University of Alberta

Promoting Physical Activity in Breast Cancer Survivors: A Randomized Controlled Trial

by

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ABSTRACT

Introduction: Breast cancer and its treatments are often associated with negative side effects that affect quality of life (QoL) and may persist even years after treatment(s). One intervention that has been found to enhance psychosocial and physical outcomes in breast cancer survivors is physical activity (PA). A recent prospective cohort study of almost 3,000 breast cancer survivors reported that higher levels of PA were associated with reduced risks of breast cancer death and breast cancer recurrence. Despite the reported benefits of PA, the majority of breast cancer survivors are not meeting public health guidelines (i.e., at least 150 min•wk of moderate- to vigorous-intensity PA). Given these findings, interventions to increase PA in breast cancer survivors are warranted.

Purpose: The purpose of this trial was to 1) develop a breast cancer-specific theory of planned behavior (TPB) based PA guidebook and evaluate the suitability and appropriateness of this guidebook, 2) determine the effects of breast cancer-specific PA print materials (PM), a step pedometer (PED), or their combination (COM), on PA and QoL in breast cancer survivors compared to survivors receiving a standard verbal recommendation for PA (SR), and 3) examine the effects of the interventions on the TPB components.

Methods: Breast cancer-specific PA print materials were developed (*Exercise for Health: An Exercise Guide for Breast Cancer Survivors*). In Study 1, expert judges (N=30) evaluated the print materials by completing the Maine Area Health Education Center's 18-item attribute checklist for evaluating written health information. A subset of TPB expert judges (n=9) also completed items designed to determine the degree of match between the guidebook content and the respective TPB components. The Activity Promotion (ACTION) Trial (i.e., Study 2 and Study 3) was a four-armed, prospective randomized controlled trial. The Alberta Cancer Registry was used to identify breast cancer survivors residing in Northern Alberta, Canada diagnosed between January, 2000 and December, 2003. Interested and eligible breast cancer survivors (N=377) were randomly assigned to receive either: breast cancer-specific PA print

materials (PM), a step pedometer (PED), or their combination (COM). Survivors completed assessments at baseline, four weeks, 3 months, and 9 months.

Results: Data from Study 1 provided preliminary evidence that the PA guidebook targeted the intended TPB components. Furthermore, these results indicated that the guidebook was suitable, appropriate, and fit to be implemented and tested. In Study 2, 377 Northern Alberta breast cancer survivors were randomly assigned to either PM, PED, or COM. Trial attrition was 10.3% (39 of 377). Data from Study 2 suggested that the PA behavior change modalities (i.e., print and pedometer) had beneficial effects on PA and QoL at 3 months and 9 months in our sample of breast cancer survivors. A combination of the PM with a step pedometer (i.e., COM) showed the greatest benefits for QoL and fatigue. Data from study 3 indicated that survivors receiving the interventions generally reported positive changes in the TPB constructs and beliefs compared to the SR group. We found partial support for our hypothesis in that changes in the TPB mediated the effects of our TPB interventions (i.e., PM and COM) on changes in PA behavior.

Conclusion: The ACTION Trial is the first study to examine the effects of PA print materials and pedometers on PA behavior and QoL in breast cancer survivors. Data from Study 1 and Study 2 suggests that PA print resources that are rigorously developed, theoretically-based, evaluated, and supplemented with an objective monitoring device (pedometer) have the potential to be valuable resources that can be used by the growing cohort of breast survivors (and other target populations). Data from Study 3 provided partial support for the use of the TPB as a framework for developing and implementing PA behavior change interventions in breast cancer survivors. Given that the majority of breast cancer survivors are not meeting public health guidelines (i.e., at least 150 min•wk of moderate- to vigorous-intensity PA), behavioral change strategies targeted toward breast cancer survivors such as print material and pedometers appear to be promising methods for facilitating PA behavior. This research

may ultimately help breast cancer survivors enhance their QoL and reduce their risk of recurrence and early death from breast cancer through regular participation in PA.

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Introduction

Approximately 22,000 Canadians and 2,000 Albertans will be diagnosed with breast cancer in 2006.[1] Fortunately, mortality rates from breast cancer have steadily declined since 1986 due to earlier detection and improved treatments. The most recent 5-year relative survival rate for breast cancer is now over 85%. The high incidence and improved survival rates have resulted in a growing cohort of long term breast cancer survivors in Canada and Alberta.[1, 2] Unfortunately, surviving breast cancer usually means enduring aggressive medical treatments (e.g., surgery, radiation therapy, chemotherapy, hormone therapy) that can substantially undermine quality of life (QoL) in breast cancer survivors. Given these effects, breast cancer survivors represent an important target population for health promotion interventions given their increased risk of psychological, biological, and physiological comorbidities.

One intervention that has been found to enhance QoL (i.e., both psychosocial and physical domains) in breast cancer survivors is physical activity (PA).[3-5] Traditionally, breast cancer survivors are offered informational and educational nonbehavioral counseling, psychotherapy, social support, and/or other nontraditional therapies such as music or art therapy.[6] Although somewhat effective, these therapies are largely psychological in nature and unlikely to address the physical and functional problems encountered by breast cancer survivors (e.g., fatigue).[7] One therapeutic intervention that may compliment existing biological therapies and address a multitude of additional QoL outcomes relevant to breast cancer is PA.[3-5] In the non-diseased population, there is strong evidence for the health benefits of PA. This evidence indicates that physically active lifestyles are associated with a reduced risk of cardiovascular disease,[8, 9] hypertension,[10] stroke,[11] type II diabetes,[12] obesity,[13] osteoporosis,[14] some cancers,[15] overall mortality,[16] and psychological well-being.[17] Given the side effects of breast

cancer treatments, a breast cancer diagnosis may further exacerbate the risk of these co morbid conditions.

Recent meta-analyses and systematic reviews suggest that PA can improve physical fitness, reduce fatigue, increase functioning, and enhance overall QoL in breast cancer survivors both during and after treatments.[3-5] Research has also shown, however, that breast cancer survivors experience a significant reduction in PA during treatments that is not recovered even years after treatments are completed. Despite the accumulating evidence documenting the associated benefits of PA in breast cancer survivors, the majority of survivors are still not meeting the minimal amounts of PA that are required for health benefit accrual as defined by the American College of Sports Medicine (ACSM) and the Centers for Disease Control and Prevention (CDC).[7, 18-21] In perhaps the largest study to date, Irwin and colleagues[20] surveyed over 800 breast cancer survivors four to 12 months postdiagnosis about their PA levels in the year before their diagnosis and in the past month since their diagnosis. These researchers found that overall PA levels decreased by two hours (i.e.,~11%) after diagnosis.[21] Research further indicates that survivors reporting permanent PA relapse report the lowest QoL indices compared with individuals who regain their prediagnosis PA patterns.[7]

Given the challenges of PA behavior change in the breast cancer population (e.g., treatment side effects), as well as the evidence of PA decline across the breast cancer experience, motivation and adherence are important issues when implementing PA programs for breast cancer survivors. These factors also make the breast cancer population a unique area of inquiry in which to study PA. For example, researchers have contended that breast cancer survivors may be motivated for health behavior change by embracing and participating in efforts aimed at health promotion.[22-24] This evidence

further suggests that the breast cancer population may be an ideal population to target for lifestyle-change efforts because of a documented high level of interest.[25, 26]

Evidence is indicating that breast cancer survivors are interested and opportunistic in pursuing PA and receiving PA counseling.[25, 26] Few interventions, however, have been developed to promote PA adoption and maintenance in breast cancer survivors. Napolitano and colleagues[27] recently contended that researchers need to develop modalities, other than face-to-face programs, "to provide individuals with information, skills, and knowledge to facilitate behavior change" (p. 93). Further, these modalities should have the ability to reach a population-base that otherwise may not participate in group or facility-based exercise programs (e.g., rural Albertans). Such modalities may be particularly effective given Demark-Wahnefried et al.'s [22, 25] contention that a cancer diagnosis might be a 'teachable moment' in which survivors may be more likely to make healthy lifestyle changes. Given that survivors may face several barriers to engaging in PA,[28, 29] (e.g., living in rural areas, lack of knowledge) researchers have advocated for the need to develop and assess the efficacy of interventions that employ *distance medicine-based approaches.*[22, 23] These approaches may be ideal for Northern Alberta breast cancer survivors given the geographical dispersion of our population. To this end, mail-mediated PA interventions have the ability to reach more people and communicate more information in a potentially succinct and attractive form. Given the contention that print material represents a feasible approach to health promotion delivery,[3, 22, 23, 30-34] it seems reasonable to suggest that print materials related to PA throughout the breast cancer experience may be a practical and sustainable medium in which to promote PA in the breast cancer population.

Objectives of the Dissertation

Objective 1

Written health/PA information (e.g., patient information leaflets, instructional guidebooks) is one method that may hold promise in promoting PA in the breast cancer population. Given the low PA participation rates among breast cancer survivors, there is a need to develop and evaluate methods of communicating and promoting PA to breast cancer survivors. Indeed, there is an interest and demand from breast cancer survivors for written health/PA information and health/PA promotion programs.[25, 35, 36] To facilitate PA behavior change, researchers advocate that written health information should be theoretically-based.[37-39] Therefore, the first objective of this dissertation was to develop and evaluate the suitability and appropriateness of a theoretically-based PA guidebook for breast cancer survivors.

Objective 2

A recent prospective cohort study of almost 3,000 breast cancer survivors reported that higher levels of PA were associated with reduced risks of breast cancer death and breast cancer recurrence. Thus, developing and evaluating methods and programs that facilitative PA behavior change and enhance QoL in breast cancer survivors are necessary. In other populations (i.e., non-cancer, healthy adults), research examining print-mediated PA interventions has provided evidence that print materials may be an efficacious, efficient, and cost-effective form of a) communicating PA information, and b) facilitating PA behavior change. Given the emerging evidence supporting the use of pedometers as a tool to facilitate mobility-related activity, researchers have contended that written health/PA material combined with an objective monitoring tools (e.g., pedometer) may result in a greater likelihood of PA behavior change and related health outcomes. Therefore, the second objective of this dissertation

was to test the effects of breast cancer-specific PA print materials (PM) (from objective 1), a step pedometer (PED), or their combination (COM), on self-reported PA and QoL in breast cancer survivors.

Objective 3

Developing intervention tools around behavioral theory can assist researchers in understanding the mechanisms through which individuals change (or do not change) their PA behavior. Measuring and analyzing potential theoretically-based mediating variables in randomized controlled trials may potentially play an important role in understanding the causes of behavior change (or no change). The theory of planned behavior (TPB) is one such theory which may help researchers understand the causal agents of PA behavior change. Therefore, the third objective of this study was to (a) examine the effects of TPB-based breast-cancer specific PM on TPB constructs and behavioral, normative, and control beliefs, and (b) to determine if the TPB mediated the effects of our TPB-based intervention on PA behavior.

Hypotheses

Given the developmental and exploratory nature of Study 1 (i.e., PA guidebook development and evaluation), no hypotheses were generated. In Study 2, it was hypothesized that survivors in the PM, PED, and COM groups would report greater increases in self-reported PA and QoL compared to survivors receiving a standard verbal recommendation (SR) for PA and that survivors in the COM group would report the greatest increases. In Study 3, it was hypothesized that (a) the TPB-based interventions (i.e., PM and COM) would have positive effects on the TPB constructs compared to the SR group, and (b) the TPB would mediate the effects of the TPB-based interventions on PA behavior and provide a theoretical explanation for why the interventions were effective in increasing PA behavior in breast cancer survivors.

Practical Implications

The proposed project relates to the control of breast cancer, and in particular, initiates a critical area of research by examining practical, sustainable, and economically viable promotional interventions designed to enhance PA and QoL in breast cancer survivors in Northern Alberta. Changing individuals' behavior is a challenging task that continues to perplex both researchers and practitioners. By examining potentially feasible and novel forms of PA promotion in the breast cancer survivor population, cancer care professionals (e.g., oncologists, nurses, oncology nurse-practitioners, psychosocial support staff, physiotherapists, dietitians) can become aware of these behavior change approaches as an effective tool for assisting in PA adoption and maintenance and further enhancing QoL after treatment for breast cancer and into survivorship. Distance-based interventions may also offer the researcher a viable opportunity to reach, target, and affect a large number of individuals that otherwise would not be able to participate in clinically-based randomized controlled trials.

Readily available PA information that improves motivation and PA behavior (and subsequent QoL) in breast cancer survivors (and that are targeted toward the breast cancer survivor population) may help improve the low PA participation rates of this population. Increased PA prevalence rates in breast cancer survivors in turn could improve general health and decrease mortality, as well as potentially improve QoL parameters that are associated with the breast cancer experience (e.g., physical well-being, functional well-being, fatigue).

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CHAPTER 2:

Literature Review

Defining and Measuring Quality of Life

Quality of life (QoL) is considered a broad concept that represents several domains of life such as occupational/role, functioning, economic, spiritual, and global QoL. The World Health Organization defines QoL as "the individuals' perceptions of their position in life, in the context of the cultural and value systems in which they live and in relation to their goals, expectations, standards and concerns."[1] Given this definition, this concept of QoL encompasses, defines, and applies to all aspects of an individual's life.

However, the definition of QoL has been refined to reflect the context in which the term is used. While the definition of QoL related to cancer and its treatment(s) has evolved, at the core of all definitions is the referral to patients' appraisal of and satisfaction with their current level of functioning as compared to what they perceive to be possible or ideal.[2] This definition has been updated to reflect the consensus that QoL is both a) health-related, and b) a multidimensional concept: "Health-related QoL refers to the extent to which one's usual or expected physical, emotional and social well-being are affected by a medical condition or its treatment."[3] Cella and colleagues conceptualize QoL as being best represented by physical well-being, emotional well-being, social well-being, and functional well-being.[4] It is also recognized that different cancer types and their related treatment(s) are associated with unique symptoms and health issues that may compromise QoL in cancer survivors (defined as *anyone who has been diagnosed with cancer from the time of diagnosis through the balance of his or her life*). As a result, researchers and clinicians are increasingly advocating for disease/condition-specific measures of QoL. Furthermore, a 'modular/domain-specific' approach to QoL assessment, in which a core of general questions are supplemented with disease- and treatment-specific items (e.g., items related to lymphedema, hormone replacement therapy, taxane-based chemotherapy) is gaining acceptance. In the field of

oncology, several working groups have adopted this approach (e.g., Eastern Cooperative Oncology Group; Functional Assessment of Cancer Therapy Measurement System).

Disease specific measures (e.g., Functional Assessment of Cancer Therapy: FACT[4]) and (for that matter) domain specific measures (e.g., FACT-Breast[5]) differ from more generic measures (e.g., SF-36[6]). Depending on the nature of research an individual is pursuing, both types of measures have advantages. Disease-specific measures provide the researcher the potential to monitor the response to a treatment intervention (i.e., change) in a specific disease group (e.g., breast cancer) with respect to disease-related symptoms and other treatment effects, whereas generic measures allow the researcher to conduct cross-condition/disease comparison(s) by applying the instrument to a wide range of populations. Therefore, if one is interested in how different disease groups respond to a specific intervention, generic QoL measures would be appropriate. Another benefit of using disease-specific measures is that they incorporate the use of items that are relevant and pertinent to the target population (i.e., pending suitable and appropriate item generation procedures were employed by the test developer). For example, researchers employing the widely-used SF-36 (i.e., a global/generic measure) in a particular population, would want to ensure that the items and dimensions within the scale are relevant and pertinent to the target audiences as items perceived as having poor face validity may affect responses on subsequent items in the scale.[7] Furthermore, items on the SF-36 reflect general health whereas items on the FACT-Breast were developed with respect to the intended population (i.e., breast cancer survivors). By using disease-specific measures, the researcher is afforded the opportunity to compare the data with other empirical evidence using the same measure.

Using generic measures in highly specified populations may result in a loss of precision and conclusions with questionable validity.

Breast Cancer and Quality of life

The primary purpose of breast cancer treatment(s) is to extend survival and improve the quality of patients' lives by either curing the disease and/or ameliorating the symptoms for as long as possible.[8] However, it is most often that treatments associated with a breast cancer diagnosis (e.g., surgery, chemotherapy, radiation) result in adverse psychological, biological, and physical sequela. From the time of diagnosis, an individual faces lifestyle changes pertaining to difficult treatment decisions, physically and psychologically exhausting treatments, uncertainty of disease course, physical changes and deformity, and possible death.

Many studies have examined the experience of breast cancer survivors who are beyond the acute phase of treatment. This research includes the period of time immediately after the cessation of primary treatment[9, 10] and up to and including 20 years post treatment.[11] Although QoL may continue to deteriorate post treatment, research has suggested that most symptoms decline between three months and one year.[12] Ganz et al.[13] reported that survivors 5 to 10 years after their initial diagnosis still demonstrate poor function on several dimensions of QoL. In another study, Kornblith et al.[11] provided evidence that individuals face minimal QoL detriments 20 years after their initial treatment. However, it must be recognized that treatments associated with a breast cancer diagnosis may have unique effects that must be taken into account. For example, different treatment modalities such as axillary lymph node dissection,[14] surgery and radiation,[15, 16] taxane and non-taxane based chemotherapies,[17, 18] and hormone therapies (e.g., Tamoxifen)[19, 20] are often associated with unique psychological and physical sequela in and of themselves.

Shapiro and Recht[18] provide the most comprehensive review of possible side effects relevant to systemic adjuvant treatment (i.e., chemotherapy and hormonal therapy) for breast cancer. Adjuvant chemotherapy (e.g., doxorubicin, cyclophosphamide) may likely result in myelosuppression (and thus anemia), nausea and vomiting, neurologic toxicity (particularly with taxane-based chemotherapies), weight gain, ovarian failure, cardiac toxicity, decreased cognitive function, fatigue, and decreased QoL. Women who are estrogen-receptor-positive (i.e., ER^+, PR^+) traditionally receive tamoxifen which is associated with cardiovascular mortality, coagulation and thrombosis, vasomotor symptoms, weight gain, and depression.

Surgery and radiation therapy (i.e., local therapies) are often associated with arm morbidity due to lymphedema,[21, 22] functional impairment,[23] fatigue,[16] and overall QoL.[24, 25] Given this information, it is necessary to examine potential treatment interventions that minimize negative symptom experiences and improve QoL and well-being in breast cancer survivors. Attempting to understand intervention modalities that improve QoL in breast cancer survivors is necessary given the strong evidence suggesting that better QoL is associated with fewer debilitative physical and mental symptoms.[26]

Physical Activity and Quality of Life in Breast Cancer Survivors

Psychosocial interventions are available for breast cancer survivors and include cognitive behavioral strategies, informational and educational nonbehavioral counseling or psychotherapy, social support, music therapy, art therapy, and other non-traditional therapies.[27] However, these therapies are largely psychologic in nature and are unlikely to address the physical and functional problems encountered by breast cancer survivors.[28] Research indicates that physical activity (PA) may be one therapeutic intervention that may compliment existing biological therapies and address a multitude of

additional QoL outcomes relevant to breast cancer survivors (e.g., physical well-being, functional well-being, fatigue).[29]

The majority of breast cancer studies have examined PA as a preventive behavior. Of approximately 55 epidemiological studies, 40 have provided evidence of decreased incidence of breast cancer with increased levels of PA. These studies suggest that PA may have protective benefits against breast cancer.[30] Research on PA and cancer also indicates that PA may also ameliorate negative physical and psychosocial side effects and enhance survivors' physical, biological, and psychosocial well-being across the breast cancer experience.[31-37] While early studies were limited in terms of their methodological design and scientific rigor,[38-40] more recent studies have implemented gold standard randomized controlled trial (RCT) methodology. Collectively, these studies have examined a wide range of psychosocial, physical, and biological outcomes such as self-esteem, body esteem, mood (e.g., anxiety and depression), cancer and cancer-treatment related symptoms (e.g., nausea, vomiting, body dissatisfaction), insulin parameters, functional capacity, and QoL (i.e., emotional well-being, subjective well-being, physical well-being, functional well-being, fatigue). In particular, these studies suggest that particular QoL domains including physical well-being, functional well-being, and fatigue appear to be domains that are most likely affected by PA. This suggests that these domains of QoL may be particularly relevant in the months and years after breast cancer treatment(s).

With the introduction of the *Consort Statement for Reporting Randomized Trials,*[41] research in the area of PA and cancer has made substantial progress. While there have been several experimental research designs, most studies have not utilized various Consort Statement elements such as blinding and intention-to-treat analysis. RCTs provide the best evidence on the efficacy of a treatment or health care

intervention. A recent systematic review and meta-analysis found 14 randomized controlled trials that have examined the effects of exercise on breast cancer patients and survivors.[29] While only four of these studies were deemed to be of 'high quality', it was nonetheless concluded that exercise is an effective intervention to improve QoL (as defined by the FACT-General and FACT-Breast), cardiorespiratory fitness, and symptoms of fatigue in breast cancer patients and survivors. A recent Cochrane systematic review corroborates these findings.[42] Since these reviews, high quality evidence continues to emerge that supports that role of PA as a safe and effective intervention to facilitate favorable QoL, physical fitness, and fatigue profiles.[31, 32, 43-46]

Physical Activity Behaviors in Breast Cancer Survivors

Evidence suggests that PA behavior substantially decreases as an individual moves through the breast cancer trajectory.[47-50] These changes in PA are most prominent after diagnosis relative to prediagnosis levels. The most recognizable change in PA occurs during chemotherapy. These studies indicate that substantial decreases in total, moderate-intensity, vigorous-intensity, and sports/recreational PA from pre to postdiagnosis are likely. This trend is of great concern particularly given recent evidence suggesting that PA after a breast cancer diagnosis may be associated with better survival, reduced risk of breast cancer recurrence, and breast cancer death (i.e., 26%-40%).[51]

There is also evidence to suggest that the decrease in PA may be a function of demographic and treatment factors. For example, Irwin[49] found that breast cancer survivors who received a combination of surgery, chemotherapy, and radiation had more substantial decreases in physical activity than surgery-only patients and surgery combined-with-radiation patients. To quantify the amount of PA loss, Irwin further estimated that the time spent engaging in PA decreases on average two hours per week

from prediagnosis to posttreatment. In a follow-up study, Irwin[50] further reported that only 32% of breast cancer survivors participated in recommended levels of PA. However, when lifestyle PA (e.g., housework, gardening) was taken into consideration, 73% met the recommended PA level. Courneya and colleagues[28] have published similar trends in that breast cancer survivors reported engaging in less mild, moderate, and strenuous PA. Although survivors reported that their PA levels increased after their treatment, PA levels typically did not recover to their (higher) prediagnosis levels of PA. Promoting PA after treatment is important given that increasing PA after diagnosis may minimize the negative physical and psychosocial sequela that are associated with the posttreatment phase of the breast cancer trajectory. These consistent trends in declining PA behavior provide a strong rationale to encourage and facilitate PA among breast cancer survivors.[50]

Walking as a Physical Activity Modality for Breast Cancer Survivors

The American College of Sports Medicine (ACSM) has expanded their traditional emphasis on formal exercise programs to include PA due to its broader public health perspective. The ACSM has taken this position to (a) increase the awareness of PA-related health benefits, (b) draw attention to the amount and intensity of PA necessary to achieve these benefits given that lower doses (of PA) than those originally thought to be necessary for a positive training effect are surfacing, and (c) emphasize that more traditional exercise recommendations[52] have overlooked the numerous health benefits associated with regular participation in intermittent, moderate-intensity PA, such as walking. Given this position, emergent literature suggests that walking is an effective PA modality in which to achieve the ACSM/CDC recommendations. Studies examining the effects of walking in women support this contention given that brisk walking is associated with a decreased risk of cardiovascular events,[53] coronary heart disease,[54, 55] reduced body weight and body fat,[56, 57] higher bone mineral density,[58] improved

neuropsychological functioning,[59] improved glucose tolerance,[60] improved cognitive functioning,[61] and improved cardiovascular fitness.[62] These results have substantial public health consequences as they negate the traditional belief that individuals must engage in PA at a vigorous intensity for health benefit accrual.[52, 54] More importantly, this line of evidence suggests that both middle-aged and older women can still achieve health benefits without engaging in vigorous bouts of PA.[55]

Given the literature suggesting that the majority of breast cancer survivors are not meeting public health guidelines for PA (i.e., ACSM/CDC), it appears that walking is also a feasible and economical form of PA to offer breast cancer survivors. PA and cancer researchers have specifically examined the effects of both home-based and supervised walking on physiological, physical, and psychological factors in the breast cancer population.[63-67] Results of these studies indicate that walking may lead to positive changes in cardiorespiratory fitness,[67] hemoglobin concentration,[67] fatigue,[64-67] anxiety,[64] symptom intensity,[63, 64] physical functioning,[63-65] emotional distress,[65] QoL,[65] psychosocial adjustment,[63] self-concept,[63] and body image.[63] Given that several of these studies were home-based walking programs, it is difficult to determine the dosage of PA that the study participants were engaging in. Although this problem is evident in most home-based PA interventions, researchers are starting to develop and implement objective PA monitoring devices to gauge and understand walking behavior in various populations.

Objective Monitoring of Physical Activity Behavior

In the non-cancer population, very few studies have tested the effect of PA intervention programs on various outcomes using step pedometers as objective indicators of PA.[59, 60, 68-71] In the breast cancer literature (or the general cancer literature for that matter), only 2 studies to date have objectively monitored the PA behavior of breast cancer survivors.[43, 45] Pinto and colleagues tested a home-based telephone-

counseling intervention for breast cancer survivors (N=86) and found that while self-report PA and pedometer counts increased, accelerometer data did not show any change across the 12-week intervention. Matthews et al. found similar results in that breast cancer survivors (n=23) were able to increase their PA as indicated by accelerometer data. Given the lack of research examining objectively monitored PA in breast cancer survivors, it is difficult to make any concluding statements regarding this method of monitoring PA.

In other populations, the most comprehensive step program to date is the 'First Step Program'[72, 73] designed for individuals with type II diabetes. Participants in this 16-week program were given step pedometers, attended 4 weekly group meetings, received a program manual containing goal-setting and problem-solving exercises, and calendars to monitor and log steps taken per day. At the end of the 16-week intervention period, participants receiving the intervention reported an increase in PA by approximately 3000 steps per day (total = 9123 $\pm$ 4539) whereas the control group reported a decline in total steps per day (total = 5622 $\pm$ 2405). Tudor-Locke et al. translated these steps into approximately 31 minutes of extra walking per day. Although significant group differences did not emerge (likely a function of the small sample size), there were significant negative correlations between overall steps per day and fasting blood glucose (hBA1c). This study provides initial evidence for the effectiveness and feasibility of a PA intervention using step pedometers to assess PA behavior in the chronic disease population.

Many researchers and public health experts advocate for individuals to strive and achieve 10,000 steps per day. However, some individuals contend this may only be a function of simplicity and ease of recall.[74] For example, Tudor-Locke and Myers[75] advise against advertising a specific step value. It has even been suggested that 10,000 steps a day is only a 'simple and unsubstantiated slogan'[68] given the current lack of scientific

rigor (e.g., non-randomized samples, small sample sizes) and scrutiny (e.g., few studies, lack of peer-reviewed evidence). Research examining outcomes related to engaging in 10,000 steps per day is sparse. This research indicates that 10,000 steps per day may be associated with reduced blood pressure and hypertension,[76] normal weight maintenance,[77] and lower BMI and reduced body fat.[78] Recently, Johnson and colleagues[79] reported that a lack of focus on PA/walking intensity may undermine the realization of intensity-dependent outcomes. In a sample of individuals with type II diabetes, Johnson reported that those individuals that established a training cadence that was 10% above their usual stepping rate improved their metabolic risk profiles.

Although health status must be taken into consideration, Tudor-Locke and Bassett[74] proposed a classification indices in which to classify pedometer-determined PA in healthy adults; a) <5000 steps per day as a 'sedentary lifestyle' index, b) 5000-7499 steps per day as a 'low –active' index, c) 7500-9999 steps per day as a 'somewhat active' index, d) ≥10,000 steps per day as an 'active' index, and e) ≥12,500 steps per day as a 'highly active' index. Regardless, more appropriately designed studies (i.e., RCTs) must examine the effect of walking 10,000 steps per day on various psychological, physical, and biological outcomes before researchers and PA advocates campaign for individuals, particularly in the diseased population, to accumulate 10,000 steps per day. Consistent with the findings of Johnson and colleagues, the intensity in which the steps are taken may be influential in realizing health benefits and outcomes.

Understanding Physical Activity Behavior in Cancer Survivors

Application of behavioral theories can assist researchers in understanding the mechanisms through which individuals change (or do not change) their behavior. The theory of planned behavior (TPB) is a widely used and validated model for predicting and explaining PA motivation and behavior in breast cancer survivors.[80-82] Overall, these studies have provided promising evidence that the TPB may be a useful model for

understanding PA in breast cancer survivors. Moreover, these studies have identified the salient beliefs about PA in breast cancer survivors that are necessary for developing behavior change interventions for this population.

Research is emerging that supports the two-component TPB model as being superior to the traditional TPB model in the PA domain.[83-85] The traditional TPB model postulates that intention is the most important determinant of behavior. Intention is, in turn, determined by subjective norm, attitude, and perceived behavioral control. Recently, TPB theorists have suggested that each TPB component is better represented by two specific subcomponents.[84-86] Subjective norm measures the perceptions of social pressure to perform the behavior and includes the more traditionally measured *injunctive* component (e.g., whether important others approve of the person performing the behavior) and a *descriptive* component (e.g., whether important others actually perform the behavior themselves). Attitude reflects the individual's overall evaluations of performing the behavior and is comprised of *instrumental* (e.g., harmful/beneficial) and *affective* (e.g., unenjoyable/enjoyable) components. Perceived behavioral control reflects the degree of personal control the individual has over performing the behavior and is comprised of *self-efficacy* (e.g., ease/difficulty, confidence) and *controllability* (e.g., personal control over behavior).

Underlying beliefs influence each of the TPB components. According to Ajzen, "behavioral interventions must try to change the beliefs that ultimately guide performance of the behavior" (p. 2).[87] Fishbein advocates identifying salient beliefs from the intended population, developing persuasive messages around the beliefs, and then developing suitable and appropriate materials based on and developed around the elicited beliefs.[88] Subjective norm is influenced by normative beliefs, which refer to the specific individuals that may approve or disapprove of the behavior and perform or not perform the behavior themselves. Attitude is determined by behavioral beliefs, which

consist of perceived advantages and disadvantages of participating in the behavior and also the factors that make the behavior enjoyable or unenjoyable. Finally, perceived behavioral control is a function of control beliefs, which refer to the degree of perceived opportunities and resources the individual has for performing the behavior.

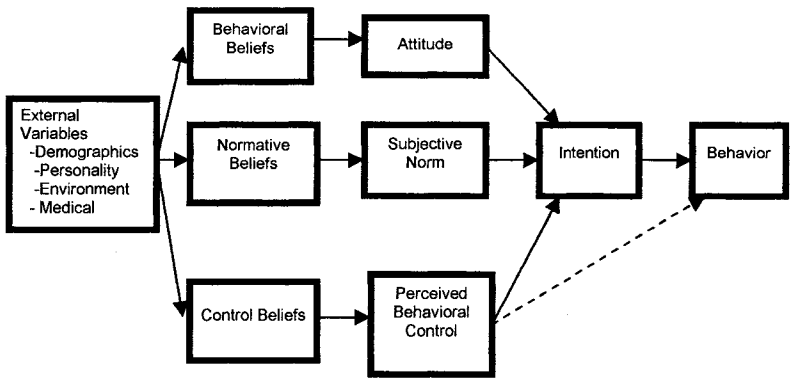

Figure 1. Schematic of the Theory of Planned Behavior

Several studies have examined the determinants of PA after a cancer diagnosis using the TPB framework.[89-95] Two studies each examined colorectal cancer[90, 96] and breast cancer survivors,[91, 94] with one study each examining non-Hodgkin's lymphoma[97] and endometrial cancer.[98] One study also examined mixed cancer patients receiving high-dose chemotherapy and bone marrow transplantation,[93] and another examined mixed cancer survivors.[95] The remaining study examined both breast cancer and prostate cancer survivors.[89] For the purposes of this section, only the studies examining the determinants of PA in breast cancer survivors will be reviewed. All three studies performed two separate hierarchical regression analyses (HRA). In the first HRA, PA behavior was regressed on intention and perceived behavioral control. These studies report that intention and perceived behavioral control predict anywhere from 10 to 35% of the variance in PA behavior. In the second HRA, intention was regressed on attitude, subjective norm, and perceived behavioral control. Results indicated that attitude, subjective norm, and perceived behavioral control explained anywhere from 23 to 49%

of the variance in intention. These studies provide some confirmation that the TPB may be an effective model for examining the cognitive antecedents of PA behavior in cancer survivors.

Theory of Planned Behavior in Physical Activity Behavior Change Interventions

The aforementioned studies provide evidence that the TPB may be an effective social cognitive model for guiding interventions aimed at promoting PA after a breast cancer diagnosis.[89] Evidence further suggests that the TPB may be effective for developing behavior change interventions. In a recent review,[99] Hardeman and colleagues identified 13 TPB-based behavior change interventions. These interventions tested TPB components via information, persuasion, goal setting, social support, modelling, increasing skills, rehearsal of skills, and planning. Although effect sizes were generally small-to-moderate, the majority of studies reported that the intervention resulted in change in the positive direction. Given the wide variety of study quality and poor reporting practices, it is difficult to judge the effectiveness of the interventions. For example, most studies did not report which TPB components were targeted in the intervention. Hardeman and colleagues propose that future studies using the TPB in behavior change interventions implement a randomized controlled design, longer follow-up period, intention-to-treat analysis, standardized, and reliable measures of constructs and more objective measures of behavior. Furthermore, recruitment and dropout rates should be reported to allow for making evaluations regarding the feasibility and acceptability of the TPB-based intervention.

Kelley and Abraham[100] recently published the first study to evaluate TPB-based PA promotional materials using a RCT design. These authors developed a health living booklet designed to target intentions and perceived behavioral control with respect to healthy eating and increasing PA levels in adults older than 65 years of age in a hospital setting. After piloting the manual, expert opinion was acquired from clinical staff. After

reading the TPB-derived statements, participants (*N*=252) were encouraged to set and write down goals (in the manual) and make PA and healthy eating plans. Participants were also encouraged to indicate whether or not they achieved their healthy eating and PA goal that day. For PA, participants in the intervention group (i.e., those receiving the manual) reported stronger intentions and PA behaviors than those in a control group (i.e., those not receiving the manual). These results suggest that the TPB-based healthy living manual increased PA intentions and behavior in older adults in an older adult, hospital setting.

Consistent with Fishbein's criticism, this study failed to demonstrate how the theory was actually used in the development (and evaluation) of the intervention.[101] Furthermore, this study did not identify the key beliefs salient to the population of study. Ajzen and Fishbein both advocate "...a good behavioral theory requires one to conduct formative research to understand the behaviour being investigated from the perspective of the particular population or culture being studied" (p. 137).[101] Future TPB-based intervention studies should take measures to implement Fishbein's guidelines for developing behavior change interventions.[88] This involves identifying salient beliefs from the intended population, developing persuasive messages around the beliefs, and developing suitable questionnaires based on the elicited beliefs.

Theory of Planned Behavior-Based Intervention Materials

Rabin et al.,[102] evaluated theoretical mediators of PA behavior change in breast cancer survivors using the transtheoretical model as a guiding framework. Survivors in the intervention group received a pedometer and a weekly telephone call for 12 weeks while survivors in the contact control group were asked not to change their current level of activity. Results indicated that decisional balance, self-efficacy, behavioral processes of change, and experiential processes of change did not mediate the effects of the

intervention on PA behavior change. Using the TPB as a mediating framework, Jones and colleagues[103] found that breast cancer survivors who received an oncologist's recommendation to exercise reported more positive attitudes, stronger subjective norms, perceptions of control, and intentions to exercise than those survivors that did not receive an exercise recommendation. Also using the TPB, Chatzisarantis and Hagger[104] found that young people (N=83, Mean age=14.6 years) who studied a persuasive message that targeted modal salient behavioral beliefs (as elicited by earlier pilot work) reported more positive attitudes and stronger intentions than those individuals that studied nonsalient behavioral beliefs. In conjunction with examining theoretical mediators of PA behavior change, researchers may also consider examining moderators of PA behavior change. For example Williams and colleagues[105] presented data suggesting that PA behavior change interventions may be more effective among individuals reporting greater enjoyment of PA at baseline.

Promoting Physical Activity in Cancer Survivors

Given the large body of evidence supporting the benefits of PA behavior across the breast cancer experience, information pertaining to the promotion of PA in breast cancer survivors is beginning to emerge, although there is very little evidence pertaining to PA promotion in breast cancer survivors published to date. In an early study to examine methods of increasing PA in breast cancer survivors, Jones and colleagues[103] examined the effects of two oncologist-centered interventions on self-reported exercise behavior in breast cancer survivors beginning treatment using a RCT design. During their initial treatment consultation, participants were randomized to receive either (a) an oncologist's recommendation to exercise, (b) an oncologist's recommendation to exercise plus a referral to a Kinesiologist, and (c) usual care (i.e., no recommendation). Results of this study indicated that participants receiving one of the exercise recommendations reported total exercise amounts that were significantly higher than

those receiving usual care (i.e., ~30 min/wk). However, given the amount of information dispensed during an initial treatment consultation, and not to mention the distress an individual might experience during their treatment consultation, it is unclear whether the treatment consultation represents the opportune time to recommend exercise. As the authors indicated, participants may have only been concerned with critical information regarding prognosis and treatment. This contention is supported in that only 59% of individuals correctly recalled the group they were randomly assigned to. Nonetheless, this trial suggests that advocating exercise behavior via an oncologist's recommendation may be an easy and efficient form of promoting exercise in breast cancer survivors.

Project LEAD (Project Leading the Way in Education Against Disease)[106, 107] is the first trial to test whether a 6-month personally-tailored telephone-counseling program is effective in improving diet and PA behaviors in early stage breast and prostate cancer survivors. Survivors (N=182) were randomized to an experimental or control group. The experimental group received a mailed workbook and telephone counseling (tailored on stage of readiness) pertaining to overall diet and PA behaviors. The control group received a mailed workbook and telephone counseling in other health-related areas. Results from Project LEAD showed a significant improvement in self-reported diet quality but not in self-reported PA or QoL over a six month intervention period and a 12-month follow-up. Project LEAD is the first attempt to examine the potential effect of print materials on PA behavior in cancer survivors, although teasing out the effects of the print materials is difficult given the design of the study.

The FRESH START trial (a randomized trial of PA and diet among cancer survivors)[108] is a similar RCT designed to evaluate the efficacy and effectiveness of personally- tailored print materials in promoting lifestyle changes in breast and prostate cancer survivors. Survivors in the intervention group will receive the FRESH START

intervention program that consists of a series of workbooks, newsletters, and update cards that are tailored based upon information collected during a baseline interview. Survivors in the control group will receive nontailored, health promotion print materials that promote PA and a healthy diet. Primary endpoints are PA behavior and dietary intake. Secondary endpoints include perceived health, QoL, depression, and weight status. Final results from the FRESH START project are pending.

These aforementioned studies will provide important information pertaining to the efficacy of distance medicine-based approaches in promoting PA in cancer survivors. Currently, there are no published data pertaining to PA print material interventions in the cancer population. In the disease-free population, research examining PA print material interventions have provided evidence of their efficacy, efficiency, and cost-effectiveness.[109-114] These studies report increases in PA ranging from 78 minutes per week[113] to 160 minutes per week.[109] These minutes translate into one to three more days of PA per week. These results are encouraging given the contention that even modest increases in PA could produce substantial health gains from a public health perspective.[114] Print materials have been compared to website materials[112] as well as telephone counseling.[110] These studies indicate that individuals' receiving print materials promoting PA are more likely to increase their PA behavior than both website and telephone intervention participants. In Smith et al.'s study, print material was most effective when combined with a physician's recommendation to PA. This effect warrants further attention given that the evidence supporting physician-based PA counseling in the non-diseased population is, at best, equivocal.[115-117] Given the neophytic nature of this area of inquiry (i.e., PA print media), research continues to emerge on the topic. Regardless, research pertaining to the effect of print material on PA behavior is promising.

To this end, mail-mediated PA interventions have the ability to reach more people and communicate more information in a succinct and attractive form.[110] Given the contention that print material is a realistic approach to health promotion delivery,[100] it seems reasonable to suggest that print material related to PA throughout the cancer experience may be an effective modality of PA promotion in the cancer population. This contention is corroborated by Demark-Wahnefried et al.'s[118] findings that the majority of breast cancer survivors indicated that they would be "very" or "extremely" interested in receiving mailed literature pertaining to PA. Furthermore, most respondents favored initiating a program at diagnosis or soon after. The breast cancer population may be an ideal population to target for lifestyle change efforts because of the high level of interest.[118, 119]

Examining the effect of PA promotion on PA behavior in breast cancer survivors is timely given the evidence that breast cancer survivors are receptive to receiving PA counseling and assistance.[119, 120] For example, Jones and Courneya[119] reported that 84% (n=248) of cancer survivors preferred to receive PA counseling at some point during their cancer experience. In a larger sample of breast and prostate cancer survivors (N=978), Demark-Wahnefried et al.[118] reported that 80% were interested in receiving health promotion programs. Furthermore, 51% indicated a specific interest in receiving PA programs. This evidence confirms Demark-Wahnefried's contention that a cancer diagnosis may function as a 'teachable moment' when individuals may be more receptive to making beneficial lifestyle changes.[107, 108]

The Activity Promotion Trial

The Activity Promotion (ACTION) Trial was a randomized controlled trial designed to determine the effects of theoretically based (i.e., TPB) breast cancer-specific PA print material, a step pedometer, or their combination, on PA and QoL in breast cancer survivors (compared to a standard verbal PA recommendation). The objectives of this trial were:

1. To develop a TPB-based PA guidebook for breast cancer survivors and evaluate the suitability and appropriateness of this guidebook.

2. To determine the effects of TPB-based PA print materials (PM), a step pedometer (PED), or their combination (COM), on PA and QoL in breast cancer survivors compared to survivors receiving a standard verbal PA recommendation (SR).

3. To examine the effects of TPB-based PA print materials on TPB constructs and behavioral, normative, and control beliefs and to determine if the TPB mediated the effects of our TPB-based interventions (i.e., PM and COM) on PA behavior.

Hypotheses

Given the developmental and exploratory nature of Study 1 (guidebook development), we did not offer any hypotheses pertaining to this study. We hypothesized that survivors in the PM, PED, and COM groups would report greater increases in self-reported PA and QoL compared to survivors receiving a standard verbal PA recommendation (SR) for PA and that survivors in the COM group would report the greatest increases. We also hypothesized that (a) the TPB-based interventions (i.e., PM and COM) would have significant effects on the TPB constructs compared to the SR group and (b) the TPB would mediate the effects of the TPB-based interventions (i.e.,

PM and COM) on PA and provide a theoretical explanation for why the TPB interventions were effective in increasing PA behavior in breast cancer survivors.

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CHAPTER 3:

Study 1: Development and Evaluation of a Theory-Based Physical Activity Guidebook for Breast Cancer Survivors

Development and Evaluation of a Theory-Based Physical Activity Guidebook for Breast Cancer Survivors

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ABSTRACT

The objective of this study was to develop and evaluate the suitability and appropriateness of a theory-based physical activity (PA) guidebook for breast cancer survivors. Content for the PA guidebook was constructed based on the Theory of Planned Behavior (TPB) using salient exercise beliefs identified by breast cancer survivors in previous research. Expert judges (N=30) completed the Maine Area Health Education Center's 18-item attribute checklist for evaluating written health information. A subset of TPB expert judges (n=9) completed five items designed to determine the degree of match between the guidebook content and the respective TPB components. Expert judges indicated that the PA guidebook achieved desirable attributes for the organization, writing style, appearance, appeal, suitability, and appropriateness of the guide. For the TPB assessment, all mean item-content relevance ratings indicated at least a "very good match" between the PA guidebook content and the keyed TPB domains. The newly developed PA guidebook successfully targets the TPB components and contains suitable and appropriate written health information. Theoretically-based written health information may be a cost-effective strategy for increasing PA in breast cancer survivors at the population-level.

Keywords: written health information; physical activity; theory of planned behavior; breast cancer survivors.

Approximately 291,000 women will be diagnosed with breast cancer in Canada and the United States in 2005 (American Cancer Society, 2005; Canadian Cancer Society, 2005) and over 95% will survive at least 5 years (American Cancer Society, 2005). The high incidence and improved survival rates have resulted in a growing cohort of long-term breast cancer survivors in these countries. Unfortunately, surviving breast cancer usually means enduring significant medical treatment(s) (e.g., surgery, radiation therapy, chemotherapy, hormone therapy) that can undermine quality of life (QoL) in breast cancer survivors even years after the completion of treatment(s) (e.g., Ganz, Kwan, Stanton, Krupnick, Rowland, Meyerowitz, Bower, & Belin, 2004).

One intervention that has been found to enhance QoL in breast cancer survivors is physical activity (PA). PA can improve physical fitness, reduce fatigue, increase functioning, and enhance overall QoL in breast cancer survivors both during and after treatments (Knols, Aaronson, Uebelhart, Fransen, & Aufdemkampe, 2005). Moreover, a recent prospective cohort study of almost 3,000 women found that higher levels of PA were associated with reduced risks of breast cancer recurrence, breast cancer-specific mortality, and all-cause mortality (Holmes, Chen, Feskanich, Kroenke, & Colditz, 2005). Given these promising findings, there is a need to develop and evaluate methods of communicating and promoting PA to breast cancer survivors. Indeed, there is an interest and demand from cancer survivors for written health information and health promotion programs (Demark-Wahnefried, Aziz, Rowland, & Pinto, 2005).

Written health information (e.g., patient information leaflets, instructional guidebooks) is one method that may hold promise in promoting PA. In other populations, written PA promotions (i.e., print-based) have shown encouraging results (e.g., Marcus, Bock, Pinto, Forsyth, Roberts, & Traficante, 1998; Marshall, Bauman, Owen, Booth, Crawford, & Marcus, 2003, 2004). Developing and distributing suitable and appropriate

written health information is desirable given its potential to improve knowledge (Cooper, Booth, Fear, & Gill, 2001), satisfaction (Fernsler & Cannon, 1991), aid coping (Harrison-Woermke & Graydon, 1993), reduce distress (Michie, Rosebert, Heaversedge, Madden, & Parbhoo, 1996), and increase adherence to the behavior being promoted (Myers, Chodak, Wolf, Burgh, McGrory, Marcus, Diehl, & Williams, 1999). Other advantages of written health information include message consistency, ease of delivery, permanence of information, self-paced learning, and a low cost to produce and update (Hoffmann & Worrall, 2004). Importantly, written health information should be evaluated for suitability and appropriateness prior to distribution to enhance the likelihood that the material is able to effectively change behaviour. Current research suggests, however, that the suitability and appropriateness of written health information resources is often not adequate and, therefore, may be limited in its effectiveness to change health behaviors (Eames, McKenna, Worrall, & Read, 2003; Rees, Ford, & Sheard, 2003; Weintraub, Maliski, Fink, Choe, & Litwin, 2004).

In order to facilitate behaviour change, researchers advocate that written health information should be theoretically-based (Fishbein, 2001). Application of behavioral theories can assist researchers in understanding the mechanisms through which individuals change (or do not change). The Theory of Planned Behaviour (TPB) is the most widely used and validated model for predicting and explaining PA motivation and behavior in cancer survivors (e.g., Courneya, Blanchard, & Laing, 2001; Courneya & Friedenreich, 1999; Courneya, Jones, Mackey, & Fairey, in press). Overall, these studies have provided promising evidence that the TPB may be a useful model for understanding PA in cancer survivors. Moreover, these studies have identified the salient beliefs about exercise in breast cancer survivors that are necessary for developing behavior change interventions for this population (Courneya et al., 2001;

Courneya & Friedenreich, 1999; Courneya et al., in press). Evidence from other behavioral domains and populations also suggests that the TPB may be effective for developing behavior change interventions (Hardeman, Johnston, Johnston, Bonetti, Wareham, & Kinmonth, 2002).

The TPB postulates that intention is the most important determinant of behavior and consists of both motivation and planning elements. Intention is, in turn, determined by subjective norm, attitude, and perceived behavioral control. Ajzen suggests that each TPB component comprises two specific subcomponents (Ajzen, 2002). Subjective norm measures the perceptions of social pressure to perform the behavior and includes the more traditionally measured injunctive component (e.g., individual believes important others want them to perform the behavior) and a descriptive component (e.g., whether important others actually perform the behavior themselves). Attitude reflects the individual's overall evaluations of performing the behavior and is comprised of instrumental (e.g., harmful/beneficial) and affective (e.g., unenjoyable/enjoyable) components. Perceived behavioral reflects the degree of personal control the individual has over performing the behavior and is comprised of self-efficacy (e.g., ease/difficulty, confidence) and controllability (e.g., personal control over behavior).

Furthermore, underlying beliefs influence each of the three TPB components. According to Ajzen, "behavioral interventions must try to change the beliefs that ultimately guide performance of the behavior." (p. 2) (Ajzen, 2005). Fishbein also advocates identifying salient beliefs from the intended population, developing persuasive messages around the beliefs, and developing suitable and appropriate materials based on the elicited beliefs (Fishbein, von Haeften, & Appleyard, 2001). Subjective norm is influenced by normative beliefs, which refer to the specific individuals that may approve or disprove of the behavior and perform or not perform the behavior themselves. Attitude

is determined by behavioral beliefs, which consist of perceived advantages and disadvantages of participating in the behavior and also the factors that make the behavior enjoyable or unenjoyable. Finally, perceived behavioral control is a function of control beliefs, which refer to the degree of perceived opportunities and resources the individual has for performing the behavior. Furthermore, TPB theorists propose that intentions to perform a behavior will more likely translate into behavior when implementation intentions are garnered (Sheeran, Milne, Webb, & Gollwitzer, 2005). Implementation intentions propose that successful behavior change is facilitated by furnishing the intention with an 'if then' plan specifying when, where, and how the individual will achieve the behavior (Sheeran et al., 2005).

To date, there have been few attempts to a) present and describe the formulation and development of written health information, and b) rigorously evaluate the suitability and appropriateness of written health information in both the general population and for breast cancer survivors. Therefore, the aim in the present study was to develop and evaluate a TPB-based PA guidebook designed specifically for breast cancer survivors.

METHOD

Preliminary Development of the Guidebook

We developed a 62-page PA guidebook for breast cancer survivors (i.e., *Exercise for health: An exercise guide for breast cancer survivors*) based on the theoretical components of the TPB. The information in the PA guidebook was formulated and written based on behavioral, normative, and control beliefs elicited from breast cancer survivors in previous research (see Table 1) (Courneya et al., 2001; Courneya & Friedenreich, 1999; Courneya et al., in press). The PA guidebook consists of 10 chapters and includes participant-centered activities designed to enhance attitude (i.e., instrumental and affective attitudes), subjective norm (i.e., injunctive and descriptive

norms), perceived behavioral control (i.e., self-efficacy and controllability), and implementation intentions (e.g., goal-setting, planning) pertaining to PA. These written activities are also designed to facilitate participant engagement in the information.

The PA guidebook was also based on previous research examining the exercise preferences of breast cancer survivors. Research into exercise preferences has indicated that breast cancer survivors prefer recreational exercise at home, particularly low to moderate intensity walking (Jones & Courneya, 2002). Therefore, our PA guidebook promoted walking as the primary mode in which to achieve the recommended frequency, duration, and intensity of exercise. Table 2 contains an overview of the PA guidebook sections, their page length, their general content, targeted theoretical components, samples of written information, the special features within the section (e.g., graphs, written activities), and other information pertaining to the characteristics of the guidebook.

MEASURES

Readability. Readability was evaluated by using the computer-based Flesch-Kincaid reading grade level statistic and the hand calculated SMOG (Simple Measure of Gobbledygook).

Maine Area Health Education Center Assessment Checklist (Maine AHEC). The Maine AHEC 18-item assessment checklist is one method of assessing the suitability and appropriateness of written health materials (Doak, Doak, & Root, 1996). Expert judges were asked to check off each of the attributes found on the checklist as they read through the PA guidebook. A missing check indicated a deficiency in the suitability or appropriateness. The AHEC checklist evaluates the suitability and appropriateness of health education materials in four domains; organization (e.g., "The cover is attractive. It indicates the core content and intended audience"), writing style (e.g., "There is little or no technical jargon"), appearance (e.g., Illustrations serve to amplify the text"), and

appeal (e.g., "Interaction is invited via questions, responses, suggested action, etc."). One extra item was added to the writing style domain that was designed to assess the reading ease based on the expert judges' perceptions (i.e., "The reading level is appropriate"). Breast cancer survivors and medical oncologists completed three extra items designed to assess the feasibility, safety, and accuracy of the PA guidebook (i.e., other concerns) (e.g., "Medical information is accurate"; "Guidebook is appropriate for women that have completed treatment(s) for breast cancer.").

Theory of Planned Behavior Content Assessment. TPB experts numerically rated the degree of match associated with the PA guidebook information and specified TPB components (i.e., attitude, subjective norm, perceived behavioral control, and implementation intentions) on a five-point Likert Scale (0 = poor match; 4 = excellent match). TPB experts also completed one item designed to assess how well they perceived that the PA guidebook was an overall representation of the TPB (0 = poor representation; 4 = excellent representation).

Written Feedback. All expert judges were given space to provide written qualitative feedback pertaining to any aspect of the PA guidebook. Written feedback is an important part of the development process given that the use of mixed method approaches enhances the breadth of feedback and the overall quality of the guidebook information (Crocker & Algina, 1986).

PARTICIPANTS AND PROCEDURES

Thirty-five expert judges were approached to participate in the evaluation. Thirty expert judges agreed to participate including (a) breast cancer survivors (n=9), (b) medical oncologists (n=5), (c) exercise oncology fitness leaders (n=5), (d) health information specialists (n=2), and (e) TPB researchers (n=9). Groups (a), (b), and (c) were selected due to their expert familiarity with the population for whom the information

is intended (Crocker & Algina, 1986). Groups (d) and (e) were selected due to their expertise in writing health information and psychological theory. All TPB judges held a doctoral degree in exercise psychology and had a track record of publishing research on either the TPB or other social cognitive theories in the exercise domain. Three TPB judges have published research applying the TPB to exercise behavior specifically in cancer survivors. The remaining six judges had published research applying the TPB to exercise behavior in other populations. All nine judges had also published research encompassing other theories of health behavior such as social cognitive theory, protection motivation theory, self-determination theory, and the transtheoretical model. All expert judges were contacted by e-mail or in person to determine their interest in participating in the assessment procedure. All expert judges were sent (either by post or hand delivery) the PA guidebook and the AHEC checklist. TPB expert judges were also sent a list of behavioral beliefs previously identified by breast cancer survivors (i.e., beliefs used to develop written information), definitions of the TPB components, and a TPB evaluation form.

ANALYSES

All numerical data were analyzed using SPSS Version 13.0. Two separate readability analyses were conducted. The first analysis included the word 'exercise' in the document (as is in the PA guidebook). In the second analysis, the word 'exercise' was dummy-coded with the word 'work'. We did this because the term 'exercise' is a polysyllabic word that may artificially inflate the reading grade level even though the term is likely to be widely recognized. Regardless, exercise was clearly defined in the PA guidebook as suggested by Doak et al. (1996) to increase reader understanding of the meaning.

To score the AHEC checklist, we calculated the average agreement percentages for each judge on each of the domains. We then calculated the average agreement for each domain across the expert judges. Before analyzing the TPB evaluation data, an initial screening of the expert judge's responses was conducted to identify discrepant evaluators. Discrepant judge evaluations were determined by computing the distance of each expert judge's rating from the median rating (JDM: Judge discrepancy from the median). JDM values close to zero are considered optimal as they indicate consistent agreement among the judges. Item ambiguity was determined by calculating the range (R: highest minus lowest rating plus 1) of ratings provided by the group of expert judges. R-values closer to 1 are desirable and suggest that there is minimal ambiguity inherent in the judge's ratings for the item being evaluated. After calculating the descriptive statistics, Aiken's item-content validity coefficients (Aiken's *V*) were calculated. Aiken's *V* provides a statistical test for relevancy and provides a method of statistically testing the extent to which the judges feel each item measures the intended domain (Aiken, 1985). *V*-coefficients range from 0 to 1 with a value closer to 1.0 indicating there is minimal ambiguity inherent in the expert ratings across the items being evaluated. A value of 1.0 indicates that all *n* judges give an item the highest possible score on the rating scale. The statistical significance of each *V*-coefficient was then established by comparing the resultant values against a right-tailed binomial probability table as described by Aiken (1985). Descriptive statistics of the TPB expert ratings were calculated to determine the mean-item content relevance ratings. Following statistical evaluation, each expert judge's written feedback was analyzed to determine if any alterations to the written text should be pursued.

RESULTS

Readability Evaluation. In the first analysis (i.e., with 'exercise') a 6.8 Flesch-Kincaid reading grade level was obtained while SMOG indicated a reading grade level of 8.0. In the second analysis (i.e., 'exercise' replaced with 'work'), a 6.0 Flesch-Kincaid reading grade level was obtained while SMOG indicated a reading grade level of 7.0.

Assessment Checklist. Overall, expert judges reported that the PA guidebook achieved the desired attributes for organization (91% agreement), writing style (94% agreement), appearance (92% agreement), and appeal (98% agreement). Medical oncologists and breast cancer survivors further supported the safety and accuracy (i.e., items in the 'other concerns' domain) of the guidebook (93% and 93% agreement, respectively).

TPB Assessment. For the TPB assessment (see Table 3), all five mean item-content relevance ratings had values at or above 3.0 indicating a "very good match" between the PA guidebook content and the keyed TPB domains. Across the 9 expert judges, JDM scores ranged from 1 to 6. Two expert judges had a JDM score of 1 while one judge had a JDM score of 6. However, this judge was retained in the analysis given that inspection of the judges' written comments revealed an understanding of the evaluation process as well as the domain to be assessed. Therefore, after careful consideration and analysis, it was deemed that there were no aberrant expert judges, therefore all judges were retained for the analysis. Analysis of the R-values suggested that only one item (i.e., implementation intentions) had an ambiguous rating (R values $\geq$ 4). This was due to one judge rating the implementation intentions item a '0' ("poor match"). Aiken's item content validity coefficients (*V*) for each TPB component (and the overall component) were all significant at the .01 level. The implementation intention

item was significant at the .05 level). These results suggest that the written information (as rated by the expert judges) is relevant with respect to the targeted TPB component .

Written Feedback and Modification. Several expert judges provided written feedback pertaining to the PA guidebook. One feedback sample from each expert judge category is presented along with an explanation on how the feedback was used to modify and enhance the PA guidebook (see Table 4).

DISCUSSION

The purpose of this study was to develop and evaluate a theoretically-based PA guidebook specifically for breast cancer survivors. The results provide preliminary evidence that our guidebook targets the intended TPB components. Furthermore, our results indicate that the guidebook is suitable, appropriate, and potentially usable.

Comparing our PA guidebook with other published data is difficult given the paucity of similar empirical data. There are a few studies in which to compare our readability data. Cardinal and Sachs (1992) identified and evaluated 54 written materials promoting PA. Overall, it was concluded that most PA promotion literature is written at a mean grade 11.3 reading level, which is incomprehensible for many adults. Only three (of the 54) were written at or below a grade 8 level. In another study, Cardinal and Seidler (1995) evaluated the 'Exercise Lite' brochure that was developed by the American College of Sports Medicine (ACSM) and the Centers for Disease Control and Prevention (CDC). Analysis of this brochure indicated that the brochure was written at a grade 17 reading level (i.e., a level similar to that of a scientific journal article). Furthermore, 70% of the participants (many of which were college students) found the brochure to be incomprehensible. Our PA guidebook, *Exercise for health: An exercise guide for breast cancer survivors* represents a substantial improvement in readability above the exercise materials examined in the aforementioned studies. Our reading level was assessed at just under a grade 7 reading level. Several researchers have argued

that the computer generated Flesch-Kincaid statistic is an underestimation of true reading grade level. Therefore we hand-calculated a SMOG index at the 8.0 grade level. SMOG statistics are typically 1-to-2 grade levels higher than the computer generated Flesch-Kincaid statistic. Nonetheless, both of these readability statistics fall within the recommended grade 6-8 level. It should be noted that writing health information materials is a difficult task given that medical information can be complex. However, Doak et al. (1996) recommend making the reading level as low as practical without sacrificing important content.

To our knowledge, our study is the first to implement the Maine AHEC attribute checklist as a tool to evaluate written health information. In this evaluation, it appears that the AHEC checklist was a suitable and relatively fast and effective method of garnering suitability information on the PA guidebook. Given that our PA guidebook was 62 pages in length, it appears that the AHEC checklist is a sufficient tool for evaluating written health information that is longer in length than typical patient information leaflets (i.e., 3-5 pages). We found that the expert judges favorably endorsed all the domains on the AHEC checklist, as well as the researcher-generated 'other concerns' items designed for medical oncologists and breast cancer survivors to assess. These results confirm the suitability and appropriateness of our guidebook. Along with the average agreement percentages per domain, the researcher can also analyze the agreement percentage per item across the judges. Evaluating at the item level is another way in which the developer of the health information can also find insufficiencies in the material and make necessary corrections. For example, in our data eight expert judges indicated that too many points were presented in some of the bulleted lists. By analyzing the evaluations at both the domain and item levels, we were able to go back and make the necessary revisions to the PA guidebook (e.g., reduce bullet list length, avoid technical jargon).

Revisions to the guidebook were also made based on inspection of the written comments from the expert judges (see Table 4) to improve the suitability and appropriateness of the information. In this paper, we highlight some examples of the types of information that a variety of expert judges from the breast cancer survivor population, adult education field, and academic arena can offer. Based on the feedback received, it was clearly evident that each category provided unique comments. Future attempts to develop and evaluate health information materials should employ expert judges from a variety of backgrounds to enhance the breadth and depth of feedback acquired. Our study provides an example of how quantitative and qualitative methods can be used in combination to gain a greater perspective of the question being asked.

To date, there are no other studies that have assessed the suitability of written PA information both for the general population, and for breast cancer survivors. Therefore, it is difficult to compare the suitability and appropriateness of our PA guidebook to other materials. However, there have been a few studies that have analyzed the suitability of prostate cancer education materials (Rees et al., 2003; Weintraub et al., 2004) and stroke rehabilitation education materials (Eames et al., 2003). After analyzing 26 educational prostate cancer materials, Weintraub et al. (2004) found that 90% had poor readability while only 76% had adequate (i.e., average) suitability. In a similar study, Rees et al. (2003) analyzed 31 prostate cancer patient information leaflets and found 65% to have only adequate suitability while 16% were deemed unsuitable. Of 18 stroke education materials, 89% were rated as only adequate while 79% had a high reading level. Eames et al. (2003) found similar results in that 68% of the 54 stroke education materials they reviewed had a reading level above grade 9. Eames and colleagues found that as suitability scores improved, patients' satisfaction with the materials increased.

Exercise for health: An exercise guide for breast cancer survivors is the first attempt to develop and empirically evaluate a theory-based PA guidebook for breast cancer survivors. Furthermore, this may be the first attempt to develop and empirically evaluate a TPB-based PA guidebook for any population. Overall, the expert TPB judges were in agreement that the written information in the PA guidebook targeted the theoretical components of the TPB. This was reflective in that all the mean item-content relevance scores were at or above the 3.0 (i.e., very good match) level. Aiken's *V* coefficients provided a statistical evaluation of the degree of item-content relevance and provided confirmation that the judges perceived that each item measured the keyed theoretical domain. Kelley and Abraham (2004) recently published the first study to test the efficacy of a TPB-based PA booklet using a randomized controlled trial design. These authors developed a 'healthy living booklet' designed to target intentions and perceived behavioral control with respect to healthy eating and increasing PA levels in adults older than 65 years of age in a hospital setting. Consistent with Fishbein's (2001) criticism, however, that study failed to demonstrate how the theory was incorporated into the development (and evaluation) of the intervention. Furthermore, this study did not identify the key beliefs salient to the population of study as is recommended when developing TPB-based intervention tools (Ajzen, 2005; Fishbein, 2001; Fishbein, von Haeften, & Appleyard, 2001).

Despite the importance and novelty of our study, there are limitations that should be taken into account when interpreting our data and planning future research. First, we used the AHEC to assess the suitability and appropriateness of our guidebook. The AHEC's checklist response format (i.e., either an attribute is present or not) poses some limitations with the precision of measurement. Other suitability assessment tools, such as the Suitability Assessment of Materials (SAM; Doak et al., 1996) may be effective in garnering information pertaining to the suitability of written educational materials. In the

future, researchers and practitioners should use these tools (and continue to develop new tools) to assess the suitability and appropriateness of materials before using them as intervention tools in both research and clinical practice.

Second, our conclusions are based on preliminary data. In the future, we plan to provide further evaluation of our guidebook in terms of its effectiveness for behavior change and modifying social cognitive beliefs. We also plan to collect data pertaining to breast cancer survivors' reactions to using the guidebook as part of an intervention (e.g., satisfaction, usefulness, time spent engaged in the material). Finally, because there are no other studies to make comparisons, it is difficult to critically appraise this study. Researchers in the area of exercise behavior change should a) publish empirical evidence providing adequate description and detail pertaining to the written health materials they are implementing, and b) continue to explore and evaluate the utility of the TPB (and other social cognitive theories) in the development of such materials.

IMPLICATIONS

It is anticipated that this study will provide researchers and practitioners with a sample of methods that can be implemented to conduct such research aimed at evaluating a) the suitability and appropriateness of written health materials, and b) the theoretical content of such materials. Publishing information pertaining to the development of written health materials (e.g., intervention materials, PA promotion materials) may assist other endeavors aimed at developing and implementing potentially effective materials. By developing materials firmly grounded in theory, researchers and practitioners can better understand the mechanisms through which individuals change (or do not change) their PA behavior. Individual's seeking such information on PA (and other health behaviors) should have access to rigorously designed health education materials to enhance the likelihood of behavior change and maintenance. Ultimately, PA

resources that are rigorously developed and evaluated have the potential to be a valuable resource that can be used by the growing population of breast survivors (and other target populations).

CONCLUSIONS

This research provides an indication that our PA guidebook is suitable and appropriate. Furthermore, data from theory experts suggests that our PA guidebook has a very good-to-excellent degree of match between the guidebook content and the constructs of the TPB. For optimal processing and uptake of the material(s), researchers should develop and evaluate health information materials that are based on theory, targeted to the intended population, and evaluated for their readability, suitability, and appropriateness. With these materials, breast cancer survivors (and other target populations) can be informed and educated about the benefits, barriers, and strategies for adopting regular PA as a part of their daily lifestyle. *Exercise for health: An exercise guide for breast cancer survivors* is currently being implemented in a randomized controlled trial examining various forms of PA promotion with breast cancer survivors.

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Table 1

Behavioral, normative, and control beliefs identified in previous research with breast cancer survivors.

Behavioral Beliefs	
Improve fitness level	Reduce the risk of cancer returning
Feel better about self	Keep my mind off cancer
Relieve stress	Improve energy level
Live longer	Improve my immune system
Feel more normal	
Normative Beliefs	
Oncologist/physician	Other breast cancer survivors
Spouse or partner	Other family members
Friends	
Control Beliefs	
Have no counselling for exercise	Don't like exercise
Have no support for exercise	Experience pain or soreness
Cancer recurrence	Additional family responsibilities
Bad weather	No time to exercise/too busy
Too tired/fatigued	Other health problems

Table 2

Order and content of *Exercise for health: An exercise guide for breast cancer survivors*

Chapter Title	# of Pages	Primary Content	Target Beliefs Category and Related TPB Component	Sample of Written Information	Special Features in Chapter
1. Let's get started	3	-Introduction to guidebook -Summary of benefits of exercise for breast cancer survivors		"The purpose of this exercise guide is to help you add exercise into your daily life. We will tell you about the benefits and the barriers to exercise that other breast cancer survivors have identified. We will also give you tips to help you keep exercising when other things (like cold weather) get in the way."	-Addresses myths about exercise -1 photo
2. How can exercise benefit me?	10	-Physical and psychosocial benefits of exercise	Behavioral Beliefs a) Instrumental Attitude b) Affective Attitude	a) "Exercise improves muscle strength. This improves your balance and helps prevent falls." b) "Make it fun. Take up a new hobby that involves exercise. Exercising more can simply be a matter of spending more time on fun things you already do."	-Activity 1 -7 photos -3 explanatory graphs based on scientific studies
3. Getting support for exercise	5	-Summary of how important others can help with exercise	Normative Beliefs a) Injunctive Norm b) Descriptive Norm	a) "All the patients that I see at our centre go for physical fitness testing and a specialized exercise program is then developed for them. Exercise is a non-toxic, inexpensive, easy activity that doesn't have to be done in a fancy facility. And it's never too late to start." b) "If your friends already exercise, see if you can join them. They can be a great source of advice."	-Activities 2 & 3 -Quotes from b/c survivors -Opinions about exercise from 3 oncologists (includes their photos) -3 photos

4. How much exercise is enough?	5	-Recommended mode, frequency, intensity, and duration of exercise -Intention formulation	Intention	"Exercise should be performed on at least 5 days of the week or more, at least at a moderate level, for 30 minutes or more. Walking quickly (like you were late for an appointment) is a moderate level exercise."	-Activities 4 & 5 (designed to assess current and intended exercise level -2 photos
5. Planning for success	6	-Goal-setting based on "SMART' guidelines: specific, measurable, attainable, reward, time frame	Implementation Intentions (action planning/goal-setting)	"The next step is to set some exercise goals. Research has shown that setting goals will help you start and maintain your new exercise program. Setting goals will also help you monitor how much exercise you are doing."	-Activity 6 -2 photos -Sample exercise goals -2 tear-out pages to record goals
6. Overcoming exercise barriers	16	-Common exercise barriers and solutions presented in a question and answer format	Control Beliefs a) Self-efficacy b) Controllability	a) "If you are tired, try to notice the days and times of the day when you feel tired. Then exercise at a time when you feel the least tired. Or you can try reducing the level at which you are exercising. Try slowing down your walk or decreasing the distance of your walk." b) "Time is the #1 factor that prevents people from exercising. Exercise experts propose the 10-minute solution. On those especially busy days, try building in 10 minutes of exercise 3 times throughout the day."	-Activities 7-10 -5 photos -Time-saving tips
7. Before you begin	1	-Knowledge about preparing to exercise, and precautions to take before and during exercise		"Try to drink 1 extra cup of water for every 15 minutes of moderate exercise. Take a water bottle when you exercise and keep sippin'."	-Phone number to provincial health link provided
8. Walking program	1	-Presents a sample walking program		"If you are looking for a structured program to get you up and walking, this is the one for you. This program was developed by the National Institutes of Health. It's easy to follow and very effective at helping people get active."	-12-week step-by-step learn to walk program

9. Learn to jog program	1	-Presents a sample jogging program		"Ready to take the next step? If you are already an accomplished walker and you would like to try jogging, try this 12-week program."	-12-week step-by-step learn to job program -1 photo
10. Internet resources	1 (back page)	-Internet links to reputable exercise and cancer organizations		American College of Sports Medicine (ACSM) http://www.acsm.org For all the latest research in sports and exercise science.	-7 exercise and cancer resources provided for individuals seeking more information about exercise
11. Overall	62	-Exercise information and behavior change strategies for breast cancer survivors based on the latest scientific evidence	All TPB components and elicited beliefs targeted.		-8.5" x 5.5" pages -Coil bound -Color cover on cardstock paper -Black and white interior w/ green spot color -Glossy pages -Inspirational quotes throughout

Table 3

Theory of Planned Behavior Expert Judge Content Assessment

Theory of Planned Behavior variables	Mean item-content relevance (0-4)	Aiken's V (0-1)	p	Median	Range
Attitude	3.6	.89	<.01	4	3
Subjective Norm	3.3	.83	<.01	3	3
Perceived behavioral control	3.4	.86	<.01	4	3
Implementation intentions	3.0	.75	<.05	4	5
Overall	3.2	.81	<.01	3	3

Table 4

Samples of written feedback from expert judges and subsequent modifications

Expert Reviewer Category	Comment	Modification
Exercise Oncology Fitness Leader	"You may want to modify the jogging program. Some participants may find it challenging to jog for the specified duration (i.e., 5-7 minutes). By incorporating some brisk walking into the jogging program, it may allow for a better progression into the program."	Review of this feedback indicated that the sample jogging program in the PA guidebook might have been too intense in the initial stages of the program (e.g., jogging for 7 minutes at the beginning of the program) for a survivor that is initiating a jogging program for the first time. Therefore, jogging time increments were decreased and the recommended time spent walking was increased.
Breast Cancer Survivor	"What is the intended age? I felt that it was intended for older women."	After review, it was determined that a majority of the photos depicted females over the age of 65. We replaced some of the photos with photos of younger females that represent breast cancer survivors of a younger age (35-40 yrs).
Medical Oncologist	"Your claim that inactivity results in red blood cells not being able to carry a lot of oxygen to your body is incorrect and needs to be reworded. It has to do with the release of oxygen into the tissues of the body."	Review of this text did indeed indicate that the information was incorrect. With the assistance of the oncologist, we were able to rewrite this message to correctly communicate how exercise affects oxygen delivery in the body.
Theory of Planned Behavior Expert	"The key to implementation intentions is the 'when' and 'where' component. This component is not well represented in the booklet. You might include an activity where participants record when and where they plan to exercise."	These comments prompted us to include some planning variables in our assessment questionnaire when we proceed to further experiment with the PA guidebook (e.g., asking participants if they have made a detailed plan regarding when to exercise, where to exercise, how they will do it, and how often they will exercise).
Health Information Specialist	"Always try to have a picture to supplement the written information that reinforces the particular behavior. Also, I recommend that you make your goal-setting section more interactive. Behaviors are reinforced when people are engaged in the material to a higher degree."	Based on this judge's recommendations, photos that were reflective of the information on the respective page were inserted. Also, the goal-setting activity was made more interactive. Specifically, the participants are now required to construct their own goals based on the information and assistance that is provided to them in the PA guidebook.

CHAPTER 4:

Study 2: Effects of print materials and step pedometers on physical activity and quality of life in breast cancer survivors: A randomized controlled trial

Effects of print materials and step pedometers on physical activity and quality of life in breast cancer survivors: A randomized controlled trial

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ABSTRACT

Purpose: To determine the effects of breast cancer-specific print materials and step pedometers on physical activity (PA) and quality of life (QoL) in breast cancer survivors. **Participants and Methods**: Breast cancer survivors (N=377) were randomly assigned to receive either: (a) a standard public health recommendation for PA, (b) previously developed breast cancer-specific PA print materials, (c) a step pedometer, or (d) a combination of the two. The primary outcome was self-reported moderate/vigorous PA minutes per week (PA min•wk) at 3 months. Secondary outcomes were QoL (FACT-B), fatigue, self-reported brisk walking, and objective step counts. Assessments were conducted at baseline, 3 months, and 9 months follow-up. **Results**: Attrition was 10.3% (39 of 377) at 3 months and 71% (266/377) at 9 months. Based on intention-to-treat analyses, self-reported PA increased by 30 min•wk in the standard recommendation group compared to 70 min•wk in the print material group (mean difference=39 min•wk; 95% CI=-10 to 89; d=.25; p=.117), 89 min•wk in the pedometer group (mean difference=59 min•wk; 95% CI=11 to 108; d=.38; p=.017), and 87 min•wk in the combined group (mean difference=57 min•wk; 95% CI=8 to 106; d=.37; p=.022) at 12 weeks. For brisk walking min•wk, all three intervention groups reported significantly greater increases than the recommendation group at 3 months. The combined group also reported significantly improved QoL (mean difference=5.8; 95% CI=2.0 to 9.6; d=.33; p=.003) and reduced fatigue (mean difference=2.3; 95% CI=0.0 to 4.7; d=.25; p=.052) compared to the standard recommendation group at 3 months. At 9 months, self-reported moderate-to-vigorous PA increased by 9 min•wk in the SR group compared to 39 min•wk in the PM group (Mean difference=30 min•wk; 95% CI=-44 to 104; d=.18; p=.425), 69 min•wk in the PED group (M difference=60 min•wk; 95% CI=-13 to 132; d=.36; p=.107), and 56 min•wk in the COM group (M difference=47 min•wk; 95% CI=-26 to 119; d=.28; p=.210). Self-reported brisk walking minutes decreased in the SR group

by -6 min•wk compared to an increase of 29 min•wk in the PM group (M difference=35 min•wk; 95% CI=-20 to 91; d=.28; p=.217), 36 min•wk in the PED group (M difference=43 min•wk; 95% CI=-12 to 98; d=.34; p=.127), and 41 min•wk in the COM group (M difference=47 min•wk; 95% CI=-8.3 to 102; d=.38; p=.096). **Conclusion**: Breast-cancer specific print materials and pedometers may be effective strategies for increasing both short (e.g., 3 months) and long-term (e.g., 9 months) PA and QoL in breast cancer survivors. A combined approach appears to be optimal. ClinicalTrials.gov Identifier NCT00221221

Key Words: Physical activity, quality of life, health promotion, breast cancer

INTRODUCTION

Breast cancer and its treatments are often associated with negative side effects that affect quality of life (QoL)[1, 2] and may persist even years after treatment(s).[3-5] One intervention that has been found to enhance psychosocial and physical outcomes in breast cancer survivors is physical activity (PA).[6-9] A recent systematic review and meta-analysis found 14 randomized controlled trials that have examined the effects of exercise on breast cancer patients and survivors.[10] While only four of these studies were deemed to be of 'high quality', it was nonetheless concluded that exercise is an effective intervention to improve QoL and fatigue in breast cancer patients and survivors. A recent Cochrane systematic review corroborates these findings.[11] Since these reviews, high quality evidence continues to emerge that supports that role of PA as a safe and effective intervention to facilitate favorable QoL and fatigue profiles.[12-17]

A recent prospective cohort study of almost 3,000 breast cancer survivors reported that higher levels of PA were associated with reduced risks of breast cancer death and breast cancer recurrence.[18] Despite the reported benefits of PA, the majority of breast cancer survivors are not meeting public health guidelines (i.e., at least 150 min•wk of moderate- to vigorous-intensity PA[19]).[20-22] Given these findings, interventions to increase PA in breast cancer survivors are warranted.

Here, we report results from the Activity Promotion (ACTION) trial. The ACTION trial was a randomized controlled trial designed to determine the effects of breast cancer-specific PA print materials (PM), a step pedometer (PED), or their combination (COM), on self-reported PA and QoL in breast cancer survivors. The primary outcome was change in self-reported moderate-to-vigorous PA between baseline and 3 months. Secondary outcomes were changes in self-reported QoL, fatigue, brisk walking, and objective step counts. We hypothesized that survivors in the PM, PED, and COM groups

would report greater increases in self-reported PA and QoL compared to survivors receiving a standard recommendation (SR) for PA and that survivors in the COM group would report the greatest increases.

PARTICIPANTS AND METHODS

Setting and Participants

The trial was conducted at the University of Alberta (Edmonton, Alberta, Canada). Ethical clearance was received from the Alberta Cancer Board and the University of Alberta. Eligibility criteria included: (a) histologically confirmed stage I-IIIa breast cancer, (b) physician approval, (c) free from chronic medical and orthopedic conditions that would preclude PA (e.g., congestive heart failure, use of a mobility aid, recent knee or hip replacement), (d) ability to read and understand English, (e) completed adjuvant therapy except hormone therapy, (f) no current breast cancer, and (g) interested in increasing PA.

Design and Recruitment

This study was a four-armed, prospective randomized controlled trial. The Alberta Cancer Registry was used to identify breast cancer survivors residing in Northern Alberta, Canada diagnosed between January, 2000 and December, 2003. The trial was conducted between July and October, 2005. Each survivor's physician was required to provide approval to participate in the study. Each approved survivor was sent a letter of invitation. Interested and eligible survivors were then mailed a baseline assessment package that contained: a) cover letter, b) consent forms, c) baseline questionnaire, d) pedometer, e) 7-day step log, and f) postage paid business reply envelope. Before randomization, all survivors were required to complete and submit the baseline questionnaire and a 7-day pedometer step test which consisted of wearing a pedometer for 7 days and recording their daily step totals.

Random Assignment to Groups

Survivors were randomly assigned to one of four groups using a computer generated random numbers list (GraphPad Software, San Diego, CA, USA). A research assistant generated the group assignments in sequentially numbered and sealed opaque envelopes. The envelopes were concealed from the project coordinator. Survivors were notified via telephone of their random group allocation the following day (i.e., SR, PM, PED, or COM).

Intervention Groups

All groups received a standard recommendation to perform 30 minutes of moderate-to-vigorous PA on 5 days of the week. Participants meeting PA guidelines at baseline were encouraged to further increase their minutes and/or days spent engaged in PA. The SR group received no further intervention materials. The PM group received a copy of *Exercise for health: An exercise guide for breast cancer survivors*[23]. A detailed description of the guidebook is published elsewhere.[23] The PED group received a Digi-Walker SW-200 pedometer (i.e., New Lifestyles Inc., Lee's Summit, MO, USA) and a 12-week step calendar. The COM group received both interventions (i.e., print material and pedometer). Survivors randomized to the COM and PED groups were instructed to wear their pedometer everyday for the 3-month duration of the study (i.e., 84 days) and record their daily step totals at the end of each day. The SR and PM groups only wore their pedometer for baseline and 3-month assessments. Participants were not instructed to achieve a step target (e.g., 10,000 steps).

MEASURES

Demographic and medical characteristics assessed included age, marital status, education, family income, employment status, height, weight, co-morbidities, body mass index (BMI), and menopausal status. Medical data were extracted from the Alberta

Cancer Registry and included tumor stage and grade, treatment(s) received, and time since diagnosis.

Adherence to the guidebook was assessed by asking survivors a) how many times they read the entire guidebook and b) how long they spent reading the guidebook. Survivors that received a guidebook and completed the trial (i.e., n=163) were asked if a) they found the guidebook helpful, b) the information about PA was informative, c) the guidebook helped to overcome barriers, and d) setting goals was effective in helping increase PA. Survivors indicated their responses on a 5-point Likert scale ranging from 1 (not at all) to 5 (very much). We report the average response for the entire sample as well as the percentage of survivors that indicated a score of at least 3 (somewhat) on the Likert scale.

Self-reported PA was assessed at all three time points (i.e., baseline, 3 months, 9 months) by the leisure score index (LSI) of the Godin Leisure-Time Exercise Questionnaire (GLTEQ).[24] The LSI contains three questions that assess the average frequency of mild, moderate, and strenuous exercise during free time in a typical week in the past month. We modified the LSI so that average duration was also provided. For the present study, we calculated the total minutes of moderate plus strenuous exercise for each of the three time periods (i.e., baseline, 3 months, 9 months). An independent evaluation of the GLTEQ found its reliability to compare favorably to nine other self-report measures of exercise based on various criteria including test-retest scores, objective activity monitors, and fitness indices. The LSI demonstrated a one-month test-retest reliability of .62 and concurrent validity coefficients of .32 with an objective indicator (CALTRAC accelerometer), .56 with VO_{2max} (as measured by expired gases), and -.43 with percent body fat (as measured by hydrostatic weighing).[25]

We also collected self-report brisk walking using the LSI format. The item assessed the average frequency and duration of brisk walking (defined as *'walking like*

you were late for an appointment') during a typical week in the past month. Objective walking behavior was assessed via a 7-day step test using the Digi-Walker pedometer. Survivors completed this assessment at baseline and once again at 3 months and 9 months. During the 7 days, survivors recorded their daily step counts at the end of the day, and reset the pedometer to zero each morning.

QoL was assessed at all three time points by the Functional Assessment of Cancer Therapy – Breast (FACT-B) scale.[26, 27] The FACT scale contains items pertaining to the consequences of a cancer diagnosis and its related treatments (e.g., fatigue, symptom expression). The FACT-B includes five subscales designed to measure physical well-being (PWB: 7 items pertaining to the perceived and observed bodily function or disruption), functional well-being (FWB: 7 items pertaining to one's ability to perform the activities related to personal needs, ambitions, and social role), emotional well-being (EWB: 6 items pertaining to positive affect as well as negative affect), social well-being (SWB: 7 items pertaining to coping with and adapting to illness, and maintenance of gratifying relationships with friends and significant others), and symptoms specific to breast cancer (BCS: 10 items pertaining to unique concerns related to breast cancer such as altered sense of femininity, feelings of decreased attractiveness, and problems associated with treatment-related arm swelling). The PWB, FWB, EWB, and SWB subscales can be summed to form the FACT-General (FACT-G) score. Fatigue was assessed using the Fatigue Scale (FS)[28] from the FACT measurement system. On all QoL and fatigue scales, higher scores represent better QoL/fatigue, or less severe symptoms. All FACT questions are rated on a 5-point Likert scale ranging from 0 = "not at all" to 4 = "very much." On all QoL subscales, higher scores represent better QoL, or less severe symptoms. The FACT scales are brief, easy to administer, and have suitable evidence of internal consistency, test-retest reliability, and convergent and discriminant validity.[27] Using both distribution and anchor-based

methods, researchers have suggested clinically important differences (CID) for the FACT-An = 7.0; FACT-G = 4.0; TOI-An = 7.0; TOI-F = 5.0; and FS = 3.0.[29, 30]

Sample Size Calculation and Statistical Analyses

To detect a medium standardized effect (d=.50) on our primary outcome (i.e., self-reported PA at 3 months) with a power of .80 and a two-tailed alpha <.05, we needed 63 survivors per group. Baseline comparisons were performed using univariate analysis of variance (ANOVA) for continuous variables (e.g., self-reported PA and QoL variables) and chi-square analyses for categorical variables (e.g., breast cancer stage, employment). For all analyses, we employed the intention-to-treat (ITT) approach.[31] Linear mixed-model analyses[32] were used to assess differences in group changes from baseline to 3 months, and baseline to 9 months. Linear mixed models use all available data and provide a valid analysis when data are missing at random. As a sensitivity analysis, we also analyzed the data using last-observation-carried-forward and for completers only. There were no substantive differences among the three analytical approaches and the conclusions drawn from each analyses did not differ. Therefore, we present the results from the mixed model analyses. For all self-reported PA data, outliers (i.e., Z-score > 3.29) remained in the data but were adjusted to be one unit less than the next most extreme score.[33] The primary hypothesized comparisons were the three intervention groups (i.e., PM, PED, COM) compared to SR. Secondary hypothesized comparisons were the COM group versus PM and PED. Effect sizes (*d*) for all analyses were computed based on the mixed model fits and are interpreted as d=0.20 (small), d=0.50 (medium), and d=0.80 (large).[34] No corrections were made for multiple comparisons. Therefore, care must be exercised in the interpretation of statistical significance due to the potential false positive findings.

RESULTS

Flow of Participants through the Trial

Figure 1 shows the flow of participants through the trial. Because of the high level of interest, we randomized 377 participants instead of our planned 252. Overall retention for this study was 89.7% (338/377) at 3 months and 71% (266/377) at 9 months and did not statistically differ among groups at both postintervention time points.

Baseline Characteristics and Sample Generalizability

Baseline demographic, medical, and behavioral characteristics for all randomized survivors are presented in Table 1. The groups were balanced on all study measures except the PED group had a higher proportion of postmenopausal survivors (p=.017). To examine the representativeness of our sample, we compared our sample of survivors (n=377) to non-participants (n=1213) on the medical variables we had available to us (months since diagnosis, breast cancer morphology, breast cancer stage, and treatment(s) received). Study participants were on average 11 months more proximal to their date of diagnosis. Furthermore, a greater proportion of study participants received chemotherapy (54%) than those who did not participate (41%). We also compared survivors that completed the trial (n=338) to non-completers (n=39) on sociodemographic (i.e., age, education, income, employment, ethnicity, residence) and medical variables (i.e., months since diagnosis, breast cancer stage, treatment(s) received, BMI). There were no significant differences on any variable.

Adherence to the Intervention Materials at 3 Months

Survivors in the two groups that received pedometers as an intervention (i.e., COM and PED; n=187) recorded their pedometer steps on 83.3% (70/84) of study days. Survivors in the two groups that received PM (i.e., COM and PM; n=163) reported reading the entire PM an average of 2.1 times for an average of 113 minutes.

Evaluation of the Physical Activity Guide at 3 Months

Of survivors that received the PM and completed the trial (i.e., n=163), 76.5% found the guidebook helpful (overall sample Mean=3.3), 88.3% found the information about PA informative (M=3.8), 68.9% reported that setting PA goals helped them increase PA (M=3.1), and 45.7% reported that the guidebook helped them overcome PA barriers (M=2.4).

Changes in Self-Reported Moderate/Vigorous Physical Activity at 3 Months

Table 2 presents the PA data. Baseline values for PA did not differ between groups. From baseline to 3 months, self-reported moderate-to-vigorous PA increased by 30 min•wk in the SR group compared to 70 min•wk in the PM group (Mean difference=39 min•wk; 95% CI=-10 to 89; d=.25; p=.117), 89 min•wk in the PED group (M difference=59 min•wk; 95% CI=11 to 108; d=.38; p=.017), and 87 min•wk in the COM group (M difference=57 min•wk; 95% CI=8 to 106; d=.37; p=.022).

Changes in Self-Reported and Objectively Measured Walking Behavior at 3 Months

Self-reported brisk walking minutes did not change (i.e., 0) in the SR group compared to an increase of 72 min•wk in the PM group (M difference=72 min•wk; 95% CI=20 to 123; d=.48; p=.006), 93 min•wk in the PED group (M difference=94 min•wk; 95% CI=43 to 144; d=.62; p=.000), and 58 min•wk in the COM group (M difference=58 min•wk ; 95% CI=6 to 109; d=.39; p=.028). There were no significant differences between any of the groups on objectively measured steps/day.

Changes in Quality of life at 3 Months

Table 3 presents the QoL data. The baseline value for the QoL outcomes did not differ between groups. QoL (FACT-B) improved by 6.9 points in the COM group compared to 1.1 points in the SR group (M difference=5.8; 95% CI=2.0 to 9.6; d=.33; p=.003). Fatigue improved by 3.6 points in the COM group compared to 1.3 points SR group (M difference=2.3; 95% CI=0.0 to 4.7; d=.25; p=.052). There were no significant

differences between any of the groups on BMI. Changes in PA were associated with changes in fatigue (r=.17, p=002) but not QoL (r=.09, p=.087) whereas changes in brisk walking were associated with changes in both fatigue (r=.14, p=013) and QoL (r=.20, p<.001).

Adherence to the Intervention Materials at 9 Months

38% (n=52) of survivors in the two groups that received pedometers as an intervention (i.e., COM and PED; n=136) reported that they continued to wear their pedometer during the past 6-month follow-up period. Survivors in the two groups that received PM (i.e., COM and PM; n=127) reported reading the entire PM an average of 1.3 times for an average of 42 minutes during the 6-month follow-up period.

Changes in Self-Reported Moderate/Vigorous Physical Activity at 9 Months

Table 4 presents the PA data at 9 months. From baseline to 6 months, self-reported moderate-to-vigorous PA increased by 9 min•wk in the SR group compared to 39 min•wk in the PM group (Mean difference=30 min•wk; 95% CI=-44 to 104; d=.18; p=.425), 69 min•wk in the PED group (M difference=60 min•wk; 95% CI=-13 to 132; d=.36; p=.107), and 56 min•wk in the COM group (M difference=47 min•wk; 95% CI=-26 to 119; d=.28; p=.210).

Changes in Self-Reported Walking Behavior at 9 Months

Self-reported brisk walking minutes decreased in the SR group by -6 min•wk compared to an increase of 29 min•wk in the PM group (M difference=35 min•wk; 95% CI=-20 to 91; d=.28; p=.217), 36 min•wk in the PED group (M difference=43 min•wk; 95% CI=-12 to 98; d=.34; p=.127), and 41 min•wk in the COM group (M difference=47 min•wk; 95% CI=-8.3 to 102; d=.38; p=.096).

Changes in Quality of life at 9 Months

Table 5 presents the QoL data at 9 months. QoL (FACT-B) improved by 4.9 points in the COM group compared to 2.9 points in the SR group (M difference=2.0; 95%

CI=-5.8 to 9.7; d=.11; p=.622). Fatigue improved by 1.9 points in the COM group compared to 1.7 points SR group (M difference=0.1; 95% CI=-4.1 to 4.3; d=.01; p=.962). There were no significant differences between any of the groups on BMI at 9 months.

DISCUSSION

In support of our hypothesis, we found that all three intervention groups (i.e., PM, PED, and COM) reported significantly greater increases in self-reported PA and/or brisk walking than the SR group at 3 months. The COM group, however, was not significantly more active than the PM or PED groups. There were no differences in objective walking behavior across the groups. For our second hypothesis, we found that survivors in the COM group reported significantly greater improvements in QoL and reductions in fatigue than survivors in the SR group. Although no statistical differences emerged at 6 months follow-up, substantive and clinically relevant differences between the intervention groups and the SR group on both self-reported PA and brisk walking indicate that print materials and pedometers may have merit in assisting survivors in sustaining and maintaining their PA and walking behaviors.

The strengths of our trial include the first study to examine the effects of print material and pedometers on self-reported PA and QoL in breast cancer survivors, the randomized controlled trial design, the use of a standard recommendation as our comparison group, the use of a theoretically-based and previously-evaluated print material PA intervention, high fidelity to the intervention materials, the large sample size, and minimal loss to follow-up at 3 months. Our study was limited by the self-report of PA, a 29% loss-to-follow up rate at 9 months, and failure to blind survivors from their pedometer step count during baseline and postintervention testing. Moreover, given the 22 secondary comparisons at the 3-month time-point, we would expect one false discovery by chance if all of these comparisons were actually null. Finally, given that our

study was conducted during the warmer months (July to October), it is unknown if the intervention would be equally effective during the more difficult winter months.

In our study, survivors in the PM, PED, and COM intervention groups, compared to the SR group, increased their moderate-to-vigorous PA min•wk by about 40-60 min•wk and their brisk walking by about 60-90 min•wk at 3 months. In other populations, research examining print-mediated PA interventions has also provided evidence of efficacy, efficiency, and cost-effectiveness.[35-38] Few studies, however, have focused on cancer survivors. Jones and colleagues[39] examined the effects of an oncologist's recommendation to exercise on self-reported PA behavior in breast cancer survivors beginning adjuvant treatment. Results indicated that breast cancer survivors receiving a recommendation reported significantly higher self-reported PA (i.e., ~30 minutes per week) over a 5-week period than those not receiving a recommendation.

Most comparable to our study, Demark-Wahnefried and colleagues[40] examined the effects of a home-based diet and exercise program delivered via telephone counseling and print materials in a mixed sample of 182 older breast and prostate cancer survivors. Results showed a significant improvement in self-reported diet quality but not in self-reported PA or QoL over a 6-month intervention period and a six month follow-up. Reasons for the difference in the PA findings between the two studies are unknown but could be due to the use of different self-report measures of PA (the LSI versus the CHAMPS), different theoretical models to develop intervention materials (the theory of planned behavior versus social cognitive theory and the transtheoretical model), our larger sample size (377 versus 182), our more homogeneous sample (breast cancer survivors versus breast and prostate combined), and/or our younger sample (58 versus 72 years old). In any case, our data suggest that simple and low-cost tools such as breast cancer-specific PM and/or objective PA monitoring devices may help breast cancer survivors increase their PA.

We found no change in objectively measured walking across all 4 groups. Pinto and colleagues[151] found similar results in that their home-based PA intervention did not demonstrate significant effects on an objective measure of PA (i.e., accelerometer), while self-reported PA did increase. Other pedometer-based interventions have yielded positive changes in pedometer step counts in individuals with type II diabetes[41] and COPD patients[42], however, both these interventions included other behavior change strategies to complement the pedometer (e.g., telephone counseling, meetings). There are two likely explanations for the null effect of our interventions on step counts compared to self-reported brisk walking. First, survivors in our study were not advised to achieve a specific step count (i.e., 10,000 steps) or to increase their number of steps per day. Given that all survivors were encouraged to engage in PA at least at a moderate intensity level, it is possible that survivors replaced light/casual walking steps with more moderate or purposeful steps to achieve the moderate intensity recommendation. Second, it is possible that our 7-day monitoring period at baseline and postintervention may not have been representative of PA over the entire 3-month period in which objective step counts were assessed. It is possible that the SR and PM participants used their pedometers, although instructions were given to no use them during the 3 months.

The likelihood that self-report or social desirability bias affected responses on the self-report PA questionnaires is of concern. If a response bias was present, however, we would have expected this bias across all four groups given that all groups were asked to increase PA and to provide self-report assessments of PA. Indeed, the 30 minute increase in PA we observed in the SR group (i.e., control) may partly reflect this bias, which is why we selected a standard recommendation group as our comparison group. Moreover, recent research has suggested that there is minimal evidence of social desirability for the self-report exercise scale that we used.[43] Finally, poor compliance with the objective measure is also unlikely to explain this difference because we observed

extremely high compliance with the 7-day baseline and 3-month objective measurements. Specifically, 97.3% (367/377) and 97.0% (328/338) of participants recorded their steps on all 7 monitoring days at baseline and 3 months, respectively.

The second main finding of our trial was that the COM intervention had a beneficial effect on QoL and fatigue compared to the SR group. The improvements in the COM group approached the minimal thresholds for clinically important differences (CIDs) for the FACT-B and FS (i.e., 7.0 points, and 3.0 points, respectively).[29, 30] A CID is defined as the smallest difference which individuals and healthcare providers perceive as beneficial and which would mandate a change in the individual's management. Standardized effect sizes (*d*) were in the small-to-moderate range (i.e., .25 to .50). The observed effect sizes meet or exceed that reported in a meta-analysis of other cognitive-behavioral interventions for cancer survivors.[44] The improvements in fatigue in the COM group are of particular relevance given that fatigue is a common symptom that can last well into survivorship.[45] Nonetheless, future research implementing rigorous RCT methodology is warranted to further understand the role of PA in enhancing QoL and fatigue in breast cancer survivors.

Given that our sample was on average 39 months post treatment, it is likely that some items on the FACT-B may no longer be relevant (e.g., "I have nausea"). Therefore, other QoL scales may be more sensitive to detecting changes in QoL in long term breast cancer survivors based on PA interventions (e.g., Quality of Life in Adult Cancer Survivors[46]). Therefore, it is possible that the QoL results observed in this study may be conservative estimates.

At 9 months, we found no statistically significant differences between groups on all QoL variables we assessed (i.e., QoL and fatigue). Although no statistical differences emerged, substantive and clinically meaningful differences were observed between all three intervention groups (i.e., PM, PED, COM) and the SR group on self-report PA and

brisk walking. These results indicated that survivors in the intervention groups were still reported an extra 30-60 min•wk of PA and 35-47 min•wk of brisk walking when compared to the SR group at 9 months. These differences were indicative of small-to-medium effects. Alternatively, one could speculate that an difference of an extra 30 min•wk of PA is the equivalent of one extra day per week of PA. The decrease in sample size at the 9-month time point along with a noticeable increase in variability in self-reported PA in the PED group may explain why statistical significance was not achieved. These results suggest that print material and pedometers have merit in promoting long term (i.e., 9 months) PA maintenance. Research examining print material and PA behavior is typically suggestive of diminished effects at the long-term maintenance time-points.[36, 37] It appears that the utilization of user-friendly self-monitoring devices such as a pedometer may enhance the likelihood of PA behavior maintenance. Researchers and practitioners should incorporate more interactive strategies during follow-up to encourage PA behavior maintenance (e.g., telephone calls, frequent mailings).

Our data suggest that PA behavior change modalities such as PM and a step pedometer may have beneficial effects on self-reported PA and QoL in breast cancer survivors both at 3 months and 9 months (with the exception of QoL and fatigue). Combining print material with a pedometer showed the greatest benefits for QoL and fatigue at 3 months. Further research should determine if other distance-based strategies are effective in assisting survivors in becoming more physically active. The distance-based option is low-cost [e.g., print materials=$14.00US per participant (includes design costs); pedometers=$16.00US per participant] and may have greater generalizability and ecological validity for long-term cancer survivors than clinic-based interventions. These types of interventions and programs can be implemented in most communities and may consequently benefit the greatest number of breast cancer survivors.

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Authors' Disclosures of Potential Conflicts of Interest

We indicate no potential conflicts of interest.

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Table 1.

Baseline demographic, medical, and behavioral profile of participants overall and by group assignment.

Variable	Overall (N=377)	SR (n=96)	PM (n=94)	PED (n=94)	COM (n=93)
Demographic Profile					
Age, Mean (Rg), y	58 (30-90)	57 (37-90)	57 (31-88)	58 (34-75)	58 (38-86)
Age => 60, No. (%)	134 (35.5%)	35 (36.5%)	28 (29.8%)	34 (36.2%)	37 (39.8%)
Married, No. (%)	272 (72.1%)	70 (72.9%)	62 (66.0%)	71 (75.5%)	69 (74.2%)
Completed university, No. (%)	112 (29.7%)	37 (38.5%	35 (37.2%)	40 (42.6%)	38 (40.9%)
Income >$80,000/year, No. (%)[1]	99 (26.3%)	28 (29.2%)	19 (20.2%)	24 (25.5%)	28 (30.1%)
Full-time employed, No. (%)	114 (30.2%)	32 (33.3%)	29 (30.9%)	29 (30.9%)	24 (25.8%)
Canadian ethnicity, No. (%)	160 (42.4%)	36 (37.5%)	39 (41.5%)	39 (41.5%)	46 (49.5%)
European ethnicity, No. (%)	85 (22.6%)	21 (21.9%)	20 (21.3%)	18 (19.2%)	26 (28.0%)
Rural resident, No. (%)	112 (29.7%)	31 (32.3%)	25 (26.6%)	30 (31.9%)	26 (28.0%)
Medical Profile					
Weight, Mean (SD), kg	74.7 (15.8)	76.4 (17.8)	74.5 (16.4)	74.1 (15.6)	73.5 (13.4)
BMI, Mean (SD), kg/m^2	27.7 (5.6)	28.2 (6.7)	27.9 (5.5)	27.4 (5.3)	27.2 (4.6)
Overweight, No. (%)	141 (37.4%)	34 (35.4%)	31 (33.0%)	31 (33.0%)	45 (48.4%)
Obese, No. (%)	111 (29.4%)	31 (32.2%)	31 (33.0%)	29 (30.9%)	20 (21.5%)
Obese class I, No. (%)	77 (20.4%)	17 (17.7%)	23 (24.4%)	23 (24.4%)	14 (15.1%)
Obese class II, No. (%)	17 (4.5%)	9 (9.4%)	3 (3.2%)	2 (2.1%)	3 (3.2%)
Obese class III, No. (%)	17 (4.5%)	5 (5.2%)	5 (5.3%)	4 (4.3%)	3 (3.2%)
Postmenopausal, No. (%)	232 (62.0%)	55 (57.3%)	50 (53.2%)	70 (74.5%)	57 (61.3%)
Months postdiagnosis, Mean (SD),	39.0 (11.3)	39.9 (11.2)	38.9 (10.7)	38.5 (11.5)	38.7 (11.6)
Disease stage, No. (%)					
I (T1N0)	194 (51.5%)	48 (50%)	53 (56.4%)	38 (40.4%)	55 (59.1%)
IIa (T1N1,T2N0)	111 (29.4%)	27 (28.1%)	26 (27.7%)	35 (37.2%)	23 (24.7%)
IIb (T2N1,T3N0)	50 (13.3%)	13 (13.5%)	11 (11.8%)	15 (16.0%)	11 (11.8%)
IIIa (T1N2,T2N2,T3N1-2)	22 (5.8%)	8 (12.0%)	4 (4.3%)	6 (6.4%)	4 (4.3%)

Treatments					
Surgery, No. (%)	377 (100%)	96 (100%)	94 (100%)	94 (100%)	93 (100%)
Chemotherapy, No. (%)	203 (53.9%)	52 (54.2%)	47 (54%)	56 (59.6%)	48 (51.6%)
Radiation, No. (%)	261 (69.2%)	65 (67.8%)	62 (66.0%)	75 (79.8%)	59 (63.4%)
Hormones, No. (%)	252 (66.8%)	65 (67.7%)	66 (70.2%)	63 (67.0%)	58 (62.4%)
Current Hormone Therapy					
Tamoxifen, No. (%)	182 (48.3%)	47 (49.0%)	37 (39.4%)	51 (54.3%)	47 (50.0%)
Aromatase inhibitor, No. (%)	42 (11.1%)	12 (12.5%)	13 (13.8%)	11 (11.7%)	6 (6.5%)
Comorbidities					
Diabetes, No. (%)	41 (10.9%)	10 (10.4%)	8 (11.8%)	12 (12.8%)	11 (11.8%)
Hypertension, No. (%)	122 (32.4%)	31 (32.3%)	27 (28.7%)	32 (34.0%)	32 (34.4%)
High cholesterol, No. (%)	100 (26.5%)	22 (22.9%)	27 (28.7%)	26 (27.7%)	25 (26.9%)
Behavioral Profile					
Current exerciser, No. (%)	127 (33.7%)	35 (36.5%)	32 (34.0%)	32 (34.0%)	28 (30.1%)
Exercise limitation*, No. (%)	117 (31%)	27 (28.1%)	31 (33.0%)	28 (28.8%)	31 (33.3%)

Data are presented as the mean (standard deviation) for continuous variables and the frequency (percentage) for categorical variables.
SD=standard deviation; No.=number; BMI=body mass index.
[1]N=356.
SR=standard recommendation; PM=print material; PED=pedometer; COM=print material and pedometer combined.
Obese class I=BMI 30.0 – 34.9; Obese class II=BMI 35.0 – 39.9; Obese class III=BMI $\geq$ 40.0.
*Denotes survivors that indicated that a health condition limited their exercise participation either 1) a little, 2) somewhat, 3) quite a lot, or 4) completely.

Table 2.

Effects of print materials and pedometers on physical activity and walking behavior in breast cancer survivors at 3 months (N=377).

Variable	Baseline* M (SD)	3 months** M (SD)	Mean change† M [95% CI]	Between groups comparison M [95% CI]	P
Moderate/vigorous PA combined min•wk					
SR (n=96)	133 (144)	163 (121)	+30 [-4 to 65]	COM vs. SR: +57 [8 to 106]	.022
PM (n=94)	126 (159)	197 (160)	+70 [34 to 105]	PED vs. SR: +59 [11 to 108]	.017
PED (n=94)	123 (154)	214 (178)	+89 [55 to 123]	PM vs. SR: +39 [-10 to 89]	.117
COM (n=93)	119 (163)	211 (169)	+87 [53 to 123]	COM vs. PED: -2 [-63 to 67]	.947
				COM vs. PM: +21 [-45 to 87]	.532
Brisk walking min•wk					
SR (n=96)	101 (143)	102 (105)	+0 [-36 to 36]	COM vs. SR: +58 [6 to 109]	.028
PM (n=94)	77 (121)	153 (206)	+72 [35 to 108]	PED vs. SR: +94 [43 to 144]	.000
PED (n=94)	69 (118)	162 (221)	+93 [57 to 129]	PM vs. SR: +72 [20 to 123]	.006
COM (n=93)	64 (105)	121 (146)	+58 [21 to 94]	COM vs. PED: -36 [-98 to 27]	.260
				COM vs. PM: -18 [-81 to 45]	.576
7-day pedometer stepcount					
SR (n=96)	7938 (3905)	8028 (3457)	+91 [-1021 to 1203]	COM vs. SR: -301 [-1887 to 1304]	.710
PM (n=94)	8306 (3831)	8114 (3778)	-191 [-1323 to 941]	PED vs. SR: -146 [-1718 to 1425]	.885
PED (n=94)	8476 (3248)	8420 (5226)	-55 [-1166 to 1055]	PM vs. SR: -282 [-1870 to 1304]	.727
COM (n=93)	7993 (3559)	7783 (3048)	-210 [-1341 to 921]	COM vs. PED: -155 [-1740 to 1430]	.848
				COM vs. PM: -19 [-1619 to 1581]	.982

M=mean (minutes or steps per day); SD=standard deviation; CI=confidence interval.
*Baseline data based on all study participants (N=377).
**3 month data based on participants that completed the 3 month assessment (n=338).
†Mean change scores based on mixed model analysis. Note: Mean change score may not precisely reflect postintervention minus baseline scores given that means are mode-fitted.
SR=standard recommendation; PM=print material; PED=pedometer; COM=print material and pedometer combined.

Table 3.

Effects of print materials and pedometers on quality of life and fatigue in breast cancer survivors at 3 months (N=377).

Variable	Baseline* M (SD)	3 months** M (SD)	Mean change† M [95% CI]	Between groups comparison M [95% CI]	P
FACT-B (0-148)					
SR (n=96)	117.5 (17.3)	119.2 (17.3)	+1.1 [-3.7 to 1.6]	COM vs. SR: +5.8 [2.0 to 9.6]	.003
PM (n=94)	115.3 (17.9)	118.3 (16.2)	+1.7 [-1.0 to 4.4]	PED vs. SR: +1.8 [-1.9 to 5.5]	.347
PED (n=94)	117.4 (17.2)	120.5 (16.1)	+2.9 [0.2 to 5.5]	PM vs. SR: +0.6 [-3.2 to 4.4]	.752
COM (n=93)	115.1 (18.7)	121.8 (16.5)	+6.9 [4.2 to 9.6]	COM vs. PED: +3.6 [-3.6 to 10.7]	.326
				COM vs. PM: +4.9 [-2.2 to 12.1]	.177
FS (0-52)					
SR (n=96)	41.1 (9.3)	42.6 (8.7)	+1.3 [0.4 to 2.9]	COM vs. SR: +2.3 [0.0 to 4.7]	.052
PM (n=94)	39.7 (9.7)	42.2 (8.8)	+1.8 [0.1 to 3.5]	PED vs. SR: +1.2 [-1.1 to 3.5]	.310
PED (n=94)	40.3 (9.9)	42.8 (7.6)	+2.5 [0.8 to 4.1]	PM vs. SR: +0.5 [-1.9 to 2.9]	.673
COM (n=93)	39.8 (10.3)	43.1 (8.9)	+3.6 [1.9 to 5.3]	COM vs. PED: +1.1 [-2.7 to 4.9]	.583
				COM vs. PM: +1.8 [-2.0 to 5.7]	.349

M=mean; SD=standard deviation; CI=confidence interval.
*Baseline data based on all study participants (N=377).
**3 month data based on participants that completed the 3 month assessment (n=338).
†Mean change scores based on mixed model analysis. Note: Mean change score may not precisely reflect postintervention minus baseline scores given that means are mode-fitted.
FACT-B=functional assessment of cancer therapy-breast; FS=fatigue scale.
SR=standard recommendation; PM=print material; PED=pedometer; COM=print material and pedometer combined.

Table 4.

Effects of print materials and pedometers on physical activity and walking behavior in breast cancer survivors at 9 months (N=377).

Variable	Baseline* M (SD)	9 months** M (SD)	Mean change† M [95% CI]	Between groups comparison M [95% CI]	P
Moderate/vigorous PA combined min•wk					
SR (n=96)	133 (144)	142 (126)	+9 [-42 to 60]	COM vs. SR: +47 [-26 to 119]	.210
PM (n=94)	126 (159)	165 (170)	+39 [-14 to 92]	PED vs. SR: +60 [-13 to 132]	.107
PED (n=94)	123 (154)	192 (218)	+69 [17 to 120]	PM vs. SR: +30 [-44 to 104]	.425
COM (n=93)	119 (163)	175 (182)	+56 [4 to 107]	COM vs. PED: -13 [-86 to 60]	.725
				COM vs. PM: +17 [-57 to 91]	.429
Brisk walking min•wk					
SR (n=96)	101 (143)	94 (124)	-6 [-45 to 33]	COM vs. SR: +47 [-8 to 102]	.096
PM (n=94)	77 (121)	106 (128)	+29 [-11 to 69]	PED vs. SR: +43 [-12 to 98]	.127
PED (n=94)	69 (118)	106 (127)	+36 [-2 to 75]	PM vs. SR: +35 [-21 to 91]	.217
COM (n=93)	64 (105)	105 (131)	+41 [1 to 80]	COM vs. PED: +4 [-51 to 59]	.882
				COM vs. PM: +12 [-44 to 68]	.679

M=mean (minutes or steps per day); SD=standard deviation; CI=confidence interval.
*Baseline data based on all study participants (N=377).
**9 month analyses based on participants that completed the 9 month assessment (n=266).
†Mean change scores based on mixed model analysis. Note: Mean change score may not precisely reflect postintervention minus baseline scores given that means are mode-fitted.
SR=standard recommendation; PM=print material; PED=pedometer; COM=print material and pedometer combined.

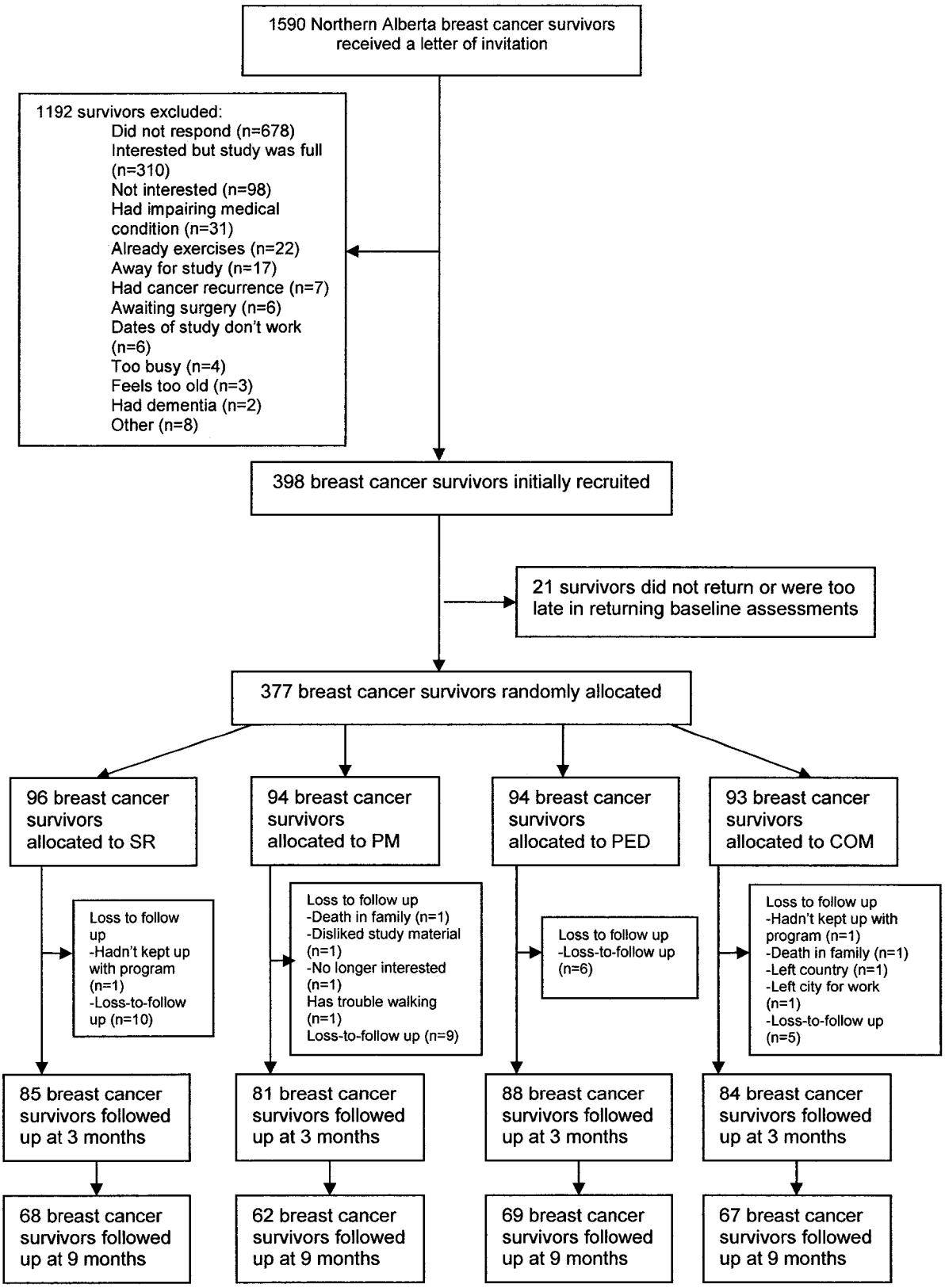
Table 5.

Effects of print materials and pedometers on quality of life and fatigue in breast cancer survivors at 9 months (N=377).

Variable	Baseline* M (SD)	9 months** M (SD)	Mean change† M [95% CI]	Between groups comparison M [95% CI]	P
FACT-B (0-148)					
SR (n=96)	117.5 (17.3)	120.4 (16.4)	+2.9 [-2.5 to 8.4]	COM vs. SR: +2.0 [-5.8 to 9.7]	.622
PM (n=94)	115.3 (17.9)	116.9 (16.9)	+1.6 [-4.1 to 7.3]	PED vs. SR: +1.0 [-6.7 to 8.8]	.797
PED (n=94)	117.4 (17.2)	121.4 (14.5)	+4.0 [-1.5 to 9.4]	PM vs. SR: -1.35 [--9.2 to 6.5]	.736
COM (n=93)	115.1 (18.7)	120.0 (20.9)	+4.9 [-0.6 to 10.4]	COM vs. PED: +0.9 [-6.8 to 8.7]	.813
				COM vs. PM: +2.4 [-5.5 to 10.3]	.556
FS (0-52)					
SR (n=96)	41.1 (9.3)	42.8 (9.0)	+1.7 [-1.3 to 4.6]	COM vs. SR: +0.1 [-4.1 to 4.3]	.962
PM (n=94)	39.7 (9.7)	41.5 (9.0)	+1.9 [-1.2 to 4.9]	PED vs. SR: +0.2 [-4.1 to 4.2]	.992
PED (n=94)	40.3 (9.9)	42.0 (8.1)	+1.7 [-1.3 to 4.7]	PM vs. SR: +0.2 [-4.0 to 4.4]	.926
COM (n=93)	39.8 (10.3)	41.5 (9.1)	+1.8 [-1.2 to 4.7]	COM vs. PED: -0.7 [-4.2 to 4.1]	.971
				COM vs. PM: +0.1 [-4.2 to 4.1]	.963

M=mean; SD=standard deviation; CI=confidence interval.
*Baseline data based on all study participants (N=377).
**9 month analyses based on participants that completed the 9 month assessment (n=266).
†Mean change scores based on mixed model analysis. Note: Mean change score may not precisely reflect postintervention minus baseline scores given that means are mode-fitted.
FACT-B=functional assessment of cancer therapy-breast; FS=fatigue scale.
SR=standard recommendation; PM=print material; PED=pedometer; COM=print material and pedometer combined.

Figure 1. Flow of Participants through the Study



CHAPTER 5:

Study 3: Analyzing theoretical mechanisms of physical activity behavior change in breast cancer survivors: Results from a randomized controlled trial

Analyzing Theoretical Mechanisms of Physical Activity Behavior Change in Breast Cancer Survivors: Results from the Activity Promotion (ACTION) Trial

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ABSTRACT

Background: Promoting physical activity (PA) in breast cancer survivors may enhance quality of life (QoL) and reduce the risk of recurrence and early death from breast cancer. We previously reported that a PA behavior change intervention based on the theory of planned behavior (TPB) increased PA and QoL in breast cancer survivors. Here, we examine the theoretical mechanisms of these changes. **Purpose:** To examine the effects of our interventions on TPB variables and to determine if the changes in PA were mediated by changes in the TPB. **Methods:** Breast cancer survivors (N=377) were randomly assigned to receive either a standard public health recommendation for PA (SR group) or one of two TPB-based behavior change interventions (INT group) that consisted of either TPB-based breast cancer-specific print materials, or print materials combined with a step pedometer. The primary outcomes were changes in the TPB constructs from baseline to 4 weeks. **Results:** Attrition was 10.3% (39 of 377). Compared to the SR group, survivors in the INT (i.e., those receiving one of the two TPB-based interventions) reported more favorable changes in instrumental attitude (mean difference=0.17; 95% CI=-0.01 to 0.33; d=.26; p=.041) and intention (mean difference=0.39; 95% CI=0.13 to 0.65; d=.37; p=.004). Structural equation modeling demonstrated that INT had direct effects on PA behavior change (β=.13, p=.023) as well as indirect effects through instrumental attitude (β=.12, p=.033), injunctive norm (β=.10, p=.083), and intention (β=.13, p=.011). Several specific salient beliefs were also changed. **Conclusions:** Our TPB-based behavior change interventions improved constructs in the TPB and these improvements partially mediated the effects of our TPB interventions on PA behavior change. The TPB warrants further research as a framework for developing, implementing, and evaluating PA behavior change interventions in breast cancer survivors.

INTRODUCTION

Physical activity (PA) is an effective intervention to improve quality of life (QoL), cardiorespiratory fitness, physical functioning and fatigue in breast cancer patients and survivors (1, 2). Furthermore, a recent prospective cohort study of almost 3,000 breast cancer survivors reported that higher levels of PA were associated with reduced risks of death, breast cancer death, and breast cancer recurrence (3). Despite the reported benefits of PA, the majority of breast cancer survivors are not meeting public health guidelines (i.e., at least 150 min•wk of moderate- to vigorous-intensity PA) (4-6). For example, Irwin and colleagues surveyed over 800 breast cancer survivors 4 to 12 months postdiagnosis and reported that only 32% of breast cancer survivors were meeting public health PA guidelines (6). Given these statistics, interventions are needed to increase PA behavior in breast cancer survivors (7, 8).

In order to facilitate behavior change, researchers advocate that written health information should be theoretically-based (9). Application of behavioral theories can assist researchers in understanding the mechanisms through which individuals change (or do not change) their behavior. Theory-based mediating variables in randomized controlled trials may potentially play an important role in understanding the pathways to behavior change (10). The theory of planned behavior (TPB) is a widely used and validated model for predicting and explaining PA motivation and behavior in breast cancer survivors (11-13). Overall, these studies have provided promising evidence that the TPB may be a useful model for understanding PA in breast cancer survivors. Moreover, these aforementioned studies have identified the salient beliefs about PA in breast cancer survivors that are necessary for developing behavior change interventions for this population.

Research is emerging that supports the two-component TPB model as being superior to the traditional TPB model in the PA domain (14-16). The traditional TPB model postulates that intention is the most important determinant of behavior. Intention is, in turn, determined by subjective norm, attitude, and perceived behavioral control. Recently, TPB theorists have suggested that each TPB component (i.e., subjective norm, attitude, and perceived behavioral control) is better represented by two specific subcomponents (15-17). Subjective norm measures the perceptions of social pressure to perform the behavior and includes the more traditionally measured *injunctive* component (e.g., whether important others approve of the person performing the behavior) and a *descriptive* component (e.g., whether important others actually perform the behavior themselves). Attitude reflects the individual's overall evaluations of performing the behavior and is comprised of *instrumental* (e.g., harmful/beneficial) and *affective* (e.g., unenjoyable/enjoyable) components. Perceived behavioral control reflects the degree of personal control the individual has over performing the behavior and is comprised of *self-efficacy* (e.g., ease/difficulty, confidence) and *controllability* (e.g., personal control over behavior).

Underlying beliefs influence each of the TPB sub-components. According to Ajzen, "behavioral interventions must try to change the beliefs that ultimately guide performance of the behavior." (p. 2) (18). Fishbein advocates identifying salient beliefs from the intended population, developing persuasive messages around the beliefs, and then developing suitable and appropriate materials based on the elicited beliefs (9). Subjective norm is influenced by normative beliefs, which refer to the specific individuals that may approve or disapprove, or perform or not perform, the behavior themselves. Attitude is determined by behavioral beliefs, which consist of perceived advantages and disadvantages of participating in the behavior and also the factors that make the behavior enjoyable or unenjoyable. Finally, perceived behavioral control is a function of

control beliefs, which refer to the perceived opportunities and resources the individual has for performing the behavior.

A criticism of the TPB is its failure to account for how motivational intentions (volitional phase) can translate into actual behavior (deliberative phase) (i.e., "the intention-behavior gap"). TPB theorists propose that intentions to perform a behavior will more likely translate into behavior when implementation intentions are garnered (19, 20). Implementation intentions (such as action planning) propose that successful behavior change is facilitated by furnishing the intention with an 'if then' plan specifying when, where, how, and how often the individual will perform the behavior (20). Previous research has demonstrated the beneficial effects of formulating an implementation intention via action planning on PA behavior change in various populations (21-23).

The Activity Promotion (ACTION) Trial was a randomized controlled trial designed to determine the effects of breast cancer-specific PA print materials (PM) developed based on the two-component TPB model, a step pedometer (PED), or their combination (COM), on PA and QoL in breast cancer survivors compared to a comparison group receiving a standard public health recommendation for PA (SR). Previously, we reported that breast-cancer specific PA print material and pedometers may be effective strategies for increasing PA and QoL in breast cancer survivors (24). Specifically, moderate-to-vigorous PA increased by about 40 to 60 min•wk in the interventions groups compared to the SR group, and brisk walking increased by about 60 to 90 min•wk in the intervention groups compared to the SR group. The COM group also reported significantly improved QoL and reduced fatigue compared to the SR group.

The primary purpose of this study was to examine the effects of breast-cancer specific PM TPB constructs and behavioral, normative, and control beliefs. The secondary purpose was to determine if the TPB mediated the effects of our TPB-based interventions on PA behavior. We hypothesized that: (a) the TPB-based interventions

would have significant effects on the TPB constructs compared to the SR group and (b) the TPB would mediate the effects of the TPB-based interventions on PA and provide a theoretical explanation for why the intervention was effective in increasing PA behavior in breast cancer survivors.

METHODS

Design and Procedures

The methods of the study have been reported in detail elsewhere (24). In brief, the study was a four-armed, prospective randomized controlled trial. The Alberta Cancer Registry was used to identify breast cancer survivors residing in Northern Alberta, Canada diagnosed between January, 2000 and December, 2003. Eligibility criteria included (a) histologically confirmed stage I-IIIa breast cancer, (b) physician approval to participate in the study, (c) free from chronic medical and orthopedic conditions that would preclude PA (e.g., congestive heart failure, use of a mobility aid, recent knee or hip replacement), (d) ability to read and understand English, (e) postadjuvant therapy except hormone therapy, (f) no current disease, and (g) interested in increasing PA. The trial was conducted between July and October, 2005.

Intervention Groups

All groups received a standard public health recommendation to perform 30 minutes of moderate-to-vigorous PA on 5 days of the week. Survivors meeting PA guidelines at baseline were encouraged to further increase their minutes and/or days spent engaged in PA. The SR group received no further intervention materials. The PM group received a copy of *Exercise for health: An exercise guide for breast cancer survivors* (25). A detailed description of our guidebook, as well as evaluative evidence to support its suitability, appropriateness, and theoretical basis is published elsewhere (25). The PED group received a Digi-Walker SW-200 pedometer (i.e., New Lifestyles Inc., Lee's Summit, MO, USA) and a 3-month step calendar. The COM group received both

interventions (i.e., print material and pedometer combined). Survivors randomized to the COM and PED groups were instructed to wear their pedometer everyday for the initial 3-month duration of the study and record their daily step totals at the end of each day. The SR and PM groups only wore their pedometer for baseline and 3-month assessments.

MEASURES

Data were collected at baseline, 4 weeks, and 3 months. All PA beliefs were measured in accordance with the guidelines proposed by Ajzen (26). The specific behavioral, normative, and control beliefs were taken from previous research with breast cancer survivors (11-13). The demographic and medical characteristics assessed included age, marital status, education, family income, employment status, height, weight, co-morbidities, body mass index (BMI), hormonal therapy use, and menopausal status. Medical data was extracted from the Alberta Cancer Registry and included tumor stage and grade, treatment(s) received, and months since diagnosis.

Physical Activity: Self-report PA was assessed by the leisure score index (LSI) of the Godin Leisure-Time Exercise Questionnaire (GLTEQ) (27). The LSI contains three questions that assess the average frequency of mild, moderate, and strenuous exercise during free time in a typical week. The LSI demonstrated a one-month test-retest reliability of .62 and concurrent validity coefficients of .32 with an objective indicator (CALTRAC accelerometer), .56 with VO_{2max} (as measured by expired gases), and -.43 with percent body fat (as measured by hydrostatic weighing). An independent evaluation of this measure found its reliability and validity to compare favorably to nine other self-report measures of exercise based on various indices (28, 29). We modified the LSI so that average duration was also provided. For the present study, we calculated the total minutes of moderate plus strenuous exercise for each of the two time periods (i.e., baseline and postintervention).

Before any survivors completed the TPB items, a definition of *regular exercise* was provided. Regular exercise was defined as 1) at least 20 minutes of vigorous intensity activity on at least three days per week (e.g., heavy breathing, difficult to talk, lots of sweating), or 2) at least 30 minutes of moderate intensity activity on at least five days of the week (e.g., light sweating, some increase in heart rate, still able to talk).

Intention: Intention to exercise was assessed using two items rated on 7 point scales: (1) "I intend to exercise regularly over the next 12 weeks" (strongly disagree to strongly agree) and (2) "How motivated are you to exercise regularly over the next 12 weeks?" (extremely unmotivated to extremely motivated). Internal consistencies (α) for the intention scale were .88 at the baseline timepoint (T1) and .88 at the 4-week timepoint (T2).

Attitude: Attitude was measured using bipolar adjective scales that assessed both instrumental (harmful-beneficial, useless-useful, bad-good) and affective (unenjoyable-enjoyable, boring-fun, unpleasant-pleasant) attitude. The verbal descriptors ranged from extremely 'negative' to extremely 'positive'. The statement that preceded the adjectives was "For me, exercising regularly over the next 12 weeks would be...." Internal consistencies (α) for the affective scale were .79 and .90 at T1 and T2, respectively. Internal consistencies (α) for the instrumental scale were .89 at T1 and .88 at T2.

Subjective Norm: Subjective norm was measured by four items rated on 7 point scales that ranged from 1 to 7 (strongly disagree to strongly agree). The three injunctive norm items were "Most people who are important to me would: (a) approve, (b) encourage, and (c) support me if I exercise regularly over the next 12 weeks". The descriptive norm item was "Most people who are important to me will exercise regularly themselves over the next 12 weeks." Internal consistencies (α) for the injunctive norm scale were .92 at T1 and .91 at T2.

Perceived behavioral control: Perceived behavioral control was measured by two self-efficacy items and two controllability items. The self-efficacy items were "If you were really motivated, exercising regularly over the next 12 weeks would be..." (extremely difficult to extremely easy) and, "If you were really motivated, how confident are you that you could exercise regularly over the next 12 weeks" (not at all confident to extremely confident). The controllability items were "If you were really motivated, how much control do you feel you would have in exercising regularly over the next 12 weeks" (very little control to complete control) and "Whether or not I exercise regularly over the next 12 weeks is completely up to me" (strongly disagree to strongly agree). Internal consistencies (α) for the self-efficacy scale were .80 at T1 and .82 at T2. Internal consistencies (α) for the controllability scale were .48 at T1 and .63 at T2.

Behavioral Beliefs: The behavioral beliefs focused on the perceived benefits of exercising regularly during the study. All behavioral belief items are listed in Table 1. The behavioral belief items were preceded by the statement "If I were to exercise regularly over the next 12 weeks, I would likely..." and rated on a 7-point scale ranging from 1 to 7 (extremely unlikely to extremely likely).

Normative Beliefs: The normative beliefs addressed the extent to which important specific others would be supportive of exercising regularly. All normative belief items are listed in Table 1. The normative beliefs were preceded by the statement "How supportive do you think each of the following people would be of you exercising regularly over the next 12 weeks" and rated on a 7-point scale ranging from 1 to 7 (extremely unsupportive to extremely supportive).

Control Beliefs: The control beliefs focused on the extent to which certain barriers would interfere with exercising regularly. All control belief items are listed in Table 1. The control belief items were preceded by the statement "If you were really motivated, how

confident are you that you can exercise regularly over the next 12 weeks even if..." and rated on a 7-point scale ranging from 1 to 7 (not at all confident to completely confident).

Implementation Intentions - Action Planning: Action planning was measured by four items. Action planning items were preceded by the statement "I have made a detailed plan regarding..." and included a) when to exercise, b) where to exercise, c) how to exercise, and d) how often to exercise. Planning items were rated on a 7-point scale ranging from 1 to 7 (not at all true to exactly true). These items have been used in previous research examining action planning and implementation intentions (21, 30, 31).

Statistical Analyses

To establish the appropriate temporal sequencing of the TPB changes and PA changes, we used the TPB change scores from baseline to four weeks and the PA change scores from baseline to 3 months. Analyses were performed using SPSS version 14.0 for Windows (SPSS Inc., Evanston, IL, USA). For all PA data, outliers (i.e., Z-score > 3.29) remained in the data, but steps were taken to minimize their impact. As recommended, transformed scores (i.e., Z-scores) were adjusted to be one unit less than the next most extreme scores (32). We collapsed the two intervention groups that received the TPB intervention (i.e., PM and COM) and labeled this group *Intervention* (INT). Given the PED group did not receive the theoretical intervention, they were excluded from the analyses. Change-score analyses using univariate analysis of variance (ANOVA) were implemented to compare the combined effect of the INT group with the SR group. Data are presented as the mean (and standard deviation) with 95% confidence intervals (CI). For all analyses, we employed the intention-to-treat (ITT) approach (33). We employed the last-observation-carried-forward procedure for survivors who did not complete the 4-week TPB questionnaire and 3-month self-reported PA assessment.

Structural Equation Modeling (SEM) procedures using Arbuckle's AMOS version 4.0 program (SmallWaters Corp., Chicago IL) (34) were used to examine the associations among group assignment (SR=0; INT=1), change in TPB constructs and PA behavior change. SEM allows for both statistical significance tests for the size of each theoretical relation in the model and the assessment of overall model fit. Model fit was assessed using multiple indices. The chi square goodness-of-fit test (χ^2) tests the null hypothesis that the overidentified (reduced/pathways have been deleted) model fits the data as well as does a just-identified (full, saturated/all pathways present) model. Some argue that a nonsignificant χ^2 indicates that the reduced model fits the data well. However, given the χ^2 statistic's sensitivity to sample size, researchers recommend including incremental fit indices (IFI) when assessing model fit (35). IFIs measure the proportionate improvement in the fit by comparing a target model with a more restricted baseline model. The Root Mean Square Error of Approximation (RMSEA) estimates lack of fit compared to the saturated model and is also reported as an index of absolute model fit. The comparative fit index (CFI) is included as an index of incremental fit. Acceptability of model fit using these indexes are >.94 for the CFI and <.07 for RMSEA (36). Constructs that emerged with significant standardized beta coefficients are shown by a direct path to the construct.

RESULTS

Study Flow and Participant Characteristics

Results from the ACTION trial pertaining to baseline characteristics of the sample have been presented elsewhere (24) and are summarized here. In brief, study invitation letters were mailed to 1590 breast cancer survivors living in Northern Alberta. A total of 708 (44.5%) survivors expressed interest in participating in the study. Because of the higher than expected level of interest, we accepted the first 398 (25%) as potential study participants. Of these, 21 were late in returning their baseline assessments and were not

randomized. Therefore, 377 (23.7%) survivors were randomized to receive either PM (n=94), PED (n=94), COM (n=93), or SR (n=96). Overall retention for this study was 93% at the 4-week timepoint, and 90% at the 3-month timepoint. Retention rates did not differ between PM (86%), PED (89%), COM (95%), and SR (92%) (p=.392). The mean age of the sample was 58 years (Rg=30-90), 72% were married, 62% were postmenopausal, 81% were stage I or II, 49% were currently receiving hormone therapy, and the mean months since diagnosis was 39 (SD=11.3). The groups were balanced at baseline on the major demographic and medical variables, TPB constructs, and PA behavior.

Change in TPB Constructs

Descriptive statistics and TPB change scores (at 4 weeks) across the two groups are presented in Table 2. With the exception of the controllability construct [likely due to unacceptable internal consistency (Cronbach's α) estimates], changes in the remaining seven TPB constructs favored the INT group over the SR group with three of the changes being significant or approaching significance. Specifically, the INT group was superior to the SR group for changes in instrumental attitude (mean difference=0.17; 95% CI=0.01 to 0.33; d=.26; p=.041) and intention (mean difference=0.39; 95% CI=+0.13 to 0.65; d=.37; p=.004).

Change in PA Beliefs

Descriptive statistics and change scores for behavioral, normative, and control beliefs across the two groups are presented in Table 1. For changes in the beliefs, 7/10 behavioral, 4/6 normative, and 10/10 control beliefs favored the INT group with two of the changes approaching significance. Specifically, the INT group was borderline superior to the SR group for the behavioral belief "live longer" (mean difference=0.21; 95% CI=-0.08 to 0.50; d=.18; p=.154) and the control beliefs "feeling tired or fatigued" (mean difference=0.42; 95% CI=-0.02 to 0.86; d=.24; p=.063), and "having additional

family responsibilities" (mean difference=0.33; 95% CI=-0.09 to 0.74; d=.20; p=.125). When combined, the INT group was superior to the to the SR group for behavioral beliefs (mean difference=0.30; 95% CI=-0.05 to 0.64; d=.24; p=.096).

Associations between group assignment, TPB changes, and PA behavior change

Table 3 shows the bivariate correlations among variables (change scores). The model shown in Figure 1 provided an acceptable fit (χ2=41.1, df=16, p<.01, CFI=.98, IFI=.98, RMSEA=.065, 95% CI=.04 - .09). Significant paths and their standardized coefficients (β) are depicted in Figure 1. The model indicated that group assignment (β=.13, p=.023) and planning (β=.11, p=.044) had direct effects on PA behavior change. Intention had a direct effect on planning (β=.32, p=.000). Group assignment (β=.11, p=.011), affective attitude (β=.18, p=.001), injunctive norm (β=.23, p=.000), self-efficacy (β=.12, p=.091), and controllability (β=.12, p=.059) all had direct effects on intention. Self-efficacy had a direct effect on planning (β=.20, p=.001). Finally, group assignment had a direct effect on injunctive instrumental attitude (β=.12, p=.033).

DISCUSSION

The primary purpose of this study was to examine the effects of breast cancer-specific PM on TPB constructs and to determine if the TPB mediated the effects of these TPB-based interventions on PA behavior change. In support of our hypotheses, we found that survivors receiving the TPB-based interventions generally reported positive changes in the TPB constructs and beliefs compared to the SR group. Several of these effects were significant or borderline significant including changes in instrumental attitude, injunctive norm, intention, and several specific behavioral and control beliefs. We also found partial support for our hypothesis that changes in the TPB would mediate the effects of our TPB-based interventions on changes in PA behavior. Overall, these results provide support for the use of the TPB as a framework for developing,

implementing, and evaluating PA behavior change interventions in breast cancer survivors.

This study is important given the limited number of studies that have examined the underlying theoretical mechanisms in PA behavior change interventions. To our knowledge, this study represents the first attempt to examine the underlying theoretical mechanisms of a TPB-based intervention in breast cancer survivors. In the cancer population, only two other studies have examined the effects of theoretically-based print interventions on PA behavior (8, 37). In the general population, few researchers have developed and evaluated print intervention materials based on the TPB (38, 39) while most studies have implemented print intervention materials based on the transtheoretical model (40-45). Collectively, these print intervention materials have been successful in facilitating PA behavior change. Although researchers often state that their respective intervention materials are developed around a particular theory of behavior change, typically little or no evidence to support the theoretical basis of the intervention is provided. The ACTION Trial is the first PA intervention trial to: (a) document the development of the intervention material and evaluate its theoretical merit (25), (b) provide evidence of its effectiveness in facilitating behavior change and positive health outcomes (24), and (c) attempt to explain the underlying theoretical mechanisms of the PA behavior change.

Given the paucity of existing research examining theoretical mediators of PA behavior change in randomized controlled trials implementing print-based materials, making comparative evaluations are difficult. Perhaps most relevant, Rabin et al., (46) evaluated theoretical mediators of PA behavior change in breast cancer survivors using the transtheoretical model as a guiding framework. Survivors in the intervention group received a pedometer and a weekly telephone call for 12 weeks while survivors in the contact control group were asked not to change their current level of activity. Results

indicated that decisional balance, self-efficacy, behavioral processes of change, and experiential processes of change did not mediate the effects of the intervention on PA behavior change. Using the TPB as a mediating framework, Jones and colleagues (37) found that breast cancer survivors who received an oncologist's recommendation to exercise reported more positive attitudes, subjective norms, perceptions of control, and intentions to exercise than those survivors that did not receive a recommendation. Also using the TPB, Chatzisarantis and Hagger (38) found that young people (Mean age=14.6 years) who studied a persuasive message that targeted modal salient behavioral beliefs (as elicited by earlier pilot work) reported more positive attitudes and stronger intentions than those individuals that studied nonsalient behavioral beliefs.

Admittedly, the magnitudes of the TPB changes reported in this study are small (effect size *d*s around 0.2). Such small changes, however, may be important from a public health perspective. Health promotion experts have advocated that practical, low/minimal intensity interventions that might not have large clinical effects, but can be delivered to large numbers of participants, are more likely to have a broader health impact (47). The small changes that we observed may have also been due to a ceiling effect and low variability in some of the TPB components. Courneya et al. (15) noted that it is not uncommon in the exercise domain to observe means on the 7-point scales greater than 6.0 with standard deviations less than 1.0. To expect substantial changes in these cognitive variables as a function of a minimal contact intervention utilizing print material as the sole method of information delivery may be unrealistic. Given our findings, future research should examine the effect of other behavior change strategies (e.g., telephone counseling, face-to-face counseling, social support groups) on facilitating PA behavior change. It is possible that behavioral interventions that have more contact-time with the participant(s) are more likely to elicit greater changes in cognitions. Furthermore, a test of a TPB-based intervention with participants that have

less favorable beliefs than our motivated sample may result in larger cognitive and behavior changes.

We performed structural equation modeling (SEM) to examine whether the TPB explained the effects of our TPB-based interventions on PA behavior change. Overall, the final model fit the data reasonably well. Path coefficients indicated that receiving the TPB-based interventions (i.e., INT) resulted in positive changes in perceived approval and support from significant others (i.e., injunctive norm), a more favorable evaluation of PA as a beneficial behavior (i.e., instrumental attitude), and stronger motivation to participate in PA (i.e., intention). Favorable changes in injunctive norm, affective attitude, self-efficacy, and controllability resulted in a stronger intention to perform PA. The final pathway of our interventions to PA behavior change was through planning. Results also indicated, however, a direct effect of our interventions on PA behavior change unmediated by the TPB. It is not clear if other social cognitive beliefs may have provided a more complete mediation of the type of intervention we tested. Researchers have noted that other additions to the TPB may enhance the utility and function of the TPB (48, 49).

A list of PA beliefs that we targeted in our print materials are located in Table 1. We found that changes in intention were predicted by favorable changes in perceptions of support from physician (β=.10, p=.063), and confidence in exercising even when the weather is very bad (β=.10, p=.072), when feeling tired or fatigued (β=.16, p=.023), when not liking exercise (β=.11, p=.079), and when having no support (β=.13, p=.020). We also found that receiving the intervention caused favorable changes in beliefs that exercise will help you live longer (β=.08, p=.100), and confidence to exercise when the weather is very bad (β=.09, p=.008), when feeling tired or fatigued (β=.09, p=.086), when having additional family responsibilities (β=.10, p=.057), and when not liking exercise

(β=.09, p=.098). Analyzing data at the individual belief level offers important information not provided by the common practice of aggregating potentially disparate beliefs (50). Our data supports this contention given that specific beliefs having unique associations with PA behavior change were obscured when aggregated. Analyzing data at the belief(s) level also allows researchers to identify components of the intervention materials that were effective at causing behavior change. Future research examining theoretically-based print material should continue to analyze beliefs at the individual level, in addition to forming belief-based constructs by way of aggregation.

It is not surprising that our interventions were significantly associated with positive changes in injunctive norm given the emphasis on oncologist approval to exercise in our TPB-based print materials. Jones and colleagues (51) found similar results in that an oncologist's recommendation to exercise was significantly associated with feelings of approval and support from others. Chatzisarantis and Hagger's data indicated that the effects of a TPB-based intervention on intentions were mediated by attitudes, but not subjective norms or perceived behavioral control (38). Given our results, as well as those reported by Jones et al. (51), it appears feasible to suggest that significant others may be a salient and appropriate source of motivation for breast cancer survivors. Unfortunately, we did not measure the specific normative referent for oncologists. Rather, to be consistent with previous elicitation studies in with breast cancer survivors, we listed the physician in general (11-13). Future interventions may benefit from including an item specifically about approval and encouragement from oncologists.

Our print material contained a comprehensive goal-setting/planning component. Results from our SEM analysis suggest that individuals likely formulate an intention, formulate a specific plan to carry out their intentions, and then follow through with their plan for engaging in PA behavior. These results are consistent with previous research

demonstrating the beneficial effects of formulating an implementation intention on PA behavior change in various populations (21-23). Theorists have speculated that the influence of implementation intentions on behavior may be explained by various mediating mechanisms such as strategic automaticity, formulation of specific action plans, and self regulation which may lead to immediate responding (52). Nonetheless, given the results from our study it appears that adding a goal-setting/action planning component to PA interventions may facilitate the process of translating motivations and intentions into actual PA behavior.

Our study has several important strengths and limitations that should be taken into account when interpreting our data and planning future research. One strength of our study is the implementation of the "two-component" model of the TPB. Research is emerging that supports the two-component TPB model as being superior to the traditional TPB model in the PA domain (14-17). Other strengths of our study include: a) implementing previously developed and evaluated breast cancer-specific PA print materials, b) being the first randomized controlled trial to examine the underlying theoretical mechanisms of PA behavior change in breast cancer survivors using print materials, c) using a validated theoretical model to examine motivation and PA behavior, d) using previously validated measures of the TPB constructs, e) obtaining a large and representative sample of breast cancer survivors, and f) achieving a high study completion rate with limited loss to follow-up.

Our study was limited by the self-report of PA. However, it is a challenge to collect objective PA given the distance-based approach to the intervention. The self-report measure we used (the LSI from the GLTEQ) is one of the best in the literature for the purpose of testing behavior change interventions. It is important to note that our sample of breast cancer survivors were highly motivated given their already favorable beliefs about PA as elicited at the baseline timepoint. This factor may have possibly

worked against our hypotheses and our results may have been even stronger if we had a sample with less favorable beliefs about PA. Future trials should be more proactive at recruiting less motivated survivors to avoid possible ceiling effects. Furthermore, there was a high level of endorsement on the TPB measures which may in turn limit the predictive utility of the model.

In summary, our results provide support for the use of the TPB as a framework for developing, implementing, and evaluating PA behavior change interventions in breast cancer survivors. This research may ultimately help breast cancer survivors enhance their QoL and reduce their risk of recurrence and early death from breast cancer through regular participation in PA.

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Table 1

Effects of the TPB interventions (PM and COM) on physical activity beliefs at 4 weeks (N=283)

Variable	Baseline M (SD)	4-week M (SD)	Mean change M [95% CI]	B/w groups comparison M [95% CI]	d	P
Behavioral Beliefs						
All beliefs combined						
INT (n=187)	5.95 (0.82)	6.04 (0.73)	+0.09 [-0.03 to 0.21]	+0.05 [-0.16 to 0.25]	.06	.664
SR (n=96)	5.86 (0.88)	5.91 (0.92)	+0.05 [-0.12 to 0.22]			
Feel more like having a normal lifestyle						
INT (n=187)	5.52 (1.30)	5.63 (1.20)	+0.11 [-0.10 to 0.32]	-0.14 [-0.51 to 0.22]	-.09	.446
SR (n=96)	5.55 (1.30)	5.80 (1.15)	+0.25 [-0.04 to 0.55]			
Feel better and improve my well-being						
INT (n=187)	6.24 (0.76)	6.25 (0.76)	+0.01 [-0.12 to 0.14]	-0.04 [-0.26 to 0.18]	-.04	.739
SR (n=96)	6.11 (0.99)	6.16 (1.06)	+0.04 [-0.15 to 0.24]			
Reduce the risk of my cancer recurring						
INT (n=187)	5.68 (1.21)	5.87 (1.12)	+0.19 [+0.01 to 0.38]	+0.15 [-0.17 to 0.48]	.12	.349
SR (n=96)	5.46 (1.51)	5.50 (1.36)	+0.04 [-0.24 to 0.31]			
Relieve my stress						
INT (n=187)	5.86 (1.14)	6.03 (0.96)	+0.17 [+0.00 to 0.34]	+0.03 [-0.27 to 0.32]	.03	.866
SR (n=96)	5.78 (1.14)	5.93 (1.18)	+0.15 [-0.09 to 0.38]			
Improve my energy level						
INT (n=187)	6.06 (0.95)	6.20 (0.80)	+0.14 [-0.01 to 0.28]	+0.06 [-0.19 to 0.31]	.06	.656
SR (n=96)	6.02 (0.96)	6.10 (1.01)	+0.08 [-0.13 to 0.30]			
Get my mind off cancer						
INT (n=187)	5.26 (1.52)	5.60 (1.39)	+0.34 [+0.10 to 0.57]	+0.26 [-0.14 to 0.67]	.16	.201
SR (n=96)	5.36 (1.52)	5.44 (1.51)	+0.07 [-0.27 to 0.42]			

Live longer						
INT (n=187)	6.03 (1.13)	6.14 (0.99)	+0.11 [-0.06 to 0.28]	+0.21 [-0.08 to 0.50]	.18	.154
SR (n=96)	5.93 (1.19)	5.82 (1.25)	-0.10 [-0.34 to 0.14]			
Improve my fitness						
INT (n=187)	6.49 (0.82)	6.44 (0.74)	-0.04 [-0.17 to 0.08]	-0.06 [-0.28 to 0.15]	-.06	.556
SR (n=96)	6.32 (0.91)	6.34 (0.84)	+0.02 [-0.16 to 0.20]			
Control my weight						
INT (n=187)	6.24 (0.95)	6.17 (0.95)	-0.06 [-0.22 to 0.10]	+0.04 [-0.23 to 0.31]	.13	.770
SR (n=96)	6.15 (1.11)	6.04 (1.17)	-0.10 [-0.33 to 0.12]			
Improve my immune system						
INT (n=187)	6.11 (0.95)	6.12 (0.87)	+0.01 [-0.15 to 0.17]	+0.02 [-0.25 to 0.29]	.02	.875
SR (n=96)	6.01 (1.04)	6.00 (1.07)	-0.01 [-0.24 to 0.22]			
Normative Beliefs						
All beliefs combined						
INT (n=187)	6.07 (0.92)	5.91 (1.00)	-0.15 [-0.30 to -0.01]	+0.02 [-0.23 to 0.27]	.07	.868
SR (n=96)	6.25 (0.76)	6.08 (0.84)	-0.18 [-0.38 to 0.03]			
Spouse / partner*						
INT (n=129)	6.20 (1.20)	6.09 (1.34)	-0.10 [-0.28 to 0.07]	+0.00 [-0.28 to 0.29]	.02	.975
SR (n=76)	6.54 (0.70)	6.43 (0.72)	-0.11 [-0.35 to 0.14]			
Other family members						
INT (n=187)	6.14 (1.09)	6.02 (1.20)	-0.12 [-0.29 to 0.06]	+0.07 [-0.23 to 0.36]	.06	.661
SR (n=96)	6.25 (0.97)	6.07 (1.14)	-0.18 [-0.42 to 0.06]			
Best friend(s)						
INT (n=187)	6.20 (1.03)	5.95 (1.28)	-0.25 [-0.44 to 0.06]	-0.17 [-0.50 to 0.15]	-.07	.289
SR (n=96)	6.26 (0.94)	6.19 (1.02)	-0.07 [-0.33 to 0.18]			
Other friends						
INT (n=187)	5.79 (1.19)	5.57 (1.37)	-0.22 [-0.41 to -0.03]	+0.00 [-0.32 to 0.33]	.07	.987
SR (n=96)	6.00 (1.07)	5.77 (1.19)	-0.23 [-0.49 to 0.04]			
Family physician						
INT (n=187)	6.42 (0.97)	6.36 (0.95)	-0.06 [-0.20 to 0.08]	+0.16 [-0.08 to 0.42]	.18	.188
SR (n=96)	6.59 (0.75)	6.37 (0.91)	-0.22 [-0.43 to -0.02]			

Co-workers						
INT (n=187)	5.67 (1.19)	5.49 (1.25)	-0.18 [-0.38 to -0.02]	-0.12 [-0.47 to 0.23]	-.07	.492
SR (n=96)	5.76 (1.12)	5.70 (1.13)	-0.06 [-0.34 to 0.23]			
Control Beliefs						
All beliefs combined						
INT (n=187)	4.42 (1.29)	4.61 (1.20)	+0.18 [-0.02 to 0.39]	+0.30 [-0.05 to 0.64]	.24	.096
SR (n=96)	4.48 (1.21)	4.37 (1.32)	-0.11 [-0.40 to 0.17]			
Weather was very bad						
INT (n=187)	4.82 (1.83)	4.92 (1.73)	+0.37 [-0.03 to 0.77]	+0.37 [-0.32 to 1.06]	.13	.295
SR (n=96)	5.21 (1.66)	4.88 (1.71)	-0.00 [-0.56 to 0.56]			
You felt tired or fatigued						
INT (n=187)	4.51 (1.59)	4.72 (1.46)	+0.21 [-0.05 to 0.46]	+0.42 [-0.02 to 0.86]	.24	.063
SR (n=96)	4.80 (1.51)	4.59 (1.53)	-0.21 [-0.56 to 0.15]			
You had medical / health problems						
INT (n=187)	4.03 (1.57)	4.23 (1.43)	+0.20 [-0.07 to 0.46]	+0.26 [-0.19 to 0.72]	.14	.259
SR (n=96)	4.13 (1.55)	4.06 (1.53)	-0.06 [-0.43 to 0.30]			
You got very busy and had limited time						
INT (n=187)	4.45 (1.52)	4.69 (1.31)	+0.23 [-0.02 to 0.48]	+0.18 [-0.24 to 0.60]	.09	.405
SR (n=96)	4.36 (1.69)	4.42 (1.63)	+0.05 [-0.30 to 0.40]			
You had a recurrence of your cancer						
INT (n=187)	3.61 (1.97)	4.00 (1.77)	+0.39 [+0.09 to 0.52]	+0.28 [-0.23 to 0.79]	.14	.283
SR (n=96)	3.82 (1.86)	3.93 (1.81)	+0.11 [-0.32 to 0.53]			
You had pain or soreness						
INT (n=187)	4.15 (1.55)	4.52 (3.07)	+0.37 [-0.03 to 0.77]	+0.37 [-0.32 to 1.06]	.13	.295
SR (n=96)	4.30 (1.54)	4.30 (1.45)	+0.00 [-0.52 to 0.52]			
You had additional family responsibilities						
INT (n=187)	4.51 (1.42)	4.66 (1.39)	+0.16 [-0.08 to 0.10]	+0.33 [-0.09 to 0.74]	.20	.125
SR (n=96)	4.49 (1.44)	4.32 (1.66)	-0.17 [-0.51 to 0.17]			
You didn't like exercise						
INT (n=187)	4.79 (1.65)	4.72 (1.58)	-0.07 [-0.34 to 0.21]	+0.32 [-0.16 to 0.79]	.17	.189
SR (n=96)	4.89 (1.62)	4.51 (1.65)	-0.38 [-0.77 to 0.01]			

Exercise didn't fit into your routine						
INT (n=187)	4.52 (1.63)	4.61 (1.53)	+0.09 [-0.18 to 0.37]	+0.12 [-0.35 to 0.59]	.06	.616
SR (n=96)	4.26 (1.65)	4.23 (1.60)	-0.03 [-0.41 to 0.36]			
You had no support						
INT (n=187)	4.85 (1.75)	4.99 (1.54)	+0.14 [-0.15 to 0.43]	+0.17 [-0.33 to 0.66]	.09	.508
SR (n=96)	4.45 (1.87)	4.42 (1.78)	-0.02 [-0.43 to 0.38]			

Data are presented on a seven point scale.
M=Mean; SD=standard deviation; CI=confidence interval; *d*=effect size (mean difference / pooled SD).
SR=standard recommendation to exercise; INT=intervention (i.e., PM and COM).
*Sample sizes do not equal 283 given that several survivors reported no spouse/partner.

Table 2

Effects of the TPB interventions (PM and COM) on TPB constructs at 4 weeks (N=283)

Variable	Baseline M (SD)	4-week M (SD)	Mean change M [95% CI]	B/w groups comparison M [95% CI]	*d*	P
Instrumental Attitude						
INT (n=187)	6.36 (0.68)	6.34 (0.60)	-0.02 [-0.11 to 0.07]	+0.17 [+0.01 to 0.33]	.26	.041
SR (n=96)	6.45 (0.60)	6.26 (0.80)	-0.19 [-0.32 to -0.06]			
Affective Attitude						
INT (n=187)	5.63 (0.84)	5.68 (0.91)	+0.04 [-0.09 to 0.18]	+0.10 [-0.13 to 0.33]	.11	.388
SR (n=96)	5.72 (0.84)	5.66 (0.93)	-0.05 [-0.24 to 0.13]			
Injunctive Norm						
INT (n=187)	6.48 (0.83)	6.40 (0.90)	-0.08 [-0.20 to 0.04]	+0.16 [-0.05 to 0.37]	.19	.125
SR (n=96)	6.69 (0.55)	6.45 (0.83)	-0.24 [-0.41 to -0.08]			
Descriptive Norm						
INT (n=187)	4.94 (1.75)	4.96 (1.63)	+0.01 [-0.22 to 0.25]	-0.02 [-0.42 to 0.39]	-.01	.941
SR (n=96)	5.17 (1.46)	5.20 (1.58)	+0.03 [-0.31 to 0.37]			
Self-efficacy						
INT (n=187)	5.90 (0.95)	5.89 (1.00)	-0.01 [-0.17 to 0.15]	+0.14 [-0.15 to 0.42]	.12	.345
SR (n=96)	5.90 (0.95)	5.75 (1.16)	-0.15 [-0.38 to 0.09]			
Controllability						
INT (n=187)	6.17 (0.93)	6.21 (0.92)	+0.04 [-0.12 to 0.19]	-0.05 [-0.32 to 0.21]	-.05	.705
SR (n=96)	6.18 (0.87)	6.27 (0.87)	+0.09 [-0.13 to 0.31]			
Intention						
INT (n=187)	6.23 (0.86)	6.23 (0.78)	-0.00 [-0.15 to 0.15]	+0.39 [+0.13 to 0.65]	.37	.004
SR (n=96)	6.33 (0.70)	5.94 (1.31)	-0.39 [-0.61 to -0.17]			

Action/Planning						
INT (n=187)	4.99 (1.70)	5.65 (1.36)	+0.66 [+0.39 to 0.92]	+0.33 [-0.13 to 0.79]	.18	.156
SR (n=96)	4.91 (1.77)	5.23 (1.70)	+0.33 [-0.04 to 0.70]			

Data are presented on a seven point scale.
M=Mean; SD=standard deviation; CI=confidence interval; *d*=effect size (mean difference / pooled SD).
SR=standard recommendation to exercise; INT=intervention (i.e., PM and COM).

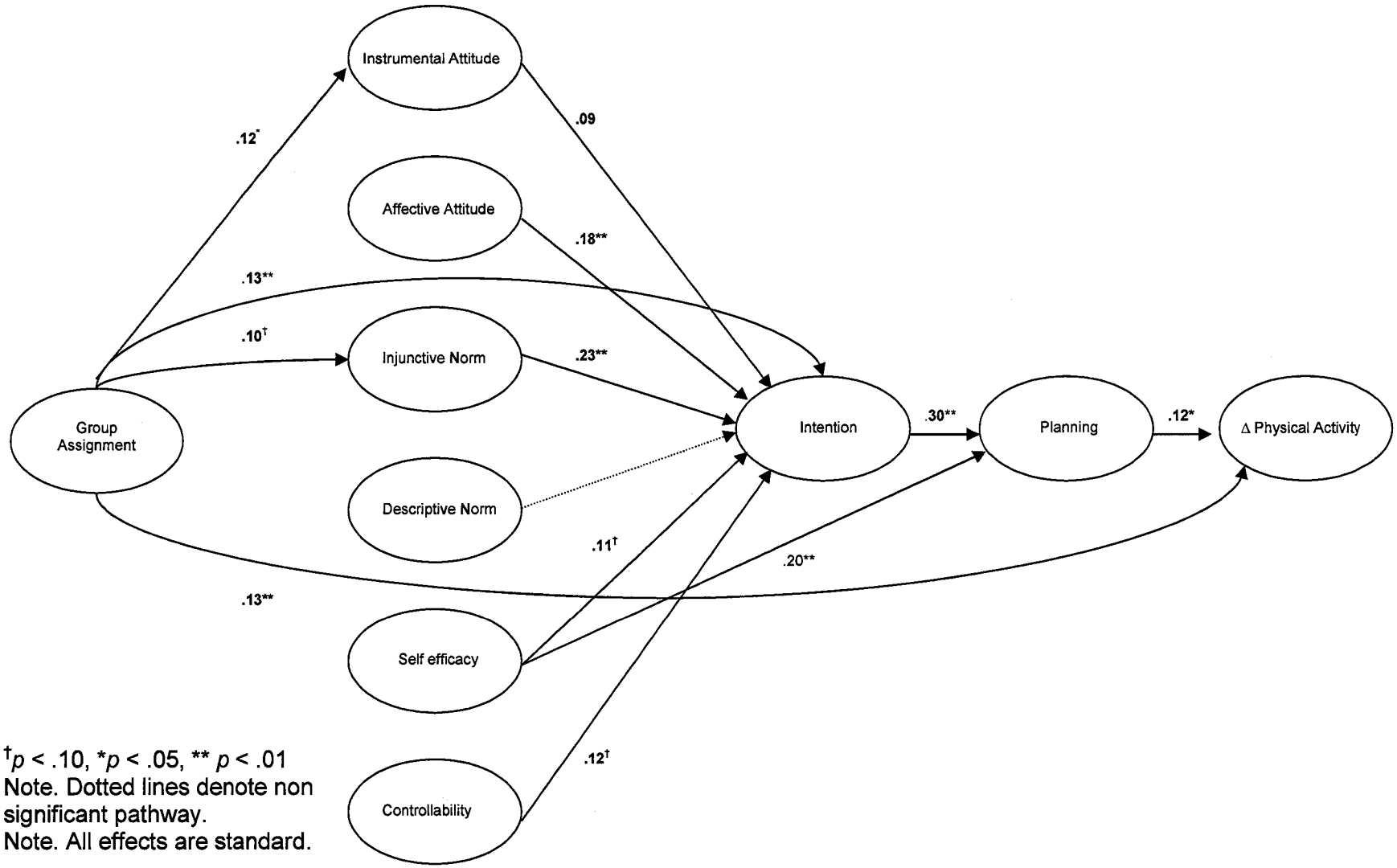
Table 3.

Bivariate Pearson product-moment correlations among TPB change-scores at 4 weeks and physical activity behavior change scores at 3 months

Variable	2.	3.	4.	5.	6.	7.	8.	9.	10.
1. Intervention	.09	.03	.09	.00	.05	-.03	.15**	.07	.14**
2. Instrumental Attitude		.45**	.45**	.25**	.43**	.36**	.42**	.28**	-.03
3. Affective Attitude			.29**	.35**	.38**	.26**	.43**	.29**	.08
4. Injunctive Norm				.42**	.39**	.32**	.45**	.29**	.01
5. Descriptive Norm					.25**	.19**	.27**	.23**	.05
6. Self-efficacy						.56**	.44**	.26**	.01
7. Controllability							.35**	.14**	.06
8. Intention								.38**	-.07
9. Planning									.12*
10. Physical Activity Behavior Change									

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

Figure 1. SEM pathways for TPB constructs using TPB change scores at 4 weeks and physical activity behavior change scores at 3 months



†$p < .10$, *$p < .05$, ** $p < .01$
Note. Dotted lines denote non significant pathway.
Note. All effects are standard.

CHAPTER 6:

Conclusions

The rising number of breast cancer survivors has led to a need for efficacious interventions to improve quality of life (QoL) and survival in this population. This has led to an increasing interest in the area of physical activity (PA) as a possible means of alleviating some of the physical, functional, psychological and emotional impairments associated with the breast cancer experience and its treatments as well as increasing survival.[1, 2] While research to date in the field of PA and breast cancer has started to demonstrate convincing evidence for the supportive role of PA for recovery and survival from breast cancer,[3, 4] interventions designed to improve the prevalence of PA among the community of breast cancer survivors are lacking.

The Activity Promotion (ACTION) Trial was a randomized controlled trial designed to 1) to develop and evaluate the suitability and appropriateness of a TPB-based PA guidebook, 2) to determine the effects of breast cancer-specific PA print materials (PM), a step pedometer (PED), or their combination (COM), on PA and QoL in breast cancer survivors compared to survivors receiving a standard recommendation to exercise (SR), and 3) to examine the effects of TPB-based PA print materials on TPB constructs and behavioral, normative, and control beliefs and to determine if the TPB mediated the effects of our TPB-based interventions on PA behavior

Development of the Intervention Material

In order to facilitate behavior change, researchers advocate that written health information should be theoretically-based.[5] Application of behavioral theories can assist researchers in understanding the mechanisms through which individuals change (or do not change) their PA behavior. In Chapter 3 (Study 1), we described the development a 62-page PA guidebook for breast cancer survivors (i.e., *Exercise for health: An exercise guide for breast cancer survivors*) based on the theoretical components of the TPB.[6] The information in the PA guidebook was formulated and written based on behavioral,

normative, and control beliefs elicited from breast cancer survivors in previous research. The PA guidebook was also based on previous research examining the exercise preferences and determinants of breast cancer survivors.[7-10] Evaluative procedures (i.e., expert judge ratings, written feedback) yielded preliminary evidence that our guidebook targeted the intended TPB components.[6] Furthermore, results indicated that the guidebook was suitable, appropriate, and usable. This dissertation is the first attempt to develop and empirically evaluate a TPB-based PA guidebook for any population.

It is anticipated that this study will provide researchers and practitioners with a sample of methods that can be implemented to conduct such research aimed at a) evaluating the suitability and appropriateness of PA print materials, and b) evaluating the theoretical content of such materials. Publishing information pertaining to the development of PA print materials (e.g., intervention materials, PA promotion materials) may assist other endeavors aimed at developing and implementing potentially effective PA print materials. By developing print materials firmly grounded in behavioral theory, researchers and practitioners can better understand the mechanisms through which individuals change (or do not change) their PA behavior. Given the results from this study, *Exercise for health: An exercise guide for breast cancer survivors* was deemed suitable for testing using randomized controlled trial methodology.

Physical Activity Behavior and Quality of Life

In Chapter 4 (Study 2), we reported that breast cancer survivors in the PM, PED, and COM intervention groups, compared to the SR group, increased their mod/vig PA min•wk by about 40-60 min•wk and their brisk walking by about 60-90 min•wk at the 3 month time-point. Furthermore, only survivors in the COM group reported significantly greater improvements in QoL and reductions in fatigue than survivors in the SR group. These improvements in the COM group approached the minimal thresholds for clinically important differences (CIDs) for the FACT-B and FS (i.e., 7.0 points, and 3.0 points

respectively).[11, 12] A CID is defined as the smallest difference which individuals and healthcare providers perceive as beneficial and which would mandate a change in the individual's medical management.[13] Standardized effect sizes (*d*) were in the small-to-moderate range (i.e., .25 to .50). The observed effect sizes meet or exceed that reported in a meta-analysis of other cognitive-behavioral interventions for cancer survivors.[14] The improvements in fatigue in the COM group are of particular relevance given that fatigue is a common symptom that can last well into survivorship.[15]

At 9 months, we found no statistically significant differences between groups on all QoL variables we assessed (i.e., QoL and fatigue). Although no statistical differences emerged, substantive and clinically meaningful differences were observed between all three intervention groups (i.e., PM, PED, COM) and the SR group on self-report PA and brisk walking. These results indicated that survivors in the intervention groups were still reported an extra 30-60 min•wk of PA and 35-47 min•wk of brisk walking when compared to the SR group. These differences were indicative of small-to-medium effects. One could speculate that a difference of an extra 30 min•wk of PA is the equivalent of one extra day per week of PA. The decrease in sample size at the 9-month time-point along with a noticeable increase in variability in PA in the PED group may explain why statistical significance was not achieved. These results suggest that print material and pedometers have merit in promoting long term (i.e., 9 month) PA maintenance. Typically, research in the non-cancer domain examining the effects of print materials on PA behavior is suggestive of diminished effects at the six-month/follow-up time-point.[16-19] Nonetheless, researchers and practitioners should incorporate and implement more interactive strategies during follow up to encourage PA behavior maintenance (e.g., telephone calls, frequent mailings).

Given the paucity of studies examining PA promotion strategies in breast cancer survivors, comparing these results with others is challenging. Most relevant to our study,

Demark-Wahnefried and colleagues examined the effects of a home-based diet and exercise program delivered via telephone counseling and print materials in a mixed sample of 182 older breast and prostate cancer survivors.[20] Results showed a significant improvement in diet quality but not in PA or QoL over a six-month intervention period and a six-month follow-up. Reasons for the differences in the PA findings between the two studies are unknown but could be due to the use of different self-report measures of PA (the LSI versus the CHAMPS), different theoretical models to develop intervention materials (the TPB versus social cognitive theory and the transtheoretical model), our larger sample size (377 versus 182), our more homogeneous sample (breast cancer survivors versus breast and prostate combined), and/or our younger sample (58 versus 72 years old). Demark-Wahnefried and her colleagues also published a design paper that outlined and described one current and ongoing randomized controlled trial designed to test whether various health behavior counseling methods (e.g., print materials, pedometers) affect exercise behavior and fruit and vegetable consumption in breast and prostate cancer survivors (i.e., FRESH START).[21] Results from the FRESH START study (which are not yet available) will provide further valuable insight into the value of behavior change tools in assisting cancer survivors in become physically active.

The results from Study 2 are especially important given results from a recent prospective cohort study of almost 3,000 breast cancer survivors that suggested that higher levels of PA in breast cancer survivorship were associated with reduced risks of breast cancer death and breast cancer recurrence.[4] Given that the majority of breast cancer survivors are not meeting public health PA guidelines,[22-25] behavioral strategies targeted such as print material and pedometers appear to be viable methods of facilitating PA behavior.[1, 16-19, 26-28] By facilitating PA, breast cancer survivors can a) experience the associated health benefits of PA,[1, 2] and b) reduce their risk of breast cancer recurrence and breast cancer death.[4]

Mechanisms of Physical Activity Behavior Change

In Chapter 5 (Study 3), we examined the effects of TPB-based PA print materials on TPB constructs. The purpose of this study was to determine if the TPB mediated the effects of our TPB-based interventions on PA behavior change at 3 months. In support of our hypotheses, we found that survivors receiving the TPB-based interventions generally reported positive changes in the TPB constructs and beliefs compared to the SR group. Several of these effects were significant or borderline significant including changes in affective attitude, injunctive norm, intention, and several behavioral and control beliefs. We performed structural equation modeling (SEM) to examine whether the TPB explained the effects of our TPB-based interventions on PA behavior change. Structural path coefficients indicated that receiving the TPB-based interventions resulted in positive changes of perceived approval and support from significant others (i.e., injunctive norm), a more favorable evaluation of PA as a useful health behavior (i.e., instrumental attitude), and stronger motivation to participate in PA (i.e., intention).

This study followed Baranowksi's contention that while behavioral theories provide the basis for understanding PA behavior, behavioral theories should also be used as a framework for designing interventions and for understanding how interventions work to promote change in PA (in both the cancer, and non-cancer population).[29] This study is important given the limited number of studies that have examined the underlying theoretical mechanisms in PA behavior change interventions in the breast cancer population.[30, 31] To our knowledge, this study represents the first attempt to examine the underlying theoretical mechanisms of a TPB-based print material intervention in breast cancer survivors. In the cancer population, only two other studies have examined the effects of theoretically-based PA interventions on social cognitive/theoretical constructs.[30, 31] Jones and colleagues found that breast cancer survivors who received an oncologist's recommendation (framed around the theoretical

tenets of the TPB) to exercise reported more positive attitudes, stronger subjective norms, perceptions of control, and intentions to exercise than those survivors that did not receive a recommendation. As well, Rabin et al.[31] evaluated theoretical mediators of PA behavior change in breast cancer survivors using the transtheoretical model as a guiding framework. Survivors in the intervention group received a pedometer and a weekly telephone call for 12 weeks while survivors in the contact control group were asked not to change their current level of activity. Results indicated that decisional balance, self-efficacy, behavioral processes of change, and experiential processes of change did not mediate the effects of the intervention on PA behavior change.[31]

Limitations

Despite the importance and novelty of this dissertation, there are limitations that should be taken into account when interpreting our data and planning future research. In Study 1, we used the Maine Area Health Education Center Checklist (AHEC)[32] to assess the suitability and appropriateness of our guidebook. The AHEC's checklist response format (i.e., either an attribute is present or not) poses some limitations with the precision of measurement. Other suitability assessment tools, such as the Suitability Assessment of Materials[32] may be effective in garnering information pertaining to the suitability of written educational materials. Because there are no other studies to make comparisons, it is difficult to critically appraise this study.

In the development of the guidebook, PA preferences as well as behavioral, normative, and control beliefs were elicited from previous research that has elicited these variables from the breast cancer survivor population.[7-10] Given that the aforementioned evidence was published as far back as 1999,[8] it is possible that this evidence may be outdated. Specifically, current focus group work and/or elicitation procedures may indeed elicit different preferences and beliefs given the increasing

recognition and emergence of PA as an effective rehabilitative modality for breast cancer survivors.

In Study 2, our intervention was limited by the self-report of PA and failure to blind survivors from their pedometer step count during baseline and 3-month testing. It is also possible the SR and PM participants used their pedometers during the initial 3-month intervention, even though instructions were given to refrain from use. There are several limitations to using pedometers to gauge PA behavior. First, pedometers only provide a measure of ambulatory activity (i.e., walking) and therefore give no indication of the intensity of the activity (e.g., mild walking, brisk walking, jogging). Given this limitation, more sophisticated objective monitors such as accelerometers may provide more complete information given that variables such as energy expenditure and caloric expenditure can be elicited from these devices. Second, even though participants were encouraged to maintain their usual activity patterns during baseline and 3-month testing, there is a possibility that participants deliberately participated in more walking/PA during these testing periods given that they were wearing a pedometer. However, if indeed this were occurring, it is expected that this effect would occur at both time points and thus negate any 'pedometer effect' that may be evident. Finally, given that our study was conducted during the warmer months (July to October), it is unknown if the intervention would be equally effective during the more difficult winter months. However, Study 2 was deliberately conducted during a time period that was deemed to be most representative and generalizable to the region's 12-month weather trends.

In Study 3, it was clearly evident that our sample of breast cancer survivors was highly motivated given their already favorable beliefs about PA as elicited at the baseline time point. This factor may have possibly worked against our hypotheses and our results may have been even stronger if we had a sample with less favorable beliefs about PA. Furthermore, to preserve statistical power in the SEM analyses, the INT grouping

variable consisted of the two intervention groups that received the theoretical material (i.e., PM and COM). Therefore, it was not possible to determine the effects of the pedometer alone (i.e., PED) on the TPB variables.

Even though only 34% of participants were physically active prior to participating in the ACTION Trial, It is still possible that a selection bias may exist given the transparent purpose of the study and the 24% participation rate (although substantially more were interesting in participating). Perhaps only breast cancer survivors interested and likely to engage in PA may have participated in this study. The possible selection bias may affect the scope in which the results from the ACTION Trial can generalize. This finding underscores the importance in attracting breast cancer survivors that are less inclined to participate in trials of a similar nature, such as breast cancer survivors that are not physically active.

Another limitation of this dissertation is the partial reliance on self-report measure of PA. However, the likelihood that self-report or social desirability bias affected responses on the self-report PA questionnaires is small. If a response bias was present, however, we would have expected this bias across all 4 groups given that all groups were asked to increase PA and to provide self-report assessments of PA. Indeed, the 30 minute increase in PA we observed in the SR group (i.e., control) may partly reflect this bias, which is why we selected a standard recommendation group as our comparison group. Moreover, recent research has suggested that there is minimal evidence of social desirability for the self-report PA scale that we used.[33]

Strengths

Exercise for health: An exercise guide for breast cancer survivors is the first attempt to develop and empirically evaluate a theory-based PA guidebook for breast cancer survivors.[6] The findings from this study are important because they not only warrant future randomized controlled trials examining PA promotion strategies with

cancer survivors, but also give valuable information on the design of optimal programs that effectively target the relevant determinants of PA in this group. Other strengths of our trial include the first study to examine the effects of breast cancer-specific print material and step pedometers on PA and QoL in breast cancer survivors, use of the two component model of the TPB, the randomized controlled trial design, the use of a standard recommendation as our comparison group, high fidelity to the intervention materials, the large sample size, the minimal loss-to-follow up, the use of a breast cancer-specific (i.e., disease-specific) QoL measure, and the generalizability of our sample given no statistical differences in demographic, medical, and behavioral variables compared to a) survivors not participating in the trial, and b) survivors that were loss-to-follow up.

The ACTION trial is one example of the process of knowledge translation. The Canadian Institutes of Health Research (CIHR) defines *knowledge translation* as the process of supporting the uptake of health research in a manner that improves the health and health care of Canadians through improved understandings, processes, services, products or systems. For successful knowledge translation, CIHR proposes a series of criteria that must occur. The ACTION trial has achieved these criteria. These criteria (and examples based on the ACTION trial) include 1) including several active participants in the process (e.g., involvement of oncologists, health communication experts, breast cancer survivors), 2) developing targeted interventions based on the intended user(s) (print materials designed and implemented exclusively for breast cancer survivors), 3) information dissemination (e.g., academic publication, professional conference presentation), 4) revision based on new knowledge (e.g., print material content assessment and revision), and 5) movement beyond academic publication (e.g., dissemination of print material to interested practitioners and cancer care professionals).

Future Directions for Research

The results of the three studies comprising this dissertation give rise to a number of important research questions that warrant further investigation. To our knowledge, there are no other studies that have assessed the suitability of written PA promotion material for breast cancer survivors. Given that this is the first study to empirically evaluate theoretically-based print materials, future researchers must rigorously evaluate their behavior change strategies (e.g., print material, internet content) before implementation into evaluative efforts such as randomized controlled trials. Researchers and practitioners should continue to use suitability evaluation tools (and continue to develop new tools) to assess the suitability and appropriateness of materials before using them as intervention tools in both research and clinical practice. It is essential that researchers in the area of PA behavior change need to a) publish empirical evidence providing adequate description and detail pertaining to the written health/PA materials they are implementing, and b) continue to explore and evaluate the utility of the TPB (and other social cognitive theories) in the development of such materials.

Future research in PA promotion strategies with breast cancer survivors should examine a wider spectrum of PA determinants that includes medical, demographic and behavioral variables as well as other factors such as the physical environment, culture, personality, and policy. Given nearly all research to date has applied the TPB as a framework for understanding social cognitive components of PA in breast cancer survivors, researchers should more rigorously examine other theories of health behavior in order to discover what theoretical frameworks are the most effective to use with breast cancer survivors. If deemed suitable, these determinants should be used as the basis for PA promotion strategies. Only after these variables are explored and considered will we have a more thorough understanding of a) the determinants of exercise in breast cancer

survivors, and b) best practice for assisting breast cancer survivors in achieving the adequate dose of PA necessary for health benefits.

Given that intervention materials based on the TPB rely on changing the individual's underlying beliefs regarding the behavior in question, researchers in this area should continue to investigate the most optimal methods of changing breast cancer survivors' knowledge, attitudes, and beliefs about PA. This will assist in the development and refinement of PA promotion tools (e.g., print materials, physician counseling, internet resources) in future research and PA information dissemination endeavors.

Given our findings, future research should examine the effect of other more intensive behavior change strategies (e.g., telephone counseling, face-to-face counseling, social support groups, physician counseling) in facilitating PA behavior change. It is possible that behavioral interventions that have more contact-time with the participant(s) are more likely to elicit greater changes in cognitions and behavior. Furthermore, a test of a TPB-based intervention with participants that have less favorable beliefs than our motivated sample may result in larger cognitive and behavior changes. Future trials should be more proactive at recruiting less motivated survivors to avoid these possible ceiling effects.

This dissertation research extends the work of Jones and colleagues[34] that examined the effect of an oncologists exercise recommendation at the time of treatment consultation. Future research should continue to examine PA behavior change strategies at different points of time throughout the breast cancer trajectory (e.g., final radiotherapy appointment, 6-month follow up appointment with oncologist, 1-year follow up). Furthermore, research should examine the most effective source of PA information delivery (e.g., medical oncologist, clinical nurse oncologist, physiotherapist, kinesiologist). While PA behavior change is critical, future researchers must also

examine relevant outcomes that may be associated with PA behavior change (e.g., QoL, cardiorespiratory fitness, body composition).

Ultimately, research examining PA and QoL in breast cancer survivors should continue to use disease-specific measures of QoL. Furthermore, a 'modular/domain-specific' approach to QoL assessment, in which a core of general questions is supplemented with disease- and treatment-specific items is gaining acceptance. These results further support the increasing advocacy and role for disease/condition-specific measures of QoL in the oncology field. Given that there is limited evidence for the effectiveness of PA programs for generic health-related QoL (e.g., SF-36),[1] research in this area should continue to explore breast cancer-specific measures of QoL (Eastern Cooperative Oncology Group; Functional Assessment of Cancer Therapy Measurement System, Cancer Rehabilitation Evaluation System Short Form, Quality of Life in Adult Cancer Survivors). Furthermore, researchers should take a modular approach to QoL assessment so that the effect of PA on specific aspects of a breast cancer diagnosis and its related treatments and side effects (e.g., lymphedema, taxane-based chemotherapy, hormone replacement therapy) can be captured. Generic measures of QoL are not able to capture relevant side effects associated with the aforementioned breast cancer-related factors.

Further research is also warranted to determine if other distance-based strategies are effective at assisting breast cancer survivors in becoming more physically active (e.g., telephone counseling, internet). Most importantly, researchers should actively engage in knowledge translation by sharing empirical evidence with practitioners, clinicians, health promotion practitioners, the population under study (e.g., breast cancer survivors). Nonetheless, the ACTION trial provides researchers and practitioners with valuable information and justification for the design of future PA

promotion trials for breast cancer survivors. Ultimately, as more evidence emerges that supports PA as a supportive therapy for other cancer groups (e.g., colorectal, prostate, older survivors, late stage survivors), and the determinants and beliefs regarding PA are elicited in these populations, researchers should pursue research avenues dedicated towards the development and evaluation of PA behavior change strategies in these populations.

Conclusion

The rising number of breast cancer survivors has led to a need for behavior change strategies and interventions that can potentially improve QoL and survival for this population. With this has come an increasing interest in the area of PA as a possible means of alleviating some of the physical, functional, psychological and emotional impairments associated with the cancer experience and its treatments as well as increasing survival. Recent reviews of the PA literature in breast cancer survivors[1-3, 35] have brought attention to this gap and recommendations have been made to extend the research to these other tumor types.

The ACTION Trial is an advancement over previously conducted studies[20, 34] given the a) empirical development and evaluation of the TPB-based PA print material, and b) design of the study that allows for testing the effects of the print material and the relevant theoretical mechanisms that may be the causal agent of change. To this end, results from our study provide further support for the use of the TPB as a framework for developing and implementing PA behavior change interventions in breast cancer survivors. This research may ultimately help breast cancer survivors enhance their QoL and reduce their risk of recurrence and early death from breast cancer through regular participation in PA.

This project initiates a critical area of research by examining practical, sustainable, and potentially effective promotional interventions designed to enhance PA and QoL in breast cancer survivors in Northern Alberta. The strategies implemented in this study are consistent with the need to develop and assess the efficacy of interventions that employ distance medicine-based approaches.[20, 21, 36] Although breast cancer survivors have indicated a strong interest in receiving PA counseling and advice,[10, 37] changing individuals' behavior is a challenging task that continues to perplex both researchers and practitioners. With the guidance of cancer care professionals, breast cancer survivors can be informed and educated about the beneficial effects of adopting regular PA as a part of their daily lifestyle, and pursue these avenues to improve their QoL. Ultimately, this distance-based medicine approach was a low-cost, feasible, and safe rehabilitation modality that the breast cancer control team can feasibly incorporate into daily practice. The results from the ACTION trial contribute to the expanding base of knowledge indicating that PA is a safe, feasible, and effective intervention for breast cancer survivors.[1, 2] More importantly, the results from this study may strengthen the argument that breast cancer survivors do not have to perform vigorous PA to accrue the health benefits associated with activity. Moreover, breast cancer survivors can experience the benefits of PA by engaging in activity that is moderate in intensity (e.g., brisk walking), easy, and enjoyable.

Ultimately, the results from this study suggest that the distance-based option is low-cost option [e.g., print materials=$14.00US per participant (includes design costs); pedometers=$16.00US per participant] that may have greater generalizability and ecological validity for long term breast cancer survivors than clinically-based interventions. These types of interventions and programs can be implemented and accessed in most communities and rural settings and may consequently benefit the greatest number of breast cancer survivors. Furthermore, these interventions are

consistent with the need to develop and assess the efficacy of interventions that employ distance medicine-based approaches and may be ideal for Alberta breast cancer survivors given the geographical dispersion of our population. These data provide valuable information and justification for the design of future PA promotion interventions and trials for breast cancer survivors.

The availability of PA information that improves motivation, PA behavior, and QoL in breast cancer survivors and feature activities that this group will enjoy and adhere to (e.g., utilizing elicited PA preferences) may help improve the low PA participation rates of this population. Increased PA prevalence rates in breast cancer survivors in turn could improve general health and decrease mortality, as well as potentially improve QoL parameters associated with the breast cancer experience.

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Appendix 1:

Oncologist Letter

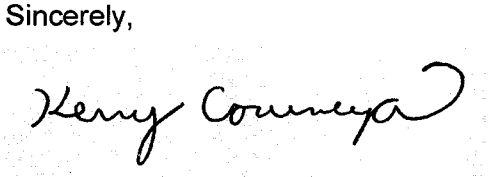
Dear Dr.

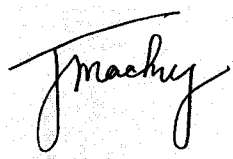
My name is Dr. Kerry Courneya and I am a Professor in the Faculty of Physical Education and an Adjunct Professor in the Department of Oncology at the University of Alberta. I am also a member of the Scientific Staff at the Cross Cancer Institute (Edmonton). I conduct research in the area of exercise and cancer. Dr. John Mackey and I are initiating a physical activity study that requires the voluntary participation of breast cancer survivors in Northern Alberta (please see the attached study protocol for more details). In this study, we are testing the effect of various methods of physical activity promotion (i.e., pedometers and physical activity print information) on home-based activity levels. The Alberta Cancer Board's Research Ethics Board has approved this study. You have been contacted because you are the treating medical or radiation oncologist or family physician of an individual, or individuals, whose name(s) have been identified through the Alberta Cancer Registry as meeting our inclusion criteria. As part of the current ethical approval process, we must obtain "active consent" from the physicians of these individuals before we can invite any individual to participate in our study. You can either (a) grant blanket approval for all your identified patients, (b) grant approval on a case-by-case basis, or (c) deny approval for all patients

We are only asking your permission to mail the identified individual(s) a study information package. The individual will then have the option of whether to volunteer for the study or not. If you consent to the contact of this/these individual(s), or there are any compelling reasons for not mailing study information to this/these individual(s), please phone the Behavioral Medicine Laboratory: Jeffrey Vallance (780) 492-2829, **Fax: (780) 492-8003**, or e-mail: vallance@ualberta.ca

I hope to hear from you, or from one of your representatives, in the near future. If I have not received correspondence from you within the next 3 weeks, I will then be in contact with you by telephone at that time. Thank you for your help and cooperation.

Sincerely,





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Appendix 2:

Invitation to Participate

Re: New home-based exercise study for breast cancer survivors

Dear:

My name is Jeff Vallance and I am a doctoral student here at the University of Alberta. Together with Dr. Kerry Courneya from the University of Alberta and Dr. John Mackey, a medical oncologist from the Cross Cancer Institute, we are starting a research project designed to test and examine different ways of promoting exercise in breast cancer survivors in Alberta. We want to know what the most effective ways of promoting exercise are.

Your oncologist has given us permission to contact you to see if you are interested in participating. We are currently gathering participants to the study and have noted through the Alberta Cancer Registry that you meet our eligibility criteria. Therefore we would like to invite you to participate in our study.

Is this study for you?

- ❑ Are you interested in exercising more?
- ❑ Do you want to learn how exercise can be fun and easy to fit into your daily life?
- ❑ Do you struggle to find time during the day to exercise?
- ❑ Want to learn about the latest research in exercise and breast cancer?

If you answered yes to any of these questions, this study is for you! You are eligible to participate in this study whether you currently exercise or not. If you are already an exerciser, we'll give you some extra guidance. If you don't exercise, we'll help you get started in a way that is enjoyable for you.

What are we doing?

We are interested in determining the best and most effective ways of promoting exercise for breast cancer survivors. We have developed various tools (e.g., step pedometers, exercise guidebooks, exercise diaries) that are designed to help people start and maintain exercise. For this study, we are providing participants with exercise information to determine whether it helps people like yourself improve their exercise levels.

Do I have to travel anywhere to participate in this study?

You **do not** need to travel anywhere for this study. This study is a home-based exercise study. That means that everything related to the study can be done in the comfort of your own home. You can even participate if you are on vacation! You **do not** need to come into an exercise centre as all the study information and materials will be sent directly to your home.

What do I have to do if I join the study?

Over a 12-week period (starting July 1, 2005) you will be asked to:

- Complete three questionnaires that will ask you about your current physical ability, any lingering symptoms you may be experiencing (e.g., fatigue), your previous exercise habits, and your thoughts and opinions about exercise.

- Complete a 7-day exercise monitoring period once at the beginning and once at the end of the study. These monitoring periods will require you to wear a step pedometer (that we will send you) for 7 days in a row, and record your daily step total before you go to bed each night in an exercise diary that we will provide you.

- Once you have completed and returned the pre-study assessments (i.e., questionnaire, exercise diary), you will then receive your exercise promotion materials to use during the 12-week period. You can use these materials whenever it is convenient for you!

What are the benefits of participating?

There are lots of benefits to participating! By participating in this study, you will be given valuable information and strategies about starting and maintaining an exercise program. Also, the information you provide us will also help us to understand whether promoting exercise is an effective way to help others exercise. For completing the 12-week study, you will receive your own step pedometer, instructional exercise guidebook, and a Dry-Fit long-sleeve exercise shirt. Of course, there is no financial cost for anything in this study.

If you think you might be interested, or would like to hear more about the study we are doing, you can either:

- ❑ Place a checkmark in the appropriate box on the enclosed 'Study Response Form' **and return it to us in the enclosed business reply envelope**. A research coordinator will contact you shortly after receiving your reply. No postage is necessary on this envelope.

- ❑ Phone Jeff Vallance or Celeste Shaw (research coordinators) at 492-8274 if you would like more information. If you are from outside of Edmonton, call us toll free at 1-800-492-8274.

- ❑ Or email Jeff Vallance at vallance@ualberta.ca.

Thank you for considering our study and we hope to hear from you soon! It is only through voluntary participation in research projects that we can increase our knowledge of exercise and the cancer experience.

Thank you in advance,

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Appendix 3:

Baseline Questionnaire

EXERCISE AND HEALTH STUDY

CROSS CANCER INSTITUTE
AND THE
UNIVERSITY OF ALBERTA

Alberta Cancer Board

Instructions*

Thank-you for agreeing to participate in this study! In this questionnaire, we are going to ask you a series of questions about yourself. There are no right or wrong answers and all we ask is that you provide responses that are as honest and accurate as possible. The questionnaire should take about 30-40 minutes to complete. All responses are completely confidential and will never be used in any way that could link them to you. It is important to complete all questions. Please remember that you will never be individually identified in any reports or presentations. Data are presented as group averages.

After completing your questionnaire, please place it (along with your 3-month step calendar and your 7-day step test sheet) back in the stamped addressed envelope provided.

Keep one copy of the informed consent for your records and sign and return the other with this questionnaire. Many thanks in advance for considering our study.

For further information or if you have any questions about completing the questionnaire, please contact Jeff Vallance or Celeste Shaw (project coordinators). If you are calling within Edmonton, call us at 492-8274. If you are calling from outside of Edmonton, call us toll free at 1-866-492-8274 or email at vallance@ualberta.ca.

Please indicate the extent to which you have experienced each of the statements during the past 7 days by circling the appropriate number using the following scale. Please complete the questions even if the symptom (s) are not associated with your previous breast cancer diagnosis. If you do not experience any of the particular symptoms, please indicate so by circling 0 (not at all).

0	1	2	3	4
not at all	a little bit	somewhat	quite a bit	very much

During the past week:

1. I have a lack of energy	0	1	2	3	4
2. I have nausea	0	1	2	3	4
3. Because of my physical condition, I have trouble meeting the needs of my family	0	1	2	3	4
4. I have pain	0	1	2	3	4
5. I am bothered by side effects of treatment	0	1	2	3	4
6. I feel ill	0	1	2	3	4
7. I am forced to spend time in bed	0	1	2	3	4
8. I feel close to my friends	0	1	2	3	4
9. I get emotional support from my family	0	1	2	3	4
10. I get support from my friends	0	1	2	3	4
11. My family has accepted my illness	0	1	2	3	4
12. I am satisfied with family communication about my illness	0	1	2	3	4
13. I feel close to my partner (or the person who is my main support)	0	1	2	3	4
14. I am satisfied with my sex life (leave blank if not applicable)	0	1	2	3	4
15. I feel sad	0	1	2	3	4
16. I am proud of how I am coping with my illness	0	1	2	3	4

During the past week:

17. I am losing hope in the fight against my illness	0	1	2	3	4
18. I feel nervous	0	1	2	3	4
19. I worry about dying	0	1	2	3	4
20. I worry that my condition will get worse	0	1	2	3	4
21. I am able to work (include work at home)	0	1	2	3	4
22. My work is fulfilling (include work at home)	0	1	2	3	4
23. I am able to enjoy life	0	1	2	3	4
24. I have accepted my illness	0	1	2	3	4
25. I am sleeping well	0	1	2	3	4
26. I am enjoying the things I usually do for fun	0	1	2	3	4
27. I am content with the quality of my life right now	0	1	2	3	4
28. I have been short of breath	0	1	2	3	4
29. I am self-conscious about the way I dress	0	1	2	3	4
30. My arms are swollen or tender	0	1	2	3	4
31. I feel sexually attractive	0	1	2	3	4
32. I have been bothered by hair loss	0	1	2	3	4
33. I worry that other members of my family might someday get breast cancer	0	1	2	3	4
34. I worry about the effect of stress on my illness	0	1	2	3	4
35. I am bothered by a change in weight	0	1	2	3	4
36. I am able to feel like a woman	0	1	2	3	4
37. I have certain parts of my body where I experience significant pain	0	1	2	3	4

0	1	2	3	4
not at all	a little bit	somewhat	quite a bit	very much

During the past week:

38. I feel fatigued	0	1	2	3	4
39. I feel weak all over	0	1	2	3	4
40. I feel listless ("washed out")	0	1	2	3	4
41. I feel tired	0	1	2	3	4
42. I have trouble starting things because I am tired	0	1	2	3	4
43. I have trouble finishing things because I am tired	0	1	2	3	4
44. I have energy	0	1	2	3	4
45. I am able to do my usual activities	0	1	2	3	4
46. I need to sleep during the day	0	1	2	3	4
47. I am too tired to eat	0	1	2	3	4
48. I need help doing my usual activities	0	1	2	3	4
49. I am frustrated by being too tired to do the things I want to do	0	1	2	3	4
50. I have to limit my social activity because I am tired	0	1	2	3	4

51. On which side was your breast operation?

Left **Right** (please circle one)

52. Movement of my arm on this side is painful	0	1	2	3	4
53. I have a poor range of arm movements on this side	0	1	2	3	4
54. My arm on this side feels numb	0	1	2	3	4
55. I have stiffness of my arm on this side	0	1	2	3	4

This set of questions asks for your views about your health. This information will help us keep track of how you feel and how well you are able to do your usual activities. Answer every question by marking the answer as indicated. If you are unsure about how to answer a question please give the best answer you can.

1. In general, would you say your health is:

   - ❑ Excellent
   - ❑ Very good
   - ❑ Good
   - ❑ Fair
   - ❑ Poor

2. Compared to one year ago, how would you rate your health in general now?

   - ❑ Much better now than a year ago.
   - ❑ Somewhat better now than a year ago.
   - ❑ About the same as one year ago.
   - ❑ Somewhat worse now than one year ago.
   - ❑ Much worse now than one year ago.

3. The following items are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

   a. Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports.

      - ❑ Yes, limited a lot.
      - ❑ Yes, limited a little.
      - ❑ No, not limited at all.

   b. Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf.

      - ❑ Yes, limited a lot.
      - ❑ Yes, limited a little.
      - ❑ No, not limited at all.

   c. Lifting or carrying groceries.

      - ❑ Yes, limited a lot.
      - ❑ Yes, limited a little.
      - ❑ No, not limited at all.

d. Climbing several flights of stairs.

- ❑ Yes, limited a lot.
- ❑ Yes, limited a little.
- ❑ No, not limited at all.

e. Climbing one flight of stairs.

- ❑ Yes, limited a lot.
- ❑ Yes, limited a little.
- ❑ No, not limited at all.

f. Bending, kneeling or stooping.

- ❑ Yes, limited a lot.
- ❑ Yes, limited a little.
- ❑ No, not limited at all.

g. Walking more than one mile.

- ❑ Yes, limited a lot.
- ❑ Yes, limited a little.
- ❑ No, not limited at all.

h. Walking several blocks.

- ❑ Yes, limited a lot.
- ❑ Yes, limited a little.
- ❑ No, not limited at all.

i. Walking one block.

- ❑ Yes, limited a lot.
- ❑ Yes, limited a little.
- ❑ No, not limited at all.

j. Bathing or dressing yourself.

- ❑ Yes, limited a lot.
- ❑ Yes, limited a little.
- ❑ No, not limited at all.

4. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

    a. Cut down the amount of time you spent on work or other activities.

        ❑ Yes
        ❑ No

    b. Accomplished less than you would like.

        ❑ Yes
        ❑ No

    c. Were limited in the kind of work or other activities.

        ❑ Yes
        ❑ No

    d. Had difficulty performing the work or other activities (for example, it took extra time).

        ❑ Yes
        ❑ No

5. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

    a. Cut down the amount of time you spent on work or other activities.

        ❑ Yes
        ❑ No

    b. Accomplished less than you would like.

        ❑ Yes
        ❑ No

    c. Didn't do work or other activities as carefully as usual.

        ❑ Yes
        ❑ No

6. During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?

   - ❑ Not at all
   - ❑ Slightly
   - ❑ Moderately
   - ❑ Quite a bit
   - ❑ Extremely

7. How much bodily pain have you had during the past 4 weeks?

   - ❑ Not at all
   - ❑ Slightly
   - ❑ Moderately
   - ❑ Quite a bit
   - ❑ Extremely

8. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?

   - ❑ Not at all
   - ❑ Slightly
   - ❑ Moderately
   - ❑ Quite a bit
   - ❑ Extremely

9. These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks...

   a. did you feel full of pep?

      - ❑ Almost all the time
      - ❑ Most of the time
      - ❑ A good bit of the time
      - ❑ Some of the time
      - ❑ A little of the time
      - ❑ None of the time

b. have you been a very nervous person?

- ❑ Almost all the time
- ❑ Most of the time
- ❑ A good bit of the time
- ❑ Some of the time
- ❑ A little of the time
- ❑ None of the time

c. have you felt so down in the dumps nothing could cheer you up?

- ❑ Almost all the time
- ❑ Most of the time
- ❑ A good bit of the time
- ❑ Some of the time
- ❑ A little of the time
- ❑ None of the time

d. have you felt calm and peaceful?

- ❑ Almost all the time
- ❑ Most of the time
- ❑ A good bit of the time
- ❑ Some of the time
- ❑ A little of the time
- ❑ None of the time

e. did you have a lot of energy?

- ❑ Almost all the time
- ❑ Most of the time
- ❑ A good bit of the time
- ❑ Some of the time
- ❑ A little of the time
- ❑ None of the time

f. have you felt downhearted and blue?

- ❑ Almost all the time
- ❑ Most of the time
- ❑ A good bit of the time
- ❑ Some of the time
- ❑ A little of the time
- ❑ None of the time

g. did you feel worn out?

- ❑ Almost all the time
- ❑ Most of the time
- ❑ A good bit of the time
- ❑ Some of the time
- ❑ A little of the time
- ❑ None of the time

h. have you been a happy person?

- ❑ Almost all the time
- ❑ Most of the time
- ❑ A good bit of the time
- ❑ Some of the time
- ❑ A little of the time
- ❑ None of the time

i. did you feel tired?

- ❑ Almost all the time
- ❑ Most of the time
- ❑ A good bit of the time
- ❑ Some of the time
- ❑ A little of the time
- ❑ None of the time

10. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting friends, relatives, etc.)?

- ❑ Almost all the time
- ❑ Most of the time
- ❑ Some of the time
- ❑ A little of the time
- ❑ None of the time

11. How TRUE or FALSE is each of the following statements for you?

a. I seem to get sick a little easier than other people

- ❑ Definitely true
- ❑ Mostly true
- ❑ Don't know
- ❑ Mostly false
- ❑ Definitely false

b. I am as healthy as anybody I know

- ❑ Definitely true
- ❑ Mostly true
- ❑ Don't know
- ❑ Mostly false
- ❑ Definitely false

c. I expect my health to get worse

- ❑ Definitely true
- ❑ Mostly true
- ❑ Don't know
- ❑ Mostly false
- ❑ Definitely false

d. My health is excellent

- ❑ Definitely true
- ❑ Mostly true
- ❑ Don't know
- ❑ Mostly false
- ❑ Definitely false

In this next questionnaire, we would like you to recall your <u>average weekly exercise in the past month</u>. Considering a typical week (7 days) this past month how many times on average, did you perform the following kinds of exercise?

When answering these questions please:

- Only count exercise sessions that lasted **10 minutes or longer** in duration.
- **Include only exercise that you do during your leisure time** (e.g., going to Curves, walking the dog, swimming, bicycling). **Do not** include activities you do at work or around the house (e.g. mowing the lawn).
- If you have not performed any exercise, please write '0' in that space.
- Note that the main difference between the three categories is the intensity of the exercise.
- Please write the average frequency (i.e., times per week) on the first line and the average duration (i.e., in minutes/hours) on the second line.

In the past month, my average weekly exercise has been:

	Times Per Week	Average Duration
a. STRENUOUS EXERCISE (HEART BEATS RAPIDLY, SWEATING) (e.g., Curves workout, aerobics classes, jogging, swimming laps, hard bicycling, singles tennis, soccer)	_____	_____
b. MODERATE EXERCISE (NOT EXHAUSTING, LIGHT PERSPIRATION) (e.g., brisk walking, doubles tennis, easy bicycling, pilates, yoga, easy swimming, popular and folk dancing, golf without a powercart)	_____	_____
c. MILD EXERCISE (MINIMAL EFFORT, NO PERSPIRATION) (e.g., easy walking, lawn bowling, shuffleboard, golf with a powercart)	_____	_____

Now we only want you to think about how much walking you do. In this next questionnaire, we would like you to recall your average weekly walking in the past month. Considering a typical week (7 days) this past month how many times on average, did you perform the following kinds of walking?

When answering these questions please:

- Only count walking sessions that lasted **10 minutes or longer** in duration.
- **Only include walking that you do during your leisure time** (e.g., exercise, walking the dog, walking through the river valley).
- If you have not performed any walking, please write '0' in that space.
- Note that the main difference between the two categories is the intensity of the walking.
- Please write the average frequency (i.e., times per week) on the first line and the average duration (i.e., in minutes/hours) on the second line.

In the past month, my average weekly walking has been:

	Times Per Week	Average Duration
a. BRISK WALKING (NOT EXHAUSTING, LIGHT PERSPIRATION, HEART BEATS FASTER (e.g., walking like you were late for an appointment, power walking, hiking, golfing without a powercart)	_____	_____
b. MILD WALKING (BREATHING NORMALLY, NO PERSPIRATION) (e.g., daily household activities, walking at work, gardening, evening stroll, golfing with a powercart)	_____	_____

The next section of this questionnaire will ask you specifically about regular exercise. We define regular exercise in two ways:

1. at least 20 minutes of vigorous intensity activity on at least 3 days per week (e.g., heavy breathing, difficult to talk, lots of sweating). Some examples include jogging, aerobics classes, hard biking, swimming, and soccer.

OR

2. at least 30 minutes of moderate intensity activity on at least 5 days of the week (e.g., light sweating, some increase in heart rate, but can still talk). Some examples include brisk walking, hiking, and golfing (walking).

Please use the scale below to guide your responses to the next set of 10 questions.

1	2	3	4	5	6	7
extremely unlikely	quite unlikely	slightly unlikely		slightly likely	quite likely	extremely likely

If I were to exercise regularly over the next 12 weeks, I would likely...

1. feel more like I have a normal lifestyle	1	2	3	4	5	6	7
2. feel better and improve my well-being	1	2	3	4	5	6	7
3. reduce the risk of my cancer recurring	1	2	3	4	5	6	7
4. relieve my stress	1	2	3	4	5	6	7
5. improve my energy level	1	2	3	4	5	6	7
6. get my mind off cancer	1	2	3	4	5	6	7
7. live longer	1	2	3	4	5	6	7
8. improve my fitness	1	2	3	4	5	6	7
9. control my weight	1	2	3	4	5	6	7
10. improve my immune system	1	2	3	4	5	6	7

Please use the scale below to guide your responses to the next set of 6 questions.

1	2	3	4	5	6	7
extremely unsupportive	quite unsupportive	slightly unsupportive		slightly supportive	quite supportive	extremely supportive

How supportive do you think each of the following people would be of you exercising regularly over the next 12 weeks?

1. spouse / partner (if applicable)	1	2	3	4	5	6	7
2. other family members	1	2	3	4	5	6	7
3. best friend (s)	1	2	3	4	5	6	7
4. other friends	1	2	3	4	5	6	7
5. family physician	1	2	3	4	5	6	7
6. co-workers	1	2	3	4	5	6	7

1	2	3	4	5	6	7
not at all confident			moderately confident			completely confident

If you were really motivated, how confident are you that you can exercise regularly over the next 12 weeks even if…

1. the weather was very bad	1	2	3	4	5	6	7
2. you felt tired or fatigued	1	2	3	4	5	6	7
3. you had medical / health problems	1	2	3	4	5	6	7
4. you got very busy and had limited time	1	2	3	4	5	6	7
5. you had a recurrence of your cancer	1	2	3	4	5	6	7
6. you had pain or soreness	1	2	3	4	5	6	7
7. you had additional family responsibilities	1	2	3	4	5	6	7
8. you didn't like exercise	1	2	3	4	5	6	7
9. the exercise didn't fit into your routine	1	2	3	4	5	6	7
10. you had no support	1	2	3	4	5	6	7

Overall, how would you evaluate exercising regularly over the next 12 weeks? Please use the scale below each item to guide your responses. Please complete all 6 items (i.e., a through f).

For me, exercising regularly over the next 12 weeks would be…

a.	1 extremely unenjoyable	2 quite unenjoyable	3 slightly unenjoyable	4	5 slightly enjoyable	6 quite enjoyable	7 extremely enjoyable
b.	1 extremely harmful	2 quite harmful	3 slightly harmful	4	5 slightly beneficial	6 quite beneficial	7 extremely beneficial
c.	1 extremely boring	2 quite boring	3 slightly boring	4	5 slightly fun	6 quite fun	7 extremely fun
d.	1 extremely useless	2 quite useless	3 slightly useless	4	5 slightly useful	6 quite useful	7 extremely useful
e.	1 extremely unpleasant	2 quite unpleasant	3 slightly unpleasant	4	5 slightly pleasant	6 quite pleasant	7 extremely pleasant
f.	1 extremely bad	2 quite bad	3 slightly bad	4	5 slightly good	6 quite good	7 extremely good

Please remember to complete all the above items (i.e., a through f)

Overall, how much support do you feel you will receive if you exercise regularly over the next 12 weeks? Please use the scale below each question to guide your responses.

1. Most people who are important to me would approve if I exercise regularly over the next 12 weeks.

1	2	3	4	5	6	7
strongly disagree	moderately disagree	slightly disagree	neither	slightly agree	moderately agree	strongly agree

2. Most people who are important to me would encourage me to exercise regularly over the next 12 weeks.

1	2	3	4	5	6	7
strongly disagree	moderately disagree	slightly disagree	neither	slightly agree	moderately agree	strongly agree

3. Most people who are important to me would support me exercising regularly over the next 12 weeks.

1	2	3	4	5	6	7
strongly disagree	moderately disagree	slightly disagree	neither	slightly agree	moderately agree	strongly agree

4. Most people who are important to me will exercise regularly themselves over the next 12 weeks.

1	2	3	4	5	6	7
strongly disagree	moderately disagree	slightly disagree	neither	slightly agree	moderately agree	strongly agree

Overall how easy or difficult will it be for you to exercise regularly over the next 12 weeks if you were really motivated? Please use the scale below each question to guide your responses.

If you were really motivated, exercising regularly over the next 12 weeks would be...

1	2	3	4	5	6	7
extremely difficult	quite difficult	slightly difficult	neither	slightly easy	quite easy	extremely easy

If you were really motivated, how confident are you that you could exercise regularly over the next 12 weeks?

1	2	3	4	5	6	7
not at all confident			moderately confident			extremely confident

If you were really motivated, how much control do you feel you would have in exercising regularly over the next 12 weeks?

1	2	3	4	5	6	7
very little control			moderate control			complete control

4. Whether or not I exercise regularly over the next 12 weeks is completely up to me.

1	2	3	4	5	6	7
strongly disagree	moderately disagree	slightly disagree	neither	slightly agree	moderately agree	strongly agree

Overall, do you plan on exercising regularly over the next 12 weeks? Please use the scale below to guide your responses. For questions #3 and #4, please fill in the frequency (number of times) and duration (minutes) that you intend to do vigorous and moderate intensity exercise.

1. I intend to exercise regularly over the next 12 weeks.

1	2	3	4	5	6	7
strongly disagree	moderately disagree	slightly disagree	neither	slightly agree	moderately agree	strongly agree

2. How motivated are you to exercise regularly over the next 12 weeks?

1	2	3	4	5	6	7
extremely unmotivated	quite unmotivated	slightly unmotivated	neither	slightly motivated	quite motivated	extremely motivated

3. How often do you intend to do **vigorous** intensity exercise over the next 12 weeks?

_____ times per week for _____ minutes each time

4. How often do you intend to do **moderate** intensity exercise over the next 12 weeks?

_____ times per week for _____ minutes each time

5. I have decided exactly how I am going to exercise regularly over the next 12 weeks. Circle the number that best represents how you feel:

Definitely No 1 2 3 4 5 6 7 **Definitely Yes**

6. I have made plans about how I am going to exercise regularly over the next 12 weeks. Circle the number that best represents how you feel:

Strongly Disagree 1 2 3 4 5 6 7 **Strongly Agree**

7. I have made a detailed plan regarding...(answer a through d)

a. when to exercise over the next 12 weeks

not at all true 1 2 3 4 5 6 7 **exactly true**

b. where to exercise over the next 12 weeks

not at all true 1 2 3 4 5 6 7 **exactly true**

c. how to exercise over the next 12 weeks

not at all true 1 2 3 4 5 6 7 **exactly true**

d. how often to exercise over the next 12 weeks

not at all true 1 2 3 4 5 6 7 **exactly true**

The next few questions are <u>about the neighborhood you live in</u>. For each statement, please tell us if you strongly disagree, disagree, are unsure, agree, or strongly agree with what we have said:

		Strongly disagree	Disagree	Unsure	Agree	Strongly agree
1.	It is safe to walk in your neighborhood.	1	2	3	4	5
2.	Dogs frighten people who walk in your neighborhood.	1	2	3	4	5
3.	The neighborhood is friendly.	1	2	3	4	5
4.	Crime is high in the neighborhood.	1	2	3	4	5
5.	There are pleasant walks to do in your neighborhood.	1	2	3	4	5
6.	Shops and services are in walking distance.	1	2	3	4	5
7.	You often see people out on walks in your neighborhood.	1	2	3	4	5
8.	Your neighborhood is kept clean and tidy.	1	2	3	4	5
9.	There are busy streets to cross when out on walks.	1	2	3	4	5
10.	The footpaths are in good condition.	1	2	3	4	5
11.	There is heavy traffic.	1	2	3	4	5
12.	It is safe to cycle in your neighborhood.	1	2	3	4	5
13.	The streets are well lit.	1	2	3	4	5
14.	There are steep hills.	1	2	3	4	5
15.	There are open spaces (such as parks) for people to walk in or around my neighborhood (e.g., shops, parks, services).	1	2	3	4	5

This part of the questionnaire is needed to help understand the characteristics of the people participating in the study. For this reason, it is very important information. All information is held in strict confidence.

1. Marital Status:

Never married_____ Married_____ Common law _____

Widowed _____ Divorced _____ Separated _____

2. Education (please check highest level attained):

Some high school _____ Completed high school _____

Some university/college _____ Completed university/college _____

Some graduate school _____ Completed graduate school _____
(e.g., master's degree or PhD)

3. Annual family income:

< 20,000 _____ 20-39,999 _____ 40-59,999 _____

60-79,999 _____ 80-99,999 _____ >100,000 _____

4. Employment status:

Disability _____ Retired _____ Part-time _____

Full-time _____ Homemaker _____ Temporarily _____
Unemployed _____

5. Which ethnic or cultural group do you belong to?

_____

6. Please weigh yourself in the morning and measure your height without shoes and report it here:

Height: _____ Weight: _____

7. In the past month, was your participation in exercise limited by a health condition, injury, or disability (circle one)?

No Yes

If yes, how much did this limit you from exercising (circle one)?

1	2	3	4	5
slightly	a little	somewhat	quite a lot	completely

8. Has a doctor or nurse ever told you that you have had the following? Please check all that apply.

a. Angina____yes ____no
b. Heart attack ____yes ____no
c. Stroke ____yes ____no
d. Diabetes ____yes ____no
d. High blood press____yes ____no
e. High blood chol____yes ____no
f. Other cancer ____yes ____no
g. Other_____

9. Are you currently on any cancer therapy? If so, please specify:

_____

10. Are you currently on any other medications? If so, please specify:

_____

11. What is your menopausal status (please check one)?

a. I have not yet reached menopause:_____

b. I am currently going through menopause: _____

c. I have completed menopause:_____

12. Have you participated in an **exercise** study before at the Cross Cancer Institute or the University of Alberta?

Yes No If so, do you remember what study you participated in?

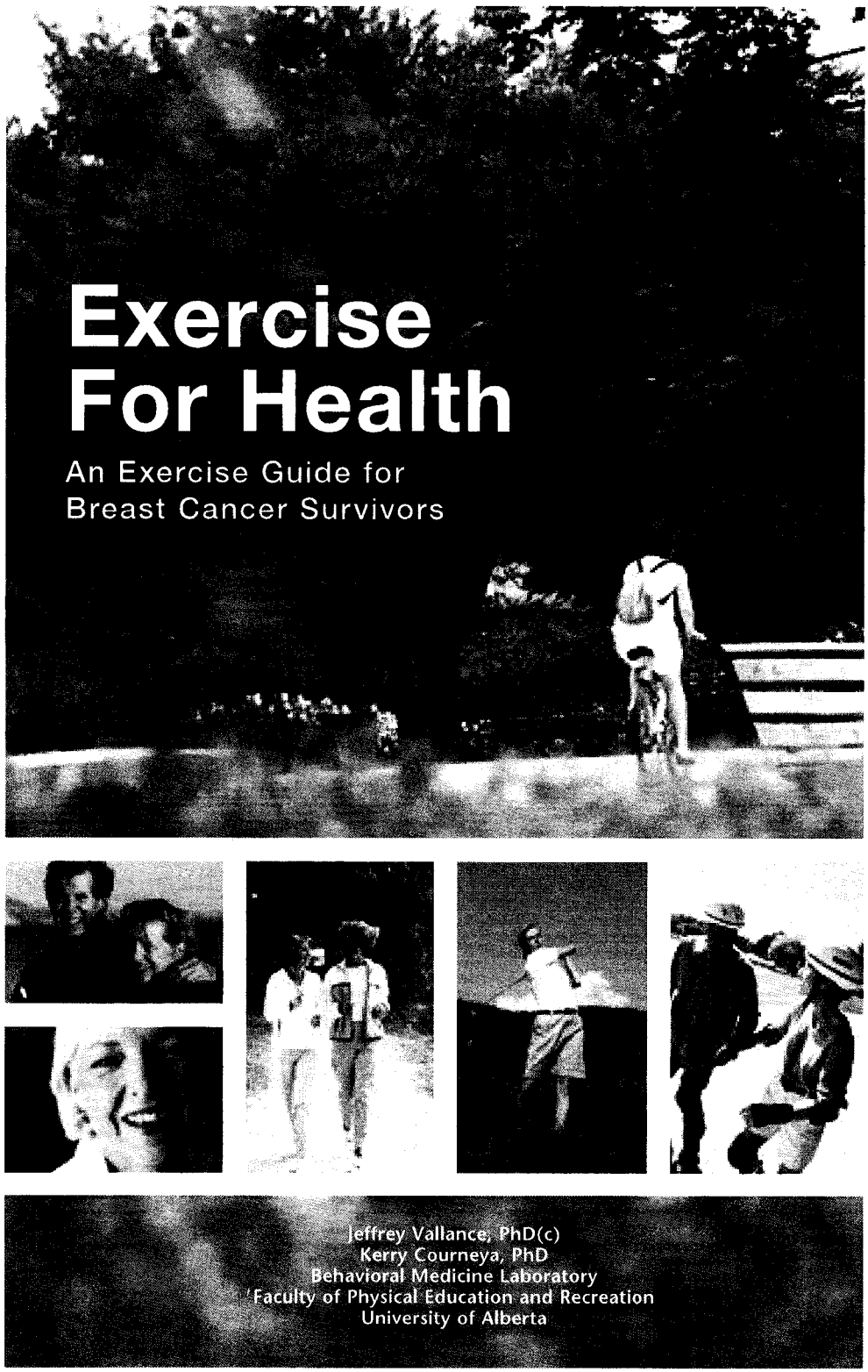
_____

Is there anything else you would like to tell us? On this final page, please feel free to make any comments concerning your diagnosis or treatment, the study itself, or exercise. All comments are extremely helpful to us.

Thank-you very much for your participation in this research project. Please place the completed questionnaire and your completed 7-day steplog in the stamped addressed envelope provided.

Appendix 4:

Cover Page: Exercise for Health: An Exercise Guidebook for Breast Cancer Survivors



Trust in the Lord with all your heart
and lean not on your own understanding;

In all your ways acknowledge Him,
and He will direct your paths.

Proverbs 3:5-6