

Reducing Metabolic Syndrome and Unmet needs Among Rural Breast Cancer Survivors During the Survivorship Transition

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1.0 Objectives

The objective of the present study is to determine the feasibility of a manualized, theory based, occupational therapist delivered, preventative intervention to increase habit development (HD) of healthy dietary and physical activity behaviors, and reduce metabolic syndrome (MetS) among high-risk, rural breast cancer survivors (BCS). Using a pilot 1-arm pre-post design, we will implement an intervention that is personalized, low burden (the majority of interactions are telecoaching sessions), and delivered during the initial survivorship transition. To determine the feasibility and preliminary effects of the intervention 48 community-dwelling BCS (ages 18 and older) will receive the 12-week intervention consists of three home-based face-to-face consultations with the therapist, 9 weekly telecoaching sessions, and the use of implementation intentions, environmental modifications, and tailored text messages to support physical activity and dietary habit formation. Feasibility metrics will be collected throughout the intervention. To assess feasibility of data collection practices, data collection for proposed primary and secondary outcomes will be collected at baseline and post intervention (week 13). We hypothesize the intervention will be feasible to implement and satisfactory to participants. The one specific aim is:

Aim 1. To determine the feasibility and acceptability of the intervention for BCS. We will evaluate trial recruitment, trial engagement and retention rates, treatment satisfaction, and the feasibility of the data collection processes for the primary behavioral measures of HD and the primary clinical measures of MetS as well as the secondary measures of improved dietary quality, physical activity engagement, physical and social functioning, self-reported unmet needs, and quality of life.

2.0 Background

One in 8 women will be diagnosed with breast cancer in their lifetime,¹ and 90% will survive at least five years post diagnosis.² For many BCS, however, Cardiovascular disease (CVD) related deaths are a greater risk to early mortality than cancer recurrence, accounting for 35% of deaths among BCS.³⁻⁵ Some BCS are at risk for CVD development at the time of their initial cancer diagnosis. Many more women however, develop MetS, a cardinal CVD risk factor during or after treatment, in part, as a result of cardiotoxic cancer treatment regimens.⁶⁻⁷ The presence of MetS increases the risk of developing CVD up to five fold,⁸⁻⁹ and includes having three of the following five criteria: (a) a large waistline; (b) elevated blood pressure; (c) elevated HbA1c levels; (d) elevated triglyceride levels; and (e) low HDL cholesterol levels.⁹

Modifying dietary and physical activity behaviors remains the best means of reducing MetS and CVD risk among the general population.¹⁶⁻¹⁸ Only a handful of studies, however, have examined the impact of such changes on MetS among BCS. Those studies, while small, suggest that healthful dietary and physical activity behavior change results in improvements in quality of life and biomarkers of cardiovascular health and reductions in cancer-related physical symptoms (e.g., fatigue, limited mobility),¹⁹⁻²¹ as well as empowering BCS to take control over their risk of cancer recurrence.²² Considering the potential benefits of MetS reduction programming, there is a need to create programs that are accessible to a range of populations.

An additional concern however is that intervention trials in cancer survivors and the general population repeatedly demonstrate that health behavior changes made during interventions are

seldom maintained.^{28, 34-35} We suspect that this lack of maintenance is, in part, because participants fail to develop those new behaviors into highly automatic ‘habits’, defined for the purposes of the intervention as *behavior patterns operating below conscious awareness*.³⁶⁻³⁷ Dual process theories posit that behavior is initiated by two competing pathways: an intentional pathway (based on deliberative thought and action), and an automatic (habitual) route.³⁸ Yet, current approaches to fostering behavior adoption and maintenance have neglected the role of habit in behavior, and few utilize habit science or evidence-based habit development (HD) strategies to foster behavioral automaticity. The *scientific premise* for the HD approach is founded in the theoretical and empirical work on HD that demonstrates that habits are important to health behavior—behavioral automaticity (habit strength) predicts health behavior engagement and maintenance, and is a key moderator of the ‘black-box’ of behavior change, the intention-behavior gap.³⁹⁻⁴⁶ Moreover, primary strategies used to foster HD (environmental modifications,⁴⁹⁻⁵² implementation intentions⁵³⁻⁵⁴ self monitoring, and reminder systems^{35, 37}) have proven effective across a range of behaviors; easy to implement; satisfactory to participants; and tailorable to the individuals’ unique context and physical capacities.⁵⁵⁻⁵⁹ Thus, while the scientific literature suggests a HD could enhance existing approaches to MetS reduction, no studies to date have applied HD strategies as a treatment modality to reduce MetS factors, and no interventions have targeted rural BCS.

3.0 Study Design

Experimental Design and Methods

We will use a 1-arm pre-post design to examine the feasibility and preliminary effect of the intervention compared to enhanced usual care. We will randomize $n = 48$ BCS (ages 18 and older) with MetS, to either the treatment or enhanced usual care condition. All participants will complete baseline and follow-up data collection at weeks 0 and 13 respectively. To track habit formation during the intervention, treatment participants will complete a text message delivered, single item behavioral automaticity measure two weeks apart (week 0-2).

Trial Setting, Sampling, and Recruitment. We will recruit our sample of $n = 48$ BCS in collaboration with the Karmanos Cancer Institute’s Detroit hospital clinic. Trained RAs located at the clinics will screen, consent, and enroll eligible participants following an IRB approved protocol. We will also recruit participants from the Cancer Survivorship in Metropolitan Detroit study (IRB# 120714MP2F). We will submit a data request to obtain the contact information of participants who may meet the criteria for MetS and who have agreed to be contacted in the future about additional research studies (see recruitment below). A trained RA will then call the participant and using an IRB approved script, screen the potential participant for eligibility and provide an overview of the study.

Inclusion Criteria: English speaking, females ages 18 and older with a diagnosis of stage 1-3 histologically confirmed first cancer of the breast will be invited to participate. Three of the following 5 criteria must be present for MetS: a large waistline (> 40 inches for men and > 35 inches for women); systolic blood pressure ≥ 130 ; HbA1c of $\geq 5.7\%$; triglyceride levels > 150 mg/dL; and HDL cholesterol levels < 50 mg/dL. However, since we will be recruiting participants from a variety of setting, and not all sources will have available MetS data, we will use a modified classification criteria, based on recruitment source. Those procedures are described below.

Exclusion Criteria: We will not exclude participants based on hormone receptivity. We will exclude pregnant patients and those with any history of the following conditions that could prevent participation in physical activity, obscure our ability to detect changes in MetS factors, or limit participant understanding of study procedures: resistant HTN; steroid-dependent asthma or COPD; cirrhosis or hepatic failure; a major cardiovascular event (e.g., stroke, myocardial infarction) within the previous 90 days; chronic kidney disease on renal replacement therapy; stage 4 cancer; those with a secondary cancer (except for nonmelanomatous skin cancers and carcinoma of the cervix in situ); taking weight loss medications; current involvement in a formal lifestyle behavior program; or neuropsychiatric disorder or dementia. The screening document used to screen participants for inclusions/inclusion criteria contains further detail about each criteria, and is attached at the end of the protocol.

Clinic-based recruitment. Participant screening and consent will occur as follows: (1) a trained clinic-based RA will screen potential participants first through clinic chart review. Once potential participants are identified, the RA will confirm preliminary inclusion/exclusion with the treating physician; (2) once eligibility is confirmed, the RA will approach the potential participant with an IRB approved recruitment script and notify them of their potential eligibility to participate in the study. If the potential participant is interested, the RA will use the script to provide the participant an overview of the study; (3) if the participant is still interested in participating, the RA will obtain informed written consent in the clinic using an IRB approved consent form. The RA will also tell the potential participant that confirmation of Mets, via blood testing will occur after obtaining informed consent. The RA will also explain to the potential participant that if the confirmatory blood tests do not indicate that the individual has Mets, then they would be automatically disenrolled from the study and notified of the disenrollment. Once consented, the RA will measure the participant's waist, and confirm the participant's blood pressure through measuring the mean of 3 reads on the same arm (for the day of the visit), and ensure the physician orders the lab blood draw and that the participant completes the lab draw so that samples can be sent to the clinical laboratory for analysis of MetS factors. The RA will discuss with the participant that the remaining baseline data collection will occur once MetS status has been confirmed from the blood test and that an RA from WSU will contact the participant to notify them of their eligibility status post-blood draw.

Cancer Survivorship in Metropolitan Detroit recruitment. We will submit a data request [IRB # 120714MP2F] to obtain the contact information of participants that agreed to be contacted in the future about research studies and who self-reported a history of two of the following four criteria: high cholesterol, hypertension, diabetes, and a BMI of ≥ 25 . Potentially eligible ROCs participants will be contacted by a trained RA and further screened for study eligibility over the phone. Once eligibility is confirmed, the RA will notify them of their potential eligibility to participate in the study. If the potential participant is interested, the RA will make an appointment to go to the participant's home (or the study lab-participant choice) to obtain informed written consent.

Trial Procedures

Upon completion of study consent the RA will make arrangements for baseline data collection within 7-14 days following the informed consent process.

Confirmatory MetS Testing and Baseline Data Collection

Clinic-based participants. After the clinic-based RA confirms the participants MetS status from the blood draw results, the clinic RA will email the participant's MetS data and contact information via secure encrypted email to the study coordinator. The study coordinator will review the MetS data and confirm eligibility. If the participant is still eligible to participate in the study, the coordinator will then schedule a visit to come to the participant's home for the first of two baseline data collection visits. If the participant is no longer eligible to participate after reviewing the MetS data, the coordinator will contact the participant to notify them that they have been disenrolled.

For eligible participants, the coordinator will next contact the participant and schedule the first of two baseline data collection visits. The first visit be in person and will consist of the participant completing psychosocial measures, a 24 hour dietary recall, and being shown how to use an activity tracking device to track their activity (if asked to complete this component) as well as be shown how to complete the symptom burden tracking (if selected to complete this component). The second visit will be conducted over the phone and consist of the RA completing the online dietary recall with the participant. Seven days after the first visit, and only if the participant was asked to either complete the activity tracking, an RA will visit the participant at their home to pick up the activity tracker.

Cancer Survivorship in Metropolitan Detroit participants. After signing the informed consent the RA will make an appointment to collect baseline data. Data collection, including a blood draw to confirm MetS status will occur in the participant's home. A phlebotomist from the Karmanos Cancer Institute's Epidemiology Research Core (ERC) will travel to the participants home to conduct a blood draw. Results of the blood testing and the participant contact information will be emailed via secure encrypted email to the study coordinator. The study coordinator will review the MetS data and confirm eligibility. If the participant is still eligible to participate in the study, the coordinator will then schedule a visit to come to the participant's home for the first of two baseline data collection visits. If the participant is no longer eligible to participate after reviewing the MetS data, the coordinator will contact the participant to notify them that they have been disenrolled.

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The first intervention visit occurs 2 weeks after the participant completes baseline data collection (including any optional study activities). Participants will participate in the initial coaching session, followed by 11 additional sessions during weeks 2-12. We will schedule all participants for clinic-based follow-up data collection visits at week 13 where we will collect a consistent set of study measures. One exception to the clinic based data collection is the NCI dietary recall measure, which, similar to baseline data collection, will be conducted over the phone with the participant on two non-consecutive days during week 13. Participants will receive

a total of \$100 in compensation paid via pre-paid Visa cards for completing the weeks 0 and 13 study visits. Participants who complete the option data collection are eligible to receive an additional \$25 in compensation for their time and effort. Optional activities include symptom reporting, activity tracking and exit interview.

Treatment Description.

C.4.2 Habit Development Intervention: An OT interventionist delivers the manualized intervention and will complete training at WSU with Dr. Fritz (PI), who is an OT with 10 years of clinical experience, and a certified health coach trained in motivational interviewing. Training will focus on familiarizing the interventionist with the study protocol, tracking and fidelity procedures, principles of evidence-based health coaching,⁷⁵ HD strategies, and the manual developed by Dr. Fritz. During implementation, Dr. Fritz will provide weekly supervision via video conference calls or site visits to the interventionist. The intervention is delivered through three face-to-face sessions, 9 tele-coaching sessions, and weekly text messages. Participants are asked to select two dietary and physical activity related behaviors every two weeks over the 12-week intervention period that they want to develop into habits ($n = 10$ habits per person). Gains behavioral automaticity can be detected in as little as two weeks,⁴⁷ however it takes longer to develop ‘strong habits’ (range: 18-254 days; mean 66 days)^{37,47} and depends on the behavior complexity and the frequency of context-consistent performances. Two initial home-based sessions (lasting approx. 120 min.) are followed by 8 weekly coaching sessions (lasting approx. 30 minutes; weeks 3-12). A home visit also occurs in week 6.

Initial Home Visit: On the initial home visit, the interventionist welcomes the participant to the program, discusses MetS, its relationship to breast cancer survival, and the role of dietary and physical activity habit formation. The interventionist also uses a validated clinical interview tool, the Canadian Occupational Performance Measure (COPM), to assess and deficits in activity performance or participation. The results of the COPM are discussed with the participant as well as a plan to address performance and participation deficits (if any are noted). The interventionist plan to address performance and participation deficits may include education, home instructions, and adaptive equipment recommendations. The OT also uses information about the environmental context gleaned from the initial home visit when working with the participant to identify dietary and physical activity behaviors that could be developed into habits, and to propose contextual modifications to support HD. During the second home session (week 2), the interventionist presents educational materials about MetS, dietary and physical activity recommendations for cancer survivors⁷⁶, HD principles, and conducts the behavioral skill training needed to formulate HD plans 1 and 2.

Habit Development Sessions and Support: Sessions occurring during weeks 2, 4, 6, 8 and 10 focus on identifying 2 suitable dietary and physical activity related behaviors each time to develop into habits and behavioral skills training (see below). Because physical activity related habits can take a greater amount of time to develop³⁸, and be the habits most likely impacted by physical problems experienced because of cancer and its treatment, physical activity habits are initiated during week 2. Each HD session thereafter focuses on a different dietary component: reducing dietary sodium and sugar (week 4), increasing fruits, vegetables, (week 6), and whole grains (week 8), and reducing unhealthy fats and increasing healthy fats (week 10). Support coaching calls occur during weeks, 3, 5, 7, 9, and 11 to ‘check in’ with participants about their progress towards their HD plans, to assist with modifying plans as needed. During the

intervention closure session (week 12) the interventionist works with the participant to develop habit maintenance plans. Sessions are augmented with a participant workbook and tailored text messages. The workbook contains educational materials and worksheets for participants to document their HD plans and self-monitor progress to plans.

Implementation Intentions: Implementation intentions are a form of “when-then” goal-setting that fosters engagement across a range of behaviors.⁴⁴ Implementation intentions aid habits by creating a mental representation of the situation, thereby making it more highly accessible in memory and accessible when the situation is encountered.⁴²⁻⁴⁴ Text messages provided (3x/week or daily; participant choice) are tailored to the participant’s implementation intentions.

Context Modification: For HD to occur the context must support behavioral engagement.⁵⁰ After identifying target behaviors to develop into habits, environmental modifications are proposed to support habit formation. In conjunction with implementation intentions, environmental modification improves the likelihood of new HD.³⁸⁻⁴² Our preliminary data suggest that small-scale modifications (e.g., placing table salt out of sight and salt-free seasoning on the counter) were acceptable and useful to participants.

Participant Confidentiality

The study protocol will be approved by the WSU institutional review board prior to engaging in any research related activities. Multiple steps will be taken to protect participant confidentiality. All stored paper forms will be handled in a confidential manner. Specifically, paper consent documents will be stored locally in the Macomb and Detroit clinics in designated research offices. Scanned copies of the consent and participant contact sheets will be uploaded to the secure Oncore data management platform. All questionnaire data will be deidentified and only coded with a participant ID number and will be store at Dr. Fritz’s primary research office at the Eugene Applebaum College of Pharmacy and Health Sciences and the master list of participant names and ID numbers will be kept on a secure WSU server in a separate location, Dr. Fritz’s second research office at the Institute of Gerontology. All electronic data will be stored in an encrypted file on a password-protected server. Access to the files will be restricted to study staff. Policies regarding the confidential nature of the data collected, processed, and stored at WSU will be explained to all research staff hired to work on the project, who must then sign a confidentiality certification and complete CITI training before gaining access to confidential information.

Safety Reporting

Definition of Adverse Event/ Serious Adverse Events. An adverse event is any reaction, side effect or untoward event that occurs during the course of the study. Adverse events are categorized as serious (see below) or non-serious, as related or not related to the study intervention, and as expected or unexpected. For the purpose of the present trial, clinically insignificant events will be excluded from any type of AE documentation. These include colds, flu, cuts, scrapes, coughs, headaches, stomach complaints, general fatigue and mild symptoms. Behavioral AEs that will be tracked in this trial include increases in emotional distress and increases in participant’s difficulty managing their metabolic syndrome risk factors (e.g., functional changes).

Serious adverse events (SAEs) are defined as deaths, life-threatening events, permanently

or substantially disabling events, congenital anomalies, events requiring an initial hospitalization or prolonging a current hospitalization, or events that require intervention to prevent permanent impairment or damage. SAEs in this trial could include inpatient hospitalization for cardiovascular or other cardio-metabolic disease related problems.

Monitoring Adverse Events. Although our study is not expected to result in any adverse events, we will implement AE/SAE procedures in preparation for a larger, subsequent trial. Once the protocol has begun, the following procedures will be followed. Participants will be screened for AEs and SAEs monthly during the intervention during each intervention contact. AEs and SAEs will be formally elicited at each scheduled data collection point, using an AE worksheet that will include the expected AEs discussed above and general probes for other physical or behavioral difficulties since the last study contact. AEs that are reported to research staff at times other than those detailed above (e.g. during a phone call to schedule data collection, or during coaching calls) will also be recorded and reported as described below.

AEs will be categorized as an SAE or non-SAE, as expected or unexpected, and as likely or unlikely to be related to the study treatment. All AEs will be reported to the WSU study coordinator who will review each AE report for concurrence regarding relatedness to the intervention, seriousness, and appropriate resolution. The PI (Dr. Fritz) will track any SAEs until resolution has been achieved. All SAEs and AEs will be entered into the study database so that they may be reported to the data and safety monitoring board (DSMB). If an SAE is determined to be related to the intervention, it will be reported to the WSU IRB in real time (within 48 hours of occurrence or identification by study personnel).

4.0 Endpoints & Other Study Variables

Primary Outcomes of Intervention Feasibility and Acceptability: Follow CONSORT⁷³ guidelines and the example of Tickle-Dengnen (2013), we will track multiple indicators of trial feasibility:

Participant accrual: Accrual will be assessed using the mean weekly accrual rate throughout the duration of the study. Our feasibility criterion threshold is set at a mean weekly accrual of ≥ 2 participants per week.

Participant Randomization: We will assess feasibility of randomization in two ways. First we will assess the number of participants who refuse randomization versus the number randomized. Given our small sample of $n = 48$ participants, we will consider the randomization scheme feasible if ≤ 4 participants refuse randomization. We will consider our randomization scheme to be feasible by assessing the balance among the total number of participants allocated to each group at the end of the intervention. We will consider the randomization scheme feasible if group imbalance is $\leq 2\%$.

Participant retention: We will assess participant retention as the total number of participants that complete the week 13 data collection visit versus the number that were enrolled in the study expressed as a % retained. Based on a recent review of trial retention of physical activity and dietary interventions delivered to breast cancer survivors with MetS (Spark et al., 2013), which suggest that average trial retention rates across studies were 83%, we have set our feasibility criterion to be conservative at 80%.

Intervention engagement: Treatment sessions occur every 2 weeks. We will allow a 1-week window to make up missed sessions before we consider the session “missed”. We will assess

intervention engagement as the number of treatment sessions scheduled ($n = 12$) versus number attended ($n = X$), expressed as the % attended. Our feasibility criterion threshold for intervention engagement is a mean engagement rate of $\geq 80\%$.

Treatment satisfaction: We will assess treatment satisfaction at week 13 as the means score on the 8-item Client Satisfaction Scale.⁷⁵ Upon study completion, we will consider a mean score of ≥ 29 (range 8-32) on the client satisfaction scale to be satisfactory for consideration of a subsequent trial. In addition, after the week 13 final visit we will conduct qualitative semistructured interviews with a subsample of $n = 12$ participants to obtain their views about the survivorship transition and participation in health behavior programs, as well as impressions of the intervention and suggestions for improving it. Participants who agree to participate in the exit interview will be compensated an additional \$25 via a Visa pre-paid gift card.

Protocol adherence: Each session, coaches are required to document session adherence tracking sheets. We will track session adherence throughout the study to enable us to address training related issue with coaches, as well as at the end of the study. To evaluate protocol adherence (both at session level and study level), we will calculate the number of session components adhered to versus the number required as per the protocol tracking sheets.

Suitability of inclusion and exclusion Criterion: Throughout the intervention we will track the number of participants screened, the number who refused (and reasons why), and the number of screen fails due to failure to meet inclusion/exclusion criteria. We will conduct a post-study review with our consulting physician (Dr. Michael Simon) to determine if further revision of the inclusion/exclusion criteria is warranted before progressing to a full trial.

Rationale for Secondary Measures: The trial includes two primary treatments: OT intervention to address unmet needs, and HD treatment to help foster healthy dietary and physical activity habits. OT intervention to address psychosocial and physical symptoms should lead to improvements in physical function and social participation and QOL, and reduction in unmet needs. Habit development training should lead to increases in behavioral automaticity (Habit strength). Habitually engagement in healthy dietary and physical activity behaviors should translate to improved clinical outcomes.

Data Collection Feasibility: We will evaluate the feasibility of data collection for the following primary and secondary behavioral and clinical measures at baseline and week 13. Feasibility of data collection will be assessed as the mean % missingness. The mean % missingness will be derived for each instrument individually and for the battery as a whole. Feasibility criterion thresholds for data collection feasibility are as follows. Data missingness for any individual instrument must be $\leq 97\%$ and missingness across the battery must be $\leq 95\%$.

Behavioral Measures: We will measure *Behavioral automaticity* using the following item ('Behavior X) is something I do without thinking') from the Self-Report Behavioral Automaticity Index (SRBI).⁷⁶ The SRBAI is a validated self-report instrument that measures perceptions of behavioral automaticity for an identified behavior. A single item was chosen base on our own, and other's preliminary data that suggest that participants struggle to understand the full four SRHI items.⁷⁶⁻⁷⁷ The chosen item has shown satisfactory content and predictive validity, and convergent validity with its parent index.⁷⁶⁻⁷⁷ To track HD during the intervention, the

SRBAI will be administered to treatment condition participants every two weeks to assess changes in HD for their self-selected habits. Resources are not available as part of this exploratory/developmental project to objectively evaluate the co-secondary behavioral outcomes of dietary intake and physical activity engagement. We have, therefore, selected self-report measures intended to maximize data quality and that will be administered at weeks 0 and 13: Dietary Quality for two non-consecutive days (a trained RA will call participants and complete the ASA 24 with them) using the National Cancer Institute's ASA 24®⁷⁸⁻⁷⁹ and coded using the validated Alternative Healthy Eating Index,⁸⁰ The ASA can be accessed at the following URL, (<https://epi.grants.cancer.gov/asa24/>). We will measure Subjective Physical Activity Engagement using the *Yale Physical Activity Scale*.

Objective Physical activity (subsample of participants). We will collect data for baseline objective physical activity using the ActivPal⁷³ wireless activity tracker. The ActivPal is a wireless activity tracker that adheres to the thigh using Tegaderm. Participants will wear an ActivPal device on their thigh for seven days to collect data on total physical activity during their waking hours. The Activpal does not require any effort on the part of the participant once it is adhered. The RA will remove the tracker after a 7 day data collection period. In week 13 the researcher will call them again and ask them to wear the device again (for 7 days) during week 13.

We will collect data for Quality of life using the 26-item validated WHOQOL-BREF at weeks 0 and 13.⁸³ Physical Function will be measured using the 20-item NIH PROMIS Physical Function measure. Participation will be measured using the 8-item NIH PROMIS Ability to Participate in Social Roles and Satisfaction with Participation in Social Roles measures. With the exception of the NCI ASA, copies of all measures are included in the appendices.

Clinical Measures: We will collect data for MetS component factors by assessing changes from baseline to week 13 in Systolic blood pressure, Weight, Hemoglobin A1c (HbA1c), and Triglyceride and HDL levels. Anthropometry and biomarker measures will be collected in the clinic following established anthropometry guidelines.⁸⁴

Symptom burden: We will collect data for symptom burden in a subsample of participants using and Ecological Momentary Assessment (EMA) called Movisens XS. A subsample of participants will be asked to download the Movisens application on their phone via a QR code texted to the participant (Android phones only). The application will prompt participants twice per day (12 pm and 8pm) to answer questions about daily symptoms (e.g., fatigue or pain) on the phone. The severity of 13 common cancer-related symptoms (EMA appendix) during the previous two hours will be assessed on a 0–10 numerical rating scale, with 0 being “not present” and 10 being “as bad as you can imagine.” Participants will also be asked to rate the quality of their sleep (first thing in the morning only) and to describe, using free text, what they are doing at the time of the EMA prompt (e.g., washing dishes, watching TV). Participants will be asked to complete the symptom reporting throughout the intervention (12 weeks). It will take about 30-50 seconds to complete each report.

Demographic and Descriptive Variables of Interest (Measured at baseline): These include Health Literacy, measured using the Rapid Estimate of Adult Literacy⁸⁵; Depression,

using the Geriatric Depression Scale⁸⁶; *comorbidity*, using a comorbidity checklist; *cognitive function* using the 6-CIT, and *Sociodemographic* factors (e.g., age, gender, education).

Statistical analysis plan

As the aim of the study is to assess feasibility, descriptive statistics will be used to assess feasibility metrics. There are no plans to analyze outcomes for general inference.

5.0 Bibliography

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