

Digitally Mediated Occupational Therapy to Increase Physical Activity in Urban and Rural Breast Cancer Survivors: A Pilot Feasibility Study

Tara C. Klinedinst, Zachary C. Pope, Michael C. Robertson, Nadia Stanley,
Audrey Wint, Christina Henson, Darla E. Kendzor

Submitted to: JMIR Research Protocols
on: March 11, 2025

Disclaimer: © The authors. All rights reserved. This is a privileged document currently under peer-review/community review. Authors have provided JMIR Publications with an exclusive license to publish this preprint on its website for review purposes only. While the final peer-reviewed paper may be licensed under a CC BY license on publication, at this stage authors and publisher expressly prohibit redistribution of this draft paper other than for review purposes.

Table of Contents

Original Manuscript.....	5
Supplementary Files.....	16
Figures	17
Figure 1.....	18
Multimedia Appendixes	19
Multimedia Appendix 1.....	20
Multimedia Appendix 2.....	20
Multimedia Appendix 3.....	20
CONSORT (or other) checklists.....	21
CONSORT (or other) checklist 0.....	21

Digitally Mediated Occupational Therapy to Increase Physical Activity in Urban and Rural Breast Cancer Survivors: A Pilot Feasibility Study

Tara C. Klinedinst^{1,2} PhD, OTR; Zachary C. Pope^{3,4} PhD; Michael C. Robertson^{4,5} PhD, MPH; Nadia Stanley⁴ BA; Audrey Wint² OTR; Christina Henson⁶ MD; Darla E. Kendzor^{4,5} PhD

¹ Department of Internal Medicine OU-TU School of Community Medicine Tulsa US

² Department of Rehabilitation Sciences College of Allied Health University of Oklahoma Health Sciences Center Tulsa US

³ Department of Health Promotion Sciences Hudson College of Public Health University of Oklahoma Health Sciences Center Oklahoma City US

⁴ TSET Health Promotion Research Center Stephenson Cancer Center University of Oklahoma Health Sciences Center Oklahoma City US

⁵ Department of Family and Preventive Medicine College of Medicine University of Oklahoma Health Sciences Center Oklahoma City US

⁶ Department of Radiation Oncology College of Medicine University of Oklahoma Health Sciences Center Oklahoma City US

Corresponding Author:

Tara C. Klinedinst PhD, OTR

Department of Internal Medicine
OU-TU School of Community Medicine
4502 E. 41st St. 2D31
Tulsa
US

Abstract

Background: The 5-year survival rate for breast cancer (BC) has increased in recent years. However, functional limitations associated with BC treatment (e.g., loss of strength, fatigue, lymphedema) often have far-reaching effects on survivors' physical and mental health. Aerobic physical activity (PA) and muscle strengthening exercise (MSE) can reduce functional limitations, and occupational therapy (OT) can support these health-promoting behaviors after treatment. Yet, barriers to access among BC survivors (e.g., time burden, distance to OT clinic) limit access to OT programming. This is particularly true in Oklahoma, where 33% of residents live in rural counties. Digital technologies (e.g., telehealth) can help rural and urban BC survivors circumvent these barriers.

Objective: We are investigating the feasibility of a novel OT program among rural and urban BC survivors that features 1) eight once-weekly telehealth OT sessions targeting constructs grounded in Self-Determination Theory (SDT), and 2) self-regulatory strategies known to support aerobic PA and MSE in BC survivors including self-monitoring via a wearable PA tracker, goal setting, and the provision of timely feedback.

Methods: This is a single arm feasibility trial. We are recruiting 38 BC survivors from local organizations, community-based advertising, and via referral from a collaborating oncologist. Participants include individuals who have undergone breast conserving surgery or mastectomy for BC in the last 12 months and who do not meet recommended PA levels at the time of enrollment. We will assess self-reported program acceptability and feasibility via recruitment rates, study retention, and protocol adherence. Program safety will be assessed by tracking BC-related lymphedema events, musculoskeletal injuries, and other adverse events. Finally, we will assess changes in aerobic PA and MSE participation during the program period using self-report and objective measurement tools.

Results: We received funding in March 2024 and Institutional Review Board approval in September 2024. We began recruiting in November 2024, and we anticipate completing data collection by November 2025. We hypothesize that the SDT-grounded OT program will be acceptable, feasible, and safe. We also expect pre- to post-program improvements in 1) SDT-informed determinants of PA; 2) levels of aerobic PA and MSE engagement; and 3) health-related quality of life.

Conclusions: The novel OT program under investigation is designed to decrease barriers to engaging in aerobic PA and MSE among people who have undergone breast conserving surgery or mastectomy. The study is focused on the transition from active treatment to the post-treatment period. The program combines tailored exercise instruction, guided by a qualified professional, with the benefits of telehealth delivery and health behavior change theory to adapt, modify, and integrate PA into the daily

routines of people transitioning to life beyond cancer. If shown to be acceptable and feasible, this program will be amenable to widescale dissemination.

(JMIR Preprints 11/03/2025:73554)

DOI: <https://doi.org/10.2196/preprints.73554>

Preprint Settings

1) Would you like to publish your submitted manuscript as preprint?

✓ **Please make my preprint PDF available to anyone at any time (recommended).**

Please make my preprint PDF available only to logged-in users; I understand that my title and abstract will remain visible to all users.

Only make the preprint title and abstract visible.

No, I do not wish to publish my submitted manuscript as a preprint.

2) If accepted for publication in a JMIR journal, would you like the PDF to be visible to the public?

✓ **Yes, please make my accepted manuscript PDF available to anyone at any time (Recommended).**

Yes, but please make my accepted manuscript PDF available only to logged-in users; I understand that the title and abstract will remain visible to all users.

Yes, but only make the title and abstract visible (see Important note, above). I understand that if I later pay to participate in a JMIR journal, my accepted manuscript PDF will be visible to all users.

No. Please do not make my accepted manuscript PDF available to anyone.

Original Manuscript

Research Protocol

Digitally Mediated Occupational Therapy to Increase Physical Activity in Urban and Rural Breast Cancer Survivors: A Pilot Feasibility Study

Tara C. Klinedinst^{1,2}, Zachary C. Pope^{3,4}, Michael C. Robertson^{3,5}, Nadia Stanley³, Audrey Wint¹,
Christina Henson⁶, & Darla E. Kendzor^{3,5}

¹Department of Rehabilitation Science, College of Allied Health, University of Oklahoma Health Sciences, Tulsa, OK, USA

²Department of Internal Medicine, OU-TU School of Community Medicine, Tulsa, OK, USA

³TSET Health Promotion Research Center, Stephenson Cancer Center, University of Oklahoma Health Sciences, Oklahoma City, OK, USA

⁴Department of Health Promotion Sciences, Hudson College of Public Health, University of Oklahoma Health Sciences, Oklahoma City, OK, USA

⁵Department of Family and Preventive Medicine, College of Medicine, University of Oklahoma Health Sciences, Oklahoma City, OK, USA

⁶Department of Radiation Oncology, College of Medicine, University of Oklahoma Health Sciences, Oklahoma City, OK, USA

(H1) Digitally Mediated Occupational Therapy to Increase Physical Activity in Urban and Rural Breast Cancer Survivors: A Pilot Feasibility Study

(H2) Abstract (450 words max, currently at 445)

Background: The 5-year survival rate for breast cancer (BC) has increased in recent years. However, functional limitations associated with BC treatment (e.g., loss of strength, fatigue, lymphedema) often have far-reaching effects on survivors' physical and mental health. Aerobic physical activity (PA) and muscle strengthening exercise (MSE) can reduce functional limitations, and occupational therapy (OT) can support these health-promoting behaviors after treatment. Yet, barriers to access among BC survivors (e.g., time burden, distance to OT clinic) limit access to OT programming. This is particularly true in Oklahoma, where 33% of residents live in rural counties. Digital technologies (e.g., telehealth) can help rural and urban BC survivors circumvent these barriers.

Objectives: We are investigating the feasibility of a novel OT program among rural and urban BC survivors that features 1) eight once-weekly telehealth OT sessions targeting constructs grounded in Self-Determination Theory (SDT), and 2) self-regulatory strategies known to support aerobic PA and MSE in BC survivors including self-monitoring via a wearable PA tracker, goal setting, and the provision of timely feedback.

Methods: This is a single arm feasibility trial. We are recruiting 38 BC survivors from local organizations, community-based advertising, and via referral from a collaborating oncologist. Participants include individuals who have undergone breast conserving surgery or mastectomy for BC in the last 12 months and who do not meet recommended PA levels at the time of enrollment. We will assess self-reported program acceptability and feasibility via recruitment rates, study retention, and protocol adherence. Program safety will be assessed by tracking BC-related lymphedema events, musculoskeletal injuries, and other adverse events. Finally, we will assess changes in aerobic PA and MSE participation during the program period using self-report and objective measurement tools.

Results: We received funding in March 2024 and Institutional Review Board approval in September 2024. We began recruiting in November 2024, and we anticipate completing data collection by November 2025. We hypothesize that the SDT-grounded OT program will be acceptable, feasible, and safe. We also expect pre- to post-program improvements in 1) SDT-informed determinants of PA; 2) levels of aerobic PA and MSE engagement; and 3) health-related quality of life.

Conclusions: The novel OT program under investigation is designed to decrease barriers to engaging in aerobic PA and MSE among people who have undergone breast conserving surgery or mastectomy. The study is focused on the transition from active treatment to the post-treatment period. The program combines tailored exercise instruction, guided by a qualified professional, with the benefits of telehealth delivery and health behavior change theory to adapt, modify, and integrate PA into the daily routines of people transitioning to life beyond cancer. If shown to be acceptable and feasible, this program will be amenable to widescale dissemination.

Keywords:

self-determination theory, muscle-strengthening exercise, telehealth, supportive care

(H2) Introduction

The 5-year breast cancer survival rate across all races is 90%¹. However, given that most breast cancer diagnoses lead to either breast-conserving surgery or mastectomy, survivors tend to experience considerable functional limitations caused by both cancer and its treatment. These functional limitations include lymphedema, reduced range of motion, fatigue, and pain, and often impact survivors' physical and mental health-related quality of life (HRQoL)². Unfortunately, these functional limitations can restrict participation in health promoting activities, such as aerobic physical activity (PA) and muscle strengthening exercise (MSE)³, placing survivors at increased risk of morbidity and premature mortality.^{3,4} Therefore, developing programs that reduce functional limitations and engage breast cancer survivors in aerobic PA and MSE is critical to improving health and well-being while decreasing risk factors.

Physical activity is safe and beneficial for most cancer survivors^{2,5}, and can improve HRQoL via increased self-efficacy and physical, emotional, social, and functional well-being.⁶ Yet, less than 20% of breast cancer survivors meet recommended aerobic PA and MSE guidelines.⁷⁻⁹ Qualitative research highlights that breast cancer survivors are uncertain about how to integrate aerobic PA and MSE into their lives after transitioning out of formal care settings. Support is needed to help this population with lingering functional limitations to transition into sustained, self-directed PA and MSE in community- and home-based settings.¹⁰

Occupational therapy (OT) is uniquely capable of addressing the functional limitations that restrict PA and MSE in breast cancer survivors through a combination of rehabilitation for physical function, adaptation of activity for functional limitations, environmental modification, and through developing supportive habits and routines. The goal of OT for cancer survivors is to safely and independently return to activities of daily living following cancer treatment. As such, OT is a critical post-treatment component for breast cancer survivors, who are likely experiencing multiple functional limitations. Self-Determination Theory (SDT) posits that the satisfaction of people's core psychological needs (i.e., autonomy, competence, and relatedness) facilitates the formation of autonomous motivations for health-related behaviors (i.e., enjoyment, interest, identity, and values).^{11, 12} Importantly, SDT has been proposed as an ideal theoretical framework for guiding OT (see Figure 1).^{13, 14} Grounding OT treatment in SDT can support sustained, self-directed PA and MSE through orienting survivors toward growth and development.

Digitally mediated OT is uniquely suited to helping breast cancer survivors (in particular, rural survivors) transition to sustained community- and home-based PA after undergoing breast surgery, dramatically increasing the accessibility of expert-provided PA/MSE programming. The use of digital technologies, such as telehealth, can help rural and urban breast cancer survivors circumvent these challenges to receiving OT programming.¹⁵⁻¹⁷ Emerging evidence suggests that technology-mediated OT is feasible for urban and rural breast cancer survivors.^{18, 19} Yet, more research is needed to understand if a telehealth-delivered OT program based on the tenets of SDT and focused on promoting post-surgery aerobic PA and MSE will be acceptable and feasible to urban and rural breast cancer survivors.

To that end, we propose an ORBIT Phase II²⁰ trial to investigate the acceptability and feasibility of a novel 8-week OT program among 38 rural and urban breast cancer survivors that features: 1) 8 once-weekly telehealth OT sessions, and 2) self-regulatory strategies known to support aerobic PA and MSE adoption and maintenance¹, emphasizing components of the SDT, and the provision of a wearable device (e.g., a fitness tracker) programmed to supplement individually tailored goals. Our Specific Aims, Hypotheses, and Milestones are detailed below.

(H3) Aim 1: Assess participants' perceptions of the acceptability and usefulness of the SDT-grounded, OT-based aerobic PA/MSE program (hereafter 'program'). Hypothesis 1: Participants will report the program's components to be acceptable, useable, and useful. Milestone 1a: Thematic analyses of qualitative data will suggest the program was enjoyable and improved physical and mental well-being. Milestone 1b: Quantitative assessments of items reflecting program acceptability will have a median of 5 or higher on 7-point Likert-type

scale.

(H3) Aim 2: Evaluate program feasibility and safety. Hypothesis 2: The program will be feasible and safe as demonstrated by satisfactory participant retention and adherence to program components and no serious adverse events related to the program. Milestone 2a: At least 80% of participants who complete baseline measures will subsequently complete post-program measures. Milestone 2b: Participants will average $\geq 80\%$ attendance at OT sessions. Milestone 2c: The frequency of breast cancer-related lymphedema, musculoskeletal injuries, and any adverse events will be at or below normative values—indicative of a safe program.⁴⁻⁶

(H3) Exploratory Aims: Evaluate pre- to post-program changes in 1: SDT-related constructs (autonomy, competence, and relatedness) as key mechanisms of action; 2: aerobic PA and MSE; and 3: patient-reported outcomes (PROs, e.g., physical function, anxiety, pain intensity/interference) and goal attainment. Exploratory Hypotheses: Pre- to post-program changes in SDT-related components, aerobic PA and MSE behaviors, and PROs/goal attainment will be favorable. Milestone 3a: Measures of perceived autonomy, competence, and relatedness—key SDT components in the context of aerobic PA/MSE—will improve from pre- to post-program.⁷ Milestone 3b: Participants will demonstrate a median aerobic PA increase of ≥ 10 minutes/day and will engage in at least two MSE bout per week by post-program. Milestone 3c: An average pre- to post-program change of 2-6 T-score points, dependent on the PRO being assessed, as measured by the Patient-Reported Outcomes Measurement Information System (PROMIS), with most participants ($\geq 75\%$) achieving their pre-program goals by post-program.

(H2) Methods

(H3) Participants and Recruitment. Participants ($N = 38$) in this feasibility trial are urban and rural breast cancer survivors within Oklahoma City and the greater state of Oklahoma. We define rurality at the county level using the USDA ERS's 2013 Rural-Urban Continuum Codes (RUCC; i.e., Metropolitan [1-3] vs. Micropolitan, Small Town, and Rural [4-10]). Eligible participants must be ≥ 18 years old, able to speak/read English and provide informed consent, must have received a histologically confirmed diagnosis of invasive breast carcinoma, have undergone breast conserving surgery or mastectomy for breast cancer in the last 12 months, own a smartphone and/or computer with internet access, and be willing to participate in once-weekly telehealth-delivered OT sessions for eight weeks. Individuals are not eligible if they are currently undergoing chemotherapy or radiation as primary cancer treatment, planning or preparing for surgery as primary treatment or as a reconstruction procedure in the next three months, have a distant metastasis, or report a Physical Activity Readiness Questionnaire (PAR-Q+) score that indicates PA may potentially be unsafe, unless the participant produces a signed doctor's note. Additionally, individuals are not eligible if they are already engaging in ≥ 75 min/week of vigorous-intensity PA, ≥ 150 min/week of moderate-intensity PA, or an equivalent combination of both over the last 3 months, if they are currently seeking occupational therapy or physical therapy treatment, or if they are a prisoner, pregnant, or planning to become pregnant.

We are conducting rolling recruitment, with a target accrual rate of ~ 5 participants/month. We are recruiting English speaking participants from local survivorship organizations/events, by approaching patients and posting flyers at the Stephenson Cancer Center (SCC), through University of Oklahoma Health Sciences (OUHS) social media advertising, and via direct referral from a collaborating oncologist. We are evaluating the eligibility of prospective breast cancer survivor participants using a screening questionnaire administered via REDCap. Qualifying breast cancer survivors are then contacted by a study team member to set up their baseline consenting and orientation appointment.

(H3) Program Description. The telehealth-based OT program is grounded in SDT (see Appendix

1). The program is designed to help breast cancer survivors transition from recovery after surgery to achieving levels of aerobic PA and MSE that are recommended according to each participants' specific treatment course and desired outcomes.^{2, 10, 21} Participants are engaging in eight once-weekly OT sessions with a licensed occupational therapist using videoconference software (via the Zoom platform). Each session lasts up to about an hour and is centered on psychoeducational and skill-building techniques to 1) reduce functional limitations

associated with cancer and its treatment and 2) develop behavioral skills for maintenance of aerobic PA and MSE. During the first session, participants work with the occupational therapist to choose exercise equipment from a list of options (see Supplemental Material) that supports their preferences and valued occupations (value of up to \$100). The selected equipment is then mailed to the participant by the research team. During the second OT session, the occupational therapist works with participants to identify and set goals related to aerobic PA and MSE choices that align with their values, interests, and strengths. Participants then use their selected exercise equipment to engage in tailored aerobic PA and MSE throughout the remainder of the sessions, with the occupational therapist also tracking participant attendance at each week's OT session for each participant as one of several adherence measurements.

Participants are also provided with a Fitbit Charge 6 fitness tracker. The occupational therapist has access to these trackers' data via a cloud-based platform, Fitabase (www.fitabase.com), that queries the Fitbit API. During the weekly OT sessions, the occupational therapist promotes self-regulatory techniques known to be useful for PA initiation and maintenance²². These include the provision of timely feedback on PA levels, encouraging specific, attainable goal setting (e.g., planning gradual increases in step counts), use of strengths-based problem solving, and action planning (e.g., when and how participants plan to meet aerobic PA/MSE goals). Fidelity of each OT session is being evaluated using an established fidelity checklist method with occupational therapist and supervisor assessment.⁵² Briefly, Zoom sessions are being videorecorded, and 20% of the sessions will be randomly selected for review and rating by a PhD-level occupational therapist (TCK).²³ Further, participants' goal attainment throughout the program is being evaluated with the Goal Attainment Scale²⁴ embedded within the fidelity checklist. Finally, it is notable that participants wear the ActiGraph GT3X accelerometer for 10 days before and after receiving the 8-week OT program. Wear instructions and a tracking log to document accelerometer wear patterns are being provided.

(H3) Outcomes, Measurements, and Analyses by Study Aim. We are collecting sociodemographic and medical information at baseline to describe our sample, including: age, sex, race/ethnicity, education, height and weight, marital status, annual household income, date of breast cancer diagnosis and stage at diagnosis, type of treatment(s) received, comorbidities [e.g., type II diabetes], readiness to change, and overall health status.

(H4) Aim 1 – OT Program Acceptability and Usefulness. To assess participants' perceptions of the OT program's acceptability, we are using qualitative and quantitative methodologies. For qualitative Aim 1, a research team member is conducting semi-structured interviews with each participant following study completion. Interviews are guided by a predetermined list of questions about the program meant to discern what program components participants liked (i.e., found acceptable and useful) and disliked, as well as which aspects of the program they believe could be improved (i.e., to enhance the program in future iterations). The research team member probes participants for further context regarding their answers as needed. Qualitative interviews are recorded and will be transcribed verbatim by a HIPAA-compliant third party. Transcripts will be analyzed via thematic content analysis using qualitative analysis software.²⁵ The MPIs will perform coding together for two transcripts to establish a consensus for coding procedures, then code the remaining transcripts independently. The thematic content analysis will include both deductive codes (i.e., codes determined *a priori* that reflect program acceptability) and inductive codes (i.e., codes reflecting emergent phenomenon noted by data analysts). Identified themes will then be discussed among the MPIs, with discrepancies noted and resolved and final themes reported. Our quantitative Aim 1 assessment of program acceptability and usefulness will be measured post-program. Participants will complete a questionnaire designed to provide insight into various facets of program acceptability (e.g., perceived usability, usefulness, enjoyability, etc.).

(H4) Aim 2 – OT Program Feasibility and Safety. We are assessing program feasibility via measurements of recruitment rates, study retention, and protocol adherence. Recruitment rates are being reported as the proportion of breast cancer survivors enrolled in the study divided by the number of breast cancer survivors who complete the screening survey. Enrollment will be considered feasible if $\geq 70\%$ of breast cancer survivors expressing interest, and who are eligible, ultimately enroll in the study. Study retention is being evaluated

similarly, with the number of breast cancer survivors completing the program divided by the number that started. Retention will be considered feasible if $\geq 70\%$ breast cancer survivors who complete the baseline measures also complete measures post-program. The number of weekly telehealth-delivered OT sessions (out of eight total sessions) that each participant attends is being used as the program adherence metric. Adherence will be considered feasible if at least 80% of participants average $\geq 80\%$ attendance in OT sessions. Assessments of program safety are being assessed by tracking any breast cancer-related lymphedema events, musculoskeletal injuries, and adverse events. The occupational therapist is tracking this information each week during each participant's telehealth-delivered OT session. The program will be considered safe if these events occur at or below published normative values.²⁶⁻²⁸ Results for program feasibility and safety will be reported descriptively as frequencies and percentages.

(H4) Exploratory Aims – SDT-related Constructs, Aerobic PA and MSE, and PRO Changes. The proposed project is a pilot trial focused on testing a new interventional model and using observations to refine various intervention (aka, program) components. The project is not powered to detect statistically significant changes in outcomes. As such, while we propose measuring the outcomes below to properly inform future larger studies, we will only calculate descriptive statistics (i.e., means and 95% CIs) for study outcomes.^{29, 30} Notably, we will use the Clopper-Pearson exact method to calculate all 95% CIs.

We are assessing participants' pre- to post-program changes in SDT constructs through examinations of basic psychological needs satisfaction in exercise. We are operationalizing these constructs using the Basic Psychological Needs in Exercise Scale (BPNES).³¹⁻³⁴ The BPNES is an 11-item Likert-type scale that features three subscales that measure perceptions of autonomy, competence, and relatedness (1: "I don't agree at all"; 5: "I completely agree"). Psychometric analyses have provided support for this scale's reliability, discriminant validity, and measurement invariance across gender and various cultures, and we will score subscales individually using the recommended protocol.³¹⁻³⁴ We are also evaluating theory intervention fidelity at post-program using the Theory-Intervention Fidelity Test (TIFT). This measure will allow us to assess participants' perceptions of having experienced the SDT's underlying mechanisms of behavior change (autonomy, competence, and relatedness) as well as meaning associated with the program's aim (i.e., to increase engagement in personally meaningful physical activities). Responses are on a 5-point Likert-type scale (1: "Strongly disagree"; 5: "Strongly agree"). For the BPNES, we will calculate participant's pre- to post-program change in perceived autonomy, competence, and relatedness (each construct will be calculated separately). Using these data, we will calculate participants' mean change scores and corresponding 95% CIs. For the TIFT, we will present data descriptively overall and for each construct (i.e., autonomy, competence, relatedness, and meaning).

Measurements of pre- to post-program changes in aerobic PA are being measured using ActiGraph GT3X accelerometers. Daily durations of moderate-vigorous PA [MVPA], light PA [LPA], and sedentary behavior (SB) will be reported. ActiGraph GT3X accelerometers have demonstrated evidence of validity for the measurement of free-living PA and SB.³⁵ To ensure the collection of reliable data, participants are wearing the accelerometers at baseline before the first OT session and donning of the Fitbit as well as during the 9th week following the OT program. Established protocols for placement and duration are being followed.³⁶ Wear instructions and an accelerometer wear log are also provided to all participants. Analysis: We will exclude days not meeting established thresholds (≥ 10 hours per day of wear time, at least three weekdays and one weekend day). We will then use established cut points to analyze PA durations per day for all valid days at each time point for each participant.³⁷ Daily durations of SB, LPA, and MVPA will be reported for baseline and the 9th week, with mean pre- to post-program changes and associated 95% CIs calculated. Notably, we may also use data from participant's Fitbit Charge 6 to calculate more granular data on the above PA metrics as well as daily steps. Critically, Fitbits, and the Fitbit Charge Series, have good accuracy vs. criterion for PA tracking in laboratory settings, with only slight underestimations in free-living settings (~ 1 step/minute with outliers removed).^{38, 39} Pre- to post-program changes in weekly MSE bouts are being tracked as the occupational therapist discusses PA goals with each participant during their once-weekly OT session. The occupational therapist's notes will be used to determine the percentage of program weeks that breast cancer survivors meet

the recommended two bouts of MSE per week.⁴⁰

Finally, we are evaluating pre- to post-program changes in HRQoL using PROs. We are assessing the following eight components of physical and psychological health at baseline and post-program using the PROMIS: physical functioning, fatigue, anxiety, depression, pain interference, pain intensity, sleep impairment, and sleep disturbance.⁴¹ Measurements on the PROMIS are on a 5-point Likert-type scale, with 5 reflecting worse outcomes on all components aside from physical function wherein a higher score reflects better physical function. These PROMIS measures have been observed as reliable tools for the assessment of these outcomes.⁴² Baseline and post-program scores for each of the eight PROMIS components will be calculated using established procedures, then converted to T-scores. A pre- to post-program change of 2-6 T-score points is considered a minimal important change relative to published normative values.^{42, 43} We are measuring goal attainment via goal attainment scaling (GAS). GAS allows for reporting the extent to which a participant meets weekly goals using a 5-point scale (-2: performance was much worse than expected; +2: performance was much better than expected). Measurement of pre-post changes will be obtained through transforming responses into a single aggregate score using established protocols.²⁴

(H4) Missing data. We are working to enhance participant retention and, therefore, data completeness, through follow-up phone calls, incentives, and focusing on meaningful participant goals. Our study coordinator is also frequently checking for missing data, which will be flagged in our study database, located in REDCap (Research Electronic Data Capture; Vanderbilt University). We are identifying and coding any missing data (i.e., non-response to questions, missed study visits), looking for patterns, and identifying the appropriate assumptions of missing data (i.e., MCAR, MAR, or MNAR). Due to the nature of the study, we will not need to perform sensitivity analyses, however, if we have multiple participants with incomplete data, we will decide between complete case analysis and last observation carried forward at the recommendation of our biostatistician.

(H3) Data and Safety Monitoring Plan. All data are being securely stored in REDCap. As this is an MPI study, the MPIs are jointly responsible for monitoring the safety environment of participants and ensuring that appropriate medical care and coverage is provided to all participants if necessary. The primary mentor (DEK) has also pledged to take responsibility to help lead and oversee all aspects of the research with human subjects. The safety monitor (study oncologist; CH) has also pledged to oversee participant safety.

The MPIs are also responsible for monitoring procedures during conduct of the study for each participant, including eligibility, enrollment, data collection, evaluation of study outcomes, problems with informed consent, and subject safety and well-being. This is being undertaken under the guidance of the primary mentor.

The plan includes:

1. Weekly review of screening results by the MPIs.
2. Immediate reporting of adverse events by team members to the MPIs, then to the IRB if needed.
3. Quarterly review of collected data by the MPIs.
4. Annual review by the MPIs, primary mentor, and OUHS IRB.
5. To ensure safety, the study oncologist is providing an ad-hoc review of adverse events. They will be sent this information within two weeks, or immediately for potentially serious/severe events.

Screening data are being reviewed weekly during recruitment periods by the MPIs. The MPIs are ensuring that any values indicating ineligibility and/or unsafe practices are flagged. Flagged participants may be excused from the study or instructed on safer practices, as needed. These decisions are being made in consultation with the study oncologist. We will not convene an external Data Safety and Monitoring Board. Should the study sponsor or the collaborating cancer center request that we do so, we will take advantage of protocols used in the past by investigators associated with our University.

Anticipated non-serious adverse events include non-serious injuries (e.g., joint pain) and illnesses, minor

discomfort, and possible loss of confidentiality. If an anticipated adverse event occurs, the MPIs and primary mentor will determine whether the event requires reporting to the IRB and/or to the study sponsor. The attribution and impact of each event on the overall project's risk/benefit ratio will then be determined in consultation with the study mentor and oncologist.

All unanticipated, serious, fatal, and/or life-threatening adverse events will be immediately reported to the IRB within 24 hours of occurrence. The IRB, MPIs, and primary mentor are responsible for determining if modifications are needed to the consent form and/or protocol based on the event. All protocol modifications will be reported to the IRB. If a determination is made that participants are exposed to unacceptably high risk in comparison to benefit, the study will be suspended until proper modifications are made for participant safety. Should cessation of study activities be required (temporarily or permanently), the program officer will be notified immediately.

(H2) Results

This research study was funded in March 2024. We received approval from the OUHS IRB in September 2024, and we began recruiting in November 2024. We anticipate having all data collected by November 2025 and that the primary results manuscript submitted for publication in Spring of 2026.

(H2) Discussion

(H3) Conclusions. This study addresses a common and serious problem for individuals who have undergone breast conserving surgery or mastectomy: engaging in aerobic PA and MSE during the transition period from active treatment to everyday life. This health behavior theory-grounded program uses the expertise of occupational therapists to adapt, modify, and integrate these exercises into daily routines while delivering the program via telehealth (decreasing salient barriers to accessing supportive care) in a manner that is personally-meaningful; thus, increasing the likelihood of continued PA engagement post-program.

(H3) Pitfalls.

In similar interventions, the most common pitfalls are adherence to the intervention and study processes, technology use, and safety of the participants. We will employ the following strategies to improve adherence: 1) follow-up phone calls, 2) compensation via stipends and personalized exercise equipment, 3) virtual delivery of the program, and 4) the use of a participant goals-focused program that establishes therapeutic rapport. To address technological issues, we provide written guides for using the Fitbit smartwatch and app, and technological assistance for Zoom. We have research coordinators available to troubleshoot any tech issues as they arise. We will ensure participant safety through standardized processes for 1) evaluating readiness for exercise, 2) reporting of adverse events, and close monitoring by a licensed occupational therapist, a professional trained in safely supporting physical activity.

(H3) Future Implications. If effective, this intervention can be scaled up and adapted to serve different populations. This research aligns with the National Cancer Institute's and American Cancer Society's priority funding areas: using technology to improve access to survivorship care and testing evidence-based interventions that lead to reaching adequate levels of exercise/PA.

(H3) Acknowledgements. This study is supported by the American Cancer Society Institutional Research Grant Program at Stephenson Cancer Center (PI: Ramesh, grant # IRG-23-1143225-04-IRG), an NCI-designated Cancer Center in Oklahoma City, Oklahoma. The content is solely the responsibility of the authors and does not necessarily represent the views of the American Cancer Society or Stephenson Cancer Center. This trial is registered on Clinicaltrials.gov (reg # 16601). Authorship statement: ZCP, MCR, and TCK wrote the protocol and manuscript; CH, NS, AW, and DK provided information for the initial protocol development and provided edits to the protocol manuscript.

(H3) Data Sharing

Due to the pilot nature of this study and potential for participant identification, data from this study will not be shared with outside entities.

(H3) Conflicts of Interest. The authors have no conflicts of interest to declare.

References

1. Society AC. *Cancer Treatment & Survivorship Facts & Figures 2022-2024*. 2022. Atlanta, GA.
2. Campbell KL, Winters-Stone KM, Wiskemann J, et al. Exercise Guidelines for Cancer Survivors: Consensus Statement from International Multidisciplinary Roundtable. *Med Sci Sports Exerc* 2019; 51: 2375-2390. DOI: 10.1249/mss.0000000000002116.
3. Braithwaite D, Satariano WA, Sternfeld B, et al. Long-term Prognostic Role of Functional Limitations Among Women With Breast Cancer. *JNCI: Journal of the National Cancer Institute* 2010; 102: 1468-1477. DOI: 10.1093/jnci/djq344.
4. Zhu J, Wang F, Shi L, et al. Accelerated aging in breast cancer survivors and its association with mortality and cancer recurrence. *Breast Cancer Res Treat* 2020; 180: 449-459. 2020/02/06. DOI: 10.1007/s10549-020-05541-5.
5. Joaquim A, Leão I, Antunes P, et al. Impact of physical exercise programs in breast cancer survivors on health-related quality of life, physical fitness, and body composition: Evidence from systematic reviews and meta-analyses. *Frontiers in Oncology* 2022; 12. Systematic Review. DOI: 10.3389/fonc.2022.955505.
6. Phillips SM and McAuley E. Physical activity and quality of life in breast cancer survivors: the role of self-efficacy and health status. *Psychooncology* 2014; 23: 27-34. 2013/09/05. DOI: 10.1002/pon.3366.
7. Smith SG and Chagpar AB. Adherence to physical activity guidelines in breast cancer survivors. *Am Surg* 2010; 76: 962-965. 2010/09/15.
8. Ottenbacher A, Yu M, Moser RP, et al. Population Estimates of Meeting Strength Training and Aerobic Guidelines, by Gender and Cancer Survivorship Status: Findings From the Health Information National Trends Survey (HINTS). *J Phys Act Health* 2015; 12: 675-679. 2014/05/17. DOI: 10.1123/jpah.2014-0003.
9. Forbes CC, Blanchard CM, Mummery WK, et al. Prevalence and correlates of strength exercise among breast, prostate, and colorectal cancer survivors. *Oncol Nurs Forum* 2015; 42: 118-127. 2015/03/26. DOI: 10.1188/15.Onf.42-02ap.
10. Schmitz KH, Campbell AM, Stuver MM, et al. Exercise is medicine in oncology: Engaging clinicians to help patients move through cancer. *CA Cancer J Clin* 2019; 69: 468-484. 2019/10/17. DOI: 10.3322/caac.21579.
11. Ryan RM and Deci EL. Self-determination theory and the facilitation of intrinsic motivation, social development, and well-being. *Am Psychol* 2000; 55: 68-78. 2001/06/08. DOI: 10.1037//0003-066x.55.1.68.
12. Deci EL and Ryan RM. Self-determination theory: A macrotheory of human motivation, development, and health. *Canadian Psychology / Psychologie canadienne* 2008; 49: 182-185. DOI: 10.1037/a0012801.
13. Ziviani J. Occupational performance: a case for self-determination. *Aust Occup Ther J* 2015; 62: 393-400. 2015/12/03. DOI: 10.1111/1440-1630.12250.
14. Dwyer LA, Hornsey MJ, Smith LGE, et al. Participant Autonomy in Cognitive Behavioral Group Therapy: An Integration of Self-Determination and Cognitive Behavioral Theories. *Journal of Social and Clinical Psychology* 2011; 30: 24-46. DOI: 10.1521/jscp.2011.30.1.24.
15. Hunter EG, Gibson RW, Arbesman M, et al. Systematic Review of Occupational Therapy and Adult Cancer Rehabilitation: Part 1. Impact of Physical Activity and Symptom Management Interventions. *The American Journal of Occupational Therapy* 2017; 71: 7102100030p7102100031-7102100030p7102100011. DOI: 10.5014/ajot.2017.023564.
16. Sheeran P, Wright CE, Listrom O, et al. Which Intervention Strategies Promote the Adoption and Maintenance of Physical Activity? Evidence From Behavioral Trials With Cancer Survivors. *Annals of Behavioral Medicine* 2023: kaad002.
17. Hirschey R, Bryant AL, Macek C, et al. Predicting physical activity among cancer survivors: Meta-analytic path modeling of longitudinal studies. *Health Psychol* 2020; 39: 269-280. 20200203. DOI: 10.1037/hea0000845.
18. Hegel MT, Lyons KD, Hull JG, et al. Feasibility study of a randomized controlled trial of a telephone-delivered problem-solving-occupational therapy intervention to reduce participation restrictions in rural breast cancer survivors undergoing chemotherapy. *Psychooncology* 2011; 20: 1092-1101. 2010/09/08. DOI: 10.1002/pon.1830.
19. Hwang NK, Jung YJ and Park JS. Information and Communications Technology-Based Telehealth Approach for Occupational Therapy Interventions for Cancer Survivors: A Systematic Review. *Healthcare (Basel)* 2020; 8 2020/09/27. DOI: 10.3390/healthcare8040355.
20. Czajkowski SM, Powell LH, Adler N, et al. From ideas to efficacy: The ORBIT model for developing behavioral treatments for chronic diseases. *Health Psychol* 2015; 34: 971-982. 20150202. DOI: 10.1037/hea0000161.
21. Patel AV, Friedenreich CM, Moore SC, et al. American College of Sports Medicine Roundtable Report on Physical Activity, Sedentary Behavior, and Cancer Prevention and Control. *Med Sci Sports Exerc* 2019; 51: 2391-2402. 2019/10/19. DOI: 10.1249/mss.0000000000002117.
22. Deci EL and Ryan RM. Self-determination theory: A macrotheory of human motivation, development, and health. *Canadian psychology/Psychologie canadienne* 2008; 49: 182.
23. Lambert JD, Greaves CJ, Farrand P, et al. Assessment of fidelity in individual level behaviour change interventions promoting physical activity among adults: a systematic review. *BMC Public Health* 2017; 17: 765. 2017/10/04. DOI: 10.1186/s12889-017-4778-6.
24. Turner-Stokes L. Goal attainment scaling (GAS) in rehabilitation: a practical guide. *Clinical rehabilitation* 2009; 23: 362-370.
25. Braun V and Clarke V. Using thematic analysis in psychology. *Qualitative Research in Psychology* 2006; 3: 77-101. DOI: 10.1191/1478088706qp0630a.
26. Cheema BS, Kilbreath SL, Fahey PP, et al. Safety and efficacy of progressive resistance training in breast cancer: a systematic review and meta-analysis. *Breast Cancer Res Treat* 2014; 148: 249-268. 2014/10/18. DOI: 10.1007/s10549-014-3162-9.
27. Henriksson A, Johansson B, Radu C, et al. Is it safe to exercise during oncological treatment? A study of adverse events during endurance and resistance training - data from the Phys-Can study. *Acta Oncol* 2021; 60: 96-105. 2020/12/20. DOI: 10.1080/0284186x.2020.1851046.
28. Schmitz KH, Troxel AB, Cheville A, et al. Physical Activity and Lymphedema (the PAL trial): assessing the safety of progressive strength training in breast cancer survivors. *Contemp Clin Trials* 2009; 30: 233-245. 2009/01/28. DOI: 10.1016/j.cct.2009.01.001.
29. Leon AC, Davis LL and Kraemer HC. The role and interpretation of pilot studies in clinical research. *J Psychiatr Res* 2011; 45: 626-629. 2010/11/03. DOI: 10.1016/j.jpsychires.2010.10.008.
30. Thabane L, Ma J, Chu R, et al. A tutorial on pilot studies: the what, why and how. *BMC Medical Research Methodology* 2010;

10: 1. DOI: 10.1186/1471-2288-10-1.

31. Vlachopoulos SP. The Basic Psychological Needs in Exercise Scale: Measurement Invariance Over Gender. *Structural Equation Modeling: A Multidisciplinary Journal* 2008; 15: 114-135. DOI: 10.1080/10705510701758398.

32. Vlachopoulos SP, Asci FH, Cid L, et al. Cross-cultural invariance of the basic psychological needs in exercise scale and need satisfaction latent mean differences among Greek, Spanish, Portuguese and Turkish samples. *Psychology of Sport and Exercise* 2013; 14: 622-631. DOI: <https://doi.org/10.1016/j.psychsport.2013.03.002>.

33. Vlachopoulos SP and Michailidou S. Development and Initial Validation of a Measure of Autonomy, Competence, and Relatedness in Exercise: The Basic Psychological Needs in Exercise Scale. *Measurement in Physical Education and Exercise Science* 2006; 10: 179-201. DOI: 10.1207/s15327841mpee1003_4.

34. Vlachopoulos SP, Ntoumanis N and Smith AL. The basic psychological needs in exercise scale: Translation and evidence for cross-cultural validity. *International Journal of Sport and Exercise Psychology* 2010; 8: 394-412. DOI: 10.1080/1612197X.2010.9671960.

35. Kaminsky LA and Ozemek C. A comparison of the Actigraph GT1M and GT3X accelerometers under standardized and free-living conditions. *Physiological Measurement* 2012; 33: 1869. DOI: 10.1088/0967-3334/33/11/1869.

36. TROST SG, MCIVER KL and PATE RR. Conducting Accelerometer-Based Activity Assessments in Field-Based Research. *Medicine & Science in Sports & Exercise* 2005; 37: S531-S543. DOI: 10.1249/01.mss.0000185657.86065.98.

37. Troiano RP, Berrigan D, Dodd KW, et al. Physical Activity in the United States Measured by Accelerometer. *Medicine & Science in Sports & Exercise* 2008; 40.

38. Chevanec G, Golaszewski NM, Tipton E, et al. Accuracy and precision of energy expenditure, heart rate, and steps measured by combined-sensing Fitbits against reference measures: systematic review and meta-analysis. *JMIR mHealth and uHealth* 2022; 10: e35626.

39. Waddell A, Birkett S, Broom D, et al. Validating the Fitbit Charge 4© wearable activity monitor for use in physical activity interventions. *Journal of Science and Medicine in Sport* 2024; 27: 314-318.

40. Services USDoHaH. Physical activity guidelines for Americans, 2nd edition. 2 ed. Washington, D.C.: U.S. Department of Health and Human Services, 2018.

41. Papadopoulou C, Kotronoulas G, Schneider A, et al. Patient-Reported Self-Efficacy, Anxiety, and Health-Related Quality of Life During Chemotherapy: Results From a Longitudinal Study. *Oncol Nurs Forum* 2017; 44: 127-136. 2016/12/20. DOI: 10.1188/17.Onf.127-136.

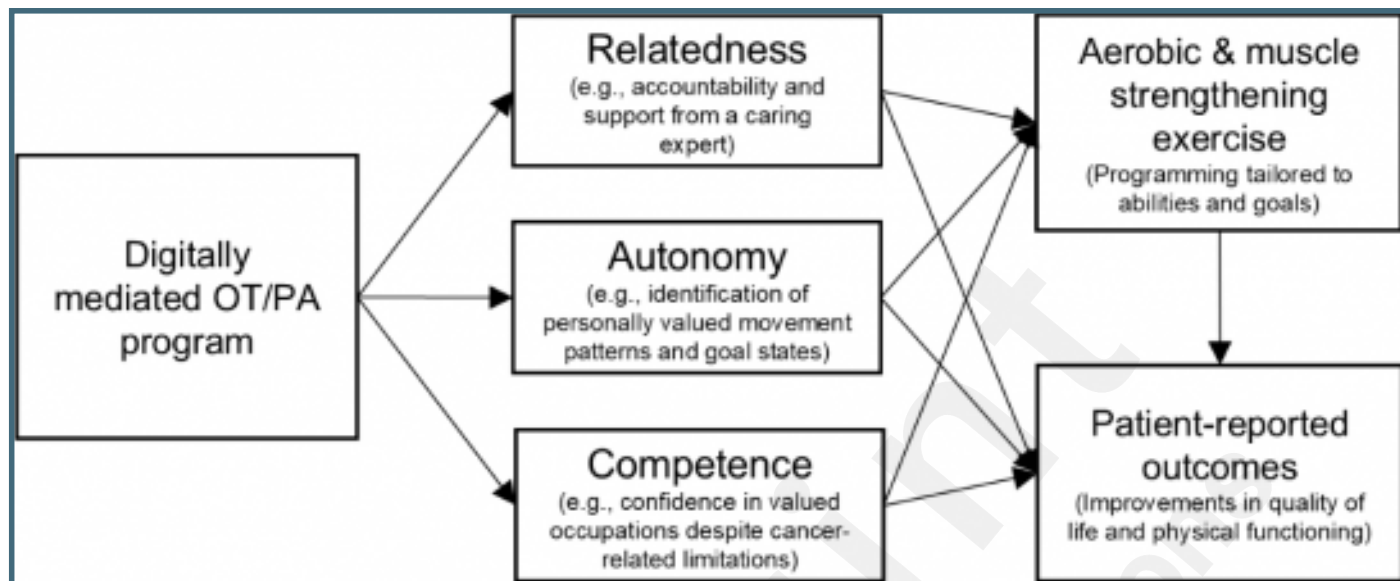
42. Cella D, Choi SW, Condon DM, et al. PROMIS® Adult Health Profiles: Efficient Short-Form Measures of Seven Health Domains. *Value in Health* 2019; 22: 537-544. DOI: <https://doi.org/10.1016/j.jval.2019.02.004>.

43. Terwee CB, Peipert JD, Chapman R, et al. Minimal important change (MIC): a conceptual clarification and systematic review of MIC estimates of PROMIS measures. *Qual Life Res* 2021; 30: 2729-2754. 2021/07/12. DOI: 10.1007/s11136-021-02925-y.

Supplementary Files

Figures

Conceptual model for a self-determination theory-informed occupational therapy (OT) program for sustained physical activity (PA).



Multimedia Appendixes

Occupational therapy (OT) elements targeting self-determination theory (SDT) constructs for sustained physical activity (PA).
URL: <http://asset.jmir.pub/assets/caeb572817b344eea43f640440cec632.docx>

Exercise equipment catalog.
URL: <http://asset.jmir.pub/assets/ccc7f554444cd51388b543b7741879d0.pdf>

Grant review.
URL: <http://asset.jmir.pub/assets/cfe967955b4bd8c442415e1235c69d9b.pdf>



CONSORT (or other) checklists

SPIRIT/SPRINT checklist.

URL: <http://asset.jmir.pub/assets/f0e114b155dd55421c015f7ad4dc1a4f.pdf>