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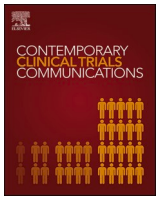

Design and methods of a translational, community-based, lifestyle weight management pilot intervention trial in breast cancer survivors with overweight or obesity

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A B S T R A C T

Background: Breast cancer survivors (BCS) with overweight or obesity are at heightened risk of cancer recurrence, cardiometabolic disease, and compromised quality of life. Given the prevalence of significant weight gain during and following breast cancer treatment, there is growing recognition of the need to develop efficacious, widely-accessible, weight management programs for BCS. Unfortunately, access to evidence-based weight management resources for BCS remains limited and little is known of the optimal theoretical basis, program components, and mode of delivery for community-based interventions. The primary aim of the Healthy New Albany Breast Cancer (HNABC) pilot trial was to determine the safety, feasibility, and preliminary efficacy of delivering a translational, evidence-based, and theory-driven lifestyle weight management intervention to BCS with overweight or obesity in the community setting.

Methods: HNABC was a single-arm, pilot trial evaluating a 24-week, multi-component intervention leveraging exercise, dietary modification, and group-mediated cognitive behavioral (GMCB) counseling components designed to facilitate lifestyle behavior change and promote sustained independent adherence. Assessments of various objectively-determined and patient-reported outcomes and theory-derived determinants of behavioral adoption and maintenance were obtained at baseline, 3- and 6-month follow-up. Measures of trial feasibility were calculated prospectively throughout the study.

Conclusion: Findings from the HNABC pilot trial will provide evidence demonstrating the feasibility and preliminary efficacy of a multi-component, community-based, GMCB lifestyle weight management intervention for BCS. Results will inform the design of a future, large-scale, randomized controlled efficacy trial. If successful, this approach could offer a widely accessible, community-based intervention model for weight management programs in BCS.

1. Introduction

Obesity is widely acknowledged as a primary modifiable risk factor for cancer and comorbid chronic disease [1]. Epidemiological evidence suggests over half of all breast cancer patients are overweight or obese at the time of diagnosis and gain ≥5% body weight following cancer treatment [2]. Recent meta-analytic data reveals that cancer-specific and all-cause mortality is significantly elevated among women with overweight or obesity [3,4]. Taken collectively, these findings suggest that breast cancer survivors (BCS) experience clinically-meaningful weight gain during and following active cancer treatment that results in heightened risk of cancer recurrence, cardiometabolic disease, and compromised quality of life [5]. These results underscore the importance of implementing behavioral weight management in the supportive care of BCS.

It is well-established within the behavioral weight management literature that combined exercise and dietary (EX + D) lifestyle interventions are integral to successfully yielding clinically-meaningful weight loss [6–8]. Given the mounting evidence suggesting BCS experience weight gain and unfavorable shifts in body composition during

Abbreviations: BCS, Breast Cancer Survivors; HNABC, Healthy New Albany Breast Cancer pilot trial; EX + D, Exercise and dietary lifestyle interventions; GMCB, group-mediated cognitive behavioral; BCTs, Behavior Change Techniques; HIPAA, Health Insurance Portability and Accountability Act; MoAs, Mechanisms of Action; FRAME, Framework for Reporting Adaptations and Modifications-Enhanced.

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and following cancer treatment, there is increased recognition of the value of integrating exercise, nutrition, and behavioral weight management counseling within contemporary approaches to cancer survivorship care [5]. Additionally, there is growing support for the development of robust clinic-to community referral pathways that connect cancer survivors with efficacious health promotion programs addressing exercise and healthy dietary intake [9,10]. Unfortunately, community access to practical, sustainable, evidence-based weight management interventions for BCS remains limited. Furthermore, despite considerable evidence demonstrating that integrating established theories of behavior to guide the design and delivery of lifestyle intervention [11,12] enhances their efficacy and impact, relatively few weight management interventions targeting cancer survivorship populations have been rooted in behavioral theory [13–15]. Indeed, many extant interventions can be characterized as theory-informed rather than theory-based [11–15], underscoring the need for developing and reporting of theory-based, efficacious interventions for BCS.

In this regard, one theory-based approach, the group-mediated cognitive behavioral (GMCB) lifestyle intervention has consistently yielded both clinically-meaningful weight loss and favorable adherence to exercise and dietary behavior change across multiple randomized, controlled trials in older adults with obesity and comorbid chronic disease [16–18]. The GMCB approach targets lifestyle behavior change through the practice and mastery of self-regulation skills, while harnessing the social dynamics of the supportive group counseling environment. It promotes adoption and independent maintenance of behavior change to better sustain intervention-induced improvements in relevant outcomes [16–18]. However, the utility of this weight management approach has yet to be systematically investigated across the cancer control continuum [11,12]. Consequently, there is a critical need to evaluate the feasibility and efficacy of implementing the theory-driven, evidence-based, GMCB lifestyle weight management intervention in the supportive care of BCS.

From a translational perspective, effective community collaborations are needed to develop the clinic-to-community pathways necessary to deliver widely accessible, cost-effective, and scalable lifestyle weight management interventions to BCS [11,17,18]. Results from our prior trials demonstrated that comprehensive GMCB lifestyle weight management interventions, combining EX + D behavior modification with behavioral counseling, yielded meaningful improvements in weight loss, physical function, and quality of life in overweight or obese adults with, or at risk for, chronic disease [16–18]. The GMCB intervention approach is uniquely suited to community translation due to the relatively few required resources, robust adaptability to population and context, and compatibility with many established programs currently offered to cancer survivors [16]. Although the efficacy of theory-based lifestyle behavior change interventions under controlled experimental conditions is supported in the literature [5–7], there remains a paucity of evidence from translational studies within community-settings. Collectively, these findings underscore the critical need to determine the feasibility of delivering safe, accessible, and cost-effective translational lifestyle weight management interventions for BCS in community-settings [9,11].

Therefore, the primary aim of the Healthy New Albany Breast Cancer (HNABC) pilot trial, was to determine the safety, feasibility, and preliminary efficacy of delivering a translational lifestyle weight management intervention, integrating a GMCB approach to promote adoption and adherence to EX + D behavior change, to BCS in the community setting. It was hypothesized that the community-based, GMCB EX + D intervention would be a feasible, safe, and well-tolerated intervention and would yield acceptable rates for recruitment, adherence, and retention with few adverse events. Additionally, the GMCB EX + D intervention would yield clinically-meaningful improvements in key theoretical determinants of behavior change and maintenance, weight loss, body composition, physical function, quality of life, and other relevant patient-reported outcomes. Effect size estimates of change in these outcomes will inform the design of an optimally-powered randomized controlled efficacy trial examining the benefits of implementing a translational, community-based lifestyle weight management intervention in the supportive care of BCS, versus the current standard of care in the community.

2. Methods

2.1. Study design and participants

HNABC was a single-arm, exploratory pilot trial designed to evaluate the safety, feasibility, and preliminary efficacy of conducting a community-based lifestyle weight management intervention in a sample of 30 BCS with overweight or obesity following the completion of active cancer treatment. A summary of the study design is shown in Fig. 1.

2.2. Participant eligibility

Given the translational focus of the present pilot, feasibility trial, the recruitment strategy implemented broad eligibility criteria designed to yield a representative sample of sedentary BCS with overweight or obesity that could benefit from participation in a community-based lifestyle weight management intervention. To be eligible to participate in the HNABC study, women had to meet the following criteria: (a) diagnosed with early-stage, non-metastatic breast cancer (Stages 0–IIIB) (b) within 5 years of last active treatment (i.e., surgery, chemotherapy, and/or radiation); and may be on continued hormone therapy; (c) overweight or obese (BMI $\geq$25 kg/m^2); (d) 30–75 years old; (e) ability to understand and be willing to sign a written informed consent; (f) willing and physically able to participate in exercise; and (g) obtained physician consent via primary care physician or treating oncologist.

2.3. Recruitment

The HNABC pilot trial focused upon recruiting a total of 30 BCS with overweight or obesity across two consecutive waves of participants. With regard to the present pilot trial's target accrual, Whitehead at al. [19] recommend pilot trial sample sizes of 25, 15, and 10 participants *per* treatment arm to guide estimates for optimally powered main trials designed to detect effect sizes of small (.20), medium (.50), and large (.80) magnitude respectively. Given the effect sizes accompanying lifestyle weight management interventions on key trial outcomes such as body weight, physical function, and quality of life typically are established and/or anticipated to range from small to large in magnitude, the target accrual of 30 BCS for the present pilot trial was used as a conservative sample size estimate that would be adequate to inform the design of a subsequent, optimally powered randomized controlled intervention trial. Recruitment efforts focused on direct solicitation methods via zip-code-based mailings, clinical collaboration with breast oncologists at the OSU James Cancer Hospital, and community-coordinated efforts involving advertisements in newsletters and social media messaging engaging local BC support groups. With regard to clinical recruitment, the project's breast oncologist (ML) coordinated identifying and recruiting eligible patients from the oncology clinics. Recruitment materials were made visible and distributed at the OSU Stephanie Spielman Comprehensive Breast Center by the trial co-investigator/breast oncologist (ML) and her colleagues at potential participants' last treatment appointment, as well as at post-treatment follow-up appointments. Consistent with the trial's translational focus and broad eligibility criteria, BCS were recruited from their treatment close-out appointment to participate in the study regardless of type or duration of treatment received. Given the exploratory design of this pilot study, it should be recognized that the target accrual did not provide optimal statistical power. However, based on recent pilot trial sample size guidelines for intervention research, the proposed sample size was adequate to obtain effect size estimates necessary to inform the design of

a subsequent, optimally-powered, randomized controlled lifestyle intervention trial [19].

2.4. Procedures

Volunteers who expressed interest in participating in the HNABC study completed a phone screening interview to determine their eligibility. Following confirmation of eligibility, and prior to participation in the intervention, participants completed a baseline screening visit during which assessments of all outcome measures were obtained by trained study staff. The baseline screening visit included verification of eligibility, medical history, informed consent, and completion of Health Insurance Portability and Accountability Act (HIPAA) authorization documents. Participants then completed all self-reported questionnaires, underwent body composition evaluation, functional performance tasks, balance testing, and strength testing. Clearance to exercise was obtained from the primary care physician or treating oncologist prior to participation in the intervention. Assessments of all study outcomes were again obtained at 3-month and 6-month follow-up visits conducted by study staff.

2.5. Informed consent

Approval of trial protocol and informed consent documents were obtained from the Ohio State University Cancer Institutional Review Board (Project Number 2018C0060) prior to the initiation of recruitment procedures. All participants completed the informed consent process and the HIPAA form prior to participation in the trial.

2.6. Lifestyle weight management intervention

The HNABC trial employed a 24-week, multi-component, GMCB intervention involving individually-tailored EX + D modification and group cognitive behavioral and self-regulatory skill counseling components. HNABC was designed to facilitate adoption of EX + D and self-regulatory behavior and promote independent adherence. The development of the HNABC intervention was based on established methods employed in our previous GMCB studies [17,18,20] and adapted to meet the needs of BCS. The theoretical and pragmatic rationale underpinning the comprehensive weight management intervention is derived from principles of Social Cognitive Theory [21] and social dynamics [22,23]. The GMCB approach involves personalized EX + D instruction and training, group-mediated cognitive behavioral self-regulatory skills counseling, and planned development of the supportive group environment to improve the likelihood of success.

Scheduling of contacts is a critical component of the GMCB intervention approach. By systematically titrating away from supervised group activities, independent practice of newly acquired EX + D behavior and self-regulation strategies is promoted. Accordingly, supervised, center-based exercise decreased from two sessions per week during weeks 1–8 (Adoption phase), to one supervised and one independent session per week during weeks 9–12 (Transition phase) of the intervention. During weeks 13–24 (Independent Maintenance phase), participants had the goal of completing two center-based exercise sessions per week independent of study staff supervision with no planned supervised sessions. While the facility was supervised by trained fitness staff members during this time, the participants had no supervisory contact with the study staff during the independent exercise sessions. Participants also transitioned from weekly group counseling during the Adoption and Transition phases, to monthly group counseling booster sessions during the Maintenance phase. All participants received a membership to the Heit Center for the duration of the 6-month HNABC trial providing critical access to the resources necessary to facilitate completion of independent exercise.

In order to ensure specificity, transparency, and replicability of the intervention procedures, relevant behavior change techniques (BCTs) were coded by authors ZLC and VRD using Michie and colleagues [24] valid Behavior Change Technique Taxonomy version 1 (BCTTv1). The inter-rater reliability, or the extent to which raters agreed on the absence and presence of BCTs in the descriptions of the intervention, was assessed using percent agreement and prevalence- and bias-adjusted kappa (PABAK) [25]. Of the 93 possible BCTs, the consolidated total number of BCTs agreed upon as used in the HNABC intervention was 42, representing 13 of the 16 (81%) clusters in the BCTTv1. The percent agreement and PABAK were 93.5% and 0.87, respectively. These results suggest a near perfect inter-rater reliability in identifying the BCTs used in the intervention. Identified BCTs were linked to hypothesized Mechanisms of Action (MoAs) using the validated [15,24] online Theory and Techniques Tool [26]. Any discrepancies in rating were resolved by discussion. All BCTs and MoAs attributed to the HNABC intervention description are provided in Table 1.

The Philip Heit Center for Healthy New Albany (Heit Center) was the community partner site for the HNABC trial. The Heit Center's direct affiliation with the OSU Wexner Medical Center, integrative approach to personalized wellness, and commitment to programming targeting the needs of cancer survivors made it an ideal community partner. All intervention activities and assessments were planned to be conducted at the Heit Center. However, due to the onset of COVID-19 pandemic limitations on in-person contacts during the second year of study, the intervention was modified to focus upon remote-delivery of select intervention sessions for participants recruited following the start of the global pandemic. Specifically, participants who were recruited into the trial after pandemic-related public health guidelines were enacted in Ohio received one of the two scheduled exercise sessions per week, as well as remotely-delivered group counseling, via Zoom video-conferencing (Zoom Video Communication, Inc.). While delivery mode was modified to ensure safety and adherence to public health guidelines during the pandemic, all remaining aspects of supervision, content, and contacts remained unchanged from pre-pandemic intervention. Local safety protocols at the Heit Center were followed during all in-person assessments and intervention sessions. Table 2 describes changes made to intervention delivery and study procedures following the Framework for Reporting Adaptations and Modifications-Enhanced (FRAME) [27] recommendations for implementation science.

2.7. Exercise component

The center-based exercise component of the intervention involved a combination of supervised aerobic and resistance exercise. Exercise was supervised by graduate students in the Exercise and Behavioral Medicine Laboratory at OSU who were certified exercise professionals. Undergraduate exercise science students and trainers from the Heit Center aided in monitoring supervised exercise sessions. The aerobic stimulus consisted of 10–30 min of supervised exercise performed at a rating of perceived exertion (RPE; 1–10) ranging from 3 ("Fairly Light") to 4 ("Moderately Hard") on the participant's choice of treadmill, stationary cycle, or elliptical trainer [28,29]. Participants were also encouraged to gradually increase independent, home-based aerobic exercise participation and purposeful physical activity, while decreasing sedentary time to progress toward accruing a volume of moderate-to-vigorous physical activity (MVPA) consistent with national guidelines for health (i.e., $\geq$150-min of MVPA/week; [30–33]. Each participant was provided with wearable Fitbit "Zip" activity trackers to self-monitor their aerobic activity (Fitbit Health Solutions).

Prescribed intensity of the progressive resistance exercise was 8–12 repetition-maximum (RM; 70–80% 1RM) and involved progressively increasing individual weekly volume by performing 1–3 sets of 8–12 repetitions maintaining a RPE within the 3 ("Moderately Hard") to 6 ("Hard") range. Approximately 10 exercises, specifically targeting adaptation across all major muscle groups, were individually tailored to accommodate for participant symptom limitations. Primary exercises included leg press, leg extension, leg curl, chest press, seated row, lat

pull-down, overhead press, triceps extension, bicep curl, and abdominal curl. However, exercise variations were prescribed when necessary in response to participant needs and preferences. In general, a 1–2 min rest interval was maintained between sets.

To address the critical resistance training principles of progression and overload, a "two-by-two" rule and load progression scheme were implemented [34,35]. When participants were able to successfully complete two additional repetitions beyond their planned repetition goal on the final set of an exercise across two consecutive weeks, the resistance load was increased by approximately 5% for upper body exercises and 10% for lower body exercises at the next session. Consequently, resistance exercise load and volume, as well as aerobic exercise duration and intensity, were auto-regulated, or guided by each participant's exercise tolerance and gradually increased across the intervention to progress toward optimal prescription ranges [33]. All combined aerobic and resistance exercise sessions lasted approximately 1-h in duration.

2.8. Dietary component

The dietary component of the intervention was based on recommendations provided by the WCRF/AICR Dietary Recommendations for Cancer Prevention and the USDA/USDHH Dietary Guidelines for Americans [36,37]. The manualized GMCB session content was modeled after previously published intervention study materials from the CLIP, IDEA-P, and LookAHEAD trials with specific emphasis on promoting self-regulated dietary behavior [17,18,38–42]. The primary objectives of the dietary intervention were to shape eating habits that facilitate achieving a healthier weight, elicit a gradual 1–2 pound/week weight loss in the intensive phase, with an end-of-study goal of a total weight loss of 7–10% and/or achieve the upper limit of standardized age-appropriate healthy weight. During the transition and maintenance phases of the trial, the extent to which participant's weight loss goals remained intact or shifted to promote weight maintenance depended on individual progress towards the target weight loss goal.

Although general calorie range recommendations were provided based on baseline body weight (i.e., <250lbs: 1200–1500 kcal/day; ≥250lbs: 1500–1800 kcal/day), caloric intake was gradually personalized to a specific range that safely and effectively facilitated appropriate progress towards the weight loss goal. Dietary composition and intake was self-monitored and reviewed by study staff. Additional dietary consulting meetings with a Registered Dietitian were initiated by study staff on an as needed basis. In general, dietary recommendations were focused on promoting a diet including foods rich in whole grains, a variety of vegetables and fruits per day, and limited consumption of processed foods which are high in fat and added sugars and low in nutrient density. Specifically, a dietary pattern consisting of approximately 45–55% complex carbohydrates, <30% fat, with particular emphasis on consuming at least 1 g/kg body weight of dietary protein to aid in offsetting muscle loss, was recommended. Participants self-monitored daily dietary intake using the MyFitnessPal app or paper logs and provided weekly summaries to study staff. Recommendations were personalized to each patient's needs and preferences.

2.9. Cognitive behavioral counseling component

Counseling sessions were led by experienced graduate associates and certified exercise physiologists skilled in using BCTs in group counseling environments within the context of behavior change intervention research. Counseling was delivered via small group sessions, lasting approximately 1-h, conducted immediately following select center-based exercise sessions during the trial. The behavioral counseling was designed to: (a) increase health knowledge of the benefits of EX + D change; (b) enhance cognitive determinants of self-managed EX + D behavior (i.e., self-efficacy, positive outcome expectancies, perceived autonomy, competence, and support) through the promotion of a series of successful experiences in changing behavior; and (c) improve self-regulation of EX + D behavior. Group leaders provided weekly educational content tailored to cancer survivorship, counseling in cognitive and behavioral self-regulatory strategies to manage EX + D behavior, and facilitated peer-initiated barrier problem solving.

The group counseling sessions in the HNABC trial focused on improving key cognitive behavioral determinants of adoption and adherence to EX + D behavior change by empowering participants to exert greater control over their behavior, cognitions, and environment. Participants had the opportunity to collaboratively develop and practice using a 'behavioral toolbox' of self-regulatory strategies (i.e., self-monitoring, goal setting, planning, problem solving, lapse and relapse prevention) within a safe and supportive group learning environment, whereby modeling desirable self-regulatory behaviors of others occurs. The GMCB intervention model emphasizes using the group as both an agent and target of change [16]. As an important source of influence over its members, cohesive groups encourage commitment to the group and adherence to behavior, promote common adaptive attitudes, provide accountability and reinforcement for individual and shared goal-striving, and yield peer-initiated solutions to barriers [17,18,22,23].

Group leaders were trained to deliver counseling sessions using standardized procedures successfully implemented in prior trials [17,18,20,38–41]. Each session proceeded in a manner consistent with the following structure: 1) *Sharing of progress* (10–15 min): the group leader welcomes the participants and begins by asking them to share thoughts about their progress over the past week or month. The leader prompts participants to share major successes and challenges towards behavioral goals and how barriers were managed. Praise is offered for accomplishments. Cognitive restructuring is suggested if necessary. 2) *Presentation of topic* (5 min): group leader transitions into presenting the new topic of the day from the manualized session content. 3) *Facilitated group discussion* (25–30 min): the group leader guides the participants in an interactive discussion of the topic and behavioral strategies for that session. Participants are prompted to participate by helping the group define the topic/strategy, sharing personal experiences and perceptions, expressing challenges in engaging with the topic/strategy, participating in problem solving opportunities, and listening to peers. 4) *Summary/Takeaways* (5 min): the group leader summarizes and highlights key points of the session. 5) *Mindfulness Reflections/Sharing of Weekly Goals* (5 min): participants reflect upon the session and revise and share goals for the upcoming week.

2.10. Measures

Assessments of all study-related outcome measures were obtained at baseline, 3-month, and 6-month screening visits by trained study staff. A timeline summarizing the assessment scheduling for all outcome measures can be found in Table 3.

2.11. Safety and feasibility

Select indicators of trial safety, assessed via tracking of adverse events, and feasibility assessed via recruitment rate, intervention adherence rate, and retention rate were calculated prospectively throughout the trial. Consistent with established feasibility trial guidelines [43,44], primary feasibility was defined as adherence and retention rates of >70%. As there is presently no established recruitment rate threshold, this feasibility outcome will be evaluated by comparing the present trial's recruitment rate to those in prior weight loss intervention trials among BCS. Recruitment rates will be calculated by determining the percentage of BCS that were enrolled in the trial relative to the total eligible BCS that were contacted by study staff. Adherence to the supervised exercise sessions and GMCB counseling sessions will be assessed by calculating the percentage of sessions attended relative to the total number of sessions provided in the intervention. Adherence

rates for attendance at the supervised exercise and counseling session will be calculated separately to determine adherence to each component of the intervention and collectively to yield a total intervention adherence measure. Retention rate will be assessed by calculating the percentage of follow-up assessment visits completed relative to the total number of follow-up assessment visits at 3 and 6 month. Acceptability assessments of participant satisfaction and additional feedback on the EX + D intervention were also completed at 3-month and 6-month follow-up.

2.12. Physical function

Objectively-determined physical function was assessed via three, valid and reliable, timed performance-related mobility tasks: the 400-m walk task (400MWT), the stair climb task, and the lift-and-carry task [45,46]. Although the 400MWT has been used as an assessment of mobility performance in select studies among BCS [47,48], focal evidence of valid and reliability of these performance measures among BCS survivors remains relatively limited. Accordingly, as well-established measures of mobility performance in prior weight management trials, this battery of assessments is included in the present pilot trial to further explore their utility among overweight or obese BCS. The 400MWT was completed in a corridor with two cones spaced 20 m apart. Individuals were instructed to walk as quickly as quickly as they could and the time to complete ten laps around the 40-m course was recorded as the performance measure. Participants may 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 task 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 task was a simulated common daily activity test involving picking up a 10-pound container from a shelf, walking 10 m 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 was used to standardize instructions for all three tasks to all participants.

2.13. Balance

Standing balance was assessed in the medial-lateral direction via root mean square excursion using a Bertec BP5050 balance plate (Bertec Inc., Columbus, OH.) which is established as a valid and reliable measure of balance performance in BCS [49,50]. One, 60-s trial was completed with the participant standing on the plate with two feet, looking straight ahead, and with eyes closed.

2.14. Muscular strength

Muscular strength was assessed using standardized 1RM testing protocols for the chest press and leg extension exercises [51]. 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-min rest interval, until a maximum weight was reached and recorded as the 1RM.

2.15. Body composition

Body composition was assessed using Dual-Energy X-ray Absorptiometry (DXA; Lunar iDXA; GE Healthcare, Madison, WI, USA) for all outcome measures. The DXA scans were used to determine total body composition including bone-mineral density, percentage body fat and fat-free mass for all body regions. Body weight was measured to the nearest 0.1 kg at all outcome assessments and planned supervised meetings using a calibrated and certified digital scale (Health-o-meter Professional, McCook, IL).

2.16. Theoretical determinants of behavior change

Participants completed a battery of valid and reliable measures of key social cognitive determinants of EX + D behavior change from Social Cognitive Theory [21] and Self-Determination Theory [52]. The Barrier Self Efficacy Scale [53] was used to measure participants’ perceived capabilities to exercise at the present time in the face of commonly identified barriers to exercise participation. Mobility-Related Self-Efficacy (MRSE), or one’s belief in their ability to successfully complete more challenging increments of each of the functional performance tasks (400MWT, stair climb, and lift-and-carry tasks), was measured using a 6-item, 10-point scale constructed consistent with Bandura’s recommendations involving hierarchically organized items assessing beliefs in successfully completing incrementally more challenging aspects of the behavior [54]. Prior research has demonstrated the construct, convergent, and divergent validity of the MRSE measure [45,55] and each of these measures has previously demonstrated sensitivity to change in prior randomized controlled lifestyle interventions [17,18,39,56,57]. Commitment to a goal of, “Getting 150 min of exercise per week (i.e., 30 min on most, if not all, days of the week” was estimated by the Goal Commitment subscale of the Goal Commitment and Difficulty Questionnaire [58,59]. Satisfaction with physical function and appearance were assessed by the Satisfaction with Function and Appearance scale [60]. These measures have previously been used to assess satisfaction and function/appearance-related outcome expectancies in prior lifestyle intervention trials in older adults [17,18,39,56,57]. The 12-item Physical Activity Self-Regulation Scale (PASR-12) [61] measured the use of self-regulation strategies including self-monitoring, goal-setting, eliciting social support, reinforcement, time-management, and relapse prevention to support adoption and adherence to physical activity.

The degree to which motivation for EX + D behavior is relatively autonomous or self-determined was assessed using the Treatment Self-Regulation Questionnaire (TSRQ) [62]. The Behavioral Regulation in Exercise Questionnaire-2 (BREQ-2) was used to assess behavioral regulations in exercise [63]. The Perceived Competence Scale for Exercise (PCS-E) and Diet (PCS-D) measured the degree to which participants feel confident about being able to make (or maintain) a change toward EX + D behavior, participate in a program, or carry out an EX + D regimen [64]. The 6-item, Health-Care Climate Questionnaire (HCCQ) assessed perceptions of the degree to which health-care providers were autonomy supportive versus controlling in health-care settings [65,66]. Evidence of valid and reliability of this battery of social cognitive and/or self-regulation measures among BCS remains relatively limited. However, as well-established measures integrated in prior weight management trials, these assessments are included in the present pilot trial to further explore their utility among overweight or obese BCS.

2.17. Quality of life

Quality of Life was assessed using a battery of valid and reliable measures including the 12-Item Short Form Survey [67], the Functional Assessment of Cancer Therapy-Breast [68], and Body Image Relationship Scale [69,70]. Fatigue was assessed with the Brief Fatigue Inventory [71]. Function and disability were assessed using the Late Life Function and Disability Instrument which is an effective instrument for assessing function and disability in older women [72]. Evidence of valid and reliability of the Body Image Relationship Scale, Brief Fatigue Inventory, and Late Life Function and Disability measures among BCS remains

relatively limited or absent. However, as well-established measures integrated in prior weight management trials, these assessments are included in the present pilot trial to further explore their utility among overweight or obese BCS.

2.18. Statistical analysis

The HNABC pilot trial was designed to explore the feasibility and preliminary efficacy of the lifestyle weight management intervention. Therefore, the target accrual of 30 BCS does not provide sufficient statistical power to detect differences in the outcomes interest through traditional general linear modeling analysis. However, based on recent recommendations for estimating sample size in pilot trials [19], the proposed sample size was adequate to obtain effect size estimates necessary to accurately set parameters for the design of a subsequent, optimally-powered randomized controlled lifestyle intervention trial. Therefore, the primary proposed analyses in the HNABC trial focused upon estimating the magnitude of mean change from baseline observed for the pilot trial's primary (weight) and secondary (body composition, physical function, balance, muscular strength, quality of life, and social cognitive) outcomes by calculating Cohen's *d* effect sizes [73]. In addition to effect size calculation of the trial outcomes, safety will be assessed by documenting adverse events and feasibility will be analyzed by prospectively tracking recruitment, adherence, and retention rates across the trial.

3. Discussion

As BCS with overweight or obesity experience significantly greater risk of cancer recurrence and serious cardiometabolic disease, developing robust clinic-to community pathway models connecting BCS with accessible, evidence-based lifestyle weight management interventions is an important consideration in advancing contemporary supportive care during survivorship [1–5]. Unfortunately, community access to evidence-based weight management interventions for BCS remains limited and few existing interventions are based on established theories of behavior change [11,12]. Furthermore, detailed reporting of intervention components, BCTs, and modes of delivery is inconsistent in the extant literature hindering accumulation of the quality of supporting evidence necessary to impact the current standard of care for weight management in community-dwelling cancer survivors [13–15]. Consequently, there is a pressing need to develop and translate well-formulated, theory and evidence-based lifestyle weight management interventions from the clinic-to-community.

The HNABC pilot trial, was the first translational, community-based study to examine the safety, feasibility, and preliminary efficacy of a GMCB lifestyle intervention among BCS with overweight or obesity. The multi-component intervention delivered in the HNABC trial is consistent with prior GMCB trial procedures [17,20,38–41]. The intervention incorporates: (a) personalization in exercise prescription and dietary intake to patient need; (b) manualized, evidence-based behavioral weight management content delivered in a supportive group learning environment; (c) group-mediated cognitive behavioral counseling to promote development of the self-regulatory skills and social support necessary for the successful adoption and maintenance of newly acquired EX + D behavior.

Findings from both our prior lifestyle intervention trials [16–18,40] and those of other investigative teams [16,74–76] support the efficacy of the GMCB approach for yielding clinically-meaningful improvements in weight loss, body composition, physical function, and quality of life in various chronic disease and cancer patient populations with overweight or obesity. Moreover, the GMCB intervention framework has guided many of our studies under the premise that groups not only aid in adoption and adherence to new behavior through mechanisms such as social modeling and peer-initiated problem solving, but provide a more scalable and cost-effective mode of delivery relative to standard individual counseling approaches. If findings from the HNABC pilot trial demonstrate acceptable safety, feasibility, and preliminary efficacy, results will inform the design of a future, large-scale, randomized controlled efficacy trial. If successful, this approach could yield a widely accessible, cost-effective, community-based model for lifestyle weight management interventions in BCS suited for use by entities embedded in the community and invested in providing supportive programs for cancer survivors. Evidence from the HNABC trial will provide empirical justification for continuing research of theory-based, EX + D weight management programs for BCS and encourage their inclusion as a vital part of supportive care programs in the community.

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Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Appendix

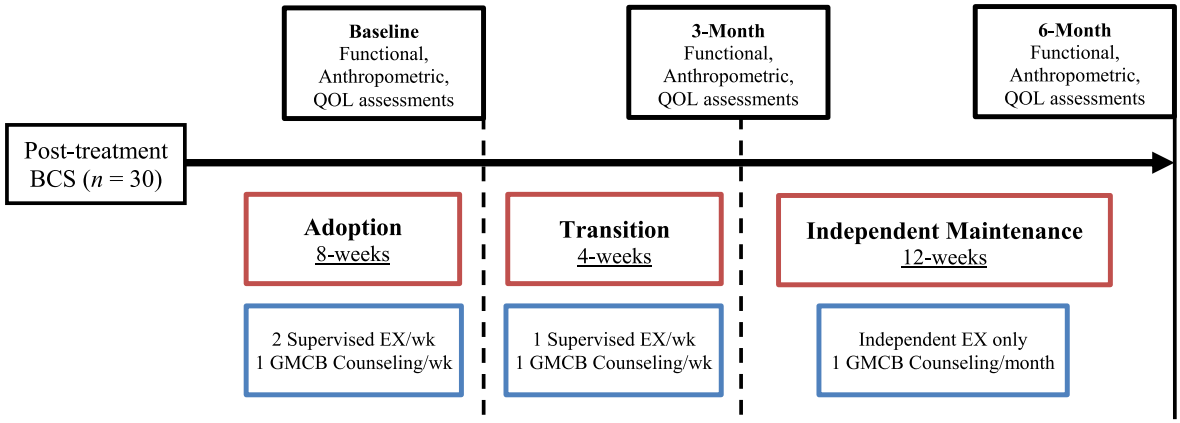

Fig. 1. Study Design and Assessment Timeline

Table 1
HNABC Intervention Components, Content, BCTs, and MoAs

Component	Schedule	Content	BCTs [MoAs]
Counseling	All sessions - opening	• Check-in: measure and discuss change in body weight; provide suggestions and reinforcement; review EX + D logs in relation to behavioral and outcome goals • Facilitate group discussion of recent behavioral successes and/or challenges • Facilitate peer-initiated problem-solving for challenges with adoption/adherence to EX + D behavior change • Employ cognitive behavioral counseling techniques (e.g., cognitive restructuring, verbal persuasion, prompt identifying/recalling of mastery experiences, self-talk etc.)	1.2 [BaCa, BR] 1.5 [Go] 1.6 [Go, FP] 1.7 [Go] 2.2 [Mo, FP] 2.3 [BR, FP] 2.4 [BR*] 2.7 [FP] 3.1 [SI] 3.3 [n/a] 10.4 [Re, SI] 11.2 [Em, BR] 13.2 [Attb] 13.3 [Attb*] 15.1 [BaCa] 15.2 [Mo,* Va*] 15.3 [BaCa] 15.4 [BaCa, MO]
	All sessions - closing	• Prompt reviewing of progress: updating EX + D behavioral goals, weight loss goals, and action/coping plans • Prompt independent practice of self-regulatory skill "toolbox" (self-monitoring; goal-setting; problem-solving; planning; etc.) and provide self-monitoring logs	1.1 [In, Go] 1.2 [BaCa, BR] 1.3 [Go, Mo] 1.4 [BC] 1.5 [Go] 2.3 [BR, FP] 2.4 [BR*] 8.1 [Sk, BaCa] 8.3 [BC] 8.7 [Sk, BaCa]
	Week 1 - Session 1	• Discuss health-related benefits of gradual change in EX + D behaviors and consequences via 'Waterfall of Disability' activity • Discuss and demonstrate EX + D self-monitoring and budgeting strategies; provide access to logs • Determine initial individual daily/weekly EX + D goals • Determine individual long-term weight loss goal	1.1 [In, Go] 1.3 [Go, Mo] 1.4 [BC] 4.1 [Kn, Sk, BaCa] 4.2 [Kn, BR] 5.1 [Kn, BaCo, In, Attb, Psv] 5.2 [BaCo, Psv] 5.3 [Kn, BaCo, Attb] 5.6 [BaCo] 6.1 [BaCa, SLI] 8.1 [Sk, BaCa] 8.3 [BC] 9.2 [BaCo, Attb, Mo, GAB] 9.3 [BaCo] 13.1 [Si]
	Week 2 - Session 2	• Introduce SMART EX + D goal-setting and IDEA barrier problem-solving tools; demonstrate use of tools; set achievable tasks using tools • Facilitate sharing of group support/discussion of tips for making healthier dietary choices	3.1 [SI] 4.1 [Kn, Sk, BaCa] 6.1 [BaCa, SLI]

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Table 1 (*continued*)

Component	Schedule	Content	BCTs [MoAs]
			8.7 [Sk, BaCa] 12.1 [ECR, BC] 12.2 [ECR] 12.3 [ECR, BC] 12.4 [n/a] 15.1 [BaCa] 15.2 [Mo,* Va*] 15.3 [BaCa] 15.4 [BaCa, Mo]
	Week 3 - Session 3	• Introduce evidence-based dietary best-practices and how to find ingredients, calorie information • Facilitate peer-initiated problem-solving for managing cravings; prompt planning of a meal	1.2 [BaCa, BR] 1.4 [BC] 4.1 [Kn, Sk, BaCa] 6.1 [BaCa, SLI] 12.1 [ECR, BC] 12.2 [ECR] 12.3 [ECR, BC] 12.4 [n/a] 15.1 [BaCa] 15.2 [Mo,* Va*] 15.3 [BaCa] 15.4 [BaCa, Mo]
	Week 4 - Session 4	• Facilitate sharing of observed physical changes due to newly adopted behavior; provide suggestions and reinforcement • Introduce how EX affects body systems; review benefits of EX	4.2 [Kn, BR] 5.1 [Kn, BaCo, In, Attb, Psv] 5.6 [BaCo] 10.4 [Re, SI]
	Week 5 - Session 5	• Facilitate group problem-solving activity for managing social gatherings with food/drink (suggest cognitive behavioral strategies/substitutions for before, during, and after the meal) • Prompt continued independent practice of IDEA problem-solving tool	1.2 [BaCa, BR] 3.1 [SI] 8.1 [Sk, BaCa] 8.2 [BR] 8.6 [Sk*] 12.1 [ECR, BC] 12.2 [ECR] 12.3 [ECR, BC] 12.4 [n/a] 13.1 [Si] 15.1 [BaCa] 15.2 [Mo,* Va*] 15.3 [BaCa] 15.4 [BaCa, Mo]
	Week 6 - Session 6	• Facilitate group discussion of the causes and effects of stress and benefits of stress management • Demonstrate and facilitate practice of stress-relief strategies	4.1 [Kn, Sk, BaCa] 4.2 [Kn, BR] 5.1 [Kn, BaCo, In, Attb, Psv] 5.6 [BaCo] 6.1 [BaCa, SLI] 8.1 [Sk, BaCa] 8.3 [BC] 11.2 [Em, BR]
	Week 7 - Session 7	• Facilitate discussion of strategies for managing restaurant dining • Prompt planning for managing barriers to dietary goals	1.4 [BC] 3.1 [SI] 4.1 [Kn, Sk, BaCa] 4.2 [Kn, BR] 12.1 [ECR, BC] 12.2 [ECR] 12.3 [ECR, BC] 12.4 [n/a] 15.1 [BaCa] 15.2 [Mo,* Va*] 15.3 [BaCa] 15.4 [BaCa, Mo]
	Week 8 - Session 8	• Introduce benefits of dietary protein intake; advise on consuming best sources • Demonstrate and prompt calculation of individual dietary protein goal • Prompt planning for managing dietary protein	1.1 [In, Go] 1.4 [BC] 4.1 [Kn, Sk, BaCa] 4.2 [Kn, BR] 6.1 [BaCa, SLI]
	Week 10 - Session 9	• Introduce how to identify dietary fat; advise on consuming best sources • Prompt planning for managing dietary fat	1.4 [BC] 4.1 [Kn, Sk, BaCa] 4.2 [Kn, BR]
	Week 12 - Session 10	• Introduce evidence-based weight maintenance strategies; advise on incorporating into lifestyle • Review and discuss motivational and self-regulatory strategies for preventing relapse	4.1 [Kn, Sk, BaCa] 4.2 [Kn, BR]
Exercise	All sessions	• Provide supervised progressive EX sessions and training materials from certified EX professionals to promote practice/mastery of independent EX behavior • Prompt accumulating independent EX/MVPA according to individual goal	4.1 [Kn, Sk, BaCa] 6.1 [BaCa, SLI] 8.1 [Sk, BaCa] 8.3 [BC] 8.6 [Sk*]

(*continued on next page*)

Table 1 (*continued*)

Component	Schedule	Content	BCTs [MoAs]
			8.7 [Sk, BaCa] 9.1 [Attb, GAB] 12.6 [Em*]
Diet	All sessions	• Provide evidence-based dietary information/behavioral strategies according to recommendations guidelines • Provide opportunities for consultation with registered dietitian	4.1 [Kn, Sk, BaCa] 9.1 [Attb, GAB]

BCT: Behavior Change Technique. *MoA:* Mechanism of Action. *GMCB:* Group-Mediated Cognitive Behavioral. *EX + D:* Exercise and Diet. *SMART:* Specific, Measurable, Achievable/Appealing, Realistic, Time-Sensitive. *IDEA:* Identify, Develop, Evaluate, Analyze. *MVPA:* Moderate to Vigorous Physical Activity. *Kn:* Knowledge. *Sk:* Skill. *BaCa:* Beliefs about capabilities. *BaCo:* Beliefs about consequences. *Re:* Reinforcement. *In:* Intention. *Go:* Goals. *MADP:* Memory, attention & decision processes. *ECR:* Environmental context & resources. *SI:* Social influences. *Em:* Emotion. *BR:* Behavioral regulation. *Attb:* Attitude towards the behavior. *Mo:* Motivation. *Si:* Self-image. *Va:* Values. *FP:* Feedback processes. *SLI:* Social learning/imitation. *BC:* Behavioral cueing. *GAB:* General attitudes/beliefs. *Psv:* Perceived susceptibility/vulnerability. *Inconclusive link. Sources: Michie et al., 2013; https://theoryandtechniquetool.humanbehaviourchange.org/tool.

Table 2
HNABC Intervention Adaptation and Modifications

Date of the Modification	March 2020	June 2020	August 2020
Description of the Specific Modification	Shift in delivery of group-based counseling from in-person groups to virtual group zoom calls for the remainder of the study (3, 1-h, group counseling calls within the maintenance phase)	Condensed battery of 6-month follow-up assessments conducted at the community center.	Development of a hybrid approach to ease the burden of in-person contacts for Wave 2. Goal was to ensure patient safety in the community center upon reopening guidelines.
Reason for the modification	COVID-19 Pandemic	COVID-19 Pandemic	COVID-19 Pandemic
By whom are modifications made?	Researcher	Research; Participant	Researcher
What is modified?	Delivery of intervention from in-person to zoom platform	Selection of primary outcome assessments included (DXA, balance, 400 M Walk, strength 1RM, and patient reported outcomes). Exclusion of lift and carry and stair climb due to collecting the data at the community center instead of the OSU EBML campus lab.	*Intensive Phase (Months 1-2):* - 2 days/week in person supervised exercise session (1 h ea.) - 1 day/week in-person group counseling session (1 h; following the second day exercise session) Wave 2 Change: - In-person: 1 day/week supervised exercise session (1 h) - Virtual: 1 day/week supervised exercise session (1 h) - Virtual: 1 day/week group counseling session (1 h; following one exercise session) *Transition Phase (Month 3):* - In-person: 1 day/week supervised exercise session (1 h) - In-person: 1 day/week group counseling session (1 h; following the exercise session) Wave 2 Change: - Virtual: 1 day/week supervised exercise session (1 h) - Virtual: 1 day/week group counseling session (1 h; following the one exercise session) *Maintenance (Months 4-6):* - In person: 1 day/month group counseling session Wave 1 and 2 Change: - Virtual: 1 day/month group counseling session
For whom were modifications made?	Individual and group level of Wave 1 (n = 11)	Individual level of Wave 1 (n = 11)	Intervention Delivery
Context of modification made?	Intervention Delivery Methods	Assessment Measures	Intervention Delivery
What is the nature of the content modification?	To ensure safety during a global pandemic the group behavioral counseling sessions transitioned from in-person group meetings to virtual group meetings via Zoom.	To ensure safety and minimal contact during the COVID-19 pandemic, participants were asked to complete a shorter assessment battery at the community center. Additionally, all participants were asked to complete the patient reported outcomes via paper at home and to mail back upon completion.	To ensure safety and minimal contact during the ongoing COVID-19 pandemic.
When: during the project was the adaption made?	During implementation. Occurred at the beginning of the maintenance phase of the project (Months 4–6)	At the 6-month assessment follow-up of Wave 1.	Pre-implementation After Wave 1 but before Wave 2 started

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Table 2 (*continued*)

Date of the Modification	March 2020	June 2020	August 2020
Why: Purpose of modification	Based on governmental shutdown guidelines. To ensure safety of patients during this pandemic	Proximity to government shutdown. While research studies were able to resume with modified research activities there were still major university and government restrictions on mask policies, capacity concerns, and overall risk reduction post 3 months from the country wide shut-down in March.	Proximity to government shutdown. While research studies were able to resume with modified research activities there were still major university and government restrictions on mask policies, capacity concerns, and overall risk reduction. The changes were largely made to help enhance recruitment to a community based programing in the midst of the COVID-19 pandemic. To ease concerns of time spent in-person for an at-risk population.
Impact: What are subjective short-term results of adaptation?	Positive – allowed for safe participation in Negative – disrupted how process data regarding paper forms of exercise tracking in maintenance phase was collected. Effect participant ability to submit these process related measures virtual. Unclear – disrupted the group dynamics of the group moving from in person to virtual delivery of the group behavioral sessions. May have impacted how participants engaged and shared in a group format virtually versus in person.	Allowed participants to complete aspects of the assessment data in a safe and efficacious manner. There was still significant concern for the COVID-19 virus as this was only 3 months post government shutdown. With objective assessment measures, there were still participants who did not want to come to the community center to complete those components of the assessment. Therefor potentially effecting retention rates at 6-months.	Allow for participation in a community-based intervention with supervised staff. Maintained supervised components of the intervention to ensure safety while adopting new exercise habits in both aerobic and resistance training. Unclear on the effects of group dynamics through the virtual delivery of all group behavioral sessions.

Table 3
HNABC Timeline of Outcome Assessments

Measure	Screening	Baseline	3 Month	6 Month
Phone Eligibility Screening	X			
Consent		X		
HIPAA		X		
Demographics		X		
Height (cm)		X	X	X
Total Body Mass (kg)		X	X	X
Body Composition		X	X	X
Balance		X	X	X
1RM Leg Extension		X	X	X
1RM Chest Press		X	X	X
400 Meter Walk (time)		X	X	X
400 M walk Self Efficacy (MRSE)		X	X	X
Stair Climb (time)		X	X	X
Stair Climb Self Efficacy (MRSE)		X	X	X
Lift and Carry (time)		X	X	X
Lift and Carry Self Efficacy (MRSE)		X	X	X
FACT-B		X	X	X
Satisfaction with Function		X	X	X
Satisfaction with Appearance		X	X	X
Perceived Competence (Diet)		X	X	X
Perceived Competence (Exercise)		X	X	X
Body Image Relationship Scale		X	X	X
Treatment Self-Regulation Questionnaire (TSRQ-Diet)		X	X	X
Treatment Self-Regulation Questionnaire (TSRQ-Exercise)		X	X	X
HCCQ Healthy Diet		X	X	X
HCCQ Exercising Regularly		X	X	X
Barrier Self Efficacy Scale (BARSE)		X	X	X
Exercise Regulations Questionnaire (BREQ_2)		X	X	X
Goal Commitment and Difficulty Questionnaire (6-Item)		X	X	X
12-Item Physical Activity Regulation Scale (PASR-12)		X	X	X
Brief Fatigue Inventory (BFI)		X	X	X
LL-FDI		X	X	X
Health and Well Being (SF-12)		X	X	X
Post-Intervention Acceptability Form			X	X

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