Title: Pink Warrior—Support Group Toolkit for Breast Cancer Survivors

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1. Specific Aims

Increasing and maintaining physical activity among female breast cancer (BC) survivors remains an unresolved problem in BC survivorship care.[1] BC survivors, from diagnosis until the end of life, go through many transitions. One major transition is the significant decline of physical activity immediately after diagnosis. Despite the known benefits of PA—speeding recovery time and reduced cancer recurrence risk—less than 30% of survivors met PA recommendations.[2] PA interventions have shown effectiveness in helping BC survivors increase PA, but limited evidence-based PA interventions have been disseminated into the clinic and community.[1] To address this limitation, we are partnering with the UTMB breast cancer support group to conduct a12-week physical activity intervention, *Pink Warrior*, which will investigate the feasibility of implementing active video game-based physical activity intervention among BC survivors within the support group setting. In cohort 1-3 participants (N = 60) will be randomized to participate in the support group using the active video game-based physical activity intervention or to participate in the existing UTMB breast cancer support group with pedometers. In the fourth cohort, participants (N=20) will be recruited and randomly assigned to intervention or control condition.

Our specific aims are:

Aim 1: Evaluate the feasibility and acceptability of active video game-based physical activity intervention among BC survivors within the support group setting. Measures of feasibility will include weekly attendance records, number of completed home-based worksheets, and number of participants completing the program activities, technological issues, and adverse events.

Aim 2: Compare the support group using the active video game-based physical activity intervention to a control condition (cohort 1-3: existing UTMB breast cancer support group with pedometer; cohort 4: Telephone-based weekly support group with UTMB support group). Primary outcomes will be changes in physical activity. Secondary outcomes will be changes in physical function, dietary pattern, and quality of life.

Aim 3: Develop tools for implementation of the Pink Warrior intervention within the clinic and community settings. A trainer's manual for the Pink Warrior intervention will be developed and UTMB Breast Cancer Support Group facilitators will be trained by research staff to implement the program.

The feasibility and acceptability findings from the intervention along with stakeholder input will guide the refinement of the *Pink Warrior* intervention for larger efficacy trials. This project will lay the ground work for accelerating disseminating a state-of-the art evidence-based program into the community and address a pressing need among BC survivors.

2. Background and Significance

The impact of physical activity on survival and health related quality of life is immense for BC survivors, especially with the growing survivor population. According to the 2010 Cancer Prevention and Research Institute of Texas report 14,163 new cases of female BC were diagnosed in Galveston and surrounding counties. In comparison to the rest of Texas, the incidence rate for female BC was significantly higher for Galveston and the surrounding

counties.[3] Higher cancer incidence leads to more cancer survivors living in Galveston. These increasing evidence shows that physical activity is a powerful tool that can reduce the severity of these side effects without adverse consequences.[4,5] Activity reduces the risk for declines in physical function.[6] Function, especially of the lower body, is critical to survivors' perceptions of their quality of life.[6,7] Intervening to prevent or reduce functional deficits would produce lasting benefits on BC survivors' quality of life.[6]

Despite the known benefits of physical activity among BC survivors, fewer than 30% of survivors meet the minimum physical activity recommendation of 150 minutes of moderate-intensity activity per week.[2] In fact, survivors were found to be similarly inactive or even more inactive than the general population or other populations with chronic conditions.[1] Furthermore, research has shown that BC survivors experience a significant decline of physical activity (2 hours/week less) after diagnosis compared to their pre-diagnosis activity levels.[8] This significant decline persisted 10 years post-treatment.[9] Common issues affecting physical activity level among BC survivors include: lack of a belief in their ability to be physically active (known as self-efficacy[10]), competing demands, lack of motivation, and fatigue.[11,12] Given both the benefits of physical activity and the increased number of BC survivors in Galveston County, there is a tremendous need for physical activity programs that target the specific needs and barriers of BC survivors.

Physical activity programs that provide a pedometer and instruction have shown effectiveness in helping BC survivors increase physical activity.[13,14] However, the findings from research has not been adequately incorporated into clinical practice or community programming, a process called dissemination.[1] Wide dissemination of evidence-based physical activity programming into the clinic and community could greatly benefit BC survivors at a population level. Two main barriers to disseminating these programs are cost and not providing what the community wants. **First**, physical activity programs designed for the research setting often are costly because they require a team of highly skilled staff.[1] **Second**, a recent review found that as many as 62% of the 122 physical activity programs were implemented under one setting—individual or group-based.[15] However, BC survivors have indicated a need for program to be offered with a mix of individual and group-based settings.[12] Thus, in addition to addressing survivors' barriers, physical activity programs would ideally be evidence-based, include social activities, and be low-cost.

Recent technology advances have produced methods that allow for low-cost, flexible physical activity programming.[16] Electronic fitness trackers and active video games contain evidence-based behavior change techniques similar to those used in research interventions,[17,18] but can be implemented at lower cost and can be used in a variety of settings. Fitness trackers expand upon pedometers' limited feedback by providing goal-setting assistance, extensive feedback on progress, and encouraging social comparison and interaction.[18] Active video games perform similar functions, but also provide opportunities for strength training (i.e. balance games) and can increase motivation to maintain activity over time.[16] Substantial research reports that women with chronic conditions and older women are willing to use new technologies[19,20] and that fitness trackers and active video games are effective at promoting physical activity.[16,21]

To address these limitations, we created *Pink Warrior*, a 12 week program to improve physical activity among BC survivors that can easily be integrated into existing infrastructure at the UTMB Breast Cancer Support Group. Pink Warrior will develop and implement a toolkit

that can be used by BC support groups to encourage physical activity among women BC survivors. Evidence-based strategies such as setting goals, self-monitoring, giving feedback on progress, and using group-based video game play to increase motivation to be active will be included.

The UTMB Breast Cancer Support Group is an excellent intervention partner for three main reasons. **First**, the UTMB Breast Cancer Support Group is facilitated by the experienced clinical staff of the UTMB Breast Health and Imaging Center at Victory Lakes. Currently the group provides informational and peer support for BC survivors and is respected by the community. **Second**, the UTMB Breast Health and Imaging Center that has become a premier BC care center for residents in Galveston County area and its affiliated support group is well known in the community. By building a partnership between researchers and stakeholders—clinicians, staff, and survivors—we will be able to disseminate effective physical activity interventions or programs that will serve the BC survivor community and increase the center's community outreach capacity. **Third**, clinic staff report a need for a structured curriculum that uses physical activity to help BC survivors cope with their treatment. Thus, the *Pink Warrior* intervention will address this existing need in the community. By using support group facilitators to promote physical activity, we will be able to reach more BC survivors during and after active cancer treatment to prevent significant physical function declines and positively impact BC survivors' quality of life.

3. Preliminary Studies

Our lab has conducted focus groups with 20 local BC survivors aged 55 to 79 to identify a list of active video games they find most appealing. Seven of the BC survivors indicated previous experience of using Nintendo Wii console, but nearly all expressed interest in active video games provided that instructions are given ahead of time. General acceptance of the active video games, especially Nintendo Wii, in the older adult population can also be found in the literature.[22-24]

The evidence based physical activity intervention the Pink Warrior was adapted from the Active Living after Breast Cancer (ALABC) program. The ALABC program focused on adding physical activity into daily living through a group-based program. ALABC used behavior change strategies and skill-building to gradually increase physical activity. ALABC was tested previously in a randomized controlled trial, which found improved physical functioning—less pain and less daily activity limitation—after the intervention. Furthermore, the ALABC program was chosen because it was designed to meet the unique needs of BC survivors by providing breast cancer-specific support and resources. However, the ALABC requires a highly skilled team to implement the program and has a focus on group-based intervention. *Pink Warrior* will adapt the ALABC program, and will include active video gaming technology and written "toolkit" materials that allow modestly ted support group leaders to implement the program. It will incorporate both a group-based and individual-based component, to satisfy the needs of the survivors.[12]

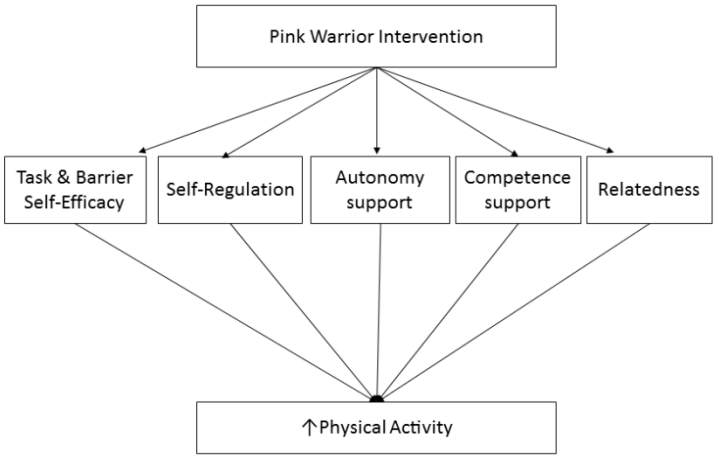
4. Research Design and Methods

This study will evaluate the feasibility and acceptability of active video game-based physical

activity intervention among BC survivors within the support group setting. In addition, we will also compare the changes in physical activity among participants who were in the active video game-based physical activity intervention support group to those who were in the existing the UTMB breast cancer support group. Participants (N=60) will be randomized to participate in the support group that uses the active video game-based physical activity intervention (intervention group) or in the existing UTMB breast cancer support group with pedometers (control group) for 12 weeks. The home-based self-paced portion of the intervention will mainly be delivered through the participant manual. In the fourth cohort, BC survivors (N=20, aged 55 to 79 due to the aging grant restrictions) will be recruited and randomly assigned to intervention or control condition for a 12-week period. The intervention group will participate in weekly active video game web-based group sessions. The control group will receive weekly conference calls plus wearable tracker to track their physical activity for 12 weeks.

4.1 Theoretical Framework. The theoretical framework used for the *Pink Warrior* intervention (see Fig. 1) are based on the constructs from the Social Cognitive Theory (SCT)[10] and Self-Determination Theory (SDT).[25] Under SCT we will mainly focus on the self-efficacy and the self-regulation constructs. Self-efficacy and self-regulation constructs have been shown to be associated with initiation and increase of physical activity.[26] However, researchers have found that increasing autonomous motivation under SDT is important to promote physical activity over time.[27] The autonomous motivation include the identified regulation (i.e. value physical activity and accepted that the behavior is his/her own behaviors), integrated regulation (i.e. being physically active is consistent with his/her own sense of self), and intrinsic motivation (i.e. motivation to be physically active because of interest and enjoyment).[25] Based on SDT, fulfillment of basic psychological needs for autonomy, competence, and relatedness will help to promote intrinsic motivation and lead to an increase in physical activity.[28] Therefore, we have created the *Pink Warrior* intervention to increase participants' autonomous motivation to engage in physical activity through targeting the self-efficacy (task and barrier), self-regulation, autonomy, competence, and relatedness constructs.

Figure 1. Theoretical Framework



The behavioral change method we will use to target the theoretical constructs central to the Pink Warrior intervention are outlined in Table 1.

Table 1. Theoretical constructs, behavioral change methods, and intervention components.

Theoretical construct[29]	**Behavioral change method[29]**	**Intervention components**	
		Active video game support group	**Existing/phone-based support group**
Task Self-efficacy	Modeling	The avatar in the active video game and other participants in the group	
	Set graded tasks	Active video game (increase difficulty until target behavior is performed)	

	Reinforcement	Unlocking games	
	Public commitment	Group session	
Barrier Self-efficacy	Reattribution training (Reinterpret previous failures)	Group session	
	Cue altering	Group session	
Self-regulation	Goal-setting	Weekly log, home-based worksheets, group session	
	Prompting self-monitoring	Wii fit meter, weekly log (Cohorts 1 to 3) Wearable fitness tracker (Cohort 4)	Pedometer (Cohort 1 to 3) Wearable fitness tracker (Cohort 4)
	Barrier identification	Group session	
	Action planning	Weekly log , home-based worksheet, and group session	
Motivation			
Autonomy support	Provide information and provide choice	Non-directive group discussion, Group game play, ACS personal health manager kit	ACS personal health manager kit (general information)
Competence support	Feedback on performance	Badges, unlocking the game, weekly progress chart based on the Wii fit meter, other participants in the group, and from the facilitator	Pedometer
Relatedness	Social support	Group play, group session, and identification with other survivors	Identification with other survivors
	Social support—Emotional support	Group sessions on survivorship issues	Group sessions on survivorship issues
	Social support—Appraisal support	See the “friends” progress in the group	

4.2 Participant Recruitment. Participants will be recruited from Galveston county and surrounding counties, the University of Texas, Medical Branch (UTMB) clinics, UTMB-associated cancer care facilities, MD Anderson clinics and from cancer or volunteer registries. Recruitment of MD Anderson patients will occur in person at MD Anderson and joint MD Anderson/UTMB clinics as well as by phone & email (following the same procedures used to identify UTMB patients to approach. Due to the possible difficulty of recruitment, we have collaborated with oncologists. The oncologists will be referring their patients. The team will not approach patients until they provided the permission for the team to approach. For the other oncologists not on our protocol, a flyer will be provided to them for referral. Participants will contact the researchers if interested in participating. MD Anderson personnel (Maria C. Swartz) will be involved in recruitment activities for the fourth cohort (Note: UTMB and MD Anderson have entered into an agreement such that the clinical site is a collaborative single site operation by both institutions.)

A recruitment letter will be mailed to contact potential participants in the cancer or volunteer registries. We will also collaborate with local cancer support groups. Newspaper advertisement and flyers will also be used as additional recruitment tools. We will recruit participants in three cohorts. First and second cohort will consist of 10 people, 5 in the intervention group and 5 in the control group. The third cohort will consist of 40 people, 20 in the intervention group and 20 in the control group. In order to randomize a total of 60 participants, we will need to recruit up to 80 individuals due to drop-outs between screening and randomization. The fourth cohort will consist of 20 people (age 55 and 79 to grant

restrictions), 10 in the intervention group and 10 in the control group. In order to randomize a total of 20 participants, we will need to recruit an additional 80 individuals to account for potential drop-outs between screening and randomization. A total of 160 individuals will be recruited for Cohort 1-4 in order to randomize a total of 80 participants. Screening script, recruitment letter, flyer, presentation blurb are presented in **Appendix A**.

4.3 Inclusion/Exclusion Criteria. Research staff will follow the screening script to determine eligibility when potential participants express interest in the study. Potential participants must meet all of the inclusion criteria in order to be eligible to participate in the study.

Primary inclusion criteria will include for Cohort 1-3:

- Provide informed consent
- Diagnosed with primary female breast cancer
- English-speaking between the ages of 18 years or older
- Able to read and write in English
- Obtained approval from oncologists for the participant to be involved in the physical activity based support group
- Able to travel to the UTMB sites (Victory Lakes or Galveston)
- Able to move arms and legs as well as ambulate
- Able to see TV screen from a distance of 2 to 4 feet

Primary inclusion criteria for Cohort 4 due to grant restrictions will include:

- Ability to provide informed consent
- Diagnosed with primary female breast cancer
- 55 years to 79
- Able to speak, read, and write in English
- Able to travel to UTMB locations and/or MD Anderson Victory Lakes
- Able to move arms and legs as well as ambulate
- Has a smartphone, tablet or computer and daily access to a reliable internet

Inclusion criteria for Cohort 4 due to pandemic (e.g., COVID-19) restrictions will include:

- Ability to provide informed consent via telephone or through internet
- Diagnosed with primary female breast cancer
- 55 years to 79
- Able to speak, read, and write in English
- Able to move arms and legs as well as ambulate
- Has a smartphone, tablet or computer and daily access to a reliable internet

Potential participant meeting any of the exclusion criteria at screening will be excluded from study participation

Ineligibility criteria will include:

- Being pregnant
- Dementia
- Currently engage in ≥150 minutes of planned moderate physical activity per week for the prior week

- Are involved in another physical activity intervention

Ineligibility criteria for Cohort 4 will include all criteria listed above. However, cohort 4 has an addition of no access to an internet-connected smart device (smartphone, tablet, or computer) being an ineligibility criterion.

4.3 Randomization Procedures. Participant in cohorts 1 to 3 will be randomly assigned to be in the active video game-based physical activity intervention group (intervention group) or the existing UTMB Breast Cancer support group with pedometer (control group). Participant in cohort 4 will be randomly assigned to be in the weekly active video game web-based group sessions with wearable tracker (intervention group) or receive weekly conference calls plus wearable tracker (control group). We will randomize participants by using sequentially numbered opaque sealed envelopes for cohorts 1 to 4. The sequentially number will be the Study ID #1 to #80 for cohort 1-3.A project staff who is not involved in the assessment will use the random number generator (https://www.randomizer.org/) to assign each study ID number to either intervention group or control group. The project staff who is not involved in the assessment will write the group assignments will be written on pieces of paper, placed under a piece of carbon paper, wrapped in aluminum foil, and then sealed one per opaque envelope. The same procedure will be used for cohort 4.

4.4 Intervention Group Procedure. The primary purpose of this study is to investigate the feasibility and acceptability of active video game-based physical activity intervention among BC survivors within the support group setting (in person for cohorts 1-3 and over the web for cohort 4) with home-based components. Cohort 4 will have the addition of yellow and red theraputty and grip exercise to the 12-week intervention components. The 12-week intervention components are presented in Table 2. Cohort 4 will not receive a Wii Fit Fitness tracker and we will mainly use Xbox 360 video games but may use the Wii video games.

Table 2. Summary of the 12-week *Pink Warrior* Program

Week	Cognitive-Behavioral skill building component (group and home-based topics)	Activity demonstration and practice component	Cancer survivorship discussion component
1	Program orientation—distribution of the *Pink Warrior* program materials Topic: Benefits of physical activity	Distribute the Wii Fit fitness tracker Wii Street U: Walking for 2 minutes, (cohort 4 only: yellow theraputty, grip exercise)	Review of the Personal Health Manager Kit and first steps for the newly diagnosed
2	Topic: Discovering values and setting long-term and short-term activity goals	Wii Street U: Walking for 5 minutes, (cohort 4: grip exercise	Communicating and making decisions and talking to your doctor
3	Topic: Time management and planning your activity	Xbox 360: Tai-Chi, (cohort 4 grip exercise)	Lymphedema
4	Topic: Uncovering barriers	Xbox 360: Yoga, (cohort 4 grip exercise)	Finding information and solving problems
5	Topic: Getting confident	Wii Street U: Walking, (cohort 4 grip exercise)	Symptom diary
6	Topic: Finding and getting support	Xbox 360: Tai-chi, (cohort 4 grip exercise)	Eating well during cancer treatment

7	Topic: Problem solving skills: (cohort 4 distribute red theraputty)	Wii Fit U: Yoga, (cohort 4 red theraputty, grip exercise)	Fatigues/Nausea and Vomiting
8	Topic: Relapse prevention	Wii Fit U: Walking, (cohort 4 grip exercise)	Cancer pain
9	Topic: Meaningful rewards	Xbox 360: Zumba, (cohort 4 grip exercise)	Negotiating and standing up for your rights
10	Topic: Thinking about problems in different ways	Wii Fit U: Yoga, (cohort 4 grip exercise)	Coping with emotional distress and fear
11	Topic: Review of long-term goals	Xbox 360: Zumba, (cohort 4 grip exercise)	Cancer and relationship
12	Topic: Finding places you can be physically active in your community	Wii Fit U: Dance, (cohort 4 grip exercise)	Managing your health records
13	Certificate of achievement ceremony	Celebration dance	Healthy snacks pot luck

Each week will consist of both structured group sessions and self-paced home-based sessions. The weekly structured group session will last approximately 90 minutes. Weekly worksheets and participant manual will be provided to promote home-based physical activities. The participant manual will consist of detailed information of the weekly topic to be reviewed within the group setting. Participant manual will be used for self-paced home-based materials. Each of the weekly sessions will consist of three components: 1) a *cognitive-behavioral skill building* component to promote the increase and maintenance of physical activity behavior, 2) an *activity demonstration and practice* component to provide guided practice and to increase mastery of activity skills, and 3) a *cancer survivorship discussion* component to provide support and resources for BC survivors. Participant manual is available for review in **Appendix B**.

Based on participant feedback we received from the first and second cohorts, we are changing the length of group sessions to 60 minutes and adding an additional healthy eating discussion topic. We will also provide cancer survivorship discussion summary sheet per participants' suggestions. Updated participant manual is available in Appendix B1. MD Anderson personnel (e.g., Maria C. Swartz) will be involved in cohort 4 intervention delivery activities.

Table 2. Summary of the 12-week *Pink Warrior* Program

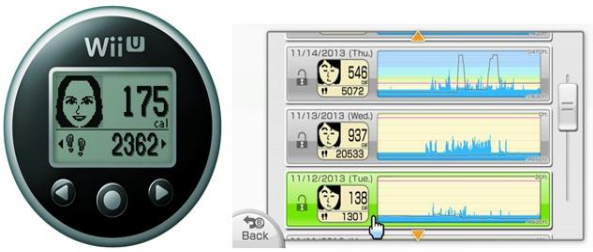
Week	Cognitive-Behavioral skill building component (group and home-based topics)	Activity demonstration and practice component	Cancer survivorship discussion component
1	Program orientation—distribution of the *Pink Warrior* program materials Topic: Benefits of physical activity	Distribute the Wii Fit fitness tracker Wii Street U: Walking for 2 minutes, (cohort 4 only: yellow theraputty, grip exercise)	Review of the Personal Health Manager Kit and first steps for the newly diagnosed
2	Topic: Discovering values and setting long-term and short-term activity goals	Wii Street U: Walking for 5 minutes, (cohort 4: grip exercise)	Communicating and making decisions and talking to your doctor
3	Topic: Time management and planning your activity	Xbox 360: Tai-Chi, (cohort 4: grip exercise)	Lymphedema
4	Topic: Uncovering barriers	Xbox 360: Yoga, (cohort 4: grip exercise)	Finding information and solving problems

5	Topic: Getting confident	Wii Street U: Walking, (cohort 4: grip exercise)	Symptom diary and Eating well during cancer treatment
6	Topic: Finding and getting support	Xbox 360: Tai-chi, (cohort 4: grip exercise)	Healthy recipes and general eating plan
7	Topic: Problem solving skills (cohort 4 distribute red theraputty)	Wii Fit U: Yoga, (cohort 4: red theraputty, grip exercise)	Fatigues/Nausea and Vomiting
8	Topic: Relapse prevention	Wii Fit U: Walking, (cohort 4: grip exercise)	Cancer pain
9	Topic: Meaningful rewards	Xbox 360: Zumba, (cohort 4: grip exercise)	Negotiating and standing up for your rights
10	Topic: Thinking about problems in different ways	Wii Fit U: Yoga, (cohort 4: grip exercise)	Coping with emotional distress and fear
11	Topic: Review of long-term goals	Xbox 360: Zumba, (cohort 4: grip exercise)	Cancer and relationship
12	Topic: Finding places you can be physically active in your community	Wii Fit U: Dance, (cohort 4: grip exercise)	Managing your health records
13	Certificate of achievement ceremony	Celebration dance	Healthy snacks pot luck

Within the *cognitive-behavioral skill building component*, the adapted *Pink Warrior* intervention content will focus on helping BC survivors overcome barriers to becoming active and to increase self-regulation skills. The behavior change strategies include: getting feedback regarding physical activity, self-monitoring, goal-setting, action planning, gaining knowledge regarding benefits of physical activity, and evaluation of value toward activity. We specifically chose these behavior change strategies because recent meta-analysis, which provided a comprehensive review of published physical activity programs, have shown effectiveness of these strategies in increasing physical activity.[30] The behavioral change strategies will address activity barriers such as: lack of self-efficacy related to physical activity, lack of time due to competing demands, and lack of motivation due to general reasons or fatigue.

Active video games that involve motion-controlled movement will be used for the *activity demonstration and practice component* of the *Pink Warrior* intervention for two reasons. First, they are a cost-effective way to deliver a physical activity program in the community setting without the need to hire an exercise trainer.[31] Second, research has shown active games are a unique and effective platform for increasing physical activity and motivation.[16] By design, active video games will produce enjoyment, increase self-efficacy, and increase motivation to increase physical activity through delivering evidence-based behavior strategies such as modeling, guided practice, providing instantaneous feedback, providing various activity options, and increases opportunity for survivors to relate to one another through social play.[16,17] Furthermore, by wearing the Wii Fit fitness tracker in cohort 1-3 (Figure 2), participants will be able to track individual and group's daily steps. They will also be recording their activities on a daily, weekly, and monthly basis. Having the ability to see the weekly accomplishments will further enhance motivation for activity through social comparison and relatedness.[16]

Figure 2. Wii Fit Meter and Group Results



For the *cancer survivorship discussion component*, resources from the National Coalition for Cancer Survivorship's cancer survival toolbox and American Cancer Society's personal health manager kit will be used to elicit survivorship discussions. It is the standard practice of the UTMB Breast Health Clinic to provide the American Cancer Society's personal health manager kit to all new cancer patients. Please see the list of contents in the personal health manager kit in **Appendix C**. This component is designed to provide resources and support for the BC survivors.

We will partner with stakeholders to iteratively develop and refine the *Pink Warrior* program. We plan to have half of participants receive all components of the *Pink Warrior* program first, so we can obtain and use the acceptability and feasibility information to refine the program before the other half of BC survivors go through the program. Furthermore, we will be able to compare the *Pink Warrior* program to the existing support group format.

The fourth cohort will be a web-based AVGs group activity intervention over the 13-week study period. An initial in person meeting or video conference via a telemedicine platform (due to pandemic restrictions) will be conducted to set up weekly step goal. Participants will be given a wearable tracker (i.e. Fitbit) with charger and wrist band, a wearable tracker account with a pseudonym to use during the study period, a phone stand, and a wall charger. All of the pseudonym accounts will be linked to a private group on the Fitbit dashboard. The weekly structured group session will be conducted through a HIPPA compliant telemedicine platform that allows simultaneous video chat. Each session will last approximately 60 minutes (Appendix B2a-c. Instructions on how to use the Fitbit and how to connect to the telemedicine platform). The same curriculum will be used as in past cohort, refer to Table 2. Weekly worksheets will be provided to encourage activities outside of the group. Each of the weekly sessions will consist of three components: 1) a cognitive-behavioral skill building component to promote the increase and maintenance of physical activity behavior, 2) an activity demonstration and practice component to provide guided practice and to increase mastery of activity skills, and 3) a cancer survivorship discussion component to provide support and resources for BC survivors.

By wearing the Fitbit, participants will be able to track individual and group daily steps on the Fitbit dashboard. Having the ability to see the weekly accomplishments will further enhance motivation for activity through social comparison and relatedness.[16]

4.5 Control group procedure. Participants in cohort 1-3 that are randomized to the control group will be introduced to the current facilitator for the existing Breast Cancer Support Group at the UTMB Breast Health and Imaging Center after the initial assessment. Control group participant will be encouraged to participate in the Breast Cancer Support Group for the next 12-weeks on a monthly basis. Examples of topics covered in the Breast Cancer Support Group are presented in **Appendix D**. The support group follows the *Navigating Life's road Map After Breast Cancer* curriculum from the Reconstruction of a Survivor (http://www.reconstructasurvivor.org/index.html) organization. Control group participant will also be provided a pedometer (Digi Walker or Omron Tri Axis HJ-

Figure 3. Digi-Walker or Omron Tri Axis HJ-321 Pedometer

321) to be worn for 12-weeks (Figure 3). Participants will have a choice to use either a Digi Walker or Omron Tri Axis pedometer. Participants in the control group will also receive the American Cancer Society's personal health manager kit as it is standard of practice at the UTMB Breast Health and Imaging Center. They will also be recording their activities on a daily, weekly, and monthly basis.

For the fourth cohort, weekly conference calls to check on participants' well-being and to provide survivorship information will be scheduled over the 13-week study period (Appendix B2d). Control group participants in the cohort 4 will be given a wearable tracker with charger to use during the study period. A list of local breast cancer/cancer support groups will also be given to the participants that is available on the UTMB website. MD Anderson personnel (e.g., Maria C. Swartz) will be involved in cohort 4 control group activities.

4.6 Measurement procedure. The intervention includes three assessments. Survivors will be provided a summary of their individual assessment results at each evaluation session (**Appendix E**). A summary of the assessment schedule is presented in Table 3. Questionnaires for the self-reported measures are presented in **Appendix F**. Questionnaires for the self-reported measures will be administered either through Assessment Center℠ (https://www.assessmentcenter.net/), through paper copies, or through telephone interviews conducted by a study staff due to pandemic restrictions. Participants will have a choice to complete the web-based format or the paper format.

We will also obtain permission from the participants at the time of recruitment to send reminders. Furthermore, prior to the 6-week and 12-week visit, a personalized email will provide instructions on how to access the website in a written form. The instructions will include a hyperlink to the Assessment Center℠ website along with a unique personal access ID number. **Appendix G** includes an example email to access Assessment Center.

Feasibility will be evaluated through weekly attendance records, number of participants who completed at least 80% of the program activities including home-based worksheets, technological issues, and adverse events. Observational forms and project staff logs will also be used to determine the ease of using the toolkit and facilitators' ability to deliver the program as planned. Participant acceptability and satisfaction will be collected at week 7 and week 12. Participant satisfaction will be determined based on a questionnaire with 5-point scale responses. Participant will be asked to report their satisfaction with the support time and length, intervention materials and staff, activity demonstrations, and discussion topics.

For the fourth cohort, feasibility at the implementation level include feedback on ease of use of the telemedicine platform, curriculum usability, ability to deliver the weekly curriculum as planned, and feedback on the curriculum. Feasibility measures at the participant level will include weekly attendance records, completion of weekly worksheets, weekly adherence to the intervention, number and type of technology issues, number and type/difficulty of games played, and adverse events. MD Anderson personnel (e.g., Maria C. Swartz) will be involved in the cohort 4 data collection activities.

Table 3a. Summary of measures and evaluation schedule (pre-pandemic restrictions)

Measures	Week 0	Week 1	Week 7	Week 14
Objective measures				
SPPB to measure physical function and Hand grip strength test		X	X(hand grip strength only)	X
Height, Weight, and Waist Circumference	X	X	X	X
Actigraph wGT3X GT monitors (Physical activity)—cohorts 1 and 2	X		X	X
Actigraph GT9X monitors (Physical activity)—cohorts 3 and 4	X		X	X
Participant self-report measures				
Demographics	X			X
Program satisfaction			X	X
CHAMPS to measure physical activity (cohorts 1, 2 and 4)	X			X
BRFSS physical activity questions (cohort 3)	X			X
Functional Assessment of Cancer Therapy (Quality of life)	X		X	X
PROMIS-Cancer Physical Function	X			X
PROMIS-Cancer Fatigue	X			X
Dietary screener/recall	X			X
Psychosocial variables related to exercise				
Exercise motivation	X		X	X
Psychological Feelings	X		X	X
Self-regulation	X		X	X
Social support	X		X	X
Task and Barrier Self-efficacy	X		X	X
Posttraumatic Growth Inventory-SF (cohort 3)	X		X	X

Table 3b. Summary of measures and evaluation schedule (during and post pandemic restrictions)

Measures	Week 0	Week 1	Week 7	Week 14
Objective measures				
SPPB and 2-minute step test to measure physical function (virtual)		X	X	X
Height, Weight, and Waist Circumference	X	X	X	X
Actigraph wGT3X GT monitors (Physical activity)—cohorts 1 and 2	X		X	X
Actigraph GT9X monitors (Physical activity)—cohorts 3 and 4	X		X	X
Participant self-report measures				
Demographics	X			X
Program satisfaction			X	X
CHAMPS to measure physical activity (cohorts 1, 2 and 4)	X			X
BRFSS physical activity questions (cohort 3)	X			X
Functional Assessment of Cancer Therapy (Quality of life)	X		X	X
PROMIS-Cancer Physical Function	X			X
PROMIS-Cancer Fatigue	X			X
Dietary screener/recall	X			X
Hand Scale		X	X	X
FRAIL index		X		X
Insomnia Severity Index	X		X	X
Psychosocial variables related to exercise				
Exercise motivation	X		X	X

Psychological Feelings	**X**		**X**	**X**
Self-regulation	**X**		**X**	**X**
Social support	**X**		**X**	**X**
Task and Barrier Self-efficacy	**X**		**X**	**X**
Posttraumatic Growth Inventory-SF (cohort 3)	**X**		**X**	**X**

Participants will also be asked to report their intention to continue using the program material, appropriateness of the program in meeting their needs, and actual use of the Wii Fit pedometer or Digi-walker/ Omron Tri Axis pedometer. Feasibility information, participant satisfaction will be used to refine the intervention and also help us refine the tools we have developed for implementation of the *Pink Warrior* intervention within the clinic and community settings.

The changes in physical activity level among breast cancer survivors who were randomized into the Pink Warrior intervention or into the existing UTMB breast cancer support group with pedometer will be evaluated at baseline and at week 14. Physical activity changes such as meeting the recommended 150 minutes per week or 7,000-10,000 steps/day will be measured by Actigraph wGT3X BT monitors. Wear time will be seven days at each assessment point. Because continuous measurement is not feasible, a week-long sample will be taken at baseline, week 7(+/- one week) and week 14(+/- one week). Physical activity estimates will only be considered as valid if the monitor is worn ≥ 10 hours per day on ≥ 4 days. Also through the community healthy activities model program for seniors (CHAMPS) self-reported questionnaire at baseline and at week 14 will be administered for participants in cohorts 1, 2, and 4. The changes in dietary pattern will be evaluated using the Dietary Screener Questionnaire used in the National Health and Nutrition Examination Survey 2009-10. The screener captures frequency of fruits, vegetables, dairy/calcium, added sugar, wholegrains/fiber, red meat, and processed meat consumption within the past 30 days.[32] Health related quality of life outcomes will be measured by using the Functional Assessment of Cancer Therapy and Patient reported Outcomes Measurement information System (PROMIS) adapted testing.[33]

For the third and fourth cohort we will measure physical activity changes (e.g., 150 minutes per week of activity or 7,000-10,000 steps/day) by using Actigraph GT9X to accommodate the increased number of participants in cohort three and four. Based on participant feedback from cohorts 1 and 2, we also removed the CHAMPS self-reported questionnaire for the third cohort to reduce participant burden. Instead, we are adding eight questions from the 2015 Behavioral Risk Factor Surveillance System (BRFSS) questionnaire to the main demographic questionnaire.

Physical function and physical changes will be objectively measured. The Short Physical Performance Battery (SPPB) will be used to objectively measure physical function for cohorts 1 and 2. The battery consists of six components: repeated chair sit and stands, balance test, semi-tandem stand, tandem stand, side-by-side stand, and eight feet walk (**Appendix H**).[34] The hand grip strength test is used to measure changes in physical strength.[35] For cohort 4 we added hand grip strengthening exercises using theraputty and home-based exercises due to low normative scores we found from cohorts 1 and 2. Grip strength will be measured using a

Dynamometer. Based on possible ceiling effect we found in cohorts 1 and 2, we are going to use the Senior Fitness Test[36] along with two subsections of the SPPB protocol—balance with time increase to 30 seconds and timed 3 meter usual walk and fastest walk. Senior Fitness Test consist of six different components: 1) chair stand test (evaluate lower body strength), 2) arm curl test (evaluate upper body strength), 3) chair sit and reach test (evaluate lower body flexibility), 4) back scratch test (evaluate upper body flexibility), 5) 8-foot up and go test (evaluate agility), and 6) 2-minute step in place test (evaluate aerobic endurance). We are also adding the Figure-of-8 Walk test to evaluate walking skills in daily life (Appendix H1).[37]

For Cohort 4, we implemented several pandemic-related changes to the physical function measures. We have chosen to make the following changes to maintain the integrity of the physical function data being collected due to the pandemic restrictions (Table 4).

Table 4. Summary of changes due to pandemic restrictions

Type of assessment	**Pre-pandemic**	**During and post pandemic**
SPPB	In-person	Via Video conference
Grip strength	In-person	The Cochin Hand Scale[38] (self-report, but collected through interview)
SFT	In-person	Collect 2-minute step in place and Timed Up and Go components via video conference. All other components will not be collected because we cannot adjust our protocol safely. Fatigue, Resistance, Ambulation, Illness, Loss of Weight (FRAIL) index[39] (self-report, but collected through interview)
Figure-of-8 Walk test	In-person	Will not be conducted

Due to equipment limitations during the pandemic, we will not be able to use a hand dynamometer to assess the hand grip strength objectively. We chose the Cochin Hand Scale instead to capture self-report daily hand function. This measure will be administered by a research coordinator/interviewer. The scale consists of 18 items with a 6-point Likert response that ranged from 0 (Yes, without difficulty) to 5 (Impossible to do). The Cochin scale had an inter-rater reliability of 0.96.[38]

Due to safety concerns and possible space and equipment limitations, we have limited the SFT test to only the Timed Up and Go (TUG) and 2-minute step test. Participants will be mailed an enrollment packet that consists of a tape measure and colored tape to measure out the walking course for SPPB, TUG, and the 2-minute step test. We added the FRAIL index measure to capture an additional physical function measure. FRAIL is a self-report functional measure that will be administered by a research coordinator/interviewer. The FRAIL index consisted of questions in 5 components—fatigue, resistance, ambulation, illness, and loss of weight. Frail scale scores can range from 0 (best) to 5 (worst). A score of 3 to 5 is categorized as frail, a score of 1-2 is categorized as pre-frail, and 0 is considered as no frailty and pre-frail.[39] Given the possible increase in psychosocial stress with the current pandemic and its negative impact on sleep, we added a sleep measure that will evaluate the impact of our

intervention on sleep. The Insomnia Severity Index (ISI) is a 7-item validated self-report scale that assesses subjective symptoms of insomnia. Items are scored on a 0-4 scale to yield a score of 0-28. Higher scores indicate greater insomnia severity. A cutoff score of ≥ 10 is optimal to detect clinical levels of insomnia. It is also sensitive to change over time.[40] A change score of -8.4 points is associated with moderate improvement.[40]

Other self-reported measures include demographics such as age, gender, race/ethnicity, education, type of cancer diagnosis, and the type of treatment the participant is receiving. Exercise motivation will be evaluated by using the Behavioral Regulation in Exercise Questionnaire-2 to assess participants' motivation towards physical activity (intrinsic, identified, introjected, or extrinsic). The questionnaire had an alpha ranged between 0.73-0.86.[41] Psychological feelings about exercise will be evaluated by using the Psychological Need Satisfaction in Exercise Scale to assess participants' perceived competence, perceived autonomy, and perceived relatedness. The questionnaire had an alpha >0.90.[42] The self-regulation will be evaluated by using the Rovinak et al. scale that assess participants' exercise goals and exercise plans. The questionnaire had an alpha raged from 0.87 to 0.89.[43] Self-efficacy will be evaluated by using the Rogers et al. scale. That assess participants' self-efficacy to over barriers and their task related self-efficacy. The questionnaire had an alpha ranged from 0.89 to 0.96.[44] We added a 10-question Posttraumatic Growth Inventory-Short Form (PTGI-SF) to capture positive psychosocial changes that developed after facing challenging life circumstances (i.e., cancer diagnosis and treatment).[45] The questionnaire had an alpha of 0.93 among cancer patients. Furthermore, we added The Physical Activity Group Environment Questionnaire (PAGEQ) for cohort 4. PAGEQ is a 21-item questionnaire on a 9-point Likert scale that ranged from "strongly agree" to strongly disagree." The questionnaire has an alpha ranged from 0.65 to 0.94. PAGEQ was added because it can influence attendance, timeliness, improve attitude towards PA, and stronger PA self-efficacy. Participants will not receive any monetary incentive (cohort 1-3). Rather, a water bottle and a tote bag will be provided to both intervention and control group participants as a thank you/token of appreciation for participating in the study.

4.7 Unscheduled visits/communication. We will download the activity monitor information during Assessment 1. If monitor activity was worn less than 10 hours per day for 4 days we will ask the participant to wear the activity monitor for 7 more days and reschedule randomization only. Some participants may attend an additional visit for randomization if we do not have a valid physical activity measurement. We may also contact participants via phone, text, or email to schedule appointments, the day before an appointment as a reminder, and if we have a question or concern regarding their participation such as following up on questionnaire responses or adverse events. Additional calls/texts/emails may occur to schedule accelerometer drop off prior to week 14 assessments. After hours texts or calls will only occur if pre-arranged for the purposes of picking up study materials. Text messages are optional. Message and data rates may apply. Any in-person contact that occurs to drop off an accelerometer will be minimal and only for the purposes of providing the monitor and instructions for its wear. If we encounter any technical difficulties with the study material we will troubleshoot the equipment. Once the equipment is ready we will contact you to mail/drop off or set up a meeting to provide the study material. We will be available by email and phone for technical consultation. We will allow up to one in-person meeting for technical support. We will reply to texts/emails/phone calls during business hours for technical problems or to schedule calls/assessments. After hours texts or calls will only occur if pre-arranged for the purposes of

picking up study materials.

4.8 Participant compensation (cohort 4). Participants will be compensated for the parking fee via parking validation. Due to funding restrictions, cohorts 1-3 were not provided monetary compensation for participation. However, cohort 4 participants will be provided gift cards totaling $15 ($5.00 at baseline, $5.00 at midpoint, and $5.00 at the final visit).A water bottle and a tote bag will be provided to both intervention and control group participants as a thank you/token of appreciation for participating in the study.

5.0 Potential Risk to Participants

- Confidentiality could be breached, as is a risk in all human subjects research. Sensitive personal health information or other sensitive information could be divulged inappropriately to outside sources.
- Physical functioning testing. Short Physical Performance Battery and hand grip strength testing may involve minimal risk. Risks include muscle soreness, fatigue, and potential muscle strain.
- Injury, pain or fatigue. Participants may experience joint discomfort, muscle soreness, or other minor injuries due to increased physical activity. Cohort 4 the addition of possible skin irritation or other minor injuries due to increased physical activity and the use of theraputty.
- Activity monitors such as the Actigraph, Wii Fit meter, and Digit-Walker pedometer, cohort 4 the use of Fitbit or Mi Xiaomi Band 3 are associated with minimal risk. Some participants might feel slight discomfort or skin irritation from the monitors' contact with the skin.
- Embarrassment. Participants may feel embarrassed to share their activity information with other participants.

We believe all identified risks are minimal given the proposed procedures for protecting against risk.

5.1 Protection Against Potential Risks. All study personnel have attended required courses on human subject protection and HIPAA regulations, and certificates of Institutional Review Board training completion are on file at UTMB. Participants that are eligible based on initial screening will be invited to attend an initial session. They will be given a group orientation to the study, including information on all aspects of the study from the principal investigator (PI). They will be able to ask questions at any time. Following this explanation, potential participants will be given informed consent information and forms to sign. After completing this information, they will proceed to the baseline assessment.

- Confidentiality All data collected will remain confidential.
    - Paper copies of screening forms and assessment forms will be kept in a locked file cabinet in the PI's locked office. ID numbers will be used on these forms to match them to individual participants. The database matching ID numbers to identifying information will be individually password-protected and kept separately on the UTMB secured server.
    - As for the web-based questionnaire administered through Assessment

Center[SM], the security statement indicated that the Assessment Center[SM] uses role-based permissions that restrict access to participant data and the privacy of data is driven by HIPAA requirements. The Assessment Center[SM] is maintained and secured at Northwestern University Research Data Center in Chicago, IL. Detail description of the security measure is described in Appendix H. Briefly, the Northwestern University Research Data Center have secure communication lines in place to prevent the interception of data transmission by utilizing various data encryption technologies (i.e. Secured Socket Layer) and digital certificates; signatures may also be used to encrypt data, validate data integrity, and authenticate the parties in a transaction. The protected health information (PHI) will be stored separately from other survey data. In addition, the PHI will only be collected and transferred only when necessary. Any data that needs to be transferred will be encrypted prior to transfer. All of the participants will be identified by a generic ID generated by the Assessment Center[SM]. Furthermore, the Northwestern University Research Data Center has an established infrastructure for confidential data management that includes having secured facilities that are being monitored 24x7, has sophisticated use of firewall technologies, has intrusion detection software, has anti-virus scans, has dedicated database and application servers, has automatic failover design, has real-time monitoring and related technological capabilities. It also is fitted with redundancy for HVAC, power, and fire detection/suppression systems (**Appendix I**).

  - The web-based questionnaire will not ask for participant's name. The research staff will provide each participant a unique study identification number. All necessary firewall and password protections will be implemented to store electronic files. The internet will be used to transfer the completed survey from the Assessment Center[SM] with study ID to UTMB secured network. The data will also be stored and formatted using SPSS for Windows (version 20) on the secured UTMB network that requires unique username and password.
  - Activity monitors will be encrypted to prevent unauthorized viewing of the application data. Participants in the intervention group will be "friends" with one another. Participants will use pseudonyms on the Wii U and Xbox 360 systems, and wearable trackers to provide additional layer of security. All information collected by the Wii Fit meter, wearable trackers, or the Digit-Walker will be generic and related to physical activity—no other health information will be collected on these devices.
  - Telemedicine platform and the conference call systems are HIPPA compliant (Appendix J).

- Physical functioning testing. Short Physical Performance Battery (cohorts 1 and 2) and Senior Fitness Test (cohort 3 and 4) and hand grip strength testing will occur at the UTMB sites with trained nursing staff nearby and will be performed by a research coordinator trained in conducting physical assessments. The location of the tests and supervision by medical personnel will ensure that, in the unlikely but possible case of injury, treatment will be immediately available.
- Injury, pain or fatigue. Walking and low impact activity that will be performed via Wii U and Xbox 360 system, and performing grip strengthening using theraputty and home-based exercise may produce minor injuries. We will reduce the risks for such events by providing detailed protocols and instructions that increase in difficulty slowly over time and that include adequate warm-up and cool-down. The home-

based grip strengthening is not contraindicated for use with breast cancer survivors. An Occupational Therapist will oversee and provide instructions to participants. During the weekly session, study staff will inquire about the participants' walking plans and how participants feel during exercise. Immediate steps will be taken if there is any indication of potential adverse events. (see data safety and monitoring plan).

- Activity monitors. We will warn participants of the risk of potential skin irritation due to wearing the measurement equipment and using theraputty. We will also provide participants with several alternative procedures that could be used to minimize discomfort, such as inserting a soft cloth between the monitor and the skin and alternative exercises for gripping.
- Embarrassment. We will provide training and discussion during the orientation on the importance of confidentiality and privacy. All participants will use pseudonyms when logged into the Wii U system to ensure that their activity information cannot be connected to their true identity.

5.2 Potential Benefits of the Proposed Research. Physical activity interventions may improve mood, fatigue, and overall health.

5.3 Importance of Knowledge to be Gained. There is a need for better understanding of strategies for increasing physical activity among breast cancer survivors. Successful intervention on these behaviors could have a large positive public health impact. If effective, implementing the physical activity intervention using commercially available active games are scalable for wide dissemination to other breast cancer support groups.

6.0 Study Withdrawal/Discontinuation

A study participant will be discontinued from participation in the study if any of the following occur:

- Serious adverse event (SAE)
- Medical condition or situation occurs that prohibits the participant to participate in intervention activities and would not be in the best interest of the subject in the opinion of the PI/treating medical staff
- Participant withdraws consent to continue in the research for any reason

6.1 Handling of Withdrawals. If participants withdraw from the study because of an SAE they will receive a follow up phone call by study personnel to collect safety data. If voluntary withdrawal occurs, study personnel will attempt to contact the participant for return of study equipment.

6.2 Termination of Study. This is a low risk study. We cannot foresee any reason to terminate the research. Individual participants will be discontinued from the protocol if they develop serious medical or psychiatric symptoms that necessitate their removal from the study. In such cases participants will be referred to appropriate care in their community.

7.0 Statistical Considerations

This is a pilot randomized controlled trial comparing the support group using active video game-based physical activity intervention to the existing UTMB breast cancer support group

with pedometer. We will measure feasibility and acceptability-related process measures and outcome measures. MD Anderson personnel (Maria C. Swartz) will lead the cohorts 1-4 data analyses and manuscript development. Data provided to MD Anderson personnel for data analyses will be de-identified.

Aim 1: Evaluate the feasibility and acceptability of active video game-based physical activity intervention among BC survivors within the support group setting. Feasibility findings will be based on descriptive analyses. We will compare our summary results to other studies. Examples of feasibility findings include: number of completed home-based worksheets, number of participant attendance on a weekly basis, number of participants who completed the program and the program activities, and weekly step goal achieved. Adherence is considered as a feasibility outcome. Weekly adherence is defined as the participant wearing Wii Fit meter for ≥ 5 days and attend at least 10 group sessions.

Aim 2: Compare the support group using the active video game-based physical activity intervention (intervention group) to the existing UTMB breast cancer support group with pedometer (control group for cohorts 1-3) or the telephone-based support group with the UTMB support group (control group for cohort 4). We will use analysis of covariance (ANCOVA) to test the post-intervention differences at 12-weeks (physical activity) between the two groups, controlling for baseline and other covariates that are significantly different at baseline. Intent to treat analysis will be used to handle missing data. ANCOVA will also be used to evaluate the secondary outcomes (physical function and quality of life). We will explore the changes in psychosocial variables using linear mixed models to investigate differences between groups and over here time points. Since this is a pilot study and it is not powered to detect significant differences of small to moderate effects, we hypothesized that the intervention group will show an improvement in physical activity, physical function, and quality of life compared to the control group. We also hypothesize that the intervention group will show an improvement in self-reported scores on self-efficacy, self-regulation, intrinsic motivation

Aim 3: Develop tools for implementation of the Pink Warrior intervention within the clinic and community settings. Development of a trainer's manual for the intervention will mainly be based on descriptive analyses using the facilitator's weekly group log. The facilitators will indicate whether or not they were able to cover the entire session as planned and facilitator will also be asked to provide feedback regarding the facilitator's guide and their feedback regarding the group activities.

7.1 Sample Size Calculation. The primary purpose of this study is to evaluate the feasibility of intervention components and study procedures to inform a larger intervention trial. This is a necessary research that is related to research focused on cancer survivors. For these reasons, a sample size of 60 is deemed appropriate to test intervention. A sample size of 60 is enough to detect an increase in 1000 to 2000 steps from baseline to follow-up based on other published pedometer-based interventions.[46,47] We will use our findings from this pilot study to establish effect sizes and inform the power and sample size estimates for larger trials. In the fourth cohort, a sample size of 20 is deemed appropriate to determine the Cohen's d effect sizes the intervention has on activity level (average number of steps/day), physical function, and self-reported quality of life.

8.0 Potential Difficulties and Limitations

8.1 Potential Difficulties. Our intervention involves human subjects and technologies, which may result in a number of potential difficulties. Study results may be affected by adherence among participants. However, preliminary study by our lab suggested that most participants will be compliant and one of the feasibility outcome is adherence. Technology issues may arise throughout the intervention. Technology issues may include, but not limited to, the Wii Fit meter or Digit-Walker malfunctioning or the Wii Fit meter syncing issue, or issues with the Wii U or Xbox 360 consoles. To address possible technology issues, the facilitator and the project staff will be available to help participant problem solve technology issues at the weekly session or will be available by phone. Participants will be urged to contact the research staff if problems arise and defective monitors will be replaced.

8.2 Limitations. The Pink Warrior intervention does involve a more extensive facilitator training than the current support group format. Therefore, time for facilitator training may be an issue for future implementations. However, if the study proves feasible, then subsequent study will be conducted to evaluate how to efficiently deliver facilitator training. In addition, this study is also limited to the greater Galveston, TX community. Even though our pilot results may not be nationally generalizable, we will use our results to inform the design of a larger and generalizable study.

9.0 Ethics and Protection of Human Subjects

Potential participants will be provided with an in-depth informed consent information prior to baseline assessments, being randomized, and beginning of study participation. The principal investigator (PI) or research staff will outline pertinent information and go over the consent form with each individual. All study personnel will be trained in the conduct of human research and only individuals authorized by the PI will have access to data on a need to know basis.

Extensive discussion of risks and possible benefits of participation will be provided to the potential participant. Consent forms describing in details the study procedures and risks will be IRB-approved and the potential participant will be asked to read and review the document. Upon reviewing the document, the investigator or staff will explain the research study to the potential participant and answer any questions that may arise. Potential participant will then sign the informed consent document prior to any study procedures. The potential participants will also have the opportunity to think about it prior to agreeing to participate.

Participants may withdraw consent at any time throughout the course of the trial. A copy of the informed consent document will be given to the participant for their records. The rights and welfare of the participants will be protected by emphasizing to them that the quality of their medical care will not be adversely affected if they decline to participate in this study.

We anticipate this study to present minimal risk depending on the age of the participant. Risks include breaches of confidentiality and acute musculoskeletal injuries (muscle soreness, sprains, skin irritation, sunburn). We have sought to minimize the risk by obtaining approval from their treating oncologist prior to participation. If participants follow the activity recommended by the program there should be no unintended consequences, but serious injuries may arise as a result of vigorous physical activity. In this event, the necessary actions defined by the IRB will be taken.

The design of this randomized controlled trial to include the control group is to assist the research team compare the different interventions. Participants in the control group still

receives a standard intervention with a basic pedometer. Despite randomization, participants in the control group will be offered the participant manual at the end of the intervention.

9.0 Data and Safety Monitoring Plan

The PI Dr. Elizabeth Lyons will make up the study safety team and oversee all participant safety and data monitoring. The PI is responsible for monitoring procedures during conduct of the study for each participant including: eligibility, enrollment, data collection, evaluation of study outcomes, problems with informed consent, and participant safety and well-being. Dr. Lyons will be the point of contact for all study-related personnel who come into contact with and monitoring the safety of research participants. An Occupational Therapist will oversee grip strengthening exercises, home exercise worksheets, and will be responsible for modification of activity. All study personnel will be responsible for monitoring for any potential adverse events or negative reactions. The coordinator will be the point of contact for study participants and will assess for all safety concerns, make necessary inquiries with participants, and document all potential adverse events.

The plan for monitoring will include:

1. Regular review of screening call logs by PI
2. Regular review of group session logs by PI
3. Regular review of collected data performed by PI and investigator team
4. Annual review by PI and UTMB IRB

Review of screening call logs on a regular basis will ensure that any values indicating ineligibility and/or unsafe practices are flagged. Flagged participants may be excused from the study or instructed on safer practices as needed. Group session logs completed by the facilitator and project staff will also be reviewed by the PI. Any indication of an adverse event or unsafe practices will also be flagged. In the case of adverse events, stand protocol for reported adverse events will be used. Study data will be reviewed by the PI and investigator team. Again, the team will identify any values indicating unsafe practices or potential adverse events that may not have been reported by participants. Finally, the UTMB IRB will review study progress yearly.

As this is a low-risk study, we do not anticipate any serious adverse events or safety concerns. Thus, we will not perform full statistical analysis during these periodic reviews. Though we anticipate possible differences in health outcomes, for the study to be rigorous, we must continue to measure all planned variables at each planned time point. The reviews will focus on indicators of safety for participants, such as large decreases in quality of life or strength, or large weight gains. We will create a list of a priori criteria for quantifying clinically significant change based on adverse events information published by the NCI. (For example, a weight gain of 5-10% would be considered a mild adverse event.)

We will not convene an external Data Safety and Monitoring Board.

Anticipated non-serious adverse events include musculoskeletal pain or mild injuries, other non-serious injuries (e.g., bruises), skin irritation, minor discomfort, cardiac events, fatigue, weight gain, and possible loss of confidentiality. If an anticipated adverse event occurs, the PI will immediately confer regarding each event. The attribution and impact of each event on the

overall project's risk/benefit ratio will then be determined.

All unanticipated, serious, fatal, and/or life-threatening adverse events will be immediately reported to the UTMB IRB within 24 hours of occurrence. The IRB and PI are responsible for determining if modifications are needed to the consent form and/or protocol based on the event. If a determination is made that participants are exposed to unacceptably high risk in comparison to benefit, the study will be suspended until proper modifications are made for participant safety. Aggregate reports of adverse events will be prepared in consultation with the regulatory key resource of the Institute for Translational Sciences at UTMB and forwarded to the IRB for review.

9.1 Plan for data management. For self-report and feasibility data, the PI is responsible for collection and storage of data initially on electronic questionnaires and saved assessment information from the paper format, then transferred to a computer database located on a secure UTMB server. Questionnaire data will not be personally identifiable. All questionnaires will use ID numbers for identification purposes, and the correspondence of ID numbers to names will be kept in a password-protected file on a password-protected, secure server. Databases will use ID numbers for identification of data and will also be stored on the secure, password-protected server. The data collected by the game consoles will not be directly linked to the participants because pseudonyms were provided for each participant. Data saved by the game consoles will be moved and erased form the console prior to further use of the console or provision to another participant.

9.2 Plan for adverse event reporting. The PI will also hold responsibility for monitoring and reporting adverse events of any kind. We do not anticipate severe adverse events, though mild and moderate events are possible. The scale to be used is the UTMB Clinical Research Center Adverse Event Grading Scale (Table 5). Examples of each level of adverse event on the scale are provided below.

- ***Mild*** events include discomfort without disruption of daily activities. No therapy or only symptomatic therapy is required. This level is equivalent to NCI Common Terminology Criteria for Adverse Events version 4.03 Grade 1 adverse events (mild; asymptomatic or mild symptoms; intervention not indicated).
- ***Moderate*** events include discomfort sufficient to modify daily normal activity. Specific therapy is required. Laboratory test alterations indicate injury without long-term risk. This level is equivalent to NCI Grade 2 (moderate; minimal, local or noninvasive intervention indicated; limiting age-appropriate activities of daily living).
- ***Severe*** events include incapacity, inability to work, inability to perform normal daily activity, hospitalization required, prolonged emergency treatment required, life-threatening events, laboratory tests indicating a serious health threat or permanent injury, and death. This level is equivalent to NCI Grades 3 (severe/medically significant but not immediately life-threatening), 4 (life-threatening, urgent intervention indicated), and 5 (death).

Table 5. Reporting of adverse events to IRB

NCI Adverse Event Grade	Expected	Unexpected
Grade 1	Reporting not required	Report within 10 days
Grade 2	Reporting not required	Report within 10 days
Grade 3 (UTMB level 3)	Report by phone within 24 hours	Report by phone within 24 hours
Grade 4 (UTMB level 3)	Report by phone within 24 hours	Report by phone within 24 hours
Grade 5 (UTMB level 3)	Report by phone within 24 hours	Report by phone within 24 hours

The PI will follow the reporting requirements for serious and unexpected adverse events outlined in the UTMB IRB Adverse Event Policy. All unanticipated, serious, fatal, and/or life-threatening adverse events will be reported to the UTMB IRB within 24 hours of occurrence or recognition. Aggregate reports of adverse events will be prepared on an annual basis and forwarded to the IRB at annual review.

Attribution will be assessed by the PI on a scale used by CRC investigators: 1) not related, 2) possibly related, 3) probably related, 4) definitely related to the study interventions.

9.3 Protection of human research participants – computer-based training. All research personnel have completed the UTMB required training course in protection of human research participants.

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12.0 List of Appendices

Appendix A. Screening script, recruitment letter, recruitment flyer, and presentation blurb

Appendix B. Participant Manual

Appendix C. American Cancer Society's Personal Health Manager Kit Content

Appendix D. UTMB Breast Cancer Support Group Topics

Appendix E. Assessment Summary Sheet

Appendix F. Questionnaires

Appendix G. Email Template for the Assessment Center

Appendix H. SPPB Protocol

H1. Senior Fitness Test Manual

Appendix I. Assessment Center Security Information

Appendix J. HIPPA Compliance information