PROTOCOL TITLE:

Whole-of-Day Approach to Physical Activity in Older Cancer Survivors

Short Title "Move for Your Health"

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1.0 Objectives

Our objective is to examine the feasibility and acceptability of a home-based lifestyle activity intervention to promote light-intensity activity and reduce sedentary activity using a whole-of-day approach. Sixty-four older cancer survivors will be randomized to either a 12-week theory-based intervention or a waitlist control. The intervention uses a wearable activity tracker that pairs with a smartphone app to promote awareness and enable self-monitoring of both activity and inactivity. Motivational counseling will be used to individually tailor strategies to achieve goals. Data will be collected at baseline, post-intervention, and 3-months post-intervention. We will pursue the following specific aims.

1.1 Primary Aims and Hypotheses

1.1.a. Determine the feasibility and acceptability of a home-based lifestyle activity intervention by assessing recruitment, retention, adherence rates, and participant satisfaction, and monitoring adverse events. We hypothesize that we will meet the accrual target of older cancer survivors within 18 months, retain 80% of the sample, and achieve 80% adherence/fidelity to the intervention with high satisfaction ratings, while limiting the number of adverse events.

1.1.b. Estimate effect sizes for primary and secondary endpoints for the adoption (baseline to 12 weeks) and maintenance (3-months post-intervention) of the intervention. We hypothesize that compared to the control condition, the intervention will result in improvements in physical function (primary outcome) and secondary outcomes: physical performance, objective measures of sedentary- and light-intensity activities, and self-reported quality of life. Further, we hypothesize that the arm differences at 12 weeks will be sustained at 3-months post-intervention.

1.2. Secondary Aim

1.2.a. Conduct a process evaluation using mailed surveys and intervention fidelity assessments to inform a larger definitive trial, and more broad dissemination and implementation.

2.0 Background

The unprecedented growth of the U.S. older adult population (≥65 years), the cancer burden in this age group (≥50% of diagnoses) and the high survival rate (≥80%),[1] is resulting in a rapidly expanding high-need population. Compared to the general population, older cancer survivors are at higher risk for physical function decline and other comorbidities (e.g., cardiovascular disease, osteoporosis), which further exacerbate the risk for functional limitations.[2-5] Given the adverse consequences of functional impairment, including mobility limitations, increased number of falls, hospital/ nursing home admissions, diminished quality of life, premature death, and substantial financial costs,[6-9] the importance of implementing strategies to delay or mitigate these effects is crucial. Despite being the majority of cancer survivors, few health behavior change interventions are conducted in older survivors with comorbidities.[10]

Regular physical activity has been shown to reduce the risk of these comorbid conditions,[11] yet <30% of cancer survivors meet the recommended goal (≥150 minutes/week of moderate-to-vigorous physical activity [MVPA]; e.g., fast walking, aerobics).[12-14] Compounding the effects of

physical inactivity are the adverse physiologic distinct effects of sedentary behavior [SB].[15,16] SB is defined as prolonged sitting or reclining with minimal energy expenditure.[17,18] SB is associated with increased risk of cardiovascular disease,[19-22] premature mortality,[23,24] and decreased physical function,[25,26] even among individuals who meet recommended activity guidelines.

To date, the predominant focus in physical activity research (including in cancer survivors) has been MVPA, since this intensity level has been found to confer the greatest health benefits.[11] However, older cancer survivors with physical functional impairment may have different needs, preferences, and barriers to being physically active, and thus require a different approach. Light-intensity activities ([LPA]; e.g., leisurely walking, gardening) are associated with better physical health,[27] including physical function[28,29] and cardio-metabolic biomarkers,[30-34] and better emotional well-being,[27,35] independent of MVPA. Changing the focus from MVPA to LPA represents a more achievable and sustainable target for vulnerable populations such as older survivors with comorbidities. Despite emerging evidence of the health benefits of LPA, few rigorously designed RCTs have been conducted to evaluate the effects of LPA on physical and psychosocial health and well-being.

The majority of physical activity studies have been clinic- or center-based, focused on common cancers (breast, prostate, & colorectal), and targeted behavior.[36,37] Few studies have focused on adults over 65 years or minority survivor populations (race-ethnic minorities, rural), and targeted outcomes meaningful to survivors (e.g., patient-reported outcomes).[36] Thus, there is a critical need for lifestyle activity interventions that are effective, low-cost, and accessible to older cancer survivors from diverse backgrounds, designed to be feasible, relevant, and meaningful for them. A home-based approach (both intervention delivery and outcomes assessment), expands the reach to underserved and underrepresented minority survivor populations.

We propose a home-based intervention focused on increasing light-intensity activity and reducing sedentary behavior throughout the day – more obtainable goals – for maintaining and improving physical function in vulnerable populations. By reducing barriers to participation, a home-based approach will expand the reach to underserved cancer survivors who are older or from rural areas.

3.0 Inclusion and Exclusion Criteria

The eligibility criteria for the pilot study will vary slightly depending on the recruitment method (NMTR vs. self-referrals). The criteria for recruitment via the NMTR are based on increasing the likelihood of identifying and contacting cancer survivors who are still alive, healthy enough to participate in the study (vs. later stage disease), and for whom the contact information may still be accurate. Additionally, there is a 2-year lag in the completeness of data collected and managed by the registry. Several of these criteria are not necessary for recruiting through the general population, i.e., self-referrals who respond to study posted flyers. As this is a feasibility study, some of the eligibility criteria will be relaxed in order to assess our primary aims: the feasibility, acceptability, and safety of the intervention.

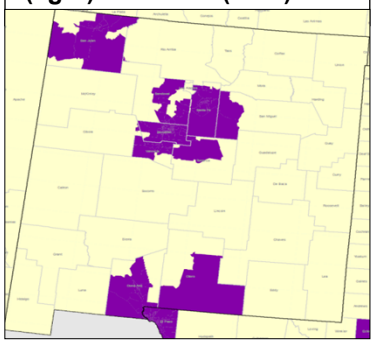
Identification of potential participants for this study will occur primarily through the New Mexico Tumor Registry (NMTR), which is one of the original Surveillance Epidemiology and End Results (SEER) Program registries. The NMTR will identify cases diagnosed in NM at age ≥60 years within the past 5 years with a local or regionally staged cancer common in older adults (**Table 1**). Random quota sampling based on ethnicity (Hispanic [H] vs. non-Hispanic [NH]) and geography

(rural vs. urban) will be employed to ensure equal numbers of subgroups. The sample frame includes the entire state of NM. Rural status is defined using codes 4-10 of the RUCA classification system (urban = codes 1-3; see NM Map, **Figure 1**).[38-40]

Table 1. Local and regionally staged cancer types common in older adults and associated with a 60% or greater 5-year survival rate

Cancer Site	Diagnosis Stage(s)	Percentage of cases by stage	5-year relative survival rate (%)	Median age at diagnosis
Bladder	In situ Localized	51.0 34.0	96.0 69.6	73
Breast (female)	Localized Regional	64.0 29.0	99.1 86.1	63
Colon & rectum (excluding carcinoid tumors)	Localized Regional	37.0 36.0	90.9 72.8	66
Endometrial	Localized Regional	67.0 20.0	94.9 69.8	63
Gastric (Stomach)	Localized	28.0	71.8	68
Kidney & renal pelvis	Localized Regional	66.0 16.0	93.0 72.3	65
Larynx	Localized	52.0	78.3	65
Leukemia	-	-	65.7	67
Melanoma of the skin	Localized Regional	82.0 9.0	99.5 70.6	65
Non-Hodgkin Lymphoma	Stage I Stage II Stage III Stage IV	23.0 15.0 18.0 35.0	86.5 78.1 72.3 63.9	67
Oral cavity (Pharynx & Larynx)	Localized Regional	28.0 50.0	86.3 69.0	64
Ovary	Localized Regional	17.0 21.0	93.1 74.2	63
Prostate	Localized Regional	73.0 14.0	100 100	67

Figure 1. NM map of rural (light) vs. urban (dark)



3.1 Screening.

Initial screening will take place through the New Mexico Tumor Registry. *Only key research staff will be able to link the name of the cancer patient/survivor with the code number* (please refer to HRPO#: 85-001). Men and women who meet the following criteria will be identified:

- Diagnosed with one of the combinations of cancer-site and stage associated with a 60% or greater 5-year relative survival rate and common among seniors (See **Table 1** for cancer types).
- Diagnosed within the past 5 years. This time frame was selected to increase the probability of obtaining accurate/current contact information for the patients. Because there is a 2 year lag in the completeness of data collected and managed by the registry, this increases the probability that the patient has completed primary cancer therapy.
- Age 60 years or older at the time of diagnosis (age 65 or older at the time of study enrollment); Selection of cancer cases from the NMTR will be based on year of diagnosis and age at diagnosis
- Known to be alive at the last ascertainment of vital status
- Per NMTR policy, a letter is sent to the cancer survivor from the NMTR to allow him/her an opportunity to refuse contact by the study research team.
- Current address within the state of New Mexico. Rural cancer survivors will be over sampled, such that 50% of the letters introducing the study will be mailed to cancer survivors with a rural census tract. Rural status is defined using codes 4-10 of the RUCA classification system (urban = codes 1-3; see NM Map, **Figure 1**).[38-40]
- Hispanic cancer survivors will be over sampled, such that 50% of the letters introducing the study will be mailed to Hispanic cancer survivors and 50% to non-Hispanic cancer survivors. Determination of ethnicity will be based on what is recorded in the tumor registry and according to an algorithm for Hispanic surnames, per standard procedures in place at the NMTR.
- Given the scope of the K07 career development award, it is not feasible to seek tribal approval for contacting American Indian/Native American cancer patients who are included in the NMTR. Therefore, per standard NMTR policies and procedures when tribal IRB approval has not been obtained, American Indian and Native American cancer survivors will not be contacted by the NMTR on behalf of the study.

The second screening will take place by telephone approximately 5-8 days after the cancer survivor has received the letter from the study that further explains the intervention and invites participation. The study coordinator/recruiter will provide additional information about the study, answer questions, and assess eligibility.

3.2 Men and women 65 years (at time of study enrollment) and older who meet the following criteria are eligible:

- Diagnosed in NM within the past 5 years with a loco-regionally staged cancer, completed primary treatment (surgery, radiation, chemotherapy), and not currently being treated for a recurrence. Individuals on hormone therapy only are eligible. (See Table 1 for cancer types)
- Mild-to-moderate physical functional impairment (raw score between 15 and 29 on the 8-item PROMIS Physical Function survey); representing individuals most at risk for functional decline and most likely to benefit from a home-based lifestyle activity intervention based on our previous research. (A score of 15 represents 0.5 standard deviation [SD] below the population mean; a score of 29 represents 1.5 SD below the population mean)
- Able to speak, read, & understand English or Spanish.
- Participating in less than 120 minutes per week of MVPA (otherwise a program to increase MVPA would be more suitable)(determined using Godin Leisure Time Exercise Questionnaire – low respondent burden).
- Living independently and capable of walking 3 blocks (approximately 1300 steps or 0.25 mile) without an assistive device (e.g., cane, walker) and without stopping to rest.
- No severe impairments (in seeing or hearing) or pre-existing medical limitations for engaging in daily LPA (e.g., severe orthopedic conditions, pending hip/knee replacement, dementia, oxygen dependent, chronic vertigo).
- No paid employment or volunteer position for greater than 20 hours per week (to avoid potential confounding by occupation activity/inactivity)
- Not currently participating in a program (personal, e.g., wearing an activity monitor, or structured, e.g., another study) to decrease sedentary time or increase physical activity.
- Not planning to move out of New Mexico within the next year.
- Own a smartphone, tablet or computer OR be willing to use a study provided smartphone capable of running the Fitbit app or website. Additionally, access to the internet or a Wi-Fi hotspot at least once per week is required. Smartphones and data plans will be provided to those individuals who are eligible but do not currently own a computer, tablet or smartphone. Participants loaned a study phone will be asked to sign form indicating they agree to return the phone at the end of the study.
- Availability of a family member or friend to be present (for safety) during remote assessment of physical performance tests.
- Willingness to be randomized to either study arm and to wear activity trackers (activPAL3 [sedentary behavior, standing, stepping] at weeks 1, 13, and 26 for 7 days; the Fitbit activity tracker during weeks 2-26 during waking hours if randomized to the immediate intervention arm; during weeks 14-26 if randomized to the delayed intervention arm).

3.3 Exclusion Criteria

- Adults not able to consent are excluded from participation
- Based on the age criteria (65 years and older), individuals who are not yet adults (infants, children, teenagers) may not participate in this study due to the same age criteria above
- Pregnant women may not participate in this study due to the same age criteria above
- Prisoners may not participate in this study as this is a study of free-living individuals

3.4 Self-referrals and Community-based recruitment

Recruitment through the NMTR is our primary recruitment method. However, we will also screen for eligibility, those individuals who self-refer to the study. We will provide study flyers to various community-based organizations, e.g., cancer support groups; community centers; senior centers; clinics; etc. Additionally, oncologists or physicians may refer their patients (cancer survivors) to the study by giving them a study flyer.

We will also contact participants of completed studies who provided permission to recontact about new studies being conducted by the PI at UNM.

Note: Given the nature of this pilot study (to assess feasibility and acceptability of the intervention among older cancer survivors), the eligibility criteria are less restrictive for self-referred participants.

Modifications to the above eligibility criteria for self-referrals include the following:

- Any cancer type and stage, as long as the patient has completed primary cancer therapy (surgery, radiation, chemotherapy) and it has been at least six months since diagnosis. Metastatic cancer patients are eligible with MD written or verbal approval.
- Cancer diagnosis greater than 5 years ago will be eligible.
- Must live in NM, but could have been diagnosed with cancer outside of NM. Eligibility is dependent on confirmation of cancer diagnosis (via NMTR or physician).

4.0 Study-Wide Number of Subjects

This study will enroll up to 70 cancer survivors. If individuals are determined to be ineligible or withdraw after consent, but prior to randomization, we will replace them with another eligible and interested individual. The goal is to randomize 64 participants. In order to achieve this accrual target, we estimate that the NMTR may need to contact 600 or more cancer patients identified in the registry due to the number of eligibility criteria and a conservative estimate of 20% participation rate.

5.0 Study-Wide Recruitment Methods

NA - This is not a multi-site study.

6.0 Multi-Site Research

NA - This is a single-site study.

7.0 Study Timeline

The table below outlines the proposed intervention trial, which is 12 weeks in duration with (telephone, email, and mail) contact by study staff followed by a 3-month maintenance period (limited contact with study staff). The trial begins with the baseline assessment (week 1) and ends with a 3-month post-intervention follow-up assessment (week 26). Recruitment will take place over a period of 15 months. This trial is individual-based vs. group-based, so the intervention for a subject begins once the subject has provided written informed consent and completed the baseline assessment. This is a 2-year study.

Study Timeline	2023		2024				2025	
Quarter:	3	4	1	2	3	4	1	2
Recruitment								
Intervention Delivery								
Ongoing data entry/cleaning								
Analyses/manuscript prep								
Prepare and submit R01								

8.0 Study Endpoints

Primary endpoints include: a) process data (enrollment, retention and adherence rates; satisfaction with the program), and b) change in self-reported physical function.

Secondary endpoints include change in: a) subjective and objective measures of sedentary- and light-intensity activities, b) physical performance, and c) self-reported quality of life (QOL).

Safety endpoints:

All adverse events associated with the physical performance tests (see section 9.0) will be tracked. The performance tests incorporate movements typically undertaken during normal daily activities (standing from a chair, sitting on a chair), and thus represent tests that are more likely to be safely performed in the home. A friend or family member will be present during the remote assessment of physical performance, which is conducted in the study participants' homes. Safety checks will be made prior to the performance tests (see section 13.0 Potential Risks to Subjects / Protection Against Risks).

Additionally, study participants will be encouraged to report any "emergencies or events" by calling the toll-free study number. See Data Safety and Monitoring Plan for more details.

9.0 Procedures Involved

Study Design

Baseline Assessment, Randomization: Interested and eligible individuals will be mailed a packet for the baseline assessment. The packet includes one activity monitor (for objective measurement of light-intensity physical activity [LPA] and sedentary behavior [SB]), instructions for use (video and print), and questionnaires (see **Table 2**). Participants will be instructed to wear the ActivPAL3™ monitor[41] during waking hours for one week, consistent with other studies.[42-44] Participants will be asked to complete a sleep and activity monitor log so during data analyses, sleep time can be distinguished from sedentary time. At the end of the week, participants will complete questionnaires on both SB and physical activity to provide context to the objective data. Instructions will be provided for returning (via self-addressed stamped mailer) the monitors and questionnaires to study staff. Upon receipt, participants will be block randomized with equal allocation to 2 arms (intervention vs. waitlist control) within four strata defined by self-reported ethnicity (Hispanic vs. non-Hispanic) and geographic location (urban vs. rural, see **Fig. 1**).

Remote assessment of physical performance: Based on our findings from the Remote Assessment of Physical Function Study (17-334), participants would prefer to use their own device (smartphone, tablet) to videoconference with the study investigators. Additionally, we learned from this study that the Time Up & Go performance test is not very accurate, given the lag/stutter of the audio and/or video. Participants' smart phone or tablet will be used to conduct the remote assessment of the physical performance tests self-administered by study participants in their own home. If a participant does not have a suitable device, the study will provide a smartphone to capture the physical performance tests. Instructions will be provided that demonstrate the performance tests and safety measures. Further instructions will be provided by the investigator via videoconferencing. The investigator will perform the assessment from a remote location (i.e., UNM) using videoconferencing software (Zoom or Skype). During the videoconference, the investigator will review the instructions for the tests, and will signal the start and stop time of the tests (the tests are timed using a standard stopwatch). A separate software (Snagit) run on a study computer will be used to record the assessments for later viewing and scoring (i.e., timing via stopwatch) for quality control purposes.

The physical performance tests include the 30-second chair stand test and the 4-stage balance test (see **Table 2**). These tests incorporate movements typically undertaken during normal daily activities, and thus represent tests that are more likely to be safely performed in the home, under supervision of a family member or friend (and remote supervision by the study investigator). Both tests are timed. The first test is the 4-stage balance test and includes four different positions, which the participant will be asked to hold for 10 seconds. The participant may decline to try any of the positions if they feel it is unsafe. Also, if the participant is unable to maintain their balance for 10 seconds, they do not proceed to the next position. The four positions include: feet side-by-side, semi-tandem (one foot slightly behind the other), full-tandem (one foot directly behind the other), standing on one foot; For the 30-second chair stand test, the participant will stand up from a chair without using their arms and sit back down again, and to repeat this for 30 seconds. The participant is instructed to perform the test quickly, but safely, and can slow down or stop before the end of the test. A friend or family member much be present for this portion of the study.

These video calls will be recorded for quality control. These video recordings will be destroyed 3 years after the study closes. The participant is provided with both written and video instructions of how to perform these tests safely, and how to prepare for the videoconference session with the study investigator.

Lifestyle Activity Intervention: The goal of the intervention is to be more active throughout the day, every day – a whole-of-day approach - without regard for frequency, intensity, or duration of activity bouts. To promote gradual and sustained change, participants will be asked to increase the number of steps per day (above their individual baseline level) during weeks 3-12, and then work to maintain their goals during weeks 13-25 **(Table 3)**. The target of 3,000 extra steps per day represents approx. 30 extra minutes of LPA,[45] which is associated with health benefits.[27,46] To encourage activity throughout the day (and reduce SB), participants will work towards 10 of 14 active hours per day (defined as >250 steps/hour in Fitbit). Frequent interruption of sitting is associated with better cardiometabolic health.[21,47-49] In accordance with SDT and MI, participants will choose their own strategies for becoming more active and achieving their weekly goals with guidance and (technology) support from their health coach. A menu of ideas will be provided in their education materials, but participants will be encouraged to identify options that work best for their lifestyle.

Table 3. Intervention Schedule

Week	# Active Hours/ day	Steps/day (above baseline)	Minimum # days / week
1	Baseline assessment randomization, Fitbit mailed to participant		
2	Establish Fitbit baseline data		
3-4	6	1000	3,5
5-6	7	1500	3,5
8-8	8	2000	3,5
9-10	9	2500	3,5
11-12	10	3000	3,5
13	Post-intervention assessment		
14-25	Maintain goals (no study contact)		
26	3-months post-intervention assess.		

Fitbit Inspire 3 ™ wearable activity tracker: During week 2, participants in the intervention group will be mailed the Fitbit Inspire 3™ activity tracker, and detailed instructions for installing the app on their smartphone or tablet and for using the tracker with the app. The distinguishing feature is an activity reminder in which the tracker gently vibrates if fewer than 250 steps were taken in the previous 50 minutes, and a suggestion to take more steps in the next 10 minutes (to achieve goal of ≥250 steps/hour). Data from the tracker is wirelessly synced to the app. Participants will be instructed to wear the tracker during waking hours and will be encouraged to track their activity via their app/website at least once a day, which includes a daily summary of total steps and number of active hours (hours with ≥250 steps). The health coach will assist with the installation, review instructions for using the tracker and app, set goals (steps per day, # active hours), and track their progress. If needed, a family member or close friend will be included on telephone calls to assist the study participant.

A Fitbit account is required as part of installing the free Fitbit app. To create the Fitbit account, the study team will use a de-identified placeholder for the participant's first and last names, and the first day and month of their true birth year. For more accurate step tracking, the participant's sex, and their self-reported height and weight will be added to the account. The study team will create and assign an email address for the sole purpose of creating each Fitbit account. The study team will manually connect the Fitbit account to the study's Fitabase account.

Fitabase (Small Steps Labs LLC): https://fitabase.com/ Fitabase is a research platform that collects data from internet connected consumer wearable activity trackers. For this study, data will be collected from each Fitbit activity tracker by Fitabase. The data to be collected includes

> Total daily steps, number of steps per minutes, estimated energy expenditure, distance moved, minutes of vigorous, moderate, and light activity, minutes of sedentary time, sleep length and quality (if Fitbit worn overnight), heart rate, and manually entered and automatically detected physical activities such as walking or running.

Once the study team connects a Fitbit account to Fitabase, Fitabase collects all new data that is collected by the device. When the device syncs (i.e., transfers data), Fitabase is notified of data availability, requests the new data, and then processes the data in order to make it available to the study. The study team will download study participant's de-identified data from Fitabase. Fitabase does not collect personally identifiable data. Each study participant is de-identified with a participant ID. Fitabase does not receive the associated email address, the Fitbit account name, Fitbit Friends list, or any GPS data.

Participants will be given Fitabase's Terms of Use and the Privacy Policy upon request. By consenting to use the Fitbit device as part of this study, the participant also consents to the Fitabase Terms of Use and Privacy Policy. At the end of the study, the participant gets to keep the Fitbit device and will receive instructions how to change the email address associated with the Fitbit account, At the end of the study or if a participant withdraws from the study we will disassociate the Fitbit account from the Fitabase account.

Health Coach Calls / MI: Research assistants will undergo MI training specific to this study. MI techniques and micro-skills will be used to guide five sessions of telephone-based health coaching, which will occur during weeks 3, 5, 7, 9, and 11. Key intervention topics and techniques include: establishing rapport; eliciting knowledge about adverse effects of inactivity/SB and benefits to becoming more active; assessing motivation, confidence, perceived importance and barriers to becoming more active; eliciting change talk; and enhancing participants' self-efficacy (competence) and motivation to be more active (e.g., small, achievable goals). The health coach also provides tech support to the participant for assessments (activPAL and performance testing) and using Fitbit with their mobile app (weeks 1, 2, 13, & 26). The first call (week 2) to help the participant set up their Fitbit may take up to 45 minutes, but can be much shorter depending on the participant's comfort level with technology. The first health coaching call may take up to 45 minutes (week 3); the remaining four health coaching calls will take 20 minutes each (weeks 5, 7, 9 and 11). Health coaching calls will be audio recorded and reviewed for quality control. Audio files will be destroyed 3 years after the study closes.

Educational Materials: Participants will be mailed educational materials (visual aids) to be used during the telephone calls with their Health Coach. The handouts include: (a) the benefits of LPA and suggestions for how to add more steps to their day, throughout the day (i.e., breaking up sedentary time through at least minimal stepping each hour); (b) reasons to be physically active; (c) example plans for meeting step goals; (d) ideas for getting more steps; and (e) pages for the participant to write their plan for each week. Instructions for setting up and using the Fitbit Inspire 3 tracker and mobile app will be included. All materials serve as reference for discussions with the health coach.

Intervention Fidelity: We will use evidence-based MI training procedures identified in previous studies.[50,51] The health coaches will receive an initial 1.5 days of in-person MI training by Dr. Walters (consultant, clinical psychologist). Prior to contacting participants, the coaches will complete 4 practice sessions, and receive feedback via 4 phone supervision sessions. Dr. Walters will code the sessions for MI fidelity by using the MI Treatment Integrity Coding System, version 4.1,[52] and use this information during supervision sessions. During the study period (15 months), the health coaches will submit one audio recording and participate in one phone supervision per week (months 1-2), then per month (months 3-15). An intervention fidelity checklist will be created to assess the other intervention components, i.e., promoting and supporting self-efficacy, knowledge and skills, self-monitoring, autonomous motivation, and social support to become more active. With HSC Affiliate status, Dr. Walters will review the selected audio files saved to the secured P drive.

A Waitlist Control was selected to help boost recruitment and retention. Participants will be asked to maintain their usual lifestyle during the 12-week intervention. After the 12-week waitlist period, participants will receive (via mail) a Fitbit Inspire 3™ monitor and education materials, and the full telephone-based MI intervention with the health coach.

Retention: To enhance recruitment, retention, and adherence rates and to compensate participants for their time and offset phone data charges, a $50 merchandise card will be provided for each outcome assessment ($150 total). Additionally, both groups will be able to keep the Fitbit activity tracker after the study ends.

Follow-up assessment: The ActivPAL3™ monitor, and instructions will be mailed to all participants to collect 1-week of data for secondary outcomes during week 13. The packet will also include questionnaires to assess subjective outcomes (see **Table 2**). The RA will call to review the instructions and answer any questions. The same procedure will be used for the 3-month post-intervention follow-up assessment.

Participant Advisory Board (PAB): The PAB will include 4-5 cancer survivors from the community. The PAB will meet twice per year (years 2-5) with the study team to provide advice and guidance on the protocol and study materials for both the validation study and RCT, interpretation of the study/RCT results, and identify next steps and strategies for the future, larger RCT (R01 application).

Study Flow: The table below describes the flow of the study from recruitment through intervention delivery to assessment of outcomes. Form of contact (phone, email, or mail) is indicated. Important information is conveyed over the phone (e.g., eligibility assessment, consent) and the use of email is dependent on participant preference for minor communication (e.g, reminders).

Fees/ Postage	Phone		Email		Mail		
	IN	OUT	IN	OUT	IN	OUT	
$						X	NMTR-> mail letter about study & flyer
	(X)		(X)		(X)		(Possible reply by potential ppts)

Fees/ Postage	Phone		Email		Mail		
	IN	OUT	IN	OUT	IN	OUT	
							NMTR releases contact info to Study Team
$						X	Mail letter of invitation, flyer, & consent form
		X		X		X	Recruitment materials to community settings
	(X)		(X)		(X)		Possible reply by potential ppts
		X					Investigator determines interest & eligibility using REDCap recruitment screener • If refusal → Refusal Qs • If interested & eligible → Go to ppt info
		X					Schedule time to review consent w/ ppt
$				(X)		(X)	Mail or email consent form (if lost copy)
		X					Review consent
$			X		X		Ppt mails signed consent form or e-signs
						X	Mail ppt photocopy of signed consent form [1]
		X					Once received, investigator contacts ppt to schedule **BASELINE** assessment, preference for surveys [2] (see Assessment Call 1 Script …)
							Verify receipt of packet and schedule remote assessment w/ Tawny via MYHealth calendar (see Assessment Call 2 Script …)
$				(X)		X	Survey packet & cover letter mailed to ppt (optional: email w/ REDCap link)
		X		X			Reminder to ppt about assessment (need another person present for physical function tests) (see Assessment Call 3 Script …)
		X					Reminder to ppt about assessment (text from Tawny with link to Zoom or Skype videoconference session for physical function tests)
		X					Remote assessment conducted / completed via Skype or Zoom
		X		X			Follow-up for incomplete surveys; return of activPAL (see Assessment Call 4 Script …)
$						X	Randomization and mail gift card: • Group A: mail thank you (on card stock) and gift card; start intervention; mail cover letter, Fitbit, Fitbit instructions, & MI Visual Aids (1st 2 Health Coaching calls)

Fees/ Postage	Phone		Email		Mail		
	IN	OUT	IN	OUT	IN	OUT	
							• Group B: mail thank you letter (maintain usual activity for 12 weeks; then receive full intervention) and gift card.
		X					Fitbit setup; verify receipt, ask if ppt would like help; reminder: maintain usual activity for 1 week; schedule 1st health coaching call
		X					1st Health Coaching Call; review Fitabase before call; record notes on MI Visual Aids;
		X					2nd Health Coaching Call; review Fitabase before call; record notes on MI Visual Aids;
$						X	Mail MI Visual Aids (calls 3-5)
		X					3rd Health Coaching Call; review Fitabase before call; record notes on MI Visual Aids;
		X					4th Health Coaching Call; review Fitabase before call; record notes on MI Visual Aids;
		X					5th Health Coaching Call; review Fitabase before call; record notes on MI Visual Aids; Schedule **13-week Assessment** • Schedule remote assessment w/ Tawny via MYHealth calendar • Ask survey preference (mail/online) • (see Assessment Call 1 Script …)
		X					Waitlist Control Group – **13-week Assessment**: • Schedule remote assessment w/ Tawny via MYHealth calendar • Ask survey preference (mail/online) • Inform ppt Fitbit will be mailed • (see Assessment Call 1 Script …)
				(X)		X	Survey packet & cover letter mailed to ppt (optional: email w/ REDCap link)
							Verify receipt of packet (see Assessment Call 2 Script …)
		X		X			Reminder to ppt about assessment (need another person present for physical function tests) (see Assessment Call 3 Script …)
		X					Reminder to ppt about assessment (text from Tawny with link to Zoom or Skype videoconference session for physical function tests)
							Remote assessment conducted / completed via Skype or Zoom

Fees/ Postage	Phone		Email		Mail		
	IN	OUT	IN	OUT	IN	OUT	
		x					Follow-up for incomplete surveys; return of activPAL (see Assessment Call 4 Script …)
						x	Mail gift card (after verifying activPAL returned, and remote assessment AND surveys completed)
						x	Mail letter to immediate intervention group (maintain usual activity; next study contact in 12 weeks)
							Start intervention for waitlist control participants (Fitbit setup, 5 health coaching calls)
							26-week assessment • Schedule remote assessment w/ Tawny via MYHealth calendar • Ask survey preference (mail/online)
							Repeat steps from 13-week assessment
							Post-study telephone survey

NOTES:

[1] Whoever conducts the consent process signs the participants' form once received; for e-consent; print consent form, sign, photocopy and keep one copy in the ppt's folder; mail a copy of signed consent to ppt

[2] Whoever conducts the consent process signs the participants' form once received; for e-consent; print consent form, sign, photocopy and keep one copy in the ppt's folder, mail a copy to ppt

Outcomes and Measurements

All measures have well-established validity and reliability, and are responsive to change.

Table 2. Outcomes & Measures (B=baseline; P=1-week post-intervention; F=3-months post-intervention follow-up to assess maintenance of behavior change & effects)(alpha=Cronbach's alpha; ICC=intraclass correlation test-retest reliability; RMSEA=root mean square error of approximation; CFI: comparative fit index)	**B**	**P**	**F**
Process Data (primary outcomes): As this is a feasibility and acceptability study, the primary outcomes relate to recruitment, retention, adherence, and adverse events, which will be carefully tracked. Collected and used to evaluate adherence: steps per day/number of active hours (downloaded from Fitbit® website), satisfaction with the program, likes & dislikes, barriers & issues, perceived degree of benefit, and intervention fidelity (see above)		**X**	**X**
Physical Function (primary outcome) / Physical Performance (secondary outcome): Subjective Measure: Self-reported physical function, a patient-reported outcome (PRO), is a key measure of physical health and well-being in cancer surviviors. Objective Measures: Two standard gerontology assessment tests will be used to measure physical performance: the 30 second chair stand test (30s-CST) and the 4-stage balance test. Both of these tests are included in the CDC Stopping Elderly Accidents, Deaths, & Injuries (STEADI) toolkit for assessment of falls [43, 44]. The 30s-CST involves standing up from a chair and sitting down as quickly and safely as possible, preferably without the use of upper extremity support [44, 51]. It is measured by the number of times a person comes to a full standing position from a chair in 30 seconds. The 30s-CST is a measure of lower extremity strength and dynamic balance, and has good validity [0.7<r<0.8] and excellent reliability [ICC=0.84-0.92][51]. The 4-stage balance test includes standing in each of four positions for 10 seconds: 1) feet side-by-side; 2) semi-tandem stand [one foot slightly behind but touching the other foot]; 3) tandem stand [one foot in front of the other; heal touching toe]; and 4) stand on one foot.	**X** **X**	**X** **X**	**X** **X**
Physical Activity and Sedentary Activity (secondary outcomes) Subjective Measures: (1) Godin leisure-time activity questionnaire will be used to screen for eligibility and to provide context for activities that changed in frequency, intensity, and duration during the intervention as objectively measured by activPAL. Godin's is a short survey with low respondent burden.[53] (2) The PACE Adult Sedentary Behavior Questionnaire will be used to estimate self-reported sedentary activities during a typical weekday and during a typical weekend. Response items range from none to 6 or more hours per day for nine common activities (e.g., watching television, using a computer, reading, etc.)[54]. Self-reported SB will provide context for SB measured objectively by ActivPAL3™ monitor. Note: Objective Measures: Daily LPA, MVPA, and SB will be objectively measured before and after the intervention using the activPAL3 monitor[55]. The ActivPAL3, worn on the thigh,[41] includes both a triaxial accelerometer and an inclinometer (to detect change in posture, i.e., sitting vs. upright posture) and is the gold standard in SB research.[27,56-59] Operational definitions:[56] (a) Total LPA & MVPA: sum of stepping bouts with a step rate of <100 and ≥100 steps per minute, respectively for activPAL. (b) Total SB: sum of all sitting/lying bouts. (c) Total steps per day. (d) Total waking hours with ≥250 steps.[60,61] Note: Fitbit™ and mobile app are used by study participants to monitor their (in)activity in real-time & prompt behavior change. The data (steps per day, hours/day with >250 steps) downloaded from the Fitbit website will only be used to assess adherence to the intervention; not to evaluate the secondary outcome.	**X** **X**	**X** **X**	**X** **X**
Quality of Life (secondary outcome): QOL will be measured using PROMIS (Patient-Reported Outcomes Measurement Information System) measures [62]. The 8-item short forms are used to assess domains in mental health (anxiety and depression), physical health (physical function, fatigue, pain, sleep disturbance, and sleep impairment) and social health (satisfaction with social roles and activities, i.e., social functioning). These instruments are valid and reliable for use in diverse clinical samples [63-66]. Surveys will be scored using the free HealthMeasures Scoring Service (https://www.assessmentcenter.net/ac_scoringservice). The service provides T-scores, which represent a linear transformation of the raw scores, normed to the general population, with a mean of 50 and a standard deviation of 10.	**X**	**X**	**X**

Sociodemographics, Health-Related Characteristics, and Medical History (other)			
Used to characterize study population and/or as predictors of adherence or moderators of intervention effects Sociodemographic Data: age, sex, race/ethnicity, education, income range, marital status (self-report)	**X**		
Health-related Behaviors: smoking status; height & weight to calculate BMI (kg/m^2)(self-report)	**X**	**X**	**X**
Cancer Data: obtained via NMTR (cancer site, stage, age & year of diagnosis, summary treatment) and self-report (treatment (yes/no): surgery, chemotherapy, radiation, hormone therapy; year primary therapy completed)	**X**		
Comorbidities: The Older Americans Resources & Services (OARS) Comorbidity Index will be used to assess the number of chronic medical conditions and symptoms and their functional impact [67]. The survey includes 42 conditions and symptoms (not including cancer), and whether each condition/symptom interferes with activities (not at all, a little, a great deal) [67]. Number/severity of comorbidities will be evaluated as predictors of adherence, & change in primary & sec. outcomes.	**X**	**X**	**X**
Fall risk: Risk for falls will be assessed by the Falls Efficacy Scale International. The survey includes 16 questions that assess how concerned someone is with doing various activities inside and outside their home.	X	X	X
Tech savviness: To prepare study team members to guide and support study participants through the technological aspects of the study (setting up and using Fitbit, videoconferencing), a short survey about the use of and comfort level of using their smartphone will be administered by the study team over the telephone.	X		
Theoretical Constructs (potential mediators)			
Self-efficacy:[68] domain specific; we will measure confidence for increasing LPA and decreasing SB with 3 items.	**X**	**X**	**X**
Social Support for Physical Activity Survey: 4 items using a 5-point scale to measure support from family and friends while making changes to physical activity.	**X**	**X**	**X**
Multidimensional Outcome Expectations for Exercise Scale: 15 items to assess physical, social, and self-evaluative beliefs about consequences of being physically active. (Good internal consistency: alpha=0.76-0.84; and Good model fit: RMSEA: ≤0.07; CFI:≥0.92 in older adults)[69,70]	**X**	**X**	**X**
Behavioral Regulations in Exercise Questionnaire (BREQ-2): 19 items to assess autonomous motivation on a continuum from amotivation to intrinsic motivation. Will be adapted using identical anchors for LPA. (Good internal consistency: alpha=0.74-0.91; excellent model fit: RMSEA=0.02; CFI=0.95)[71,SP-72]	**X**	**X**	**X**
Perceived Autonomy Support – Sport Climate Questionnaire (short form): 6 items to assess autonomy support of the health coach to characterize the quality of the social environment for influencing motivation.	**X**	**X**	**X**

****NOTE:** Additional data will be provided by the NMTR to characterize the non-responders. NMTR will provide the aggregate status (total count) based on their attempt to contact the patient, prior to releasing names to study staff. The status values include:

- Released, Patient actively or passively agreed to participant in this study
- Refused, Patient actively refused to participate in this study
- Do Not Contact, patient is eligible to participate but does not want to be contacted for any studies
- Bad Address, unable to contact the patient because the letter was undeliverable
- Ineligible, the patient was ineligible to participate in this study because of age, date of diagnosis, site, etc. This could happen if the patient notifies the NMTR of a discrepancy in their data. I.e. Date of birth is wrong or different diagnosis.
- Deceased, patient died prior to our attempt to contact them or prior to releasing the data to the study.

Additionally, for those patients referred to the study, additional aggregate data (means and standard deviations or total count) will be provided for non-responders (separately by 3 groups: ineligibles, passive refusal, active refusal): cancer site, stage of diagnosis, age and year of diagnosis, and summary treatment.

This intervention trial includes a 3 month follow-up assessment to evaluate whether the behavior change has been maintained (light-intensity physical activity, reduced sedentary activity), and whether the patient-reported outcomes have changed (e.g., quality of life, physical function and physical performance).

10.0 Data and Specimen Management

Data Management

Each participant will be assigned a unique number to identify their data. This unique number will be placed on each document (questionnaires) and included in each electronic file name (accelerometer data files created by software used to download the data) to identify the participant.

Data from questionnaires will be entered into a REDCap database. Only essential study personnel will have access to this database. Data entry will be tied to the unique number assigned to the study participant.

Data from the activPAL accelerometers will be downloaded using the PAL Technologies software packages and stored on a secure data server at UNM. The files will be identified by unique study ID number and assessment (baseline, post-intervention, or 3-month follow-up).

A data collection form will be used by the study personnel conducting the remote assessment of physical performance. This form will be identified using the unique study ID number. Data from this form will be entered into the REDCap database.

All paper files, including consent forms, will be stored in locked drawers. All electronic files, including audio recordings and video recordings will be stored on a secure data sever at UNM. All electronic files will be destroyed 3 years after the study closes. .

Recorded audio files with the Health Coaches will be saved on a secure server at UNM and saved with the unique Study ID number.

Recorded videos of remote physical performance tests will be saved on a secure server at UNM and saved with the unique study ID number.

Statistical Analyses

Overview: Outcome variables violating the normality assumption will be transformed prior to analyses. The pattern of missing data will be evaluated,[73] and the appropriate procedures for multiple imputation will be utilized. Primary analyses will be performed according to the intent-to-treat principal; as this is a feasibility study, per-protocol analyses also will be explored. ActivPAL3™ data will be downloaded using associated software, and analyzed using SAS and R software. Raw and event data (start/stop time for sitting/lying, standing, and stepping) will be processed using standard methods, e.g., determining valid wear time,[74-76] threshold values for activity intensity,[27,77,78] etc. Standard compliance criteria will be used (≥4 days with ≥10 hours/day).[27,79] Quality controls (daily logs, visual examination of heat maps) will be used to check

classification of accelerometer data. Accelerometer methods will be published according to guidelines.[80-82]

Aim 1 - Feasibility & Acceptability: For this feasibility study, we hypothesize that we will meet the accrual target of 64 inactive, older cancer survivors within 18 months, retain 80% of the sample, and to achieve 80% adherence/fidelity to the intervention. No formal statistical analyses are needed for these hypotheses.

Aim 2 - Preliminary estimates of effect sizes: We hypothesize that physical function scores will improve in the intervention group compared to the control group. We will obtain means and precision estimates for between-arm differences in physical function scores at each time point. A linear mixed-effects model will be used with group, time, and group by time interaction, adjusted for ethnicity, rural/urban status, and baseline values as needed. The appropriate variance-covariance structure will be selected to account for the potential correlation among repeated measurements from the same participant. The primary test of interest is the group by time interaction, indicating whether there was a difference between groups in the primary outcome over time. Similar analyses will be conducted for secondary outcomes.

Aim 3 - Process evaluation: will be conducted via a mailed survey. Process data (**Table 2**) and other study related outcomes will be reviewed with the PAB to identify next steps and strategies to ensure the most appropriate design and methods for the future, larger RCT, with potential for broad dissemination and implementation.

Power / Sample Size Calculation

Using a 2-sided, 2-sample t-test, with a significance level of 0.05 and 25 people per arm, we will have 80% power to detect a mean difference of 8.1 in physical function scores (a large effect size) with a standard deviation of 10. To allow for 20% attrition, we plan to enroll and randomize 32 participants per arm. The results of the feasibility trial will inform the design (sample size, effect size) of a larger trial powered to examine efficacy

Maintaining Confidentiality

The following steps will be taken to secure the data and to maintain confidentiality:

- Study participants will be assigned a unique study ID.
- All data collected will be identified with the unique study ID.
- Identifying information (e.g., name, address, etc.) will be kept separate from the participant's study data.
- The PI will have access to the electronic "link" between identifying information and the study ID (Excel spreadsheet). The link (Excel File) will be password protected and kept on a secure computer server.
- Only trained study staff will have access to the data.
- Other data collected during the study will be stored on a password and firewall protected server and accessed via secured computers in the Cancer Research Facility. Any paper forms, including informed consent forms will be kept in a locked file cabinet of the study staff for up to three years.
- Study staff are required to have completed training for the responsible conduct of research.
- For participants receiving a study purchased smartphone for use during the study, upon return to study staff, all data from the phone will be deleted prior to sending to another participant for use during the study.
- If a smartphone is provided to a study participant to use with either their Fitbit or assessment of physical performance, prior to mailing the phone to study participants, any identifying information from previous participants' use will be deleted.
- The videoconference sessions (such as Zoom or Skype) will be recorded and the files will be stored on a secure computer server. The files will be password protected and the file name will not include any identifying information (e.g., study ID number rather than participant's name). These video files will be saved in a limited-access (only key personnel) folder on the secure server for up to 3 years upon completion of the intervention trial. This time will allow for publication of the study results and to allow the PI to retrieve any additional information to inform the remote assessment for the future definitive trial, if needed.

11.0 Provisions to Monitor the Data to Ensure the Safety of Subjects

This study does not involve the testing of pharmacologic agents nor any therapeutic treatments. It is a behavioral intervention aimed at promoting physical activity using a whole-of-day approach, i.e., increasing light-intensity physical activity throughout the day while reducing and disrupting sedentary activities. Thus, it is classified as a Type 3 Study (Non-therapeutic, non-physical intervention), a minimal risk level study.

For the physical performance tests, the safety of subjects will be monitored in real-time, i.e., during the performance of the brief, timed tests. The study team will not allow the test to start or will stop it early if they believe there is a risk of injury to the participant, .e.g., if participant is feeling dizzy, is not feeling well, or has recently suffered an injury that could affect the participant's ability to safely perform the tests.

Study participants will be encouraged to report any "emergencies or events" by calling the toll-free study number. Study staff will record all reported events in the adverse event log (including the subject's name, date, and event description) and inform the principal investigator, Cindy Blair, PhD, immediately of any unanticipated study deaths or serious events that potentially jeopardize participation in the study. Dr. Blair will consult with her mentors/Co-Investigators on the action that should be taken. This communication will occur within 24 hours (for an unanticipated study death), and four business days for an unanticipated serious event. This action and date of implementation also will be recorded in the adverse event log. During the quarterly meetings, the PI and her mentors will classify any reported events as "serious" or "non-serious" (see classification below), as well as "non-attributable", "possibly attributable" or "attributable" to the intervention (unlike a pharmaceutical trial where known side effects exist, the classification of "expected" vs. "unexpected" is inappropriate for this behavioral intervention).

Serious—any event or condition that is life threatening, results in overnight hospitalization, cancer or a physical or cardiac event serious enough to require medical attention. A brief listing follows:

Fatal
Life threatening
Permanently disabling
Required or prolonged (overnight) hospitalization (Admission—not ER visit)
Overdose
Significant hazard to patient

12.0 Withdrawal of Subjects

At any time during the study, participants may ask to withdraw from the study. If the investigator feels that it is no longer safe for the participant to participate in the study, (i.e., the participant no longer meets the study eligibility criteria), the participant will be withdrawn from the study without their consent.

13.0 Potential Risks to Subjects / Protection Against Risks

This trial poses minimal risk, since the intervention specifies only light-intensity physical activity (e.g., standing, walking), which the participants are likely to already be doing, and thus may just be increasing in frequency or duration. Individuals for whom unsupervised light-intensity activity is not appropriate will be excluded from the study per the eligibility criteria. Nevertheless, there are some potential risks associated with the objective measure of sedentary activity. Sedentary activity will be assessed with a small, light-weight monitor (ActivPAL3™) worn on the thigh, and attached to the skin via an adhesive. If the attachment

causes any discomfort or irritation during the one week of data collection, the monitor will be moved to a different location if possible.

The remote assessment of physical performance poses minimal risk, since the two performance tests primarily incorporate movements typically undertaken during normal daily activities (standing from a chair, sitting on a chair), and thus represent tests that are more likely to be safely performed in a home setting. Note that both the 30 second Chair Stand test and the 4-stage balance test (see **Table 2**) have been routinely conducted in adult populations with mild to severe functional impairment such as cerebral palsy, COPD, knee osteo-arthritis, low back pain, multiple sclerosis, Parkinson's disease, renal transplant, rheumatoid arthritis, stroke, vestibular disorders, and frail elderly.[83,84] Also, remote assessment (using videoconferencing) of these physical performance tests were determined to be safe, with no adverse events.[85-87]

A friend or family member is required to be present during the physical performance testing that is self-administered by the study participant in their own home. This friend or family member must be physically and mentally capable of providing support if needed, and have access to a telephone to request medical help, if needed. Additional protection against risks during the physical performance tests will include the following:

- A fall assessment will be administered prior to the tests. Frequent fallers will require 2 people to stand nearby the study participant during the tests to provide support if needed.
- The chair used for the 30-second Chair Stand Test must include a straight back, not contain wheels, and be placed against a wall and unable to slide backwards or to the side.
- For the balance tests, the participant will be asked to stand next to a wall or counter, which can be used to steady themselves before and during the tests. In addition to the wall or counter, a sturdy chair could be used on the other side, so the participant could reach out with both arms to steady themselves if needed.
- Proper apparel and safety gear such as athletic shoes or orthopedic shoes, eye glasses (if needed), no jewelry or loose clothing that can catch on the chair or anything along the walking path.
- No pets or small children that could interfere with the test and thus jeopardize the safety of the participant will be allowed within the space used to conduct the test (e.g., will need to be in a different room during testing).

Any serious adverse events that occur while the participant is enrolled in the study will be immediately communicated to Dr. Blair, who will confer with her mentoring team. All data will be used for research purposes and will be protected and kept strictly confidential. Although steps will be taken to ensure confidentiality of collected data, there is a very slight risk that data will inadvertently be released.

14.0 Potential Benefits to Subjects

The current state of physical activity research is as follows: a) regular physical activity has numerous benefits; however, only a minority of older adults, including older cancer survivors, are physically active at the recommended levels, b) sedentary behavior, especially prolonged periods of uninterrupted sitting, has deleterious effects on health, even among individuals who exercise, and c) light-intensity activity is associated with better physical

health and psychosocial well-being. Since older cancer survivors spend up to 70% of waking hours in sedentary activities and seldom exercise, a potential benefit of participating in the proposed study is behavior change leading to increased light-intensity physical activity and reduced sedentary time. Additional potential benefits include improved physical function and quality of life. The proposed intervention is aimed at determining the feasibility and acceptability of a novel intervention to increase light-intensity activity throughout the day, ideally through at least minimal bouts of stepping each hour. If the intervention is feasible and acceptable to participants, and the data show promise, then this approach could be used to encourage inactive cancer survivors to adopt and maintain an active lifestyle, and may ultimately provide the impetus for further improvements in activity level through increased duration (longer bouts of continuous ambulation/activity) and/or intensity.

15.0 Vulnerable Populations

NA - this study is not enrolling individuals from vulnerable populations

16.0 Community-Based Participatory Research

NA - this study does not involve CBPR

17.0 Setting

This is a home-based intervention. The goal of the intervention is to increase light-intensity physical activity and reduce sedentary behavior throughout the day, every day. The baseline and follow-up assessments will be conducted in the participants' homes (self-assessment).

The New Mexico Tumor Registry will be used to identify potential study participants and establish permission to contact.

Study staff will be housed in the Cancer Research Facility, where recruitment, screening, and health coach telephone contacts will take place.

18.0 Resources Available

Study Personnel

Cindy K. Blair, PhD, Principal Investigator: Dr. Blair is an Associate Professor in the Division of Epidemiology, Biostatistics, and Preventive Health, in the School of Medicine as well as a member of the UNM Comprehensive Cancer Center (UNMCCC). Dr. Blair is a Cancer Epidemiologist and Behavioral Interventionist with 20 years of training, research experience, and collaborations in cancer epidemiology in general, and cancer survivorship and intervention development and implementation in particular. She has knowledge and experience with clinical trial design, recruitment and retention of study participants, data collection (subjective, objective, and biologic data), project management (observational studies, randomized controlled trials), supervising data collection staff and study coordinators, intervention tracking and delivery, and statistical analyses. Her background in epidemiology and biostatistics, and research experiences

have well prepared her to lead the proposed trial, coordinate all aspects of data collection and management, deliver the intervention, and conduct the statistical analyses.

19.0 Recruitment Methods

Recruitment

Potentially eligible cancer survivors will be identified via the New Mexico Tumor Registry (NMTR). Per current NMTR policy, a letter will be mailed to the cancer patient/survivor that explains the purpose of the NMTR and why the patient's cancer diagnosis is collected/maintained by the registry. The letter also very briefly describes the proposed study and provides different options for contacting the NMTR if the patient does not want to be contacted by the study investigator. A recruitment flyer will be included with the letter. Passive consent is assumed if there is no response from the subject within three weeks of receiving the letter. Contact information for patients not refusing contact is then forwarded to the study investigator.

Upon active or passive consent to contact, subjects will be mailed a letter explaining the study and inviting them to participate, a flyer, two consent forms (one to keep, one to mail back), and a self-addressed, stamped envelope. Individuals not refusing contact will be telephoned by staff to discuss the study, verify eligibility, and begin the consent process. Written informed consent for those interested and study eligible will be obtained by having the participant mail the consent form (using a pre-addressed, postage paid envelope) to study staff after being consented via telephone. Study participants will be given a copy of the consent form to keep for their records.

Note: The NMTR will be reviewing PHI (names, addresses, cancer diagnosis, etc.) from the tumor registry to identify potentially eligible subjects for the study. Therefore, we request a waiver of HIPAA authorization for screening/recruitment purposes. Note that individuals contacted by the NMTR on behalf of the study can refuse release of their contact information to the study team for additional contact and final determination of eligibility.

Individuals from previously completed studies who provided permission for future contact about new studies will receive a similar letter explaining the study and inviting them to participate and a study flyer. Individuals not refusing contact will be telephoned by staff to discuss the study, answer any questions, and verify eligibility. For interested and eligible individuals, they will either be mailed a copy of the consent form or receive a link to view the consent form via REDCap. Upon completion of the consent discussion, interested individuals will either electronically sign or sign and return the paper consent form.

Sources of Materials

Study participants for this intervention will be recruited from The New Mexico Tumor Registry (NMTR). For enrollees, data on cancer type and stage, and age and year of diagnosis will be obtained from the NMTR. For non-enrollees, aggregate (de-identified) demographic (age, sex, race-ethnicity) and cancer data (type, stage, diagnosis year) will be obtained and used to compare characteristics of respondents with non-respondents (to assess potential selection bias). Data will be collected via mailed packets (activity monitors and questionnaires) at baseline, post-intervention, and 3-months post-intervention. Data collection includes objective measures of light-intensity physical activity and sedentary activity using the activPAL3 monitor. The ActivPAL3,

worn on the thigh, includes both a triaxial accelerometer and an inclinometer (to detect change in posture, i.e., sitting vs. upright posture) and is the gold standard in SB research. Participants will receive written instructions on how to wear the activPAL monitors correctly and how to perform the physical performance tests correctly and safely. Subjective data will be collected on physical activity and sedentary activity (to provide context for objective data), health related quality of life, comorbidities, and sociodemographics. We will conduct a debriefing after the intervention to assess satisfaction with the program.

20.0 Number of Subjects

Sixty-four, inactive, older cancer survivors will be randomized to either a 12-week theory-based intervention or a waitlist control.

21.0 Provisions to Protect the Privacy Interests of Subjects

Personal identifying information such as name and address will only be provided to the study from the NMTR for cancer survivors who did not object to contact by study staff. Subjects will then be contacted by mail with a letter introducing them to the intervention study and inviting them to participate. Subsequently, subjects will be contacted by telephone by research staff to summarize the goals of the study, answer questions, and assess final eligibility.

During recruitment and the consent process, we will communicate to the study participant that their privacy is important, and what steps will be taken to protect their privacy. Examples include:

- There is a very slight chance that someone else could get your personal information from us by accident. But to keep this from happening, we will keep all your personal information in a locked file cabinet or in password-protected computer files.
- Only key research personnel will be able to access your personal information.
- All data collected during the study will be identified with only a unique identifier.

The research team will not have access to medical records or other sensitive information not provided by the subject (self-reported medical conditions) or the NMTR (cancer site and stage, age at diagnosis, year of diagnosis, first course of therapy [surgery, chemotherapy and/or radiotherapy]).

Only de-identified data will be used in data analyses. Only aggregate data will be used in presentations, reports, and publications.

22.0 Compensation for Research-Related Injury

NA - this research study does not involve more than Minimal Risk to subjects

23.0 Economic Burden to Subjects

Participants will have minimal to no economic burden to participate because they will receive a stipend of $50 in the form of a merchandise card for each outcome assessment ($150 total). This

is to compensate participants for their time and to offset phone data charges. This is a sufficient amount as there will be no travel burden to participants and appointments will be made at their convenience. Additionally, participants will be gifted the FitBit Inspire 3 ($99) used throughout the intervention to maintain an active lifestyle upon completion of the study.

24.0 Consent Process

The subject will be introduced to the study through a mailed letter of invitation. The consent form will accompany the letter, to allow the subject adequate time to read the materials before study staff follow-up with a phone call (approximately 1 week later) to review the study and answer any questions, if the subject did not already call the toll-free study number. If the subject expresses interest in the study, final eligibility will be assessed, and verbal consent will be obtained. The following questions will be asked to assess the subjects' understanding of the consent process. Do you have any questions about the study? We have covered a lot of information. Could you please describe for me what you think participating in this study requires? Do you have the toll free study telephone number?

The participant will be required to mail in the signed consent form (using a self-addressed postage paid envelope) before the baseline assessment can be scheduled. Each participant is allowed to choose when s/he begins the study, which allows for additional time to consider study participation, if needed. Research staff will be available via telephone to answer any questions that the subject may have. Additionally, staff will have received proper training in human subjects' protection. The subject may decline participation in the study or drop out of the study at any time. This will be stated both verbally (phone call, home visit) and in writing (consent form). Contact information for the researchers, the Human Research Review Committee, and the Human Research Protections Office will be made available to potential participants.

Study materials are translated into Spanish and the intervention will be offered in Spanish through our bilingual study team members. We modified this eligibility criteria in the recruitment script, so we can move our REDCap recruitment database from development to production mode. However, we will not start enrolling Spanish speakers until we have obtained HRRC approval for our Spanish study materials (anticipated in November or December of 2022).

25.0 Process to Document Consent in Writing

Either the PI, the Project Manager, or well-trained staff will obtain written informed consent from the study participants. Each participant will receive a copy of the signed consent form to keep for their records.

26.0 Devices

The activPAL3 activity-monitoring device (worn on the thigh):

a) This is not a device study, i.e., this study does not evaluate the efficacy or safety of a device. There is no information on the FDA website regarding the activPAL3 monitor (NOTE: these monitors are from a company in Scotland, UK). The activPAL3 monitors are not investigational devices as they are commercially available (http://www.paltechnologies.com/); the shipment of activPAL3 monitors was cleared by the FDA and delivered to the Study PI. These monitors are the gold standard for objectively measuring sedentary behavior and ambulation in research study participants and have been used in many trials in the U.S. activPAL3 monitors are more expensive than consumer wearable monitors (e.g., FitBit, Jawbone) and require special software to analyze the data, thus these monitors are used in research rather than being purchased by consumers. In this study, the monitors are used to measure outcomes (frequency, duration, and intensity of free-living sedentary behavior and light physical activity), and are not used to diagnose or treat disease, or to support/sustain life.
b) These monitors do not present a potential for serious risk to health, safety, or welfare of the subject. There is a potential for a small risk of skin irritation due to the adhesive used to attach the activPAL3 to the thigh. We are minimizing this risk by asking the research participants to check the monitors daily and if skin irritation occurs, to remove the monitor and contact study staff.
c) The use of the activPAL3 monitors in this study poses non-significant risk per the FDA definition: i) it is not an implanted device, ii) it is not a life-sustaining/supporting device, iii) it is not "for a use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health", and iv) it does not otherwise present "a potential for serious risk to the health safety, or welfare of a subject". As mentioned earlier, the activPAL3 is an FDA cleared Class II medical device and is commercially available.

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