,000 - $19,999

_____ 3 $20,000 - $ 39,999

_____4 $40,000 - $59,999

_____5 $60,000 - $100,000

_____6 Greater than $100,000

11. Are you currently on hormonal therapy? _____ 1 NO _____ 2 YES

12. If YES, what do you take?

_____ 1 Tamoxifen

_____ 2 Aromatase Inhibitors (Arimidex, Femara, Aromasin)

_____ 3 Other: Specify _____

13. Have you ever had a hysterectomy (i.e., removal of the womb)?

_____1 No

_____2 Yes

_____3 Don't know

14. Have you had one or both of your ovaries removed?

_____1 No, neither of my ovaries have been removed

_____2 Yes, one ovary removed

_____3 Yes, both ovaries removed

_____4 Don't know

15. Have you received any hormone replacement therapy within the past week (i.e., estrogen)?

_____1 No

_____2 Yes

_____3 Don't know

16. Have you ever received any hormone replacement therapy (i.e., estrogen)?

_____1 No

_____2 Yes

_____3 Don't know

17. Have you had a menstrual period within the past 3 months?

_____1 No

_____2 Yes

_____3 Don't know

18. Have you had a menstrual period within the past 12 months?

_____1 No

_____2 Yes

_____3 Don't know

19. Compared with 12 months ago, are your menstrual periods in the past 3 months, less regular, about the same, or more regular?

_____1 I have not had a menstrual period within the past 3 months

_____2 Less regular

_____3 About the same

_____4 More regular

_____5 Don't know

Appendix K: Medical Record Review Form

NAME Name: _____

MR# _____

DATEDX ___/___/____ (MM/DD/YY)

LOC 1 = Left 2 = Right 3 = Bilateral

SURGTYPE 1 = Lumpectomy 2 = Mastectomy3 = Lumpectomy & Mastectomy
4 = Bilateral Mastectomy 5 = Bilateral Lumpectomies 6 = Ex Biopsy
7 = Ex Lv 8 = other (specify) _____

SURGDATE ___/___/____ (MM/DD/YY)

RECON 1 = None 2 = Immediate 3 = Delayed

STAGE 0 = Stage 0 1 = Stage I 2 = Stage II

MEMSTATD 0 = Premenopausal 1 = Perimenopausal 2 = Post/Natural 3 = Post/Surgical
4 = Post/Chemical 5 = Unknown

HORTX 0 = No 1 = Tamoxifen/Nolvadex 2 = Megestrol/Megace
3=Fareston/Toremefin 4 = Medroxyprogesterone /Provera 5 = Arimidex
6 = Femara 7 = Clinical trial

HMStatus at participation 1 = Currently on 2 = Not currently on 3 = Never

XRTTX 0 = No 1 = Without Chemo 2 = Before Chemo 3 =After Chemo

XRTSTART Start Date: _____/_____/_____ (MM/DD/YY)

XRTSTOP Stop Date: _____/_____/_____ (MM/DD/YY)

CHEMOTX 0 =No
1 = Doxorubicin + Cyclophosphamide
2 = Doxorubicin + Cyclophosphamide + Taxotere
3 = Doxorubicin + Cyclophosphamide + Paclitaxel
4 = CMF (Cyclophosphamide + Methotrexate + 5FU)
5 = Doxorubicin + Taxotere
6 = Cyclophosphamide + Epirubicin + 5FU
7 = Cyclophosphamide + Epirubicin + 5FU + Paclitaxel
8 = _____
9 = _____

CHEMSTRT Start Date: _____/_____/_____ (MM/DD/YY)

CHEMSTOP Start Date: _____/_____/_____ (MM/DD/YY)

Appendix L: Physical Activity Readiness Questionnaire

PAR-Q

YES	NO	
☐	☐	1. Has your doctor ever said that you have a heart condition and that you should only do physical activity recommended by a doctor?
☐	☐	2. Do you feel pain in your chest when you do physical activity?
☐	☐	3. In the past month, have you had chest pain when you were not doing physical activity?
☐	☐	4. Do you lose your balance because of dizziness or do you ever lose consciousness?
☐	☐	5. Do you have a bone or joint problem (for example, back, knee or hip) that could be made worse by a change in your physical activity?
☐	☐	6. Is your doctor currently prescribing drugs (for example, water pills) for your blood pressure or heart condition?
☐	☐	7. Do you know of any other reason why you should not do physical activity?

SCORING:

If YES to at least one question = NOT ELIGIBLE

If NO to all questions = ELIGIBLE

Appendix M: Stages of Change for Physical Activity and Diet

PHYSICAL ACTIVITY/EXERCISE STAGES OF CHANGE

Regular Exercise is any *planned* physical activity (e.g., brisk walking, aerobics, jogging, bicycling, swimming, rowing, etc.) performed to increase physical fitness. Such activity should be performed *3 to 5 times* per week for *20-60 minutes* per session. Exercise does not have to be painful to be effective but should be done at a level that increases your breathing rate and causes you to break a sweat.

Do you exercise regularly according to that definition?	**STAGE OF CHANGE**
1. Yes, I have been for MORE than 6 months.	**Maintenance**
2. Yes, I have been for LESS than 6 months.	**Action**
3. No, but I intend to in the next 30 days.	**Preparation**
4. No, but I intend to in the next 6 months.	**Contemplation**
5. No, and I do NOT intend to in the next 6 months.	**Precontemplation**

DIET STAGES OF CHANGE – Not of interest; cover story

A healthy diet is one that is rich in fruits and vegetables. It includes whole grains, lean meats, and low-fat dairy products. A healthy diet also limits the intake of saturated and trans fats, added sugars, salt, and alcohol.

Do you regularly eat a healthy diet according to that definition?	**STAGE OF CHANGE**
1. Yes, I have been for MORE than 6 months.	**Maintenance**
2. Yes, I have been for LESS than 6 months.	**Action**
3. No, but I intend to in the next 30 days.	**Preparation**
4. No, but I intend to in the next 6 months.	**Contemplation**
5. No, and I do NOT intend to in the next 6 months.	**Precontemplation**

Appendix N: Godin Leisure Time Exercise Questionnaire

LTEQ

Please report the frequency and average duration of any exercise over the past week in the spaces below.

As an example: If you exercised four times last week at a moderate intensity you would put "4" in the frequency column following moderate exercise. We would like you to also give an average of the time spent exercising. In our example, if two of those "4" exercise sessions were 30 minutes and the other two were 20 minutes you would put 25 minutes in the average duration column following moderate exercise.

When answering these questions, please remember to:

- Only count exercise that was done in your free time (i.e., not occupational or housework).
- Note that the differences between the three categories are in the intensity of the exercise.
- If you did not engage in a type of exercise, write "0" in the frequency column.

	Frequency	**Duration**
A. STRENUOUS EXERCISE (HEART BEATS RAPIDLY, SWEATING) Examples: running, jogging, vigorous swimming, vigorous long distance bicycling, vigorous aerobic classes, roller skating, judo, basketball, football, soccer, squash	_____**times**	_____ **minutes**
	Frequency	**Duration**
B. MODERATE EXERCISE (NOT EXHAUSTING, LIGHT PERSPIRATION) Examples: fast walking, tennis, easy bicycling, easy swimming, popular and folk dancing, volleyball, badmington	_____**times**	_____ **minutes**
	Frequency	**Duration**
C. MILD EXERCISE (MINIMAL EFFORT, NO PERSPIRATION) Examples: easy walking, yoga, bowling, shuffleboard, horseshoes, golf, fishing from riverbank	_____**times**	_____ **minutes**

Appendix O: All Day Fruits and Vegetables Screener

All Day Fruits and Vegetables Screener

DIRECTIONS: Think about what you usually ate last month. Please think about all the fruits and vegetables that you ate last month. Include those that were: raw and cooked, eaten as snacks and at meals, eaten at home and away from home (restaurants, friends, take-out), eaten alone and mixed with other foods.

Report how many times per month, week, or day you ate each food, and if you ate it, how much you usually had. If you mark "Never" for a question, follow the "Go to" instruction. Mark only **one response** for each question.

1. **Over the last month**, how many times per month, week, or day did you drink **100% juice** such as orange, apple, grape, or grapefruit juice? **Do not count** fruit drinks like Kool-Aid, lemonade, Hi-C, cranberry juice drink, Tang, and Twister. Include juice you drank at all mealtimes and between meals.

☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Never (**Go to Question 2**)	1-3 times per **month**	1-2 times per **week**	3-4 times per **week**	5-6 times per **week**	1 time per **day**	2 times per **day**	3 times per **day**	4 times per **day**	5 or more times per **day**

1a. Each time you drank **100% juice**, how much did you usually drink?

☐	☐	☐	☐
Less than ¾ cup (less than 6 ounces)	¾ to 1 ¼ cup (6 to 10 ounces)	1 ¼ to 2 cups (10 to 16 ounces)	More than 2 cups (more than 16 ounces)

2. **Over the last month**, how many times per month, week, or day did you eat **fruit**? Count any kind of fruit (fresh, canned, and frozen). Do not count juices. Include fruit you ate at all mealtimes and as snacks.

☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Never (**Go to Question 3**)	1-3 times per **month**	1-2 times per **week**	3-4 times per **week**	5-6 times per **week**	1 time per **day**	2 times per **day**	3 times per **day**	4 times per **day**	5 or more times per **day**

2a. Each time you ate **fruit**, how much did you usually eat?

☐	☐	☐	☐
Less than 1 medium fruit	1 medium fruit	2 medium fruits	More than 2 medium fruits

OR

☐	☐	☐	☐
Less than ½ cup	About ½ cup	About 1 cup	More than 1 cup

3. **Over the last month**, how often did you eat **lettuce salad (with or without other vegetables)?**

☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Never (**Go to Question 4**)	1-3 times per **month**	1-2 times per **week**	3-4 times per **week**	5-6 times per **week**	1 time per **day**	2 times per **day**	3 times per **day**	4 times per **day**	5 or more times per **day**

3a. Each time you ate **lettuce salad**, how much did you usually eat?

☐	☐	☐	☐
About ½ cup	About 1 cup	About 2 cups	More than 2 cups

4. **Over the last month**, how often did you eat **French fries or fried potatoes**?

☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Never (**Go to Question 5**)	1-3 times per **month**	1-2 times per **week**	3-4 times per **week**	5-6 times per **week**	1 time per **day**	2 times per **day**	3 times per **day**	4 times per **day**	5 or more times per **day**

4a. Each time you ate **French fries or fried potatoes**, how much did you usually eat?

☐	☐	☐	☐
Small order or less (About 1 cup or less)	Medium order (About 1½ cups)	Large order (About 2 cups)	Super Size order or more (About 3 cups or more)

5. **Over the last month**, how often did you eat **other white potatoes**? Count **baked**, **boiled**, and **mashed potatoes**, **potato salad**, and **white potatoes that were not fried**.

☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Never (**Go to Question 6**)	1-3 times per **month**	1-2 times per **week**	3-4 times per **week**	5-6 times per **week**	1 time per **day**	2 times per **day**	3 times per **day**	4 times per **day**	5 or more times per **day**

5a. Each time you ate **these potatoes**, how much did you usually eat?

☐	☐	☐	☐
Small order or less (About 1 cup or less)	Medium order (About 1½ cups)	Large order (About 2 cups)	Super Size order or more (About 3 cups or more)

6. **Over the last month**, how often did you eat **cooked dried beans**? Count **baked beans, bean soup, refried beans, pork** and **beans and other bean dishes**.

☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Never (**Go to Question 7**)	1-3 times per **month**	1-2 times per **week**	3-4 times per **week**	5-6 times per **week**	1 time per **day**	2 times per **day**	3 times per **day**	4 times per **day**	5 or more times per **day**

6a. Each time you ate **these beans**, how much did you usually eat?

☐	☐	☐	☐
Less than ½ cup	½ to 1 cup	1 to 1½ cups	More than 1½ cups

7. **Over the last month**, how often did you eat **other vegetables**?
DO NOT COUNT: Lettuce salads
White potatoes
Cooked dried beans
Vegetables in mixtures, such as sandwiches, omelets, casseroles, Mexican dishes,
stews, stir-fry, soups, etc.
Rice
COUNT: All other vegetables: raw, cooked, canned, and frozen

☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Never (**Go to Question 8**)	1-3 times per **month**	1-2 times per **week**	3-4 times per **week**	5-6 times per **week**	1 time per **day**	2 times per **day**	3 times per **day**	4 times per **day**	5 or more times per **day**

7a. Each of these times that you ate **other vegetables**, how much did you usually eat?

☐	☐	☐	☐
Less than ½ cup	½ to 1 cup	1 to 2 cups	More than 2 cups

8. **Over the last month**, how often did you eat **tomato sauce**? Include tomato sauce on pasta or macaroni, pizza and other dishes.

☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Never (**Go to Question 9**)	1-3 times per **month**	1-2 times per **week**	3-4 times per **week**	5-6 times per **week**	1 time per **day**	2 times per **day**	3 times per **day**	4 times per **day**	5 or more times per **day**

8a. Each of these times that you ate **tomato sauce**, how much did you usually eat?

☐	☐	☐	☐
Less than ¼ cup	About ½ cup	About 1 cup	More than 1 cup

9. **Over the last month**, how often did you eat **vegetable soups**? Include tomato soup, gazpacho, beef with vegetable soup, minestrone soup, and other soups made with vegetables.

☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Never (**Go to Question 10**)	1-3 times per **month**	1-2 times per **week**	3-4 times per **week**	5-6 times per **week**	1 time per **day**	2 times per **day**	3 times per **day**	4 times per **day**	5 or more times per **day**

9a. Each of these times that you ate **vegetable soup**, how much did you usually eat?

☐	☐	☐	☐
Less than 1 cup	1 to 2 cups	2 to 3 cups	More than 3 cups

10. **Over the last month**, how often did you eat **mixtures that included vegetables**? Count such foods as sandwiches, casseroles, stews, stir-fry, omelets, and tacos.

☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Never	1-3 times per **month**	1-2 times per **week**	3-4 times per **week**	5-6 times per **week**	1 time per **day**	2 times per **day**	3 times per **day**	4 times per **day**	5 or more times per **day**

Appendix P: Fatigue Symptoms Inventory

FSI

For each question, check <u>one</u> box next to the number that best indicates how the item applies to you.

1. Rate your level of fatigue on the day you felt **most** fatigued during the past week:

☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
0	1	2	3	4	5	6	7	8	9	10
Not at all fatigued										**As fatigued as I could be**

2. Rate your level of fatigue on the day you felt **least** fatigued during the past week:

☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
0	1	2	3	4	5	6	7	8	9	10
Not at all fatigued										**As fatigued as I could be**

3. Rate your level of fatigue on the **average** during the past week:

☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
0	1	2	3	4	5	6	7	8	9	10
Not at all fatigued										**As fatigued as I could be**

4. Rate your level of fatigue **right now**:

☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
0	1	2	3	4	5	6	7	8	9	10
Not at all fatigued										**As fatigued as I could be**

5. Rate how much, in the past week, fatigue interfered with your **general level of activity**:

☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
0	1	2	3	4	5	6	7	8	9	10
No interference										**Extreme interference**

6. Rate how much, in the past week, fatigue interfered with your **ability to bathe and dress yourself**:

☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
0	1	2	3	4	5	6	7	8	9	10
No interference										**Extreme interference**

7. Rate how much, in the past week, fatigue interfered with your **normal work activity (includes both work outside the home and housework)**:

☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
0	1	2	3	4	5	6	7	8	9	10
No interference										**Extreme interference**

8. Rate how much, in the past week, fatigue interfered with your **ability to concentrate**:

☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
0	1	2	3	4	5	6	7	8	9	10
No interference										**Extreme interference**

9. Rate how much, in the past week, fatigue interfered with your **relations with other people**:

☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
0	1	2	3	4	5	6	7	8	9	10
No interference										**Extreme interference**

10. Rate how much, in the past week, fatigue interfered with your **enjoyment of life**:

☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
0	1	2	3	4	5	6	7	8	9	10
No interference										**Extreme interference**

11. Rate how much, in the past week, fatigue interfered with your **mood**:

☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
0	1	2	3	4	5	6	7	8	9	10
No interference										**Extreme interference**

12. Indicate **how many days**, in the past week, you felt fatigued for any part of the day:

☐	☐	☐	☐	☐	☐	☐	☐
0	1	2	3	4	5	6	7
Days							**Days**

13. Rate **how much of the day**, on average, you felt fatigued in the past week:

☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
0	1	2	3	4	5	6	7	8	9	10
None of the day										**The entire day**

14. Indicate which of the following best describes the **daily pattern** of your fatigue in the past week:

☐	☐	☐	☐	☐
0	1	2	3	4
Not at all fatigued	**Worse in the morning**	**Worse in the afternoon**	**Worse in the evening**	**No consistent pattern of daily fatigue**

Appendix Q: Center for Epidemiologic Studies-Depression Scale

CES-D

For each statement below, make an **"X"** in the box which best describes how often you felt or behaved this way-- **DURING THE PAST WEEK, INCLUDING TODAY.**

	During the past week:	**None of the time**	**A little of time**	**A moderate amount of the time**	**Most of the time**
1.	I was bothered by things that usually don't bother me	□	□	□	□
2.	I did not feel like eating; my appetite was poor	□	□	□	□
3.	I felt that I could not shake off the blues even with help from my family or friends	□	□	□	□
4.	I felt that I was just as good as other people	□	□	□	□
5.	I had trouble keeping my mind on what I was doing	□	□	□	□
6.	I felt depressed	□	□	□	□
7.	I felt that everything I did was an effort	□	□	□	□
8.	I felt hopeful about the future	□	□	□	□
9.	I thought my life had been a failure	□	□	□	□
10.	I felt fearful	□	□	□	□
11.	My sleep was restless	□	□	□	□
12.	I was happy	□	□	□	□
13.	I talked less than usual	□	□	□	□
14.	I felt lonely	□	□	□	□
15.	People were unfriendly	□	□	□	□
16.	I enjoyed life	□	□	□	□
17.	I had crying spells	□	□	□	□
18.	I felt sad	□	□	□	□
19.	I felt that people disliked me	□	□	□	□
20.	I could not "get going"	□	□	□	□

Appendix R: Profile of Mood States Vigor

POMS-V

Below is a list of words that describe feelings people have. Please read each one carefully. Then mark ONE box from the answers on the right that best describes how you have been feeling **DURING THE PAST WEEK, INCLUDING TODAY.**

		Not at all	**A little**	**Moderately**	**Quite a bit**	**Extremely**
1.	Lively	☐	☐	☐	☐	☐
2.	Active	☐	☐	☐	☐	☐
3.	Energetic	☐	☐	☐	☐	☐
4.	Cheerful	☐	☐	☐	☐	☐
5.	Alert	☐	☐	☐	☐	☐
6.	Full of pep	☐	☐	☐	☐	☐
7.	Carefree	☐	☐	☐	☐	☐
8.	Vigorous	☐	☐	☐	☐	☐

Appendix S: Perceived Stress Scale

PSS-10

		Never	Almost Never	Sometimes	Fairly Often	Very Often
1.	In the last month, how often have you been upset because of something that happened unexpectedly?	☐	☐	☐	☐	☐
2.	In the last month, how often have you felt that you were unable to control the important things in your life?	☐	☐	☐	☐	☐
3.	In the last month, how often have you felt nervous and "stressed"?	☐	☐	☐	☐	☐
4.	In the last month, how often have you felt confident about your ability to handle your personal problems?	☐	☐	☐	☐	☐
5.	In the last month, how often have you felt that things were going your way?	☐	☐	☐	☐	☐
6.	In the last month, how often have you found that you could not cope with all the things that you had to do?	☐	☐	☐	☐	☐
7.	In the last month, how often have you been able to control irritations in your life?	☐	☐	☐	☐	☐
8.	In the last month, how often have you felt that you were on top of things?	☐	☐	☐	☐	☐
9.	In the last month, how often have you been angered because of things that were outside of your control?	☐	☐	☐	☐	☐
10.	In the last month, how often have you felt difficulties were piling up so high that you could not overcome them?	☐	☐	☐	☐	☐

Appendix T: 6 Minute Walk Test Record

6MWT

Make sure you have: stopwatch, lap counter, folding chair, tape measure, masking tape

Participant ID: _____

Height: _____ft _____ in

Weight: _____ lbs

Stopped or paused before 6 minutes?

___ 1 No

___ 2 Yes: ___ 1 Chest Pain ___ 2 Intolerable Dyspnea ___ 3 Leg Cramps

___ 4 Staggering ___ 5 Diaphoresis ___ 6 Pale/Ashen Appearance

Other symptoms at end of 6 minutes?

___ 1 No

___ 2 Yes: ___ 1 Angina ___ 2 Dizziness ___ 3 Hip, Leg, or Calf Pain

Number of laps: _____ (x30 meters) + Final Partial Lap: _____ meters = _____

Total distance walked in 6 minutes: _____ meters

Comments:

_____

_____

About the Author

Yasmin Asvat Patel is from Panama City, Panama. She earned a B.S. in Psychology and English from the University of Toronto in 2004 and a M.A. in Psychology from San Diego State University in 2006. She obtained her Ph.D. in Clinical Psychology from the University of South Florida in 2013, where she trained in the specialty area of Psychosocial Oncology under the mentorship of Paul B. Jacobsen, Ph.D. at the H. Lee Moffitt Cancer Center. She completed her clinical psychology internship training at the University of Chicago Medical Center in 2013 and will continue her training as a postdoctoral fellow in psychosocial oncology in the Department of Behavioral Sciences at Rush University Medical Center in Chicago, IL.