Feasibility and Preliminary Efficacy of a Community-Based, Lifestyle Intervention on Select Body Composition, Functional, and Quality of Life Outcomes Among Breast Cancer Survivors

Thesis

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Abstract

Breast cancer survivors are a unique cancer population in that they are having success in treatment but are experiencing the negative side effects that various treatments cause, whether it be soon or very long after treatment. As a result of advances in treatment, less and less breast cancer survivors are dying from of their disease. Instead, their mortality is caused by the other conditions that they become at risk for from the treatment effects. Weight gain is an example of one of these side effects that is seen in breast cancer survivors that places these individuals at risk for poor cardiovascular and metabolic health. The combination of benefits seen from engagement in physical activity and dietary behavior change could lend itself to an optimal approach to mitigate the detrimental side effects that we see, especially weight gain. The lifestyle weight management literature in breast cancer survivors has shown that physical activity can be performed safely and effectively, and the inclusion of diet aids in further improvements in weight management. With the increased knowledge and community support for breast cancer survivor programming, assessing the feasibility and preliminary efficacy of a community-based lifestyle weight management intervention will assist in addressing the lack of community access that currently exists for breast cancer survivors after their treatment. The purpose of this study is to determine the feasibility and preliminary efficacy of a community-based lifestyle weight management intervention in breast cancer

survivors on select body composition, physical function, and quality of life outcomes during the first 3 months of the first wave of the Healthy New Albany Breast Cancer (HNABC) pilot trial. The 24-week, HNABC study is held at a community center and promotes lifestyle behavior changes through a group-mediated cognitive behavioral (GMCB) approach driven by Social Cognitive Theory, in hopes of producing meaningful results for feasibility and secondary outcomes. In the present study, 11 breast cancer survivors participated in the first wave of HNABC. The measures analyzed in this study were body composition done via dual-energy x-ray absorptiometry (DXA), physical function or mobility performance via the 400-meter walk test, and social cognitive outcomes via satisfaction with function and appearance and perceived competence with exercise and diet at the 3-month follow-up assessment.

Results

Effect size calculations and feasibility parameters were used to examine the potential effects that the intervention had on changes in body composition, physical function, and social cognitive outcomes at the 3-month follow-up. The effect sizes, using Cohen's *d*, were calculated by taking the mean difference and dividing by the pooled standard deviation to determine the magnitude of differences observed for each outcome. Meaningful changes were observed in fat mass (d= -0.14), percent fat mass (d= -0.24), lean mass (d= -0.004), and physical function (d= -0.50), some of which reached clinical relevance. Self-reported outcomes also saw meaningful improvements, which attests to the beneficial ability of the GMCB methodology in increasing perceived competence and satisfaction levels.

Conclusions

Findings from the initial wave of the HNABC pilot trial provide evidence of the feasibility, safety, and preliminary efficacy of implementing a GMCB-based lifestyle weight management intervention among overweight or obese breast cancer survivors. Given the meaningful impact that successful weight management has on reducing risk for chronic diseases, these results highlight the utility of implementing a lifestyle weight management intervention in the community for breast cancer survivors in an effort to extend the reach and availability of care during breast cancer survivorship.

Dedication

I would like to dedicate this to my mother, a living breast cancer survivor, who endured cancer treatment in such a way that inspired me to help other breast cancer survivors in whatever way I could.

Acknowledgments

Firstly, I would like to thank God for the many opportunities that I have been given to get to where I am today.

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Chapter 1. Introduction

As obesity rates climb across the US, it is increasingly important to investigate ways of producing meaningful weight loss and improvements in clinically relevant outcomes among various chronic condition populations. In spite of the data showing some reaped benefits from physical activity and/or diet interventions, majority of breast cancer survivors are not getting sufficient physical activity and are overweight or obese. One possible rationale behind this is the prominence of women facing the adverse treatment effects that are a result of the various types of breast cancer treatments. The number of women living this reality has reached great heights because of the innovative and successful treatment regimens that are now offered. This information can be overlooked and so has the implementation of lifestyle weight management interventions to help address it. There has been research published describing an "obesity paradox" that may act as a protector for cardiovascular mortality (Amundson et al., 2010). However, this data was more commonly seen with sub-optimal body compositions measures such as body mass index (BMI). As a result, if more accurate and reliable measures are used to assess body composition, this "obesity paradox" seems to fall apart (Medina-Injosa et al., 2018; Caan & Kroenke, 2017). More recent evidence has shown that gradual, intentional behavioral weight loss coupled with sufficient physical activity engagement is safe and efficacious leading to preservation and/or improvement in physical fitness and risk of

cardiovascular and metabolic diseases (Lavie et al., 2014). This underscores the real challenge that exists for inducing optimal adoption and maintenance of behavioral weight management interventions in the treatment of overweight or obese breast cancer survivors. One viable option to help address this current and pressing concern is implementing this style of intervention out in the community. However, the unique challenge in implementing effective weight management is having community access to evidence-based, lifestyle weight management interventions directed at breast cancer survivors, of which remains limited. Considerable evidence from the field of behavioral weight management underscores the complementary effects of combining physical activity and dietary behavior change in lifestyle interventions. Specifically, these interventions consistently result in superior weight loss and improvements in fundamental health- and treatment-related outcomes compared to just modification of physical activity or dietary intake alone (Rejeski et al., 2002; Rejeski et al., 2002). This presents as a crucial need to determine the feasibility of delivering a community-based, lifestyle weight management interventions to breast cancer survivors and the eventual comparable efficacy of existing community programs available to breast cancer survivors. Therefore, the purpose of the present study, the Healthy New Albany Breast Cancer Pilot (HNABC) trial, was to explore the utility of delivering a lifestyle weight management intervention integrating a group-mediated cognitive behavioral (GMCB) approach in the community setting. The specific objective of this present study was to evaluate the safety, feasibility, and preliminary efficacy of the intervention on select body composition parameters, physical function, and select patient-reported outcomes.

Chapter 2. Literature Review

Benefits of Physical Activity for Cancer Survivors

Over the past few decades, mounting evidence clearly illustrates the importance of physical activity (PA) for a variety of health, fitness, and functional outcomes in both healthy and diseased populations. Contemporary finding in the extant exercise oncology literature have extended these benefits to a wide variety of cancer patient and survivorship populations. Prior to this expanding research focus upon oncology populations, physical activity and exercise was frequently viewed by many as unsafe and high risk for cancer patients and survivors alike. According to the SEER Cancer Statistics Review, the 5-year survival rate among all cancer sites for both males and females has increased every year (data dating back to 1975), with the most recent rate being 69.3% (Cancer Statistics Review, 1975-2015—Previous Version—SEER Cancer Statistics Review, n.d.). This trend can be attributed to numerous factors, including but not limited to, improved screening methods and advanced, individualized treatment regimens. However, we cannot overlook the impact that physical activity may have on these increased survival rates. Engagement in physical activity at moderate or vigorous intensities versus less intense levels resulted in a decreased relative risk of death from breast cancer and could be performed safely with supervision (Grimmett et al., 2019; Ligibel et al., 2019). A systematic review performed by Stout and colleagues (2017) was able to show that physical activity had benefits in terms of cancer-related fatigue, physical fitness, physical function, psychological function, lean mass, quality of life, and disease-specific biomarkers (Stout et al., 2017). As the research has been conducted and

ultimately noticed by the healthcare field, clinics across the country began diving into more specialized research in this field and became aware of the benefits for themselves. These benefits can also be found throughout the cancer care continuum.

Evidence from the emerging field of exercise oncology continues to grow and provides compelling support for the safety, feasibility and efficacy of physical activity for cancer patients and survivors. Nonetheless, more work is still needed to investigate the types, intensities, durations, and frequencies that are appropriate to prescribe. The American College of Sports Medicine (ACSM) and the American Cancer Society (ACS) have each published their physical activity recommendations for those in cancer survivorship. As recently as 2019, ACSM gave the following recommendations for cancer survivors: "Overall, avoid inactivity, and to improve general health, aim to achieve the current physical activity guidelines for health (150 min/week aerobic exercise and 2x/week strength training)" (Campbell et al., 2019). This general guideline can be further divided into the specific physical activity that is sufficient to help mitigate common side effects that cancer patients and survivors experience as a result of treatments. Although each cancer is different in its prognosis and severity, physical activity is highly beneficial for a wide array of cancer diagnoses. The National Comprehensive Cancer Network (NCCN) reported that around a quarter of cancer survivors, for both females and males, are meeting these physical activity guidelines (Algotar et al., 2018). This resulted in a need for more research to investigate detailed interventions that can help increase these numbers and thus, provide more accurate standards and/or prescriptions for each cancer survivor. Cancer survivors can benefit

from engaging in physical activity, whether it be aerobic training or strength training. These positive outcomes from participating in physical activity can be seen in all aspects of health: physical, emotional, and psychological. The recommendations in place are a helpful starting point, but it is crucial to keep in mind the importance of individualization when implementing a new program or in a new cancer population. Fortunately, the research in this field has become advanced enough to show these benefits that different cancer survivors experience when they participate in a variety of physical activity types.

The Role of Physical Activity for Improving Health, Quality of Life, and Adverse Treatment Outcomes Among Breast Cancer Survivors

Considerable advances in the treatment and screening for breast cancer have emerged in recent years. Currently, there are five common treatments used for breast cancer: chemotherapy, radiation, immunotherapy, hormone therapy, and surgery. With the improvements in screening and treatment, there are steadily more women receiving a diagnosis, being treated, and thus, surviving breast cancer (Cancer Statistics Review, 1975-2015—Previous Version—SEER Cancer Statistics Review, n.d.). This vast number of breast cancer survivors are able to get back into their daily lifestyle but are at risk of developing treatment-related side effects both in the short- and long-term. Some of the common adverse treatment outcomes that can be lessened via physical activity are neutropenia, lymphedema, concentration/memory issues, pain, fatigue, and depression (CDCBreastCancer, 2019). Health professionals are becoming aware of and comfortable with promoting individualized physical activity prescriptions. There is an array of interventions and programs that have been tested for feasibility and efficacy in this cancer

group. Each has shed light on either how to yield more improvements or have actually induced some great improvements in health measures, quality of life, and adverse treatment outcomes.

Physical activity is beneficial in a variety of facets of overall health in diverse populations of cancer patients and survivors. Although the physical activity guidelines for cancer survivors developed by ACSM provide a general prescription, this type of programming is not a "one size fits all" model. There are obvious and critical differences between healthy individuals that affect the changes that they see from physical activity. Clearly, this is particularly relevant in the context of the challenges that individuals diagnosed with cancer face when undertaking physical activity promotion efforts. The current research has achieved a sufficient level where physical activity programs for cancer survivors are able to elicit benefits, whether that be improved health, quality of life, or ability to mitigate the adverse treatment outcomes.

Engagement in sufficient physical activity, for even a relatively short period of time, can improve health outcomes, both physically and physiologically. Battaglini and colleagues investigated how research has evolved over the years in terms of the components of physical activity interventions in breast cancer patients and survivors. The most recent studies (2007-2013) incorporated a combination of aerobic and/or strength training into the interventions, with majority having the strength training piece. These randomized controlled trials were able to induce positive and significant changes in body composition (drops in percent fat mass and increases in lean mass) and significant improvements in quality of life from the average training occurring 3 days per week and

lasting 23 weeks (Battaglini, 2014). Of potentially more importance for this population, is that no adverse events were reported.

Not only does physical activity induce positive changes physically and physiologically, various modes of activity can also lead to beneficial changes in aspects of a breast cancer survivor's quality of life. A review of the literature stated that physical activity was superior to usual care for quality of life (McNeely et al. 2006; Basen-Engquist et al., 2006) and physical fitness (Dieli-Conwright et al., 2018) measures in breast cancer patients and/or survivors. Although they did not report statistically significant results in terms of total body weight, positive changes in body composition were reported. Regardless of the treatment that a breast cancer patient undergoes, there is a handful of adverse outcomes that may become relevant and have a dramatic impact on their daily life. As mentioned previously, these adverse treatment effects can affect some, or all, aspects of their overall health. Lymphedema and declines in physical function are common side effects seen from breast cancer treatment and studies have shown that engaging in physical activity did not affect the development or the exacerbation of lymphedema and showed significant improvements in self-reported and objective physical function measures (Schmitz & Speck, 2010; McNeely et al., 2006; Ligibel et al., 2019). Physical activity can be performed safely and elicit positive outcomes for breast cancer survivors. However, incorporating a multi-faceted approach to reach these outcomes will simply further improve the impact that it has on each individual's health and quality of life.

Impact of Lifestyle Interventions on Weight Loss and Quality of Life

Lifestyle interventions have become an increasingly prominent study design and focus in behavioral cancer research. This type of intervention includes the promotion of exercise, a healthy diet, and ancillary supportive care components such as stress management and counseling. A comprehensive approach such as this can yield improvements in overall heath via benefits seen in specific behavioral outcomes or techniques. Thus, it would seem sensible to incorporate both the diet and physical activity aspects of this relationship. The implementation of a dietary weight loss plus physical activity intervention had superior results in total body weight and physical function versus an intervention consisting of just physical activity for older and obese individuals with poor cardiovascular health (Rejeski et al., 2011). Initial research in this field was primarily focused on the promotion of a single health practice or behavior change, without paying close attention to other aspects of life that impact whole-body health. Although this mode of emphasis is integral in continued progression of research and health professional practices, performing studies that closely mimic real-life in an all-inclusive manner will accurately show results as they relate to everyday lifestyle. As the research has evolved over the years, there has been a spike in trials done that are comprised of both aerobic and strength training, and also some form of a healthy diet component. To complete the lifestyle intervention, the utilization of a counseling-type part is at times added to allow for further assistance in behavior change. In the cancer research, this counseling-like component has commonly been presented as behavioral

therapy that is sometimes theory-based. This ensures that the participants are receiving evidence-based support in their endeavor towards a healthier lifestyle. A systematic review was done on theory-based behavioral interventions (n=10) for breast cancer survivors and some were able to see reductions in percent fat mass, waist circumference, and body mass index, with some reaching statistical significance. However, only three of the ten studies reported results of the psychosocial behavioral process variables on physical activity, and even then, the results were mixed (Rossi et al., 2018). However, earlier work in this field did not promote theory-based practices due to the lack of evidence for their use. Indeed, few lifestyle interventions targeting cancer patients and/or survivors have been based on behavioral theory (Focht et al., 2018; 2019). Through advances in research, more support has been given to the practical use of theory components in leveraging successful health behavior change in lifestyle interventions for different cancer populations (Stull et al., 2007). Some of the familiar behavioral theories guiding the design and delivery of lifestyle interventions are Social Cognitive Theory, Transtheoretical Model, Health Belief Model, and the Theory of Planned Behavior. The evidence that these theories provide can be very advantageous in improving weight status and quality of life via structured techniques, which has not be seen from standard lifestyle interventions that can attribute a decline in potential benefits due to poor post-treatment care, self-directed physical activity, and dietary behavior changes (Ettinger et al. 1997; Focht et al., 2006; Rejeski et al., 2006). Taken collectively, the majority of prior lifestyle research in cancer patients and survivors have implemented interventions that can be characterized as theory-informed rather than theory-based, thereby limiting the potential

utility of integrating these approaches in the supportive cancer care (Focht et al., 2018; 2019).

Consequently, a comprehensive approach to theory-based behavioral weight management, could yield meaningful improvements in clinical and quality of life outcomes for overweight and/or obese cancer survivors. Anecdotally, a common saying in health and fitness disciplines suggests that one "can't exercise their way out of a bad diet." Not only is this important to the generally healthy population, this is especially applicable to those who are seeking weight loss. The media in our current society has been notorious for advertising diets that result in "quick results," which is not the scientifically supported method in inducing weight loss. Research shows that weight loss can be achieved correctly and adequately when a lifestyle intervention is implemented. Intuitively, if one is to improve their overall lifestyle, improvements in quality of life may follow. With the engagement in both physical activity and healthy eating habits, an individual could see beneficial changes in a diverse amount of quality of life factors including sleep quality, fatigue, mood, stress, intellectual state, disease symptoms, and overall psychological well-being. There are many physiological changes that occur from participating in healthy eating practices and physical activity such as reduced pain, decreases in biomarkers associated with cardiac and/or metabolic risk factors, hormonal changes (Davies et al., 2011), and muscle and bone integrity, but the behavioral aspects are key players as well. Some examples of behavioral techniques that can contribute to an increased quality of life are planning and coping skills, self-efficacy, social support, and education. Increases in self-efficacy for exercise was seen as a significant finding in

cancer survivors, which could act as a mediating factor in exercise behavior improvements (Demark-Wahnefried et al., 2006). From the specific use of behavioral techniques, small to moderate effects were seen in fatigue, depression, anxiety, and health-related quality of life levels in breast cancer patients and survivors (Duijts et al., 2011). With lifestyle interventions, a dynamic is developed between its constituent parts and so quality of life is improved because of the complete focus on each aspect of a healthy lifestyle.

The Effects of Lifestyle Weight Management Interventions in Breast Cancer Survivors

Breast cancer treatments are linked with significant short-term and delayed side effects that have meaningful adverse effects upon fitness, physical function, and quality of life. One of the most widespread of these is an increase in body weight. This could be confusing initially due to the popular belief that treatment leads to drops in body weight, as appetite and energy are at low levels. It is imperative that oncologists and other cancer care professionals are aware of this information so that they can tailor and/or improve their patient's health throughout survivorship. Weight management is an area that is becoming a necessary part of lifestyle interventions, especially within those diagnosed with breast cancer. These treatments can induce menopause, which can also lead to weight gain. Although it is well-established that long-term survival rates following breast cancer diagnosis are increasing, many survivors experience significant morbidity from treatment-related side effects as well as increased risk of mortality from associated chronic disease (Mehta et al., 2018). Consequently, being overweight or obese and the

low activity levels that we see in these women puts them at an increased risk of breast cancer recurrence and also for other cardiac and metabolic issues that are also associated with weight gain. As a result, lifestyle interventions that mitigate weight gain or induce favorable intentional weight loss among breast cancer survivors is crucial since focusing on exercise alone does not consistently shown meaningful weight loss in overweight or obese adults (Jakicic et al., 2006; Wing et al., 2000). In breast cancer lifestyle interventions, the diets that are being encouraged are the MyPlate diet and the Mediterranean diet; both focusing on reducing intake of saturated fat, sodium, and added sugars. Weight changes are more likely to be seen as one controls their intake of calories from fat and also calories from protein. The American Cancer Society, American Society of Clinical Oncology, and American Institute of Cancer Research have provided guidelines for clinicians when counseling their patients in regard to weight management and physical activity (Rock et al., 2012; World Cancer Research Fund/American Institute for Cancer Research, 2018), in which they clearly state to limit consumption of high energy foods and beverages; increase intake of fruits, vegetables, and whole grains; and to engage in regular physical activity (Runowicz et al., 2016). The physical activity is typically separated into aerobic training and strength training, both of which are important for successful weight management. Aerobic training has a greater influence on fat mass, whereas strength training is tied more to changes in muscle mass. The lifestyle weight management literature fully attests to the importance of modifying both energy expenditure and energy intake to see successes in behavioral weight management (Wing, 2000; Goldberg et al., 2007; Jakicic et al., 2006). The addition of theory-based behavioral

counseling to promote the adoption and maintenance of health behavior change required for successful weight management is also integral in the utility of these approaches (Focht et al., 2018; 2019; Spark et al., 2013).

The physical activity aspect of lifestyle interventions is key in maintaining the balance between the energy intake (calories consumed via dietary intake) and the caloric expenditure. Although some findings regarding aerobic vs resistance exercise in weight loss efforts are equivocal (Rejeski et al., 2017; Beavers et al., 2017), multiple modes of physical activity and exercise can facilitate intentional weight loss when dietary intake is modified through change in total caloric expenditure. For example, in the ENERGY trial that was designed to induce change through a group-based, behavioral weight loss intervention for overweight or obese breast cancer survivors, the percentage weight loss was higher for those who participated in the intervention group versus the control group, even at a 24-month follow-up (Rock et al., 2015). Promoting both aerobic and strength training, in combination with dietary counseling, may optimize the benefits that physical activity can have on weight management, muscle maintenance or gain, and fat loss (Focht et al., 2018; Travier et al., 2014). The literature has provided more than enough information and support for benefits of lifestyle interventions for breast cancer survivors. The subsequent research and support needs to be directed towards lifestyle programs that are breast cancer-specific to help facilitate their survivorship (Lawler et al., 2017). One potential solution to address this concern is to implement community-based, lifestyle interventions specifically tailored towards breast cancer survivors to ensure that each survivor's need is being addressed in a comprehensive and appropriate way.

Implementing Community-Based, Lifestyle Weight Management Interventions in Supportive Cancer Care: A Pressing Need and Unique Challenge

Cancer research has made tremendous strides in advancing care both during and after active treatment. Researchers and clinicians are becoming increasingly well-informed of the necessary steps to take for these cancer patients to have a successful and healthy journey into and throughout their survivorship. It is becoming very well-known that evidence-based, lifestyle weight management interventions play an integral role in this process and can greatly help each cancer survivor attain their goals of becoming the person they were prior to diagnosis, or even a better version. The barriers and motives of participation in a group-based physical activity program offered in the community revealed that breast cancer survivors had concerns about scheduling but were motivated by the cancer-specific and social support aspects that it offered (Wurz et al., 2015). This motivational piece was also observed in breast cancer survivors who were regularly attending the "Curves" program. The authors clearly noted the importance of a physical activity program to possess disease-specific concerns, which would help the initiation of physical activity in a safe and comfortable environment (Sabiston et al., 2019). One concern when implementing a lifestyle or exercise-focused intervention in any cancer population is the topic of safety and proper guidance. Research has shown that physical activity is safe for a variety of cancer survivors and can be done properly and effectively to produce beneficial outcomes (Rajotte et al., 2012). Now that we know that weight management programs yield good results for this population, the translational piece of this type of intervention is the next required action. Unfortunately, there is a lack in

community access to programs that offer standard and efficacious comprehensive weight management interventions targeting breast cancer survivors. This presents as a pressing need to test and develop widely accessible, cost-effective lifestyle weight management interventions to help prevent breast cancer survivors decrease their risk of breast cancer recurrence, chronic diseases, and all-cause mortality.

Of the research that has been done on this topic, a group of investigators were able to see significant improvements in overall health-related quality of life, physical function via the 6-minute walk test, and areas of well-being (physical, emotional, and functional) (Cheifetz et al., 2014). Another community-based program centered around Social Cognitive Theory that lasted for six weeks was able to stimulate significant changes in physical activity level, physical activity self-efficacy in overcoming barriers, and fatigue. They were also able to conclude that baseline fatigue and chronic musculoskeletal symptoms were significant determinants of physical activity maintenance (Lee et al., 2016). The LIVESTRONG program is a 12-week community-based program promoting aerobic training, resistance training, and balance and flexibility training. Investigators tested this approach in breast cancer survivors, and they saw significant improvements in measures of health-related physical fitness and physical function (Foley & Hasson, 2016). Community-based, physical activity interventions have shown over and over the increases in physical function and/or fitness, but this is less commonly seen for body composition measures due to the lack in reliable and accurate methods. A 16-week oncology rehab program implemented at a cardiac rehabilitation

facility was able to assess body composition using a DXA scan and they did stimulate changes, although were shy of statistical significance (De Jesus et al., 2017).

Translating this research practice into the community and showing its potential for effectiveness, will ultimately provide the cancer care professionals and the general population with an opportunity for survivors to receive care in their own backyard. It is also important to recognize that a community-based intervention was more effective than a home-based intervention in a variety of measures such as quality of life and body composition (Harvie et al., 2019). This element demonstrates that cancer survivors can still receive effective care during their time after treatment at a nearby center instead of at a location that is sometimes great distances away. A community-based method shows true universal and scalable use as it can be delivered by instructors and staff at the center, with the appropriate and attainable training. As with any kind of research, the participants are more likely to adhere to a program or protocol that is convenient and easily accessible. The less barriers that arise for them throughout this process, the better the study receptiveness and participation. Although each individual will have preferences for different types of intervention delivery, the supervision, detailed guidance, and individualization that a community-based lifestyle intervention offers provides an ideal outlet for everyone. With where the field is currently and the data that is available, extending lifestyle weight management interventions into a community setting will just further optimize the potential to see benefits in health outcomes for cancer survivors who desperately need that tailored programming and support.

Effective behavior change takes time and requires special techniques for it to last into the long-term. Lifestyle programs that yield high adherence and produce changes that can be maintained are crucial for breast cancer survivors as more are living long past their diagnosis and experiencing adverse treatment effects. One lifestyle weight management approach that may be a viable option is group-mediated cognitive behavioral (GMCB) therapy. Both the Social Cognitive Theory (SCT) by Bandura (Bandura, 1997) and the group dynamics research (Zander, 1982) provide the basis in how the GMCB method successfully functions in showing improvements in health outcomes via lifestyle changes in cancer and chronic disease patients (Focht et al., 2012; Rejeski et al., 2003). Employing the pillars of Social Cognitive Theory supplies individuals with practical tools that allow them to reach their goals and undergo behavior change via goal setting, barrier problem solving, and self-monitoring skills. The group-mediated cognitive behavioral approach plays off of the blend of both physical activity and dietary behavior change with various self-regulatory skills to foster independent maintenance of lifestyle behavior change (Focht et al., 2017). The group atmosphere is purposefully implemented to facilitate social support and generation of solutions originating from others who are similar in health condition status. A group-based, strength training program for breast cancer survivors was done at a physical therapy clinic and improvements were seen in disease-specific outcomes while maintaining safety (Beidas et al., 2014). Secondly, a group-based intervention for breast cancer survivors was able to show the importance of a group atmosphere in maintaining confidence and also physical activity and dietary habits (Suzuki et al., 2019). Breast cancer specifically

has been heavily pushed in terms of research advancements and community outreach that these survivors would highly benefit from the comradery and evidence-base that the GMCB approach offers and supports.

In summary, findings addressed in this chapter provide sound and compelling evidence supporting the feasibility and the potential benefits of a lifestyle weight management intervention designed to promote physical activity and dietary behavior change in breast cancer survivors. Although we have seen benefit from engaging in dietary and physical activity behavior changes separately in this cancer population, recent evidence underscores the potential value of their synergistic effects on improvements in overall health and clinically relevant outcomes. However, the majority of prior lifestyle weight management research in breast cancer patients and survivors has implemented interventions that can be characterized as theory-informed rather than theory-based (Focht et al., 2018; 2019). Hence, determining the extent to which theory-driven, community-based lifestyle weight management interventions result in changes in key clinical and quality of life outcomes is important for both guiding the design and delivery of lifestyle weight management interventions and establishing the utility of integrating these approaches in the supportive care of breast cancer survivors. Consequently, additional evidence from the HNABC pilot trial addressing the quality of life, weight management, and physical function benefits among breast cancer survivors will expand knowledge of the utility of theory-based lifestyle interventions in the supportive care of breast cancer survivors.

Chapter 3: Methods

Overview

The Healthy New Albany Breast Cancer Project (HNABC) was a single arm, pilot trial designed to evaluate the safety, feasibility, and preliminary efficacy of conducting a community-based lifestyle weight management (LWM) intervention in overweight or obese breast cancer (BC) survivors after the completion of acute therapy. A total of 20 women post-treatment will be assigned to receive LWM intervention at the Philip Heit Center for Healthy New Albany. Assessment of all functional, anthropometric, and quality of life outcomes will be obtained at baseline and at 3-month and 6-month follow-up visits. Based on recent pilot trial sample size guidelines for lifestyle intervention research (Goldberg et al, 2007), the proposed sample size of 20 breast cancer survivors is sufficient to obtain accurate effect size estimates to guide the design of a future optimally powered randomized controlled trial (RCT). The primary objectives of HNABC were to determine the feasibility of delivering a community-based, LWM intervention in producing meaningful improvements in weight loss and relevant clinical and patient-reported outcomes in BC survivors. The present study focuses upon select outcomes from the initial wave of the HNABC trial. A total of 11 BC survivors in the first wave of this trial completed the first three months of the intervention. Given that this was a pilot study, it should be recognized that the target patient accrual did not provide optimal statistical power but was adequate to obtain effect size estimates necessary to inform the design of a subsequent optimally powered randomized controlled lifestyle intervention

trial.

Participant Eligibility

The inclusion and exclusion criteria were designed to target the recruitment of overweight or obese BC survivors who were able to participate in a supervised, community-based exercise and diet-focused intervention involving both resistance and aerobic training. To be eligible to participate in the HNABC trial, women had to meet the following criteria: (a) diagnosed with early-stage, non-metastatic breast cancer; (b) within 60 months after last active treatment (surgery, chemotherapy, radiation) and may be on continued hormone therapy; (c) overweight or obese (BMI > 25); (d) 30 to 75 years old; (e) ability to understand and have the willingness to sign a written informed consent; (f) wiling and physically able to participate in physical activity; and (g) obtain physician consent via primary care physician or treating oncologist.

Recruitment

Recruitment materials were visible and distributed at the Stephanie Spielman Comprehensive Breast Cancer (SSCBC) by Drs. Maryam Lustberg and colleagues at the women's last treatment appointment, as well as, at follow-up appointments post-treatment. Breast cancer patients typically progress through treatment in the following order: surgery, chemotherapy, and radiation therapy, though not all patients progress through each step. This project recruited patients from their treatment close-out appointment to participate in the study, regardless of type or duration of therapy received.

Given the goal of a feasibility study, the staff elected to have broad eligibility criteria as outlined previously. As co-investigator, Dr. Lustberg assisted with identifying and recruiting eligible patients from her clinics. In addition to these approaches, recruitment focused on direct solicitation methods (zip code-coordinated direct mailings) and community-coordinated efforts. Community recruitment was coordinated with the Philip Heit Center for Healthy New Albany staff and involved advertisements in newsletters and mailings, as well as social media.

Informed Consent

Approval of trial protocol and informed consent documents was obtained from the Ohio State University Cancer Institutional Review Board (Project Number 2018 C0060) prior to the initiation of recruitment procedures. All participants completed informed consent forms and the Health Insurance Portability and Accountability Act authorization (HIPAA) forms prior to participation in the trial. Copies of the informed consent form were given to the potential candidates to read. The PI and/or designee explained all aspects of the study in lay language and answered all the candidate's questions regarding the study. The risks of the study protocol were expected to be modest and was carefully monitored. Elements of the informed consent included explanations of 1) the purpose of the trial, 2) what the study entails, 3) alternate treatments, 4) expenses and inconveniences to be incurred, 5) discomfort and risks to the subject, 6) whether she will receive payment for participation in the study, 7) contact person to call in the event of an emergency, 8) subject rights as a result of illness or injury from trial participation, 9) her

right to withdraw from the trial at any time without prejudice, and 10) confidentiality of trial participation.

Measures

Assessments of all study measures were obtained at baseline, 3-month, and 6-month screening visits by study staff blinded to treatment group assignment. All outcome assessments were conducted at the Physical Activity and Educational Services (PAES) building on the campus of The Ohio State University. The measures in this trial demonstrated well-established validity and reliability.

Outcome Assessments

Functional Battery

The assessment of functional battery was done by both self-reported and objective measures. The objective measure of functional ability was using three valid and reliable, timed performance-related mobility tasks: 400-meter walk (primary outcome), stair climb, and lift-and-carry task (Peters et al., 1994; 1995; Reboussin et al., 2000; Rejeski et al., 1995). The 400-meter walk test was completed in a corridor with two cones spaced 20 meters apart. Individuals were instructed to walk as quickly as quickly as they could and the time to complete ten laps around the 40-meter course was recorded as the performance measure. Participants can stop and rest if necessary, but are not allowed to sit down, and are given a maximum of 15 min to complete the test. The stair climb test consisted of ascending a set of eight steps, turning around at the top, and then descending. Participants were instructed to complete the task as quickly as they could and

performance was measured as the total time (in seconds) necessary to complete the task. The lift-and-carry test was a simulated common daily activity test involving picking up a 10-pound container from a shelf, walking 10 feet around a cone, and returning the container to the starting position on the shelf. Participants were instructed to complete the task as quickly as they could, and performance was measured as the total time (in seconds) necessary to complete the task. A script is used to standardize instructions to all participants. Participants are instructed to complete the task as quickly as they can, without running. Assessments of Mobility-Related Self-Efficacy to complete each functional task was also done. Mobility-related self-efficacy scores were calculated for each task by summing the total, dividing by the total number of ratings, and multiplying by ten to yield a score ranging from 0 to 100.

Balance Test

Standing and reaching balance was estimated using a balance plate, Bertec BP5050, developed by Bertec Inc., Columbus, OH, to assess balance deficits. One, 60-second trial was completed with the participant standing on the plate with two feet, looking straight ahead, and with their eyes closed (Monfort et al., 2016; Monfort et al., 2019).

Muscular Strength and Anthropometric Measurements

Muscular strength was assessed using standardized one-repetition maximum (1RM) testing protocols for the chest press and leg extension exercises. Participants were familiarized with the chest press and leg extension machines and received instruction on

proper form. Participants began 1RM testing for each exercise by completing a warm-up set of four to six repetitions. Participants rated the difficulty of the set using a 10-point difficulty scale ranging from 1 (not at all difficult) to 10 (extremely difficult). The participant perceptions of difficulty rating were used to choose the first weight at which a 1RM test was attempted. The participant was asked to lift the weight once and to continue to perform single repetition lifts, separated by at least a 2-minute rest interval, until a maximum weight was reached and recorded as the 1RM. Body composition was assessed using Dual-energy X-ray Absorptiometry (DXA; GE Health Care Lunar, Madison, WI) for all outcome measures. The DXA scans were used to determine total body composition including bone-mineral density, as well as, percentage body fat and fat-free mass for all body regions. Body weight was also be measured to the nearest 0.1 kilogram using a calibrated and certified balance beam scale. Anthropometric measurements will be taken in a consultation room to ensure the privacy of the participant.

Quality of Life/Fatigue

Quality of Life (QOL) was assessed using both global sense and disease specific measures including the Satisfaction with Life scale (Diener et al., 1985), the SF-12, the Satisfaction with Function and Appearance (SFA) (Reboussin et al., 2000) and the Functional Assessment of Cancer Therapy- Breast (FACT-B). Fatigue was assessed with the Brief Fatigue Inventory (BFI).

Feasibility Measures and Adherence

Descriptive statistics for assessments of select indicators of trial feasibility including recruitment rates, intervention adherence, adverse events, and retention rates were calculated prospectively throughout the trial. Feasibility assessments of participants' satisfaction and any additional feedback with the exercise and dietary intervention was also completed. Adherence was defined via attendance at prescribed sessions and was assessed using exercise logs, upon which the participants recorded all exercises performed at the center or independently.

Procedures

Volunteers who expressed an interest in participating in HNABC completed a phone screening interview to determine their eligibility for the study. Prior to participation in the trial, participants made a baseline screening visit, during which assessments of the all outcome measures were obtained. At the beginning of the baseline screening visit, inclusion criteria were verified, and medical history, informed consent, and Health Insurance Portability and Accountability Act waiver documents are completed. Participants then completed the questionnaire assessments and underwent the body composition, functional performance tasks, and strength testing (1RM). Clearance to exercise was obtained from the primary care physician or treating oncologist prior to participation in the intervention. Assessments of all outcomes were obtained using exactly the same procedures at 3-month and 6-month follow-up screening visits conducted by study staff blinded to participants' intervention performance.

Intervention

The intervention was delivered at the community-based Philip Heit Center for Healthy New Albany. Drs. Focht and Lustberg have developed a collaboration with the directors of the Healthy New Albany initiative. The Center's affiliation with the OSU Wexner Medical Center, state of the art exercise, nutrition, and meeting facilities, and integrative approach to personalized wellness make it the ideal community-based location to conduct this pilot study. The directors of the Heit center support the proposed project and are committed to using the findings in an effort to develop and deliver community-based lifestyle interventions for cancer survivors. Consistent with procedures we have successfully implemented in prior lifestyle behavior trials, this LWM intervention was an evidence-based program, conceptually driven by principles from Bandura's Social Cognitive Theory (SCT) and the group dynamics literature (Bandura, 2001) that is designed to facilitate adoption and adherence to physical activity and dietary behavior change.

The exercise component involved a combination of aerobic and resistance exercise. The aerobic stimulus consisted of 10-30 minutes of exercise performed at a rating of perceived exertion ranging from 11 (Fairly Light) to 14 (Moderately Hard) on the participant's choice of a treadmill, stationary cycle, or elliptical trainer. Each participant was provided with a FitBit to self-monitor their aerobic activity. The resistance exercise stimulus involved performing 1-3 sets of 8RM-12RM repetitions at a rating of perceived exertion ranging from 12 (Moderately Hard) to 15 (Hard) of 10

different exercises (leg press, leg extension, leg curl, chest press, lat pull-down, overhead press, triceps extension, bicep curl, calf raises, and abdominal curl). Exercise duration and intensity were gradually increased based on individual exercise tolerance and capacity. All exercise sessions lasted approximately one hour in duration.

Behavioral counseling, based on Social Cognitive Theory, was also integrated with exercise to promote adherence to the exercise prescription, dietary changes, and participant retention. Counseling was delivered via small group (3-5 participants) sessions conducted immediately following center-based exercise sessions during the trial. The objective of the counseling was to increase self-efficacy for adoption and maintenance of exercise and dietary behavior change and facilitate the successful transition from supervised to independent center-based exercise participation during the trial. The behavioral counseling focused upon the acquisition and practice of self-regulatory skills in conjunction with a continuous problem-solving model of behavior change to empower participants to exert greater control over their behavior, cognitions, and environment. The behavioral counseling was designed to: a) increase health knowledge of the benefits of exercise and dietary change; b) enhance self-efficacy and positive outcome expectancies through the promotion of a series of successful experiences in changing exercise and eating behavior; and c) improve self-regulation of exercise and eating behaviors. The intervention content included education and counseling efforts involving goal setting, self-monitoring, stimulus control, cognitive restructuring, and barrier problem-solving strategies.

To foster the practice/mastery of the newly acquired exercise and behavioral skills and prevent participants from becoming dependent on the expertise of exercise staff to remain physically active, supervised, center-based exercise decreased from two sessions/week in weeks 1-8 to one supervised sessions/week in weeks 9-12 of the intervention. During weeks 9-12, participants had the goal of completing one center-based exercise session/week independent of study staff supervision during each week. During 13-24, participants had the goal of completing two center-based exercise sessions per week independent of study staff supervision. While the facility is supervised by trained fitness staff members during this time, the participants had no supervisory contact with the study staff during these independent exercise sessions. Participants also participated in one supervised exercise/group booster session per month. All participants received a membership to the community center where the intervention was being delivered for the duration of the trial to provide necessary access for aiding the promotion of independent maintenance of long-term physical activity participation.

The advantages of the approach integrating counseling and the titration away from staff supervision are that it helps participants actively apply their developing exercise and behavioral skills to exercise independently while concomitantly providing them access to the study's exercise facility to facilitate completion of the independent exercise sessions during weeks 9-24, which also allows us to evaluate uptake of independent exercise adherence in months 4-6. The efficacy of this approach for promoting exercise and dietary behavior change has been demonstrated in prior RCTs on which Dr. Focht has served as principal and co-investigator.

The dietary component of the counseling intervention included group-based counseling sessions conducted following a center-based exercise session during the trial. The specific dietary objectives of the pilot trial were to be consistent with the Therapeutic Lifestyle Changes recommended in the Adult Treatment Panel III Report of the National Cholesterol Education Program and the American Institute of Cancer Research. The nutrition intervention encouraged reductions in portion size and caloric and fat consumption together with a gradual transition from an animal-based diet to a more plant-rich diet while still incorporating animal foods including milk and meat, with an emphasis on monitoring food proportion and portion size. Specific goals of the dietary component included: (a) gradual reduction in energy intake by 500-1000 kcal per day; (b) self-monitoring, measuring, and tracking of portion sizes of all meals and snacks; (c) increase in fruit and vegetable consumption to 5 servings per day; (d) intake of 3 or more servings per day of whole grains per day and a gradual increase to at least 25 grams of dietary fiber per day.

The nutrition counseling used a group-based motivational interviewing approach that has been demonstrated to be an effective approach to promote behavior change in cancer patients. The nutrition counseling also builds upon many of the cognitive-behavioral self-management strategies utilized in the exercise intervention including self-monitoring, building self-efficacy, goal setting, and anticipating and overcoming barriers to dietary behavior change. Participants were asked to complete weekly diet logs as part of the behavioral self-monitoring effort and these records were used to guide the counseling sessions and to establish nutrition goals. Each visit consisted of establishing

specific and tailored dietary goals for the participant to work on and discussing potential barriers to meeting these goals and developing solutions to these barriers. All the exercise and dietary behavioral counseling conducted during the intervention was designed to facilitate the development of behavioral self-regulatory skills needed to successfully adopt and maintain change in exercise and dietary behavior. These contacts specifically addressed the following content: self-monitoring (recording/tracking exercise and dietary habits), goal setting, barrier problem-solving, and cognitive restructuring (developing more positive attitude/orientation towards behavior change and its associated challenges) using cognitive behavioral and motivational interviewing approaches. Due to the personalized natures of these intervention approaches, the contacts will not be scripted; rather, they will be tailored, to the challenges and/or barriers that individual participants are experiencing. An outline of the topics addressed in the exercise and dietary counseling portion of the intervention is provided below:

- **Self-monitoring:** develop awareness and commitment to tracking/recording of desired exercise and dietary behaviors

- **Goal setting:** Setting short and long-term, process and outcome-related goals for target exercise and dietary behaviors

- **Stimulus Control:** Development of appropriate behavioral, environmental, and reinforcement strategies that help to facilitate adoption and maintenance of change in exercise and dietary habits (e.g., appropriate exercise pacing, providing oneself with exercise and dietary reminders, identifying appropriate rewards for reaching desired

exercise and dietary goals, developing healthier grocery shopping/cooking strategies)

- **Barrier problem-solving:** Use of a social problem-solving approach to identify, practice, and implement self and peer-initiated strategies for overcoming common barriers to exercise and dietary behavior.

- **Cognitive restructuring:** Develop a more positive orientation towards exercise and healthy eating (e.g., monitoring affect during exercise to optimize affect/enjoyment, motivational interviewing to identify positive motives and attitudes for changing exercise and dietary behavior).

Statistical Analysis

In addition to the feasibility assessments, the effects of the intervention on the outcomes of interest were assessed to determine preliminary efficacy to guide the design of follow-up lifestyle intervention RCTs. As only data from Wave 1 participants of the ongoing trial were include in the present study, the magnitude of effects of the LWM intervention on changes in select outcomes were documented through effect size calculation. Mean change from baseline and effect size estimates were calculated for each outcome measure and effect sizes (Cohen's *d*) were calculated by taking the mean difference and dividing by the pooled standard deviation to determine the magnitude of differences observed for each outcome. Given this is a pilot trial to establish feasibility and preliminary efficacy, we were not optimally powered to detect differences in all outcomes. Nonetheless, the target accrual of 20 was adequate to obtain effect size

estimates necessary to inform the design of a subsequent, optimally powered randomized controlled lifestyle intervention trial (Goldberg et al., 2007).

Chapter 4. Results

The purpose of HNABC was to determine the feasibility and preliminary efficacy of a community-based, GMCB lifestyle weight management intervention for breast cancer survivors. This study focuses upon the results at the 3-month assessment of indicants of safety and feasibility and changes in body composition (measured via Dual-energy X-ray Absorptiometry (DXA), physical function via the 400-meter walk test, and select patient-reported outcomes.

Patient Characteristics and Flow Through the Trial

A total of 11 breast cancer survivors were enrolled in the first wave of the HNABC trial. Select demographic characteristics of the survivors at baseline are summarized in Table 1. As illustrated in the CONSORT diagram in Figure 1, 307 breast cancer survivors were contacted. A total of 90 survivors were contacted by study staff via direct mailing and 217 were reached via ResearchMatch. From these methods, 30 (9.8%) survivors expressed interest and were screened for eligibility. Primary reasons reported for not participating were work schedules, distant travel, or not meeting inclusion criteria. In the first wave of HNABC, 11 breast cancer survivors successfully completed the screening and participated in the intervention. The adherence rate calculated using the average attendance per session for this study was 66%. There was 72.7% retention at the 3-month assessment (8/11 total), with all 11 completing the baseline assessment. Given

the present study focused upon the initial wave of a pilot feasibility trial involving a sample size that did not provide adequate power to conduct meaningful traditional intention to treat statistical analysis, a completers analysis focusing upon the effect sizes accompanying each outcome was conducted for this study. Effect size estimates were calculated and are shown for each outcome measure, in addition to the Cohen's *d* values, in Table 2.

Adverse events

There were no serious adverse events attributable to the intervention reported during the first 3-month span of the trial.

Body Composition

Measures were organized by category to aid interpretation. The body composition measures encompass the entire body and includes total body mass, total lean mass, total fat mass, and body fat and body lean percentages. A summary of the individual and group average changes seen for each of the body composition outcomes are also provided (Figures 2-6).

Total Body Mass

Effect size estimates via Cohen's *d* values were calculated between the baseline and 3-month average scores. From these, there was a near negligible effect seen with $d = -0.09$. The aggregate group mean change from baseline to 3 months is illustrated in Table 2 and the accompanying individual participant and group mean changes are summarized in Figure 2.

Lean Mass (kg and %)

Effect size estimates via Cohen's *d* values were calculated between the baseline and 3-month average scores. These calculations showed that for kilograms of total lean mass, the intervention yielded a negligible effect (*d*= -0.004). Conversely, for percent lean mass, a small effect size (*d*= 0.23), was observed. The aggregate group mean change from baseline to 3 months is illustrated in Table 2 and the accompanying individual participant and group mean changes are summarized in Figures 3 and 4.

Fat Mass (kg and %)

Effect size estimates using Cohen's *d* values were calculated between the baseline and 3-month average values for both raw and percentage values for fat mass. The calculation for kilograms of fat mass showed a small effect of the intervention (*d*= -0.14). In terms of percent fat mass, the intervention also had a small effect (*d*= -0.24). The aggregate group mean change from baseline to 3 months is illustrated in Table 2 and the accompanying individual participant and group mean changes are summarized in Figures 5 and 6.

In summary, the effect sizes accompanying the changes in body composition indicated that the GMCB lifestyle intervention, designed to produce gradual intentional weight loss, yielded modest, yet clinically meaningful reductions in fat mass and body fat percentage while concomitantly preserving lean body mass.

Physical Function/Mobility Performance

The effect size estimates accompanying the change in mobility performance

revealed the lifestyle intervention yielded approximately a moderate effect size improvement in 400-meter walk performance (*d*= -0.496). The aggregate group mean change from baseline to 3 months is illustrated in Table 2 and the accompanying individual participant and group mean changes are summarized in Figure 7. In summary, the observed group mean change in mobility performance yielded a meaningful effect size that reflects the well-established minimal clinically significant difference (>20 seconds) (Focht et al., 2018; Rejeski et al., 2011).

Patient-reported/Social Cognitive outcomes

For the purpose of this study, three questionnaires were analyzed using effect size estimates with Cohen's *d* values to evaluate the impact of the GMCB lifestyle intervention upon select key social cognitive outcomes observed at the 3-month follow-up assessment. These outcomes were task mobility-related self-efficacy (for the 400-meter walk test), satisfaction with function and appearance, and perceived competence with exercise and diet. A summary of the individual and group mean changes for each of these outcomes can be seen in Figures 8-12, respectively.

Mobility-Related Self-Efficacy

The lifestyle intervention yielded a small to medium effect size improvement in mobility-related self-efficacy for the 400-meter walk test (*d*= 0.35). The aggregate group mean change from baseline to 3 months is illustrated in Table 2 and the accompanying individual participant and group mean changes are summarized in Figure 8.

Satisfaction with Function and Appearance

This effect size calculations were done separately to see the average changes in appearance and function between baseline and 3 months. From these calculations, the intervention had a large effect on both satisfaction with function (*d*= 1.47) and satisfaction with appearance (*d*= 0.89). The aggregate group mean change from baseline to 3 months is illustrated in Table 2 and the accompanying individual participant and group mean changes are summarized in Figures 9 and 10.

Perceived Competence with Exercise and Diet

An effect size calculation was conducted for perceived competence with exercise and a separate calculation for perceived competence with diet. For perceived competence with exercise average scores, the intervention resulted in approximately small to medium effect size improvement at 3-month follow-up (*d*= 0.346). The intervention also yielded an approximately small to medium effect size improvement in perceived competence with diet at 3-month follow-up (*d*= 0.339). The aggregate group mean change from baseline to 3 months is illustrated in Table 2 and the accompanying individual participant and group mean changes are summarized in Figures 11 and 12.

Collectively, the aggregate group level changes and accompanying effect sizes observed for the self-reported measures of select social cognitive and quality of life measures demonstrated that the GMCB lifestyle intervention yielded meaningful improvements in each of these outcomes at 3-month follow-up.

Chapter 5. Discussion

The HNABC trial was a pilot, feasibility trial assessing the utility and preliminary efficacy of conducting a lifestyle weight management intervention in breast cancer survivors at a community center. HNABC is one of the few community-based lifestyle weight loss interventions that integrated a theory-based approach to promote change in both exercise participation and dietary intake among breast cancer survivors. Furthermore, it is the first study to implement the theory-driven GMCB counseling approach, in combination with exercise and diet, to promote adoption and maintenance of behavior change integral to the efficacy of behavioral weight management approaches, among breast cancer survivors. The hypothesis of HNABC collectively is that the community-based lifestyle weight management intervention will be a feasible, safe, and efficacious approach that produces improvements in weight loss, body composition, physical function, and quality of life. The primary purpose of HNABC was to assess feasibility of this intervention in the community. This study focused upon the level of feasibility via recruitment, retention, and adherence rates, and preliminary efficacy of select measures of body composition, physical function, and patient-reported outcomes for Wave 1 at the 3-month mark.

With regard to the indicants of safety and feasibility, the generally favorable recruitment, retention, and adherence rates, together with the absence of intervention-

related adverse events, provide evidence that the GMCB lifestyle weight management intervention is safe and well tolerated by overweight or obese breast cancer survivors interested in achieving intentional weight loss. The retention rate was at 72.7%, as three participants did not complete the 3-month assessment. However, it is important to recognize that HNABC is a 6-month trial and all 11 participants that completed the baseline assessment and are still taking part in the intervention activities. There were 307 breast cancer survivors that were contacted, 30 expressed interest and were screened, and 11 were successfully screened and enrolled in the intervention. This recruitment rate is comparable to those observed in the exercise oncology literature. Adherence to the intervention was assessed by calculating the average attendance at the sessions held throughout the first three months. On average, each session had 66% attendance (66% adherence). It should be noted, the session adherence rate may be viewed by some readers/reviewers as somewhat low as adherence rates of >70% are typically desirable during adoption phases of lifestyle intervention trials. However, as the present sample comprises only the initial wave/cohort of what will ultimately be a multi-wave pilot trial, it is likely premature to adequately interpret the adherence pattern as disappointing or markedly different from other community-based behavioral interventions targeting breast cancer survivors.

In addition to evaluating feasibility, a secondary aim of the present trial is to explore the preliminary efficacy of implementing the GMCB lifestyle intervention among overweight or obese breast cancer survivors. In this regard, the effect sizes accompanying the baseline to 3-month change in the body composition measures, physical function, and

patient-reported outcomes demonstrated that the GMCB lifestyle intervention resulted in meaningful improvement in these clinically relevant outcomes. More specifically, the meaningful results seen in both the objective and subjective measures demonstrate a high potential for long-term success in behavioral weight management trials.

For example, with regard to body composition, the intervention elicited effect size changes that ranged from small to medium across the total body mass (*d*= -0.09), fat mass (*d*= -0.14), percent fat mass (*d*= -0.24), and percent lean mass (*d*= 0.23) outcomes. These effect sizes reflect meaningful improvements in each outcome yielding loss of total body mass, fat mass and percent fat mass, with a concomitant increase in percent lean mass at 3 months. In contrast to these body composition outcomes, a negligible change lean mass (*d*= -0.004) was observed. Close inspection of these improvements suggests that even brief, 3-month exposure to the GMCB lifestyle intervention yielded potentially meaningful shifts in select body composition outcomes that may have significant clinical, health promotion, and disease prevention implications for overweight breast cancer survivors. Notably, the intervention resulted in loss of approximately 1.24% and 1.69 kg of fat mass while simultaneously sustaining total kg of lean body mass and a more favorable percent lean body mass relative to baseline body composition values. Inspection of individual level change revealed that loss of body fat percent was observed in 6 of the 8 breast cancer survivors at 3-month follow-up. These favorable shifts in body composition are consistently associated with improved quality of life as well as reduced risk of cancer recurrence, cardiovascular disease, and metabolic syndrome (Focht et al., 2018; Ligibel et al., 2019; Rejeski et al., 2011; Schmitz & Speck, 2010). Thus, the

present preliminary findings support the promise of implementing a community-based GMCB lifestyle weight management intervention among overweight or obese breast cancer survivors.

Although in this study there was a very minimal effect on lean mass, the percentage of lean mass and fat mass to total body mass is arguably more important in predicting whole-body mobility and also takes into account individual body sizes. These body composition measures were captured by use of a DXA scan, which very few programs and interventions are able to use this highly sophisticated method to measure and assess body composition parameters. The use of a DXA in this trial is very important for this type of intervention because these machines are becoming more popular in clinic or community settings and are also able to offer the most accurate results (Foulkes et al., 2017).

Inspection of overall change in body mass/body weight demonstrates the intervention resulted in a slight loss (d = -0.09) that corresponded to approximately 2% loss of initial body weight at 3 months. In interpreting the modest weight loss observed, it is important to acknowledge that clinically meaningful weight loss of >5% often takes 6-12 months of participation in behavioral weight loss interventions to emerge among overweight and obese patients as the goal is to promote gradual weight loss of approximately 1-2lbs/week comprised of inducing fat mass loss while also preserving lean body mass (Rejeski et al., 2011; Wing et al., 2000). Moreover, close inspection of the individual level data of Wave 1 reveals that 4 of the 8 participants lost 3-4% of

baseline weight and the remaining participants remained weight stable. These body composition results support the research that show that early weight loss response in behavioral weight management trials predict and lead to long-term success in achieving the optimal weight loss that is eventually seen from these types of trials. Consequently, when considering the pattern of these weight changes together with the favorable shifts in body composition observed after only 3 months of intervention reinforce the promise of this approach to behavioral weight management for breast cancer survivors.

In assessing the role of the intervention on inducing change in physical function, the effect size calculations demonstrated the exercise and dietary intervention resulted in an approximately large effect size improvement in mobility performance at 3-month follow-up as measured by 400-meter walk performance (d= -0.496). It is notable that the magnitude of improvement in mobility performance observed with 3 months of exposure to the lifestyle intervention reflect the established minimally clinically significant difference (Focht et al., 2018; Rejeski et al., 2011). Additionally, mobility-related self-efficacy was associated with a meaningful small to moderate effect size improvement (d= 0.351). Thus, breast cancer survivor's confidence for engaging in, and successfully completing, this mobility task also demonstrated a clinically meaningful level of improvement after only 3 months of weight management intervention. The mobility performance benefits observed in the first wave of the HNABC pilot trial are consistent with findings from recent randomized controlled trials implementing similar GMCB-based exercise and dietary weight loss interventions in chronic disease patients at risk for mobility disability (Focht et al., 2018; Rejeski et al., 2011; Rejeski et al., 2017), and the

present results extend these findings to overweight and obese breast cancer survivors. Given functional limitations are a persisting post-treatment concern among overweight and obese breast cancer survivors, this favorable improvement in mobility performance further underscores the promise of integrating community-based lifestyle weight management in supportive breast cancer care.

There is now mounting evidence suggesting adoption and maintenance of change in exercise and dietary behavior are determined, in part, through a constellation of complex interactions among social cognitive variables including self-efficacy and self-regulatory processes (Focht et al., 2019; Zhang et al., 2019). An integral feature of the lifestyle weight management intervention in the HNABC pilot trial was integration of a GMCB counseling component designed to enhance self-efficacy and promote the development, practice, and mastery of behavioral self-regulatory abilities required to facilitate adoption and independent maintenance of desired changes in exercise participation and dietary intake. Consistent with this aspect of the intervention, the GMCB lifestyle intervention yielded moderate, clinically meaningful effect size improvements in mobility-related self-efficacy and perceived competence with exercise (d= 0.35) and diet (d= 0.34). These promising findings underscore the potential utility of implementing community-based lifestyle weight management intervention integrating the GMCB approach for breast cancer survivors. In light of these findings and the relevance of self-regulation in promoting successful adherence to exercise and dietary behavior, delineating the patterns of change in key social cognitive outcomes within the context of longer duration lifestyle interventions among breast cancer survivors warrants further

investigation.

With the countless advancements made in the field of breast cancer survivorship care, there are only a handful of lifestyle community-based interventions that have been conducted, and even fewer that have been grounded in theory to further aid in behavior change. However, there is no knowledge of other interventions that are done in the community, promote physical activity and diet, and are theory-based. Of the existing literature, community-based trials in breast cancer survivors (post-diagnosis) were able to induce positive changes in quality of life and/or physical function (Rajotte et al., 2012; Lee et al., 2016; Cheifetz et al., 2014; Foley & Hasson, 2016; De Jesus et al., 2017; Beidas et al., 2014). Among these trials, the length of intervention was anywhere from 6 weeks to 52 weeks. Of these listed, three incorporated a generic dietary piece via counseling or education into their program, whereas the rest solely focused on physical activity (Cheifetz et al., 2014; Rajotte et al., 2012; Lee et al., 2016). In one trial, this nutrition discussion was part of bi-monthly, educational sessions, of which were supported by self-efficacy, that covered a variety of areas: exercise safety, exercise progression, importance of maintaining an active lifestyle, and healthy diet (Cheifetz et al., 2014). A 16-week, community-based exercise program that was conducted at a cardiac rehabilitation facility showed no significant changes in body composition, which was assessed used a DXA scan (De Jesus et al., 2017). Instead, they saw small increases in body weight, fat mass, and percent fat mass, but were also able to produce a small increase in lean mass. Additionally, this intervention lacked any use of dietary or group counseling. In a recent 2019 article, Harvie and colleagues conducted a home versus

community-based weight control randomized controlled trial that utilized a DXA scan and behavioral techniques as they relate to physical activity. This was a 12-week program with follow-up timepoints occurring at 6 and 12 months. At 12 months, there were significant changes observed in the community versus control groups regarding total body weight (-2.4 kg) and fat mass (-1.4 kg) (Harvie et al., 2019). A study was done by Sabiston et al. to evaluate the "Curves" community program in breast cancer survivors. Although this was a proof-of-concept study, the researchers were able to reveal that a barrier to participation in this program was a lack in cancer-specific support. The motivating pieces of this program were the social influence, workout atmosphere, and focus on goal achievement (Sabiston et al., 2019).

The HNABC trial is one of the first trials to assess feasibility and preliminary efficacy of a community-based and theory-driven lifestyle weight management intervention in breast cancer survivors. The findings from this present study were able to show meaningful changes in body composition measures, physical function, and select social cognitive measures directly after a 12-week intervention. Consistent with extant literature, breast cancer survivors in community-based interventions were able to achieve significant improvements in particular quality of life measures and tests of physical function. Of specific interest, is the evidence of this study suggesting that the GMCB lifestyle approach resulted in meaningful and promising changes in the selected outcomes in breast cancer survivors.

Limitations

There were a handful of limitations to this study that should be acknowledged. Given that this pilot trial was intended to determine feasibility, safety, and preliminary efficacy of delivering a group- and community-based behavioral lifestyle intervention in breast cancer survivors, the sample size for this present study does not provide sufficient power to detect statistically significant changes in all relevant outcomes of interest. Additionally, as the present study focused on only the initial wave of the pilot trial, a completer's analysis was conducted. It should be recognized, not conducting an intention-to-treat analysis may result in some extent of positive bias in the observed preliminary efficacy findings. Future trials implementing randomized controlled trial designs with intention to treat analyses are needed to confirm the promise of the present preliminary results. Additionally, as the present sample was comprised of predominantly Caucasian and well-educated participants, recruitment of a more heterogeneous, diverse, representative samples in future trials is required to determine the generalizability of these results to the larger population of breast cancer survivors. There are other clinically-relevant outcomes frequently investigated in exercise-breast cancer literature, such as lymphedema symptoms and cancer-related fatigue, that may have been influenced by the GMCB intervention, that were not assessed in this pilot trial and should be explored in future trials implementing this lifestyle intervention approach. Lastly, with the 66% adherence rate from this trial, there are some factors that are worth mentioning that may have played a role in this outcome: the working age of participants (6/11 were working part-time or full-time throughout the trials) and the impact that the holiday season can

have on intervention attendance and also weight loss. During the days surrounding the holiday seasons, we encouraged the participants to shift their focus on staying weight stable versus being ambitious and trying to achieve weight loss.

Future Directions

This study demonstrated the positive effects of a lifestyle, weight management intervention performed with the support of a theory-based group counseling approach. The results of this study compare to the patient-reported outcomes and physical function improvements that have been seen from other published lifestyle interventions for breast cancer survivors. The observed improvements in key body composition measures in HNABC are more favorable than those in the majority of studies in the breast cancer literature that implemented lifestyle approaches to foster behavior change. Clearly, one potential reason for this is that the researchers had access to a DXA to accurately assess these changes. Nonetheless, these findings emphasize the potential promise of this approach for future community-based lifestyle intervention research and programming. As the majority of studies to date in the exercise oncology literature have addressed a theoretical and/or theory-informed interventions, it is imperative that future physical activity and diet intervention studies should aim to incorporate established theory-based practices or strategies to promote both adoption and long-term maintenance of behavior change. Additionally, utilizing technology in the design and delivery of the GMCB intervention could represent a promising complementary strategy that could increase access, scalability while also helping individuals reach valued lifestyle behavior goals. There is also a need to assess the GMCB approach within larger and longer studies in

breast cancer survivors of diverse backgrounds and breast cancer treatments.

Conclusions

Findings from the initial wave of the HNABC pilot trial provide evidence of the feasibility, safety, and preliminary efficacy of implementing a GMCB-based lifestyle weight management intervention at a community setting in the supportive care of breast cancer survivors. Taking into consideration that these results were seen within a 3-month time frame, these findings underscore the potential promise of this approach. These favorable changes and effect sizes for the outcomes, were comparable or superior to the improvements observed in prior community-based, lifestyle-focused interventions among breast cancer survivors. The present study is one of the first to document the favorable and promising effects of a community- and theory-based lifestyle intervention for breast cancer survivors on outcomes of body composition, physical function, and select social cognitive measures. Lastly, given that this community-based, lifestyle weight management intervention shows promise after 3 months, the utility of implementing this approach in the supportive care of breast cancer survivors should be evaluated in large-scale efficacy studies in more diverse samples of breast cancer survivors.

In summary, findings from the initial wave of the HNABC pilot trial provide evidence of the feasibility, safety, and preliminary efficacy of implementing a GMCB-based lifestyle weight management intervention among overweight or obese breast cancer survivors. The utility of implementing this approach in the supportive care of breast cancer survivors should be evaluated in future large-scale efficacy studies.

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Appendix A. Tables

Table 1 Participant Characteristics

Measure	Intervention, n (%)
Total	11
Age, mean (*SD*)	53.64 (9.719)
BMI, kg/m^2, *m*	33.15
BMI, classification	
Overweight	4
Obese	7
Stage of Breast Cancer	
0/I	7 (63.6)
II	3 (27.3)
III	1 (9.1)
Ethnicity	
Hispanic or Latino	1 (26.6)
Not Hispanic or Latino	10 (16.6)
Time since Diagnosis (months), *m* (*SD*)	31.09 (14.314)
Treatment Type	
Surgery	10 (90.9)
Radiation	5 (45.5)
Chemotherapy	8 (72.7)
Household Income	
$75,000 or more	10 (90.9)
Education Level	
Some College	1 (9.1)
College Graduate (BS or BA)	5 (45.5)
Completed a Master's Degree	5 (45.5)

Employment Status	
Currently Employed Full-Time	5 (45.5)
Currently Employed Part-Time	1 (9.1)
Employed in the Past (Full- or Part-time, but now retired)	5 (45.5)

Table 2 Effect Sizes for All Outcomes

	BLMean	BLStDev	F3Mean	F3StDev	EffectSize r	Cohen's d
400mWalk	5.11	0.6	4.81	0.6109	-0.2405	-0.4955
WalkSEtotal	93.13	19.45	98.13	5.3	0.1727	0.3508
TotalBodyMass	84.36	19.11	82.68	18.011	-0.04519	-0.0905
LeanMass	44.81	7.21	44.78	6.524	-0.00218	-0.00436
FatMass	37	12.2566	35.31	11.803	-0.0701	-0.1405
%LeanMass	53.76	4.799842	54.88	4.96	0.114	0.2295
%FatMass	43.2	4.888945	41.96	5.25	-0.1213	-0.2444
SatFunc	-0.23	2.041015	2	0.667	0.5919	1.4687
SatAppear	-1.29	1.291073	-0.08	1.411	0.4084	0.8948
CompDiet	4.72	1.594844	5.19	1.14	0.167	0.3391
CompEx	5.68	1.1736341	6.14	1.471	0.1703	0.3457

Appendix B. Figures

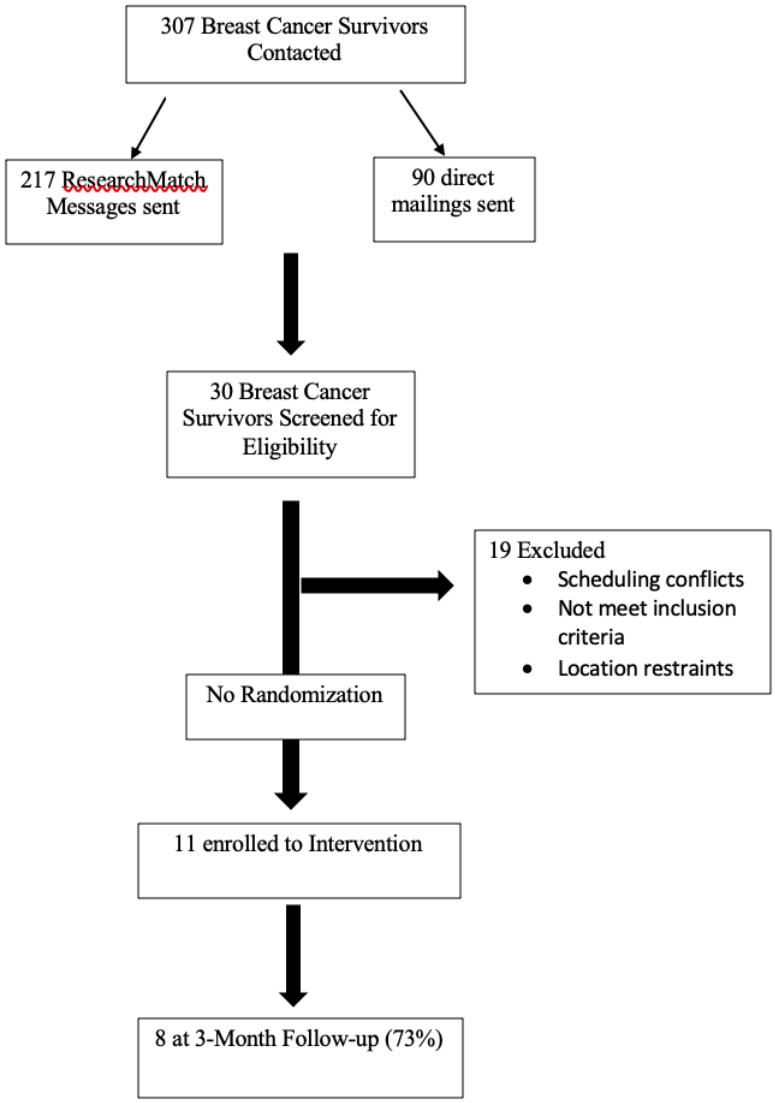

Figure 1 CONSORT Diagram

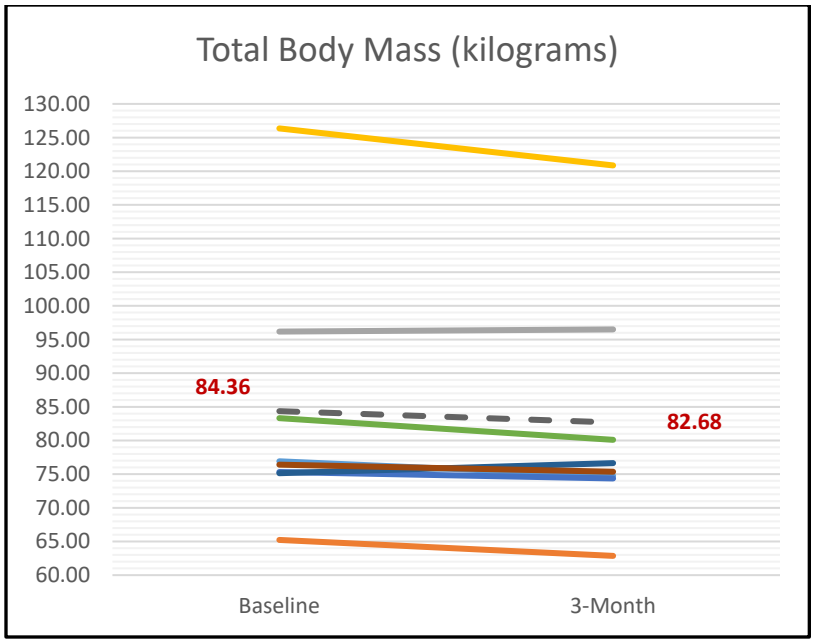

Figure 2 Individual Changes and Group Mean Change in Total Body Mass

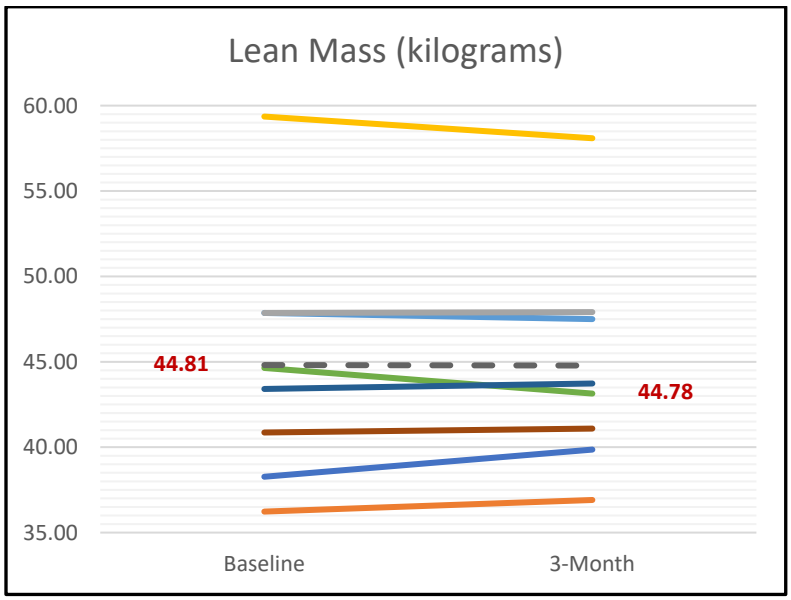

Figure 3 Individual Changes and Group Mean Change in Lean Mass

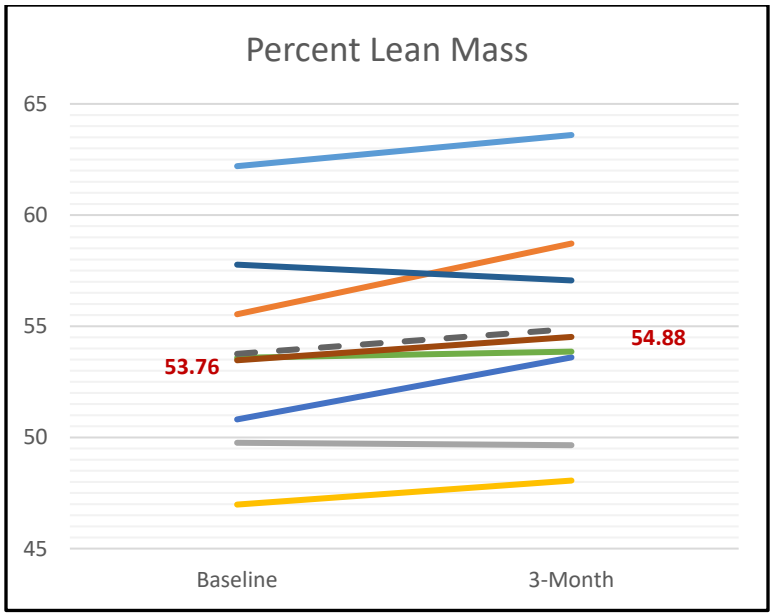

Figure 4 Individual Changes and Group Mean Change in Percent Lean Mass

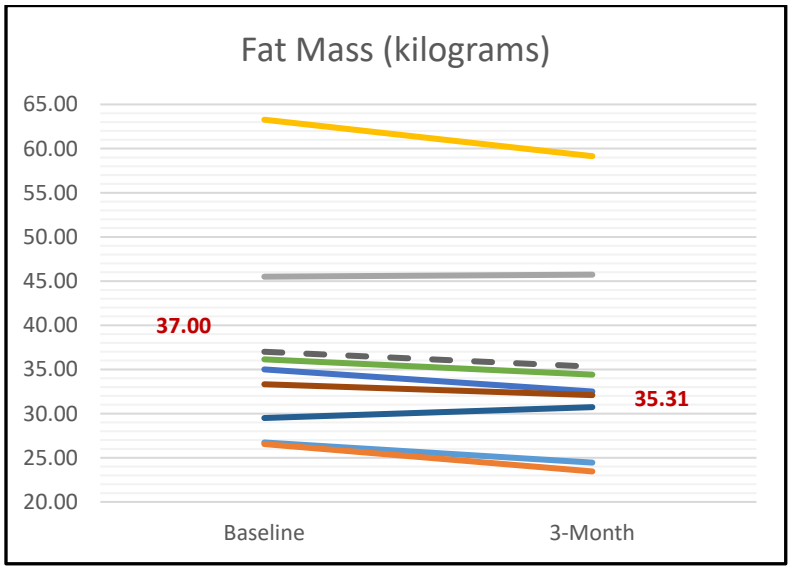

Figure 5 Individual Changes and Group Mean Change in Fat Mass

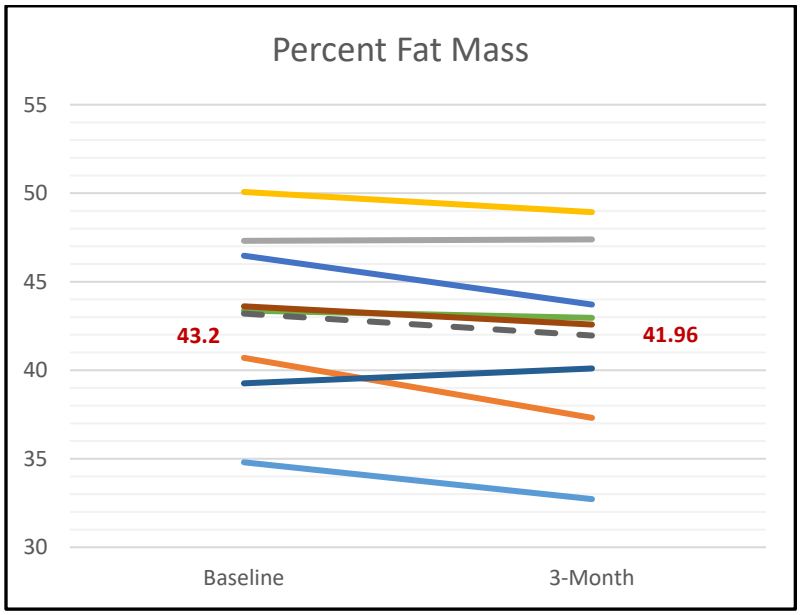

Figure 6 Individual Changes and Group Mean Change in Percent Fat Mass

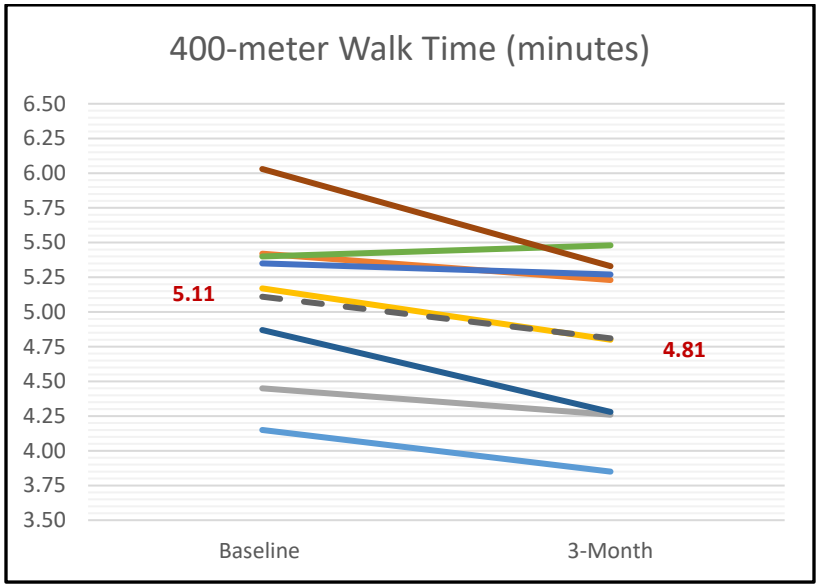

Figure 7 Individual Changes and Group Mean Change in 400-meter Walk

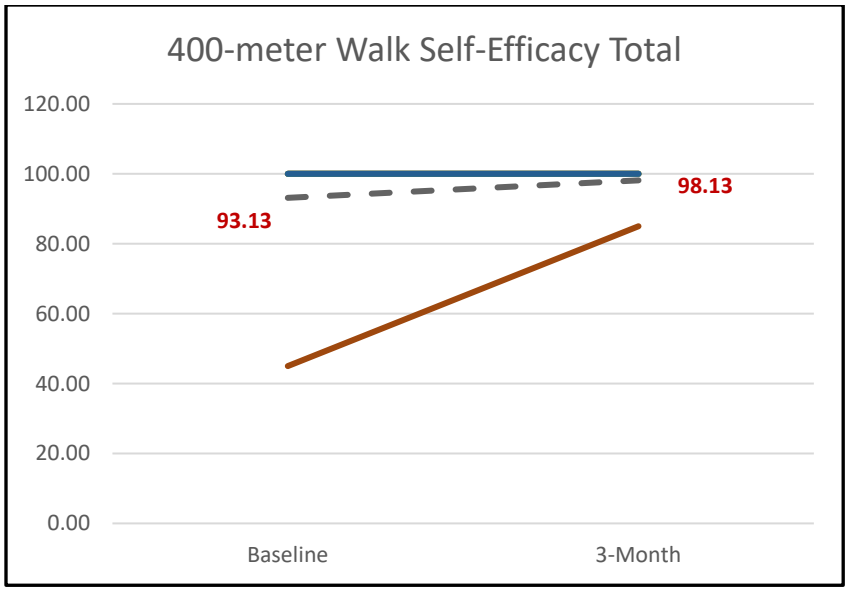

Figure 8 Individual Changes and Group Mean Change in Walk Self-Efficacy

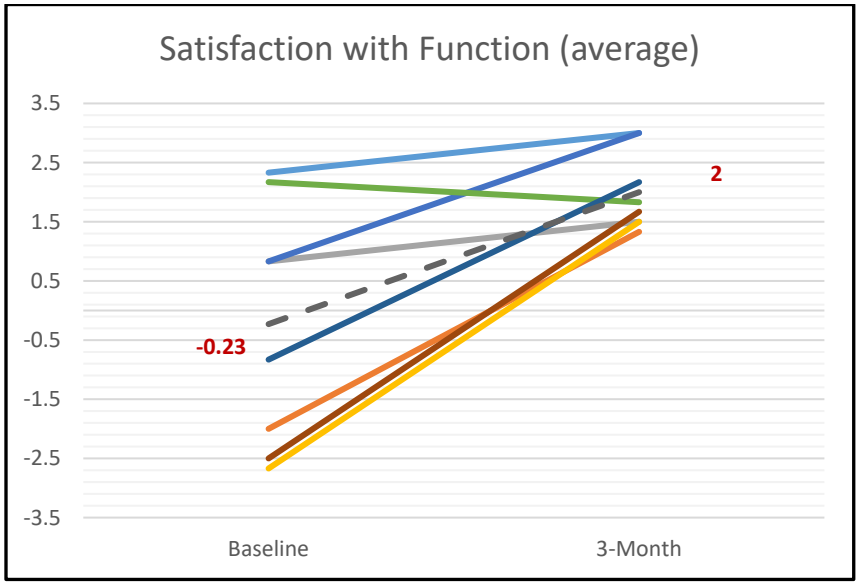

Figure 9 Individual Changes and Group Mean Change in Satisfaction with Function

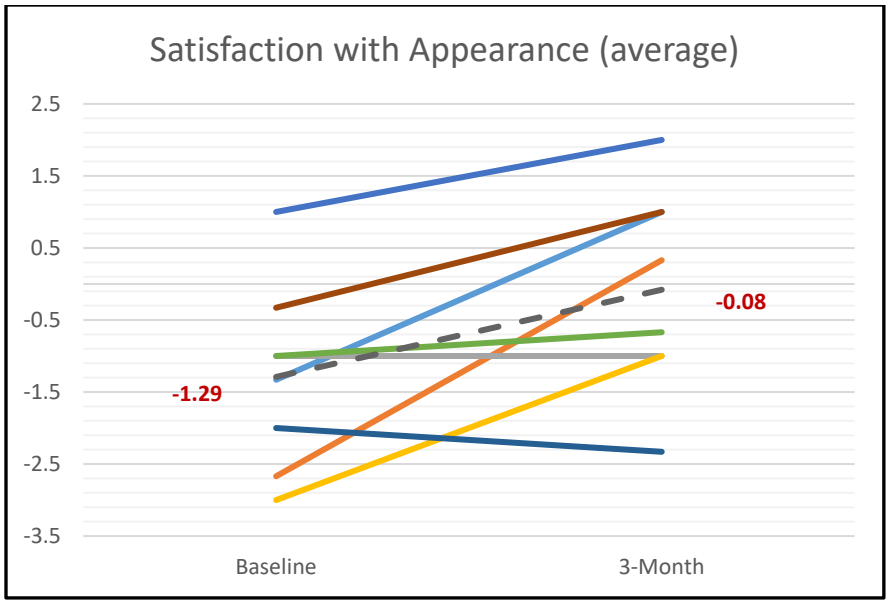

Figure 10 Individual Changes and Group Mean Change in Satisfaction with Appearance

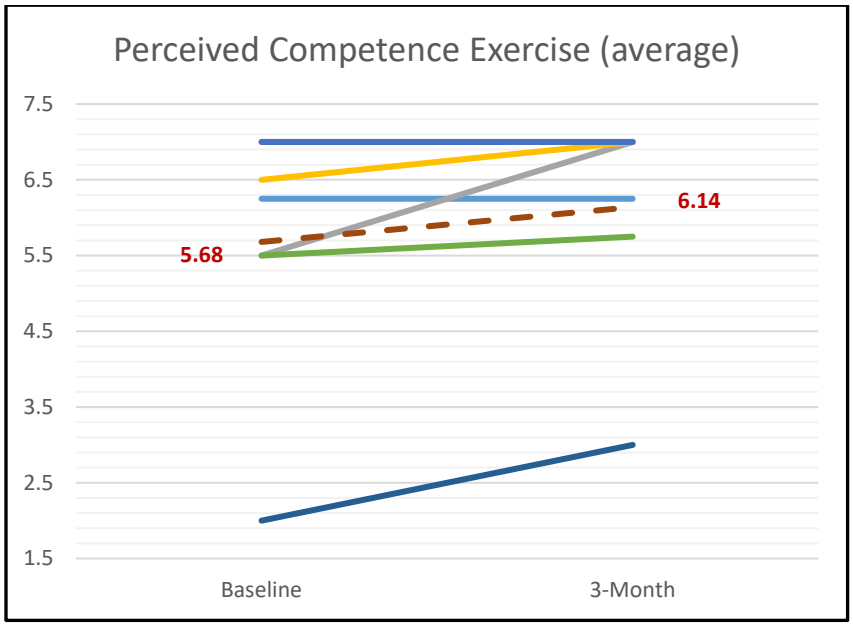

Figure 11 Individual Changes and Group Mean Change in Perceived Competence with Exercise

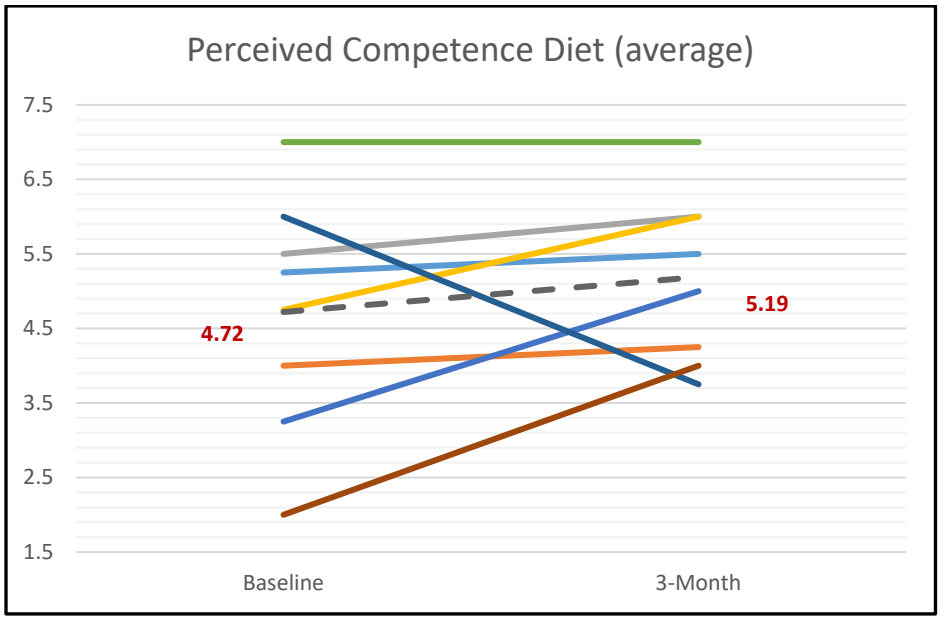

Figure 12 Individual Changes and Group Mean Change in Perceived Competence with Diet