

**Self- Monitoring Activity: a Randomized Trial of Game-oriented Applications  
(SMARTGOAL)**

**Principal Investigator:  
Elizabeth J. Lyons, PhD, MPH  
301 University Blvd., Galveston, Texas 7555-1124  
Phone: (409) 772-2575, Fax: (409) 772-2577  
Email: [ellyons@utmb.edu](mailto:ellyons@utmb.edu)**

## RESEARCH PLAN

### A. HYPOTHESIS AND SPECIFIC AIMS

Physical activity produces health benefits in breast cancer (BC) survivors, including improved quality of life and decreased risk of recurrence and mortality.<sup>1-3</sup> However, many breast cancer survivors do not meet activity recommendations,<sup>4</sup> and racial/ethnic disparities in activity rates<sup>5</sup> may exacerbate disparities in health outcomes.<sup>6</sup> Activity interventions among BC survivors improve activity levels in the short term,<sup>7</sup> but increases are rarely sustained after 6 months.<sup>8,9</sup> Since habitual activity produces greater quality of life benefits than do briefer increases,<sup>10</sup> creating sustainable interventions should be a cancer control priority.<sup>11</sup>

Breast cancer survivors consistently include lack of **motivation** as one of their primary barriers to physical activity. Autonomous (volitional) motivation is associated with long-term increases in physical activity.<sup>12-14</sup> Active video games are a promising medium for intervention with demonstrated ability to increase autonomous motivation,<sup>15</sup> fitness,<sup>16,17</sup> and quality of life.<sup>18</sup> These games are also acceptable to older<sup>19</sup> and chronically ill adults and women.<sup>20</sup> Because of their easy individualization and user-centeredness, games hold the potential for reaching a broad, diverse audience.

Games that include involved narratives may be particularly effective. **Narrative transportation**, or engagement, is highly effective in persuasion to change health behaviors.<sup>21</sup> Narrative transportation increases enjoyment directly<sup>22,23</sup> and also likely impacts autonomous motivation by increasing perceptions of autonomy, competence, and relatedness. We hypothesize that narrative-based active games in which users role-play as fit characters will lead to greater autonomous motivation, in turn leading to greater physical activity.

The goal of this research is to develop a sustainable intervention that is broadly acceptable and efficacious across a diverse population of breast cancer survivors. This study will test a 6-month game-based physical activity intervention among a sample of sedentary, overweight postmenopausal breast cancer survivors. The enhanced intervention will provide a mobile device (iPod touch) and two narrative-based walking game applications (apps). These apps include audio narratives that can change based upon player input and include rich feedback on physical activities. The standard exercise intervention will provide a mobile device with a simple activity monitor and feedback application. Both interventions will include self-monitoring and feedback through the mobile apps and additional feedback through weekly brief counseling phone calls. Thus, comparing the two interventions will allow the investigators to draw conclusions about the unique motivating aspects of the narrative games. A follow-up assessment at 12 months will further allow investigation of intervention effects on activity maintenance over time. The study will address the following specific aims:

**Aim 1. Compare a motivationally enhanced intervention to a standard intervention in a 6-month randomized controlled trial.** Sedentary, overweight postmenopausal breast cancer survivors (N = 120) will be randomized to the enhanced intervention or to a standard intervention. We will test objective measures of physical activity, physical function, and fitness at the conclusion of intervention contact (6 months) and after a 6-month maintenance phase (12 months).

**Aim 2. Compare quality of life and psychological outcomes across the two interventions at 6 and 12 months.** We will investigate quality of life (physical, social, emotional, functional, and breast-related), depression, anxiety, and fatigue at 6 and 12 months.

**Aim 3. Compare autonomous motivation across the two interventions at 6 and 12 months.** Hypothesized psychosocial predictors (Self-Determination Theory constructs and narrative transportation) will also be investigated.

**Aim 4. Investigate the cultural appropriateness of the two interventions.** At the 6 month assessment or 12 months assessment (if not collected at 6 months), we will conduct brief interviews with participants (N = 120) and stakeholders (N = 10) to investigate acceptability of intervention components. Qualitative analyses will examine racial and ethnic differences.

We hypothesize that the narrative-based enhanced intervention will produce greater increases in activity, physiological outcomes, and quality of life outcomes as compared to a standard intervention. This study will provide crucial information to inform future research and practice related to cancer control and survivorship care. Its results will provide the foundation for future efficacy and dissemination studies with the potential to quickly and significantly improve public health at a population level.

## B. BACKGROUND AND SIGNIFICANCE

Breast cancer is the most prevalent cancer in women worldwide.<sup>24</sup> Physical activity improves mood,<sup>25,26</sup> reduces inflammation,<sup>27,28</sup> improves physical functioning,<sup>29</sup> and reduces pain,<sup>29</sup> leading to improvements in quality of life and fatigue.<sup>1,30</sup> Both duration and intensity appear to have a dose-response relationship with improved health,<sup>10</sup> but large improvements can result from as little as 15 minutes per day of moderate-intensity activity.<sup>10,31-33</sup> In BC survivors, > 150 minutes of physical activity per week has been associated with decreased BC recurrence and mortality, as well as improved quality of life.<sup>2,27,34,35</sup>

However, activity levels decrease after cancer diagnosis and remain low in survivors.<sup>36,37</sup> Objective measures of activity have shown that BC survivors accumulate approximately four minutes per day of moderate to vigorous intensity activity, compared to eleven minutes in non-BC controls.<sup>38</sup> Only 37% of BC survivors meet recommendations for 150 minutes per week of moderate-intensity activity.<sup>4</sup> The downward trend appears to begin one to two years after diagnosis, and levels remain low afterward.<sup>37,39</sup>

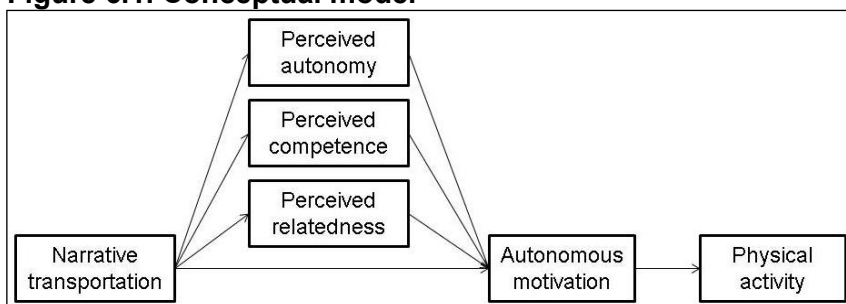
African-American and Hispanic women are at greater risk than non-Hispanic White (hereafter referred to as “White”) women for outcomes exacerbated by low activity rates. Cancer mortality is higher in African-American than in White women,<sup>40</sup> and disease-free survival, quality of life, and physical function are lower in African-American and Hispanic women.<sup>5,41</sup> Comorbidities and differences in health behaviors appear to be partially responsible for poorer survival.<sup>42</sup> Though physical activity could produce beneficial effects for survival, comorbidities, and quality of life, minority BC survivors are less active than White survivors.<sup>5,43</sup>

Breast cancer survivors are in serious need of effective physical activity intervention. Skills-based interventions (e.g., those based on SCT that target self-regulation, self-efficacy, etc.) are effective, but adherence decreases markedly and quickly over time.<sup>8</sup> For example, by week 9 of a 12-week intervention, only 53% of participants reached their activity goals.<sup>9</sup> What little is known about sustained activity comes mostly from longer-term intervention trials; measurement of behavior maintenance after investigator contact ceases is rare in physical activity studies, particularly in BC survivors.<sup>44</sup> Several secondary investigations of intervention trials and review papers have suggested that targeting autonomous motivation may be one of the most promising methods for increasing long-term activity maintenance among survivors.<sup>45,46</sup>

Thus, there is a need for improved physical activity interventions that specifically target autonomous motivation. We propose that a patient-centered, individualized intervention would best adapt to the needs of breast cancer survivors of all races and reduce ethnic/racial disparities in outcomes. Active video games that include motivating game mechanics and persuasive narratives hold promise as a medium for delivering such an intervention. Below, we discuss the theoretical background and rationale for a game-based study,

### B.1. Theoretical framework: Self-determination theory

**Figure 6.1. Conceptual model**



The theoretical framework for this intervention (see **Fig. 6.1**) includes constructs from Self-Determination Theory (SDT) and theories of narrative transportation.

SDT proposes a continuum between autonomous and controlled motivation,<sup>47,48</sup> with autonomous motivation being more strongly associated with physical activity over time.<sup>13,14</sup> Autonomous motivation for

activity includes both completely intrinsic motivation (that is, motivation in the absence of external rewards/demands) as well as integrated and identified regulation (relatively autonomous forms of motivation that involve valuing the outcomes of activity). According to SDT, autonomous motivation is predicted by the fulfillment of psychological needs for competence, autonomy, and relatedness.<sup>47</sup> Several large-scale autonomy-promoting interventions have produced excellent results, including long-term maintenance of physical activity<sup>49</sup> and weight loss.<sup>50,51</sup>

### B2. Narrative transportation

Narrative transportation (also called narrative engagement) occurs when an individual is mentally immersed in a narrative storyline. Transportation is typically described as consisting of empathy and mental imagery related to a story.<sup>52</sup> Narratives can increase enjoyment and motivation generally<sup>22,23</sup> and specifically towards physical

activity.<sup>53</sup> We hypothesize that in addition to a direct effect on autonomous motivation due to enjoyment, narrative transportation also exerts an effect on autonomy, competence, and relatedness.

When implemented as part of a video game, narratives can be particularly autonomy-supportive. Interactive storytelling involves the player by providing a series of choices that affect the rest of the narrative. Interactive narratives can be even more enjoyable than standard narratives, as they combine the suspense and enjoyment of a story with the autonomy of creating a personalized experience.<sup>54</sup> Further, active video games may be a powerful medium for such storytelling, as embodied role-play (physically acting out the story) could amplify feelings of autonomy and mastery.<sup>55,56</sup>

The use of narrative to deliver health-related information can increase persuasion and result in greater behavior change as compared to standard information provision.<sup>57</sup> This persuasion is implicit and emotional rather than overt and analytical, which may produce more enduring effects.<sup>52</sup> It is possible that active video games with a compelling narrative could persuade players that they are competent, via identification with competent characters.<sup>58,59</sup> Role-play as a fit character could also increase perceived competence via social cognitive means, by providing opportunities for practice, modeling, and mastery experiences.<sup>60</sup>

Narrative also has the power to change behavior by influencing individuals' attitudes and beliefs. Identification with characters can lead to "trying on" their personality traits and values.<sup>59,61-64</sup> Video game studies have found that playing as a soldier increased feelings of bravery, for example.<sup>59</sup> The more individuals relate a story character to themselves, the greater the impact on related health behavior.<sup>65</sup> Thus, narrative transportation may influence autonomous motivation by increasing perceptions of relatedness to story characters.

### **B3. Using active video games to increase autonomous motivation**

Active video games are video games that require or encourage body movement during play.

Increasing evidence suggests that some of these games are an appropriate delivery method for behavioral physical activity interventions. Active games are interactive and highly individualizable.

They contain many of the behavior change techniques that are found in clinical interventions.<sup>66</sup> Active games improve mood,<sup>18</sup> fitness,<sup>17</sup> and physical function<sup>67-69</sup> in older adults. Though these health outcomes should be mediated by increased physical activity, measurement of physical activity in game studies among older adults is extremely rare. Studies in other age groups suggest that these health improvements are indeed likely mediated by increased motivation leading to increased physical activity.<sup>15,16,70</sup>

Games likely produce these behavior and health benefits by increasing perceptions of autonomy, competence, and relatedness and, in turn, autonomous motivation. Several empirical studies of video games have found that part of their appeal is their potential to fulfill these psychological needs,<sup>71,72</sup> and that games that increase these perceptions more are more likely to be played again in the future.<sup>73</sup> For example, games can encourage autonomy by allowing meaningful choices.<sup>74,75</sup> They can encourage perceptions of competence (similar to self-efficacy) via modeling, practice, role-play, verbal persuasion, and mastery experiences.<sup>76</sup> Perceptions of relatedness can be increased using multiplayer game options or by encouraging parasocial interaction with engaging, compelling characters.<sup>64,77,78</sup> **Table 6.1** displays common methods by which games may influence these perceptions.<sup>75,79</sup>

Games that include an engaging narrative with compelling characters may further increase these perceptions. For example, a recent study that manipulated feelings of identification with a character in an active video game found greater exercise motivation in the high identification group.<sup>80</sup> Because video games involve enactive role playing rather than just passive observation of a narrative, they may exert a greater influence on motivation and health behavior than typical narratives.<sup>60</sup>

### **B4. Using active video games to decrease disparities in motivation and activity**

There is a need for interventions that are easily adaptable to be effective across a range of races and ethnicities, as many current programs appear to be less effective for minority women. In a recent example, poor adherence to lifestyle change recommendations among minority breast cancer survivors was hypothesized to have influenced disappointing results of a large-scale dietary intervention.<sup>81</sup> Thus, racial/ethnic minority BC survivors are in unique need of lifestyle interventions that can be individualized to suit their personal values and barriers, but current intervention techniques do not appear to be adequate to produce behavioral change.

**Table 6.1. How games impact autonomous motivation**

Construct	Mechanisms
Autonomy	Choices, motion controls, embodied role-play
Competence	Practice, feedback, mastery experiences
Relatedness	Multiplayer modes, character identification

Video games are an ideal medium for broad tailoring and specific individualization. In fact, video games are by definition individualized, as user inputs guide the experience of the game and make it unique to each player. Active games can be adapted to suit player fitness levels, use music the player prefers, and to be played according to the player's schedule. A qualitative investigation of African-American older adult women with lupus found that individualization was one of the reasons they enjoyed using an active video game.<sup>82</sup> Video games played on mobile devices may also be more likely to reach ethnic and minority women than interventions delivered via personal computer. More African-American and Hispanic individuals use smartphones than non-Hispanic Whites.<sup>83</sup>

Narrative persuasion has been suggested as well-suited for ethnic and racial minority groups when narratives involve characters who reflect their experiences and who resemble them.<sup>84,85</sup> Effects of narratives on health behavior appear to be greatly influenced by personalization. The more characters resemble the reader/viewer/player, the more effective the narrative.<sup>65</sup> Narrative is also a culturally appropriate intervention method that may contribute to greater adherence.<sup>86</sup> Thus, interactive video games that promote physical activity and that include an engaging narrative show great promise for meeting the needs of a broad range of breast cancer survivors, regardless of their ethnicity or race.

### **B.5. The role of evidentiary trials in moving forward research and practice**

Evidentiary trials represent a step between pilot testing and fully-powered efficacy testing.<sup>87</sup> These trials are powered to detect effects in intermediate outcomes – typically behaviors such as physical activity. Using physical activity as an outcome at an early stage in intervention development is very important, as large-scale trials often fail to show health outcome changes due to failures to produce sustained behavior changes in activity.<sup>88</sup> Evidentiary studies allow for true tests of intervention effects on outcomes of importance while also providing effect sizes, formative data, and a convincing rationale for investment in a large efficacy trial. It has been suggested that such trials will ultimately result in improved outcomes and cost savings.<sup>87</sup>

### **B.6. Summary of rationale**

Breast cancer survivors are a large population with an unmet need for sustainable physical activity intervention. Autonomous motivation is associated with better physical activity maintenance, and both active video games and narrative storylines are predictive of autonomous motivation. A theory-based intervention that uses narrative-based active video games could produce a large impact at the public health level, reducing morbidity and mortality in this high-risk population. Further, because these strategies are easily individualized, such an intervention may be more effective across races and ethnicities than a standard intervention. This project will advance the survivorship research literature and potentially impact clinical practice.

## **C. STATEMENT OF CANCER RELEVANCE**

There is a grave need for programs that encourage increased and sustained exercise among breast cancer survivors. Habitual physical activity improves physical and emotional health in BC survivors, with proven effects on recurrence, side effects, late effects, and quality of life. Preliminary evidence suggests that new technology, such as video games, may be an effective method for increasing motivation to be active. In comparison to traditional interventions, this technology may increase motivation by increasing feelings of autonomy, competence, and relatedness.

The purpose of this study is to test whether an intervention that uses active video games improves upon a standard physical activity intervention. We will test the intervention in a diverse sample of inactive postmenopausal breast cancer survivors. In the short term, the study will provide valuable information about the potential of mobile technology for improving health behaviors, intermediate health outcomes (cardiovascular fitness, physical function etc.), and mood. In the longer term, the results of the study have the potential to improve cancer control on a large scale, and ultimately decrease the morbidity and mortality of BC. If the intervention is ultimately successful, it could be included in survivorship care plans as a standard tool for improving physical activity, benefiting millions of survivors and lowering overall cancer burden. Because the intervention was designed to be easy to individualize, similar programs could easily be targeted to other cancers or chronic conditions.

## **D. INNOVATION**

This project is an innovative step forward for the discipline in several ways: **1)** The primary focus of the intervention is activity maintenance, with a strong theoretical rationale for each intervention component's effect on long-term change. To our knowledge, this will be the first large-scale investigation of the use of video game mechanics in an intervention among older adult cancer survivors. This strategy holds potential for a large

public health impact but has received little research attention. **2)** The individualized and user-centered nature of the intervention may be able to address barriers that contribute to racial/ethnic disparities in physical activity rates and health outcomes. **3)** The intervention incorporates tailoring and patient-centered outcomes in a way that does not decrease the potential ease of dissemination. The applications will allow for simple customization and autonomous choices.

## **E. PRELIMINARY STUDIES**

Dr. Lyons has extensive experience in the areas of technology and physical activity. The research mentors have been carefully chosen to complement these strengths and to fill gaps in knowledge and experience. The major areas of preliminary evidence for this research study are outlined below.

### **E.1. Video games and physical activity**

In her previous studies, Dr. Lyons has found that significant differences exist across active video game types in both energy expenditure and enjoyment<sup>89</sup> and that enjoyment of an active video game predicted energy expenditure.<sup>90,91</sup> Comparison of a “game” themed around exercise simulation (jogging) and a game themed around a true game (hula hooping) found that framing an activity as a playful game produced greater enjoyment than did simulating an exercise activity.<sup>90</sup> Taken as a whole, the results of this line of research indicate that more enjoyable programs that integrate video game mechanics will likely produce greater improvements than do standard programs.

### **E.2. Cancer survivors and older adults using technology to increase activity**

Dr. Lyons began her research career performing mixed methods analyses of social support provided in online mailing lists for cancer survivors and caregivers.<sup>92,93</sup> Together with Dr. Basen-Engquist, she has recently analyzed the results of a large (N = 1053) survey of BC survivors regarding technology and health promotion. Breast cancer survivors reported using computers and the Internet (86%), and were more interested than other cancer survivors in computer (36%) and mobile interventions (though interest in smartphone interventions was low, 12%). In fact, interest in computer interventions was greater than interest in clinic or telephone based interventions.

A series of focus groups and interviews with postmenopausal breast cancer survivors (N = 20, 4 ethnic/racial minority) found that these apparent low levels of interest in smartphone interventions were informed by survivors’ expectations. For example, one participant stated that she did not like video games or smartphones. Later in the discussion, she mentioned playing Angry Birds on her tablet. She saw no contradiction in these two statements, echoing attitudes of many of the other participants. They did not count the kinds of casual video games that they played as “video games,” nor did they believe that other mobile devices (tablets, iPods) and smartphones were similar. Thus, some video games and mobile devices are actually highly acceptable to older adult breast cancer survivors, despite self-reports (such as in the above study) that suggest the contrary.

A pre-experimental pilot study (N = 10, 4 ethnic/racial minority) using mobile devices in older adults included two women who were long-term BC survivors. The study protocol, which involved provision of a tablet and activity monitor, was found to be feasible and acceptable over the brief intervention period (6 weeks). Participants wore the monitors as instructed and synced their data daily or multiple times per day. Adherence was very good, with monitors worn and synced 402 out of a possible 420 days. Participants significantly improved their fitness and function compared to baseline. Measures of acceptability showed that participants found the tablet, monitor, and application to be useful and enjoyable.

An additional pre-experimental pilot (N = 10, 3 ethnic/racial minority) is investigating one of the games to be used in the proposed study (*Zombies, Run!*). We provided smartphones with the game app to adult women (18 – 69), six of whom were over 55. The study is not yet complete, so we cannot estimate adherence. However, qualitative acceptability measures taken at the midpoint indicate two major reported reasons for non-adherence: preference for using the participant’s own phone and preference for measuring lifestyle activity rather than (or in addition to) planned activity. All participants had no problems using the smartphones provided and reported finding the game and story very motivating. Despite these positive feelings, the requirements surrounding use of the game were felt to be onerous. Unlike in the above trial, participants were required to remember to turn on the app prior to planned walking bouts. Several women mentioned forgetting to carry a second phone (since they already had their own cell phone), or felt that the requirements to remember a second phone and to remember to turn on the app were burdensome. We hypothesize that using a non-smartphone mobile device (like an iPod or iPad), allowing use of participants’ own phones, and providing a choice of apps that include lifestyle monitoring (i.e., that doesn’t require pre-planned activity bouts) would improve adherence.

### E.3. Behavior change techniques and game mechanics

**Table 6.2. Differences between game and monitor apps**

	Games		Monitor
	Zombies Run!	The Walk	App
Behavior change techniques			
Goal-setting		x	x
Self-monitoring	x	x	x
Feedback	x	x	x
Game mechanics			
Competition/conflict	x		
Freedom of choice	x	x	
Dynamic/ephemeral goals		x	
Narrative	x	x	
Novelty/surprises	x	x	
Pick-ups	x		
Resource management	x		
Rewards	x	x	
Social status/reputation/support	x		
Time limits/pressure	x	x	

Dr. Lyons and colleagues recently compared the content of active video games and activity monitors to standard taxonomies of behavior change techniques.<sup>66</sup> These analyses were used to choose games and activity monitors suitable for this study. **Table 6.2** compares two narrative-based active game apps to an electronic activity monitor app. Both the game apps and the monitor app include techniques that, when implemented, are associated with increased physical activity.<sup>94,95</sup> Thus, standard intervention components are equivalent across the two app types. The major differences lie in game mechanics, which are common in the two games and entirely absent from the monitor app. Thus, a comparison of the games to the monitor would isolate the effects of game mechanics while providing both groups with the standard social-cognitive intervention components necessary in a behavioral physical activity intervention.

### E.4. Mentor areas of expertise and previous studies

The three co-mentors were chosen to address specific areas in which Dr. Lyons requires more training and education. Dr. Goodwin is an expert in aging, health disparities, and comparative effectiveness research in cancer. His perspective as a practicing geriatrician and health services researcher will be extremely useful for refining intervention components to be feasible for dissemination. He has authored or co-authored many papers on topics related to this research program, including on aspects of race related to obesity,<sup>96,97</sup> breast cancer treatment,<sup>98,99</sup> physical activity as an indicator of health in older adults,<sup>100-102</sup> patient-oriented outcomes in older adults,<sup>103,104</sup> interventions to improve outcomes in BC patients,<sup>105-107</sup> and psychosocial aspects of cancer treatment and survivorship.<sup>106,108-111</sup>

Dr. Basen-Engquist, at nearby M.D. Anderson Cancer Center, will provide expertise and mentoring specific to behavioral physical activity intervention in women cancer survivors. She is a leading expert in this field with significant expertise in intervention testing<sup>112</sup> and adaptation.<sup>113</sup> Her primary area of expertise lies in the application of health behavior theory to understanding physical activity in this population.<sup>29,114-117</sup> She has implemented multiple large-scale interventions among survivors, including breast cancer survivors.<sup>112,118,119</sup>

Dr. Volpi is an expert in muscle metabolism,<sup>120,121</sup> sedentary behavior,<sup>122</sup> aerobic exercise,<sup>123</sup> and aging.<sup>124,125</sup> She has conducted numerous clinical trials involving exercise program implementation among older adults. She will assist with conducting objective outcome measures of physical activity, function, and fitness.

Additionally, consultant Dr. Berenson is an expert in women's health research with extensive experience in recruiting diverse samples of women in the Galveston area for energy balance research.<sup>126-128</sup> Several of her research studies have specifically investigated the use of new media for health information among minority women.<sup>129-131</sup>

## F. RESEARCH DESIGN AND METHODS

### F.1. Overview and study flow

The primary purpose of the SMART GOAL (Self-Monitoring Activity: a Randomized Trial of Game-Oriented AppLications) study is to investigate the impact of an enhanced motivational physical activity intervention among sedentary postmenopausal breast cancer survivors. We will conduct a randomized controlled trial (RCT; N = 120) comparing the enhanced intervention to a standard self-monitoring intervention. The enhanced intervention will consist of provision of two active video games and a mobile device on which to play them. Participants will also receive weekly brief counseling/check-in calls. The standard intervention will consist of provision of an electronic activity monitor and a mobile device, with the same phone call content and schedule.

The trial will be conducted over the course of three years, in three yearly cohorts. Participants in the trial will each attend four visits: a baseline assessment/orientation one week later, an initial counseling/goal-setting

meeting; an assessment at 6 months, and a final assessment at 12 months. Participants may attend an additional visit for randomization if we do not have a valid physical activity measurement. A battery of physiological and anthropometric measures will be performed at all assessments, and psychosocial outcomes will be measured by questionnaire. Questionnaires will also be completed by mail at 3 and 9 months. The study is designed such that regular intervention contacts will occur for the first 6 months. The period between 6 and 12 months will be monitored as a maintenance period, to determine whether behaviors are maintained in the absence of further counseling. Participants will receive \$25 gift cards at the 6 month and 12 month assessments for a total of \$50 incentive. They will also keep the mobile device as an additional incentive. The flow of the trial is displayed in **Table 6.3**. This pattern will be repeated for each cohort.

Personnel conducting the study will include a clinical research coordinator and two graduate research assistants. The research coordinator and one of the graduate research assistants will perform counseling calls, oversee monitor data, and provide technical assistance, while the other research assistant (blinded to participant group assignments) will conduct assessments. During the maintenance phase of this intervention (6 – 12 months), the research coordinator will continue to make monthly phone and mail contact to encourage continued participation (e.g., thank you and reminder postcards, calls to check for changes in contact information). No counseling content will be offered during these contacts.

**Table 6.3. Timeline of trial assessments and phone contact by month**

Month	0	1	2	3	4	5	6	7	8	9	10	11	12
Assess-ments	Base-line			By mail			6 month			By mail			Final
Calls		Weekly calls			Monthly calls			No counseling calls; maintenance period					
Study materials		Participants use mobile apps daily											

### **F.3. Participants and procedure (Aims 2 – 4)**

For the trial, we will recruit participants in three cohorts of 40 participants each, 20 per group, with oversampling of African American and Hispanic women (at least 30% of the sample). Participants will be randomly assigned to receive an enhanced or a standard intervention. Major eligibility criteria will include female gender, postmenopausal status (cessation of menses for at least 12 months), aged 45-75, current inactivity (< 90 minutes moderate-vigorous activity per week), BMI > 25 and < 40, no psychological issues that would interfere with study completion, ability to walk for physical activity, safety of physical activity, and not currently using the monitor/application to be provided. The PAR-Q+ will be used to screen for potential contraindications to exercise<sup>132</sup>. Endorsement of any of its items will require physician clearance to participate in the study.

Based on incidence data from the Texas Cancer Registry, we estimate that approximately 1950 female breast cancer survivors aged 55 – 75 and diagnosed in the last 10 years currently live in Galveston county, 500 of whom are African-American or Hispanic. We will also sample from nearby counties (including Harris county, which includes Houston). Dr. Basen-Engquist successfully recruited a sample of 60 breast cancer survivors in two years for a physical activity intervention study<sup>112</sup> (37% African American and Hispanic) as well as larger samples for cross-sectional research (36% African American and Hispanic).<sup>29</sup> Recently, 6 of 10 older adults recruited for a similar study were African American or Hispanic. Thus, we believe our recruitment targets of 40 per year for three years and 30 - 40% minority recruitment (12 or more per year) to be feasible. We will use a combination of advertisement, community engagement, pre-screen via medical record for eligibility and clinic-based solicitation to recruit potential participants. We will sample from Galveston as well as other nearby counties (including at UTMB and MD Anderson clinics in Harris county, which includes Houston, and up to Victoria County). The clinical research coordinator also coordinates a UTMB program that encourages recruitment of ethnic/racial minorities into clinical trials, and has ample experience in recruiting from local communities.

### **F.4. Enhanced intervention**

The intervention consists of several complementary components:

- 1) Provision of a mobile device (iPod Touch) with armband and headphones
- 2) Provision of one mobile game application
- 3) Provision of online currency (e.g., iTunes gift cards) to purchase music to be used in the game (\$50)
- 4) Brief counseling phone calls that occur weekly for 3 months, then monthly until 6 months



Participants will be able to use their own smartphone devices should they wish to; however, we will provide an iPod Touch mobile device to ensure that they have access to a device compatible with the chosen apps. (It will also serve as an incentive, as iPod Touches can hold much more music and data than most smartphones and take high-quality pictures.) The iPod Touch is similar to an iPhone, but does not require cellular service for use and is primarily an app and music use device. Thus, we believe that it should be perceived as a more acceptable mobile device than a smartphone, despite its very similar functionality. In our preliminary studies (see pages 6.5 - 6.6) we found that smartphone-based interventions are acceptable among older women, but that allowing use of their own phone and/or providing a non-phone mobile device is preferred.

The game to be used is *Zombies, Run!*, created by developers Six to Start. This game was chosen due to its unique blending of an involved narrative storyline with game mechanics and extensive interactive behavioral tools. *Zombies, Run!* is a game that encourages bouts of 30 – 60 minutes of walking, jogging, or running. The accelerometer of the mobile device measures steps taken and provides extensive feedback. **Table 6.2** on page 6 shows several of the game mechanics most commonly used in the game, and **Figure 6.2** shows screenshots of the game. Players use the mobile device to set up the game, but during exercise the device is held or worn on the arm (armbands and headphones are included with the mobile device). The game plays user-chosen music and places clips of an audio narrative in between those songs, to provide an illusion of other characters “radioing in” while the player travels by foot in a post-apocalyptic world. While songs are played, the game provides audio cues when players “pick up” virtual supplies or are chased by zombies. Zombie chases (which can be turned off) require players to increase their speed by 20% for one minute in order to out-run their pursuers. If the zombies catch the player, they “drop” some of their virtual supplies to distract the zombies and escape.

The game consists of over 120 missions in the main storyline, with complementary side missions that provide additional insight into some of the characters. Additional missions will be released in April, 2015, so the storyline is long enough to sustain activity over the year-long period. The narrative is written by a professional writer and includes main characters of multiple genders and races. The player character is never referred to by name and is always addressed in second-person as “you” or “Runner 5.” Players can assume that their character is any gender, race, ethnicity, etc. Participants in the preliminary study reported high levels of parasocial interaction with the two main non-player characters (one of whom is an African-American woman). Thus, we believe that this narrative will be appropriate for testing hypotheses related to transportation/engagement.

\*Please note: A similar game called *The Walk* will be pre-loaded onto the iPod device. During orientation, interventionists will briefly reference it as a potential back-up should participants find the content of *Zombies, Run!* aversive. *The Walk* is made by the same developers and includes very similar content, but the story is different and less violent. Our intent is for participants to use *Zombies, Run!*, but we will provide the option of *The Walk* as a backup for cases in which participants feel strongly that they cannot use the zombie game.

Counseling content for the narrative game group was adapted from the narrative counseling used in the PACT study<sup>133</sup> and extended to include appropriate constructs of interest in this study. Discussions will draw from the *Zombies, Run!* game and make suggestions related to future play. For example, some sessions will call participants’ attention to the exercise imagery they engage in during walking sessions, and others will encourage participants to imagine their ideal selves when playing as their character. Participants in this group will also receive the basic counseling provided to the self-monitoring group that covers self-monitoring, feedback, action-planning, and problem-solving.

### **During the COVID-19 pandemic, the following consenting/interview methods will be implemented:**

In response to the COVID-19 pandemic and related Institutional guidelines, the following modifications are being implemented effective immediately:

All visits will be conducted entirely by teleconference call. We are done with enrollment for the protocol. Ongoing participants will receive a phone call by study staff to inform the subject of the implemented modifications. We will read the modification letter to the subject over the phone. If the subject agrees with the modifications, we will document the subject verbal response in a note to file. If we are not able to reach the subject, we will mail the subject a letter.

Session 1: Orientation (this meeting, approximately 1 hour)

We will not have any Session 1: Orientation. We are no longer recruiting for this study. We are done with enrollment.

Session 2: Baseline assessment and goal-setting (about 1 week later, approximately 2 hours)

We will not have any Session 2: Baseline assessments and goal setting since we are no longer recruiting for this study.

Session 3: Six-month assessment (approximately 2 hours)

The visit will be conducted using teleconference communication (examples: via phone, skype, zoom)

Ongoing participants will complete Session 3: Six-month assessment using teleconference. Some of the assessment will need some modification due to our current situation and to ensure the safety of our subjects, staff and community. The following assessment will be conducted via teleconference:

1. Height and weight- we will obtain self-reported height and weight. If possible, we will obtain measurements at a future face to face visit if available.
2. Physical fitness- we will not collect this information during our scheduled visit. If possible, we will conduct this at a future face to face visit if available.
3. Physical function- we will not collect this information during our scheduled visit. If possible, we will conduct this at a future face to face visit if available.
4. We will ask the participants questions about their physical activity, their motivation for exercise, and their physical and emotional quality of life using teleconference call. Study staff will document the answers.
5. We will mail an activity monitor. For the participant to wear for 7 days, for at least 10 hours per day. We will also mail a time log for participants to document the time they wear the activity monitor. We will provide mailing supplies to use to mail back the activity monitor.
6. We will ask the participants several questions about their feelings about the study during a brief interview. The questions will be similar to those in the questionnaires, but the interview will allow the participant to provide more detailed answers. Topics will include how they felt about the mobile device, aspects of the game or monitor that were motivating to the participant. The interview will be audio recorded.

We will give the option to participants to complete an assessment visit when the recommended guidelines are lifted, and we are able to have a face to face visit. The visit may be completed only if participant is within a two-month period from their scheduled appointment.

Session 4. 12-month assessment (approximately 1 hour)

The visit will be conducted using teleconference communication (examples: via phone, skype, zoom)

Ongoing participants will complete Session 4: 12-month assessment using teleconference. Some of the assessment will need some modification due to our current situation and to ensure the safety of our subjects, staff and community. The following assessment will be conducted via teleconference:

1. Height and weight- we will obtain self-reported height and weight. If possible, we will obtain measurements at a future face to face visit if available.
2. Physical fitness- we will not collect this information during our scheduled visit. If possible, we will conduct this at a future face to face visit if available.
3. Physical function- we will not collect this information during our scheduled visit. If possible, we will conduct this at a future face to face visit if available.
4. We will ask the participants questions about their physical activity, their motivation for exercise, and their physical and emotional quality of life using teleconference call. Study staff will document the answers.

5. We will mail you an activity monitor. For the participant to wear for 7 days, for at least 10 hours per day. We will also mail a time log for participants to document the time they wear the activity monitor. We will provide mailing supplies to use to mail back the activity monitor.

6. If we did not perform the brief interview during the six-month visit. We will ask the participants several questions about their feelings about the study during a brief interview. The questions will be similar to those in the questionnaires, but the interview will allow the participant to provide more detailed answers. Topics will include how they felt about the mobile device, aspects of the game or monitor that were motivating to the participant. The interview will be audio recorded.

We will give the option to participants to complete an assessment visit when recommended guidelines are lifted, and we are able to have a face to face visit. The visit may be completed only if participant is within a two-month period from their scheduled appointment.

#### Mailed questionnaire assessments

We will contact participants to ask to complete a set of questionnaires via teleconference.

#### Additional study-related procedures

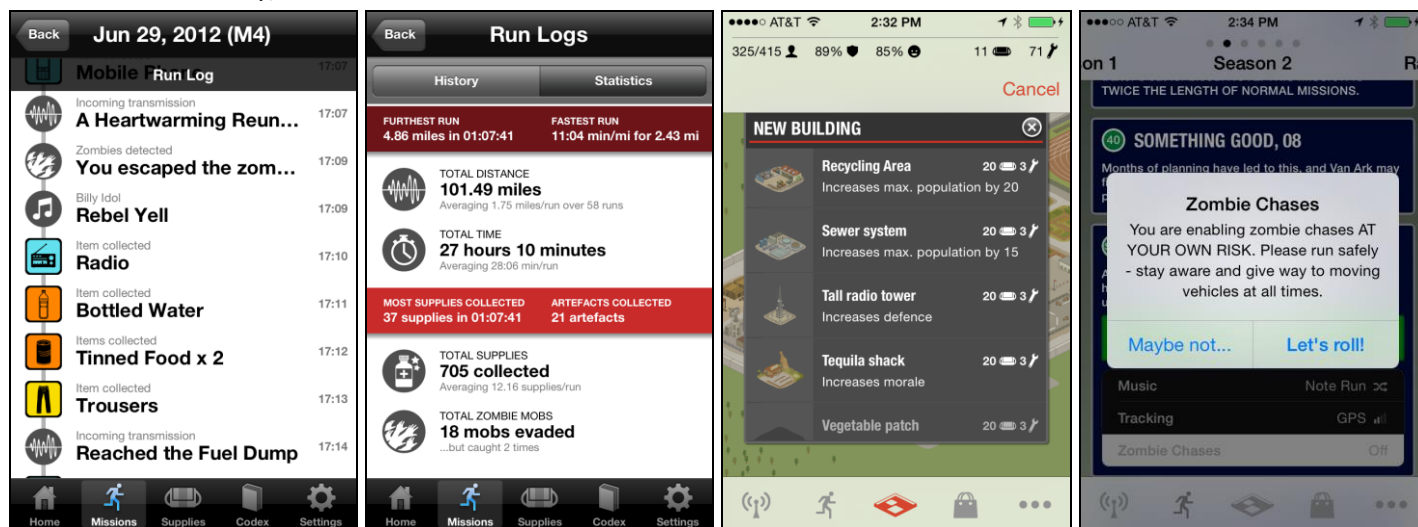
Participants will continue to participate in brief (<15 minute) phone calls during the initial six month period of the study.

During the intervention period, we will continue tracking participants activities at a distance by “friending” participants on the mobile applications. Though we will carefully watch participants pattern of activity, we will not be personally supervising the exercises. Each week, participants will be able to ask questions and receive tips and feedback on their progress during the phone calls. However, we will not be providing participants with specific oversight or guidance during their exercise sessions themselves. Study staff will not encourage exercise outside the participants home but rather other alternatives at the participants home will be encourage.

Unscheduled Visits/Phone calls: If we encounter any technical difficulties with the study material, we will troubleshoot the equipment by phone. We will be available by email and phone for technical consultation.

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. We may 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 arrange mailing of accelerometers prior to 6 month and 12 month assessments.

#### **Figure 6.2. Screenshots from *Zombies, Run!* game**



The first screenshot above shows the timeline of a walk. An audio clip from the story (which involves reuniting a father and child the player rescues) is followed by a song of the user's choosing. In this case, immediately upon beginning the song, a zombie chase occurred and was successfully completed. The player then picked up several virtual supplies during the rest of the song. Once the song was complete, another audio clip began. The third screenshot shows the base building portion of the game. Players use their virtual supplies to build their home base. Using supplies poorly or failing to protect the base adequately can have negative consequences in-game.

**Table 6.4** displays how several theoretical behavioral change strategies are matched to Self-Determination Theory constructs and narrative transportation in the games chosen for this intervention.

**Table 6.4. Examples of theoretical constructs matched to behavior change methods and strategies**

Construct	Behavior change method	Specific strategies
Autonomy support	Meaningful choices	Base building, choosing paths, choice of music, choice of character actions
	Haptic/motion controls	Inputs are task-specific and realistic, e.g. players walk as they "walk" in-game
Competence support	Verbal persuasion	Other characters reinforce competence, e.g. "You did it!"
	Modeling	Role-play as fit character, other fit characters serve as models
	Feedback	Run logs, charts, zombie moans get louder as they get "closer"
Relatedness support	Identification	Wishful identification, perceived similarity
	Parasocial interaction	Become invested in compelling characters; feel like part of a social group
Narrative transportation	Second-person narrative	"You" are addressed by other characters
	Engaging story	Suspenseful storyline with twists, action, character development
	Well-liked characters	Two main non-player characters and a large supporting cast

### F.5. Self-monitoring Intervention

Participants randomized into the self-monitoring intervention will receive a walking app preloaded onto an iPod touch device, headphones and an armband for using the device, and \$55 in credit towards purchasing music and/or additional in-app features. The app *Runkeeper* (FitnessKeeper, Inc., Boston, MA) was chosen because it includes the self-regulatory tools typical of walking/running apps without additional game- or narrative-related components. Users set up music playlists to listen during walks and indicate when they wish to begin and end their walk. On the iPod, the app measures length of time as well as steps using the device's accelerometer. Participants may also enter additional self-reported information, such as their mood upon completing the walk. Counseling will include standard self-regulatory skill building content from interventions based on Social Cognitive Theory, addressing behavior change techniques related to goal-setting, self-monitoring, feedback, problem solving, and action planning. In order to ensure that equal attention is offered to both intervention groups, counselors will spend additional time with the self-monitoring group participants by discussing monitoring and feedback topics in greater depth and with specifics related to the app (e.g., longer discussion of comparisons to past performance along with a guided tour through the app's walking logs). The purpose of the extra time spent with these participants is to match the time spent in the narrative and game group discussing narrative-specific topics.

### F.6. Measurement

**Table 6.5** displays information on the physiological and anthropometric outcomes to be assessed. Physical activity will be measured objectively using 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 the three assessment periods. Estimates will be valid if the monitor is worn  $\geq 10$  hours per day on  $\geq 4$  days. Non-wear time will be determined by 60 or more of consecutive minutes of zero activity counts. Based on criteria used for the NHANES surveys, epoch length will be one minute, and activity counts over 2020 per minute will be considered moderate-vigorous intensity.<sup>134</sup> Physical activity will be measured as minutes per week of moderate-vigorous intensity activity. Measurements from the mobile devices will also be abstracted and used as an exploratory secondary measure of physical activity. A validated and widely used self-report measure (CHAMPS) will also be used to estimate total caloric expenditure at all time points, including follow-up. The objective measure of minutes per week (measured by the armband) at 6 months will be the primary endpoint of the study, with the self-report measure providing additional insight into activity types and overall caloric expenditure.

Specific quality of life-related outcomes (depression, pain interference, anxiety, self-reported function, and sleep disturbance) will be measured using PROMIS computer adapted testing at 0, 6, and 12 months.<sup>135</sup> Participants will be emailed links to the assessment website (which stores information by ID number on a secure server). All item banks for each construct include a number of items. The computer adapted testing procedure uses item response theory to determine which items are shown to participants based upon their previous responses. No more than 12 items per construct will ever need to be answered by participants.

### 6.5. Measurement of outcomes

Variable	Measure	Specific measurement	Months Assessed	References
Physical activity	Actigraph wGT3X BT	Minutes of moderate-vigorous PA over 7 days	0, 6, 12	136
	Objective measurement from application	Frequency and duration of MVPA, steps, miles walked per day	weekly	N/A
	CHAMPS self-report questionnaire	Kilocalorie expenditure from physical activity per week	0, 6, 12	137
Physical function	Senior Fitness Test	Chair stand, back scratch, chair sit and reach, 8 foot up and go	0, 6, 12	138
Fitness	Six-minute walk test	Yards walked in 6 minutes on standard, marked track area	0, 6, 12	139
Anthropometrics	Height, weight (Tanita, Arlington Heights, IL), waist circumference	Centimeters, kilograms	0, 6, 12	N/A
Quality of life	Functional Assessment of Cancer Therapy - Breast	Physical, social, functional, emotional, breast specific	0, 6, 12	140

### Intermediate outcomes

We hypothesize in our conceptual model that several motivational and identity variables may mediate the relationship between group assignment and physical activity. Exercise identity will be measured using the Exercise Identity Scale,<sup>141</sup> a 9-item scale with subscales of exercise role identity ("Others see me as someone who exercises regularly") and exercise beliefs ("Exercise is something I think about often"). Responses range from 1 ("Strongly disagree") to 7 ("Strongly agree"). This measure is widely used with a reported Cronbach's alpha of .94, and several factor analyses have confirmed this factor structure.<sup>142,143</sup>

Motivation will be measured using the 19-item Behavioral Regulation in Exercise Questionnaire-2, which measures external ("I exercise because other people say I should"), introjected ("I feel guilty when I don't exercise"), and identified regulation ("I value the benefits of exercise"), amotivation ("I don't see why I should have to exercise"), and intrinsic motivation ("I exercise because it's fun").<sup>144</sup> We will also include four items to measure integrated regulation ("I consider exercise a fundamental part of who I am"), which is not traditionally included in exercise measures but which has been found to be an important predictor of exercise behavior.<sup>145</sup> Responses are provided on a 5-point Likert scale from 0 ("Not true for me") to 4 ("Very true for me"). The complete questionnaire with integrated regulation questions has shown reliability (between 0.70 and 0.93 for the subscales) and predictive validity.<sup>145</sup> A psychometric investigation showed discriminant validity between integrated regulation and exercise identity; though similar, these measures represent conceptually different latent constructs.<sup>143</sup>

### Other variables

We will measure several other variables in the conceptual model that relate to games and narrative. Narrative transportation will be measured using Green and colleagues' Narrative Transportation Scale.<sup>146</sup> A 15-item version will be used, which will include four items related to "imagery" that are specific to characters in the game ("While playing the game, I had a vivid image of Sam Yao") as well as the standard 11 items relating to cognitive ("I was mentally involved with the game while playing it") and affective ("The game affected me

emotionally”) aspects of transportation. Responses will be provided on a seven-point Likert scale with anchors “very much” and “not at all.” This scale is widely used and has demonstrated reliability ( $\alpha > .70$ ) in previous experiments using video games<sup>147</sup> and diverse samples of adult women viewing cancer-related narratives.<sup>148</sup> Only participants in the narrative game group will complete this scale, as its questions do not make sense in the absence of a storyline.

We will pilot test use of the Presence Self-Assessment Manikin as a crude indicator of immersion applicable to both applications. This measure consists of a row of five pictures corresponding to a nine-point Likert scale and has demonstrated predictive validity in a previous study of narrative video games.<sup>149</sup> The pictures show a figure at various distances from a TV screen. Respondents are told that “the pictures go from a person who feels he or she is inside the picture, a part of the story, a part of the action on the left end, to a person who feels he or she is outside the picture, removed or separated from the story, not part of the action on the right end.”

The Exercise Imagery Questionnaire is a widely-used measure that includes three subscales: appearance (“I imagine a leaner-me from exercising”), techniques (“When I think about exercising, I imagine my form and body position”), and energy (“To get me energized, I imagine exercising”).<sup>150</sup> An additional subscale related to enjoyment (“When I think about exercise, I imagine myself having fun while exercising”) will be included.<sup>151</sup> The resulting scale has 12 items and responses range from 1 (“Never”) to 9 (“Always”). Cronbach’s alphas ranged between 0.79 and 0.93 for the four subscales<sup>151</sup>. Tests of predictive validity have found relationships in the expected directions; for example, appearance imagery predicted controlled motivation, whereas enjoyment and technique imagery predicted autonomous motivation<sup>151</sup>.

Character identification cannot be accurately compared across groups, as the monitoring app does not include characters. To provide a proxy for character identification, we will use the procedure described by Przybylski and colleagues for investigating discrepancy between the ideal self and self while playing the game/using the app.<sup>61</sup> Participants will complete the Ten Item Personality Inventory with reference to their ideal self (at baseline), then regarding themselves while using the app (other time points). Correlations between ideal self and game-self for each of the items will be averaged, with neuroticism items reverse-coded, to create a number between -1 and 1 that indicates ideal-self and walking-self convergence. This convergence will be considered a proxy measure of the extent to which identification with the player character led to “trying on” of her characteristics.

The Play Experience Scale is a 16-item scale made up of four subscales: freedom (“I was able to make the game do what I wanted it to”), no extrinsic (“I was not worried about someone judging how I performed in the game”), play-direct (“I would characterize my experience with the game as playing”), and autotelic-focus (“When I was using the game, I was focused on the task at hand”). Responses range from 1 (“Strongly disagree”) to 6 (“Strongly agree”). This is a relatively new scale with few published studies using it, but it has demonstrated reliability ( $\alpha > .80$ ) and convergent validity with intrinsic motivation ( $r = .79$ ).<sup>152</sup>

The Basic Psychological Needs in Exercise Scale will measure autonomy (“I feel that the way I exercise is the way I want to”), competence (“I feel that exercise is an activity which I do very well”), and relatedness (“My relationships with the people I exercise with are very friendly”). Responses to this 11-item scale use a 1 – 5 Likert scale (“I don’t agree at all” to “I completely agree”). Reported alphas for the subscales were 0.75 or higher.<sup>153</sup> This scale has been used similarly in past studies, for example to investigate the relationship between perceived competence and exercise role identity (partial  $r = 0.20$ ).<sup>142</sup>

At baseline, demographic information will be collected regarding gender, race, and age. Cancer-specific information will also be collected regarding time since diagnosis, type/stage of breast cancer, and type of treatment. Participants will complete the Transportability Scale to investigate their tendency towards narrative transportation.<sup>154</sup> We will include treatment status as a covariate in our outcomes models to take into account any variability associated with treatment status.

### **Acceptability and process measures**

Acceptability and usability items will be adapted from Vandelanotte and colleagues.<sup>155,156</sup> Process measures for both groups will include logs of completed counseling phone calls, attrition, and adverse events. Objective process measures will also be recorded from the two apps. *Zombies, Run!* and *Runkeeper* will send exercise session information to the *Runkeeper* service, where an interventionist account will “friend” the participant’s account. (Participants will not have access to the *Runkeeper* account.) Number of walks per week, total minutes per week, and steps during walks per week will be abstracted from the website.

For the self-reported measures, participants will have the option to complete them on paper or on a secure website. The same website that houses PROMIS measures can be adapted to include our other questionnaire items for those who choose the Internet option.

At the 6 month assessment or 12 month assessment (if not collected at 6 months), participants will discuss intervention acceptability and individualization during in-depth interviews, which have been recommended as a method for improving the cultural sensitivity of interventions.<sup>157</sup> The interview guide will include questions related to how well the app met their individual needs and if they felt it could be tailored to their preferences. We will concentrate on personal barriers to physical activity and how apps could be individualized to better address those barriers. The questions about narrative, for the enhanced group only, will qualitatively investigate potential effects of narrative transportation on attitudes, motivation, and behavior. In addition to interviews with participants, we will also recruit 10 stakeholders from the community and ask them the same questions after a brief orientation to the study materials to be discussed. Stakeholders will be identified via pre-existing stakeholder networks and previous participants who have expressed interest in helping with intervention adaptation. Results of these interviews will be used to further adapt the intervention for better cultural sensitivity. **Table 6.7** shows example questions.

**Table 6.7. Selected questions from interview guide**

Topic	Question
Individualization	Did you feel that the app was something you could easily adapt to fit your needs and preferences?
	Is there a way the app could have been better designed to be more appropriate for you or someone like you?
Narrative	How much did you feel like the characters in the game resembled you?
	Did playing as the main character make you feel differently about yourself?

### **F.7. Power and sample size**

This study is powered to detect differences between the two groups in minutes of moderate-vigorous physical activity at 6 months. We used G\*Power to calculate sample size based on several studies that are similar to this one. Similar trials of telephone counseling and activity monitoring among BC survivors produced effect sizes ranging from 0.53 to 0.82.<sup>158-160</sup> Because our study includes a low-intensity control group that we anticipate will produce a weak effect at 6 months, we have powered for a conservative effect size for physical activity at 6 months of approximately  $d = 0.65$ , which would require an N of 78 for 80% power at an alpha of 0.05. This effect size translates to a between groups difference of approximately 20 minutes per week (SD = 30 minutes). An N of 120 would allow a fully powered test of physical activity even in the case of 20% attrition and higher variability than expected (i.e., lower effect size).

Similar studies that investigated maintenance are so few (three to our knowledge) and show such disparate results that power was difficult to calculate for this effect. For example, Rogers et al. report large differences in change scores between groups from baseline to the end of maintenance (79 vs. -22 minutes per week; 3 month follow-up),<sup>161</sup> whereas Vallance et al. report smaller differences (24 vs. -14 minutes per week; 6 month follow-up).<sup>162</sup> Even assuming large standard deviations for these change scores, our sample should be sufficient to detect group differences during the maintenance period as well.

### **F.8. Statistical analysis**

The primary endpoint of this study will be behavioral change in physical activity at 6 months (Aim 1). Our primary hypothesis is: Participants who receive the enhanced intervention will spend more minutes per week in moderate-vigorous physical activity at 6 months than will those in the standard group. To test this hypothesis, we will use an analysis of covariance to test the difference between groups at 6 months, controlling for baseline. Missing data will be imputed. As a secondary analysis, we will use linear mixed modeling to investigate changes in physical activity over time at baseline, 6, and 12 months. This procedure will provide necessary information for powering a subsequent larger trial that will require complex modeling of multiple time points. We will also use multiple imputation techniques prior to all analyses to ensure that missing data due to attrition do not bias our results. Analyses will be performed using SAS 9.2 (SAS, Inc., Cary, NC). Dr. Lyons and the research assistants will conduct all analyses in collaboration with biostatisticians from the biostatistics key resource in the Institute for Translational Sciences. Outcomes and effect sizes for other variables will be assessed using the same protocol.

Interviews with participants and stakeholders will be transcribed and coded by two trained coders. Code lists will initially be derived from Self-Determination Theory and theories of narrative transportation. Then, coders will use grounded theory to derive codes based on themes brought up by participants.<sup>163</sup> We have successfully used this procedure in the past.<sup>92</sup> NVivo qualitative software will be used to code and compare codes across

multiple coders.

#### **F.10. Potential limitations and alternative approaches**

Several limitations might hinder the project's progress.

**F.10.a. Recruitment difficulties.** First, we may have difficulty recruiting a sufficiently large sample. We will approach appropriate cancer and volunteer registries for recruitment such as the UTMB cancer registry and MD Anderson registries (email and/or phone calls). We have partnered with several area volunteer groups through which we plan to recruit, and we have budgeted for continuous newspaper, radio, and television advertisements throughout the three year data collection period. UTMB has extensive resources for assisting with recruitment, including volunteer registries and a recruitment core. If we fell behind schedule in recruitment progress, we would increase our efforts and expand recruitment to include neighboring counties (including southern Harris County, location of Houston, and up to Victoria County) and additional UTMB and M.D. Anderson clinics. Recruitment from M.D. Anderson clinics is feasible, as long drives are very common in the Houston-Galveston area. Recruitment of MD Anderson patients will occur in person at MD Anderson and joint MD Anderson/UTMB clinics as well as by phone (following the same procedures used to identify UTMB patients to approach, except by phone rather than in-person). For the two pilot studies Dr. Lyons is currently conducting, many participants live in surrounding areas  $\geq 30$  minutes' drive away from UTMB but are still willing to come in for assessments. The Breast Health Center at UTMB's mainland facility (approximately 30 minutes from Galveston and 30 minutes from downtown Houston) offers the opportunity to conduct assessments closer to Houston. We will accommodate based on location and travel convenience. We have collaborated with oncologists at various clinics to expand our effort in recruitment. A HIPAA waiver request form has been completed. With the oncologists approval, we will pre-screen patients via medical records for eligibility. The oncologists will refer their patients. We will not approach patients unless we have oncologists and patients permission.

We have allowed additional time during the five-year award period such that if recruitment is not complete in the first three years, we can continue data collection through the fourth year and still have one year for analysis and dissemination. If absolutely necessary, we can expand our inclusion criteria to include women with other cancers; we do not anticipate this being necessary, however.

**F.10.b. Retention difficulties.** The intervention and maintenance periods of the study together equal 12 months of follow-up. We have developed procedures, both within the lab and on a larger scale in the Clinical Research Core of the Claude Pepper Older Americans Independence Center at UTMB, for regular participant contact to ensure continued participation. These contacts include reminder postcards, brief phone confirmations of contact information, and collection of information on friends/family who can be listed as secondary contacts in case contact information for a participant changes unexpectedly. We will send a Thank you/holiday card during the study participation.

**F.10.c. Technical difficulties.** The monitors and/or application may present technical obstacles to some less tech-savvy participants. We will provide extensive technical assistance as needed. We will be available by email and phone for technical consultation (which we will log and measure), and will provide in-depth illustrated instructions with troubleshooting tips and frequently asked questions as part of the manual. We will allow up to one in-person meeting for technical support. We will reschedule an assessment visit twice if necessary. Based on our interventions thus far with older adults using tablets and smartphones, we believe that technical issues will not be so great as to reduce feasibility or acceptability. In case of a broken/lost ipod, we will lend one ipod for the duration of the study. We will also replace a lost charging cord one time if necessary.

**F.10.d. Phone Calls/Communication.** The calls will be generated by the research staff weekly for 3 months and monthly until 6 months (we will call two times within 15 minutes of weekly counseling phone call and arrange one make-up per week if necessary) from their randomization date. Staff will view the list on a weekly basis to make sure that calls are made on time. Once the call has been successful and the forms completed, or after 3 attempts are made, we will document the number of attempts made, the date of the last phone call and if it was successful. If a counseling call lasts longer than 20 minutes, we will end the call as quickly as possible. 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 or after-hours counseling calls. We may 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 dropping off accelerometers prior to 6 month and 12 month



assessments. 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.

### F.11. Timeline

We anticipate that data collection for this project will occur during the first 4 years of the award period, with the final year dedicated to data cleaning, evaluation, dissemination, and intervention protocol refinement (or, in the case of delays, completing data collection as well). The timeline for the award period is displayed in **Table 6.8**.

**Table 6.8. Timeline**

	Year 1				Year 2				Year 3				Year 4				Year 5			
	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
Materials purchasing and preparation																				
Recruitment																				
RCT participant contact period																				
RCT maintenance observational period																				
RCT evaluation																				
Results dissemination (manuscripts, grants)																				

Deliverables for this project include conference presentations, published manuscripts, counseling scripts, study protocols, and grant applications. We anticipate at least one publication related to the study per year, with potential examples shown in **Table 6.9**. Because this trial uses novel technology-based methods, is one of few studies that includes a maintenance period, and is fully powered on its primary behavioral outcome, we expect the outcomes papers to be published in high-impact journals. Targeting high-impact medical journals that are read by practitioners in addition to researchers (e.g., JAMA Internal Medicine, J Clin Oncol,) is part of our strategy for speeding dissemination. Ancillary papers on motivation, qualitative results, and methodology will be submitted to well-regarded discipline-specific journals. Data or specimens collected in this research might be de-identified and used for future research or distributed to another investigator for future research without your consent.

**Table 6.9. Examples of potential manuscripts based on study findings**

Year	Paper subject
1	Protocol and rationale for the study
2	Review/meta-analysis related to video game intervention studies
3	Lessons learned paper regarding recruitment, retention, and process evaluation
4	6-month outcomes paper
5	12-month outcomes paper
	Quality of life and psychological outcomes paper
	Qualitative cultural appropriateness and acceptability paper

Upon completion of data collection for the randomized controlled trial, we will draft an application for an independent research award (e.g., R01, Research Scholar Award, etc.) to fund a follow-up project. The intervention content will be modified based on process and outcome evaluation findings. The larger sample and funding of such an award will allow adequate power to detect differences in more distal health outcomes over longer intervention and maintenance periods, to formally test mediation, and to investigate moderation by race/ethnicity. Our overarching goal is to create a successful program that can eventually be incorporated into survivorship care plans and implemented on a large scale. The preliminary data provided by this research project, in combination with the training activities discussed elsewhere in this application, will provide the necessary foundation upon which a truly disseminable program can be built.

## G. EXPERIMENTAL DETAILS

### Randomization details

Participants will be randomized using sequentially numbered opaque sealed envelopes. 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 envelopes will be then thoroughly shuffled and numbered sequentially. Envelopes will be assigned to participants after baseline assessment (which will occur after orientation) in order of presentation by a member of the research team blinded to the original randomization process. The participant's ID number will be written on the envelope to ensure that the carbon paper serves as an audit trail.

### Questionnaire content

**Tables 6.9** and **6.10** display the content of several of the questionnaires to be used in this intervention, to provide context as to the nature of the theoretical constructs measured. All of the measures shown below use Likert-type response scales

**Table 6.9. Questionnaire items related to Self-Determination Theory**

Motivation	I exercise because other people say I should
	I feel guilty when I don't exercise
	I value the benefits of exercise
	I exercise because it's fun
	I don't see why I should have to exercise
	I take part in exercise because my friends/family/partner say I should
	I feel ashamed when I miss an exercise session
	It's important to me to exercise regularly
	I can't see why I should bother exercising
	I enjoy my exercise sessions
	I exercise because others will not be pleased with me if I don't
	I don't see the point in exercising
	I feel like a failure when I haven't exercised in a while
	I think it is important to make the effort to exercise regularly
	I find exercise a pleasurable activity
	I feel under pressure from my friends/family to exercise
	I get restless if I don't exercise regularly
	I get pleasure and satisfaction from participating in exercise
	I think exercising is a waste of time
Basic psychological needs	I feel I have made a lot of progress in relation to the goal I want to achieve
	The way I exercise is in agreement with my choices and interests
	I feel I perform successfully the activities of my exercise program
	My relationships with the people I exercise with are very friendly
	I feel that the way I exercise is the way I want to
	I feel exercise is an activity which I do very well
	I feel I have excellent communication with the people I exercise with
	I feel that the way I exercise is a true expression of who I am
	I am able to meet the requirement of my exercise program
	My relationships with the people I exercise with are close
	I feel that I have the opportunity to make choices with regard to the way I exercise

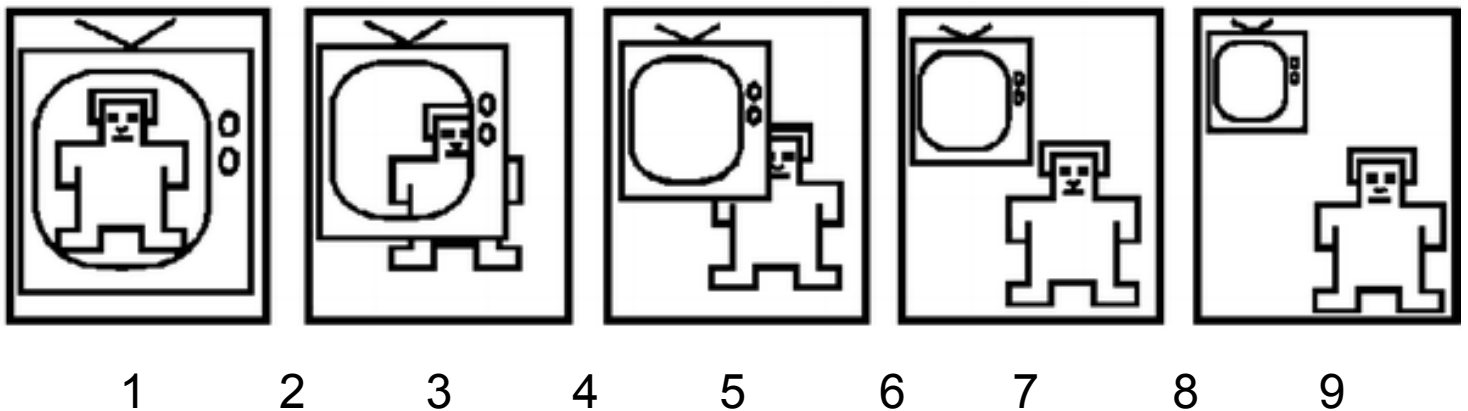
The nature of narrative transportation scales renders comparisons across groups difficult. Thus, we have included several different scales to measure different aspects of the construct. For measurement within the enhanced group, we will use the Transportation Scale,<sup>146</sup> which is widely used in the literature, and the Narrative Engagement Scale,<sup>164</sup> which provides subscales that may point to interesting areas for future work (narrative understanding, attentional focus, narrative presence, and emotional engagement). To compare the two groups, it was necessary to use a more general measure of presence (also known as engagement or immersion). Table 6.10 shows the items from the two narrative-related scales. Below the table, we have included a self-assessment manikin that is commonly used for brief but valid investigations of a general sense of engagement during a mediated experience (using an app, watching TV, playing a game, etc.).<sup>165</sup>

**Table 6.10. Questionnaire items related to Narrative Transportation**

Transportation Scale	While I was playing the game, I could easily picture the events in it taking place.
	While I was playing the game, activity going on in the room/space around me was on my mind.
	I could picture myself in the scene of the events described in the game.
	I was mentally involved in the game while playing it.
	After finishing the game, I found it easy to put it out of my mind.
	I wanted to learn how the game ended.
	The game affected me emotionally.
	I found myself thinking of ways the game could have turned out differently.
	I found my mind wandering while playing the game.
	The events in this game are relevant to my everyday life.
	The events of the game have changed my life.
	While playing the game I had a vivid image of my character.
Narrative Engagement Scale	At points, I had a hard time making sense of what was going on in the game.
	My understanding of the characters is unclear.
	I had a hard time recognizing the thread of the story.
	I found my mind wandering while using the game.
	While using the game I found myself thinking about other things.
	I had a hard time keeping my mind on the game.
	While using the game, my body was in the room, but my mind was inside the world created by the story.
	The game created a new world, and then that world suddenly disappeared when the game ended.
	At times during the game, the story world was closer to me than the real world.
	The story affected me emotionally.
	During the game, when a main character succeeded, I felt happy, and when they suffered in some way, I felt sad
	I felt sorry for some of the characters in the game.

**Below is the presence Self Assessment Manikin, with the instructions provided to participations:**

Please use the figures below to indicate your feelings or emotional response to the game. The pictures go from a person who feels he or she is **INSIDE THE PICTURE, A PART OF THE STORY, A PART OF THE ACTION** on the left end, to a person who feels he or she is **OUTSIDE THE PICTURE, REMOVED OR SEPARATED FROM THE STORY, NOT PART OF THE ACTION** on the right end. Please circle the number for the picture, or the space between any two pictures, that best represents how you felt while using the app.



### Counseling content example

Below, we present an example from our weekly brief counseling guides. The content and structure of the guides was taken from previous studies performed by co-mentor Karen Basen-Engquist. The themes for each week reflect standard behavior change counseling content and techniques, such as stimulus control, problem-solving, goal-setting, etc.

#### Week 3. Uncovering Barriers

[Discuss exercise progress report abstracted from application – ask for totals from the feedback screen(s)]

Last session we discussed finding times to fit in exercise. You mentioned that you wanted to try fitting in exercise \_\_\_\_\_. Did you try it? Did you develop plans for the rest of the week? (YES NO) Were you able to fit in exercise in times that you hadn't before? What were they? \_\_\_\_\_

We are going to use something called the IDEA process to examine ways to overcome barriers to exercise. The IDEA process stands for Identify, Develop, Evaluate, and Analyze. Let's choose one barrier and problem-solve that barrier.

I-Identify problem. \_\_\_\_\_

D- Develop creative solutions. What are some possible solutions? (just brainstorm as many as you possibly can)

\_\_\_\_\_

E- Evaluate the solutions and select the one you are most likely to implement and develop a specific plan to implement. \_\_\_\_\_

Which solution do you think would be the easiest for you to implement? This week try implement \_\_\_\_\_ and we can review next week.

A- After implementing, analyze how well it worked and revise if necessary.

HMWK: This week, think about the barrier that you chose and implement the plan. Next week we will analyze how the plan went.

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