Study Protocol and Statistical Analysis Plan
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Engaging in regular physical activity (PA) is consistently inversely associated with risk of breast and colon cancers, [3-17] with additional evidence for suggesting PA helps prevent endometrial,[18,19] pancreatic,[20] and lung[21,22] cancers. Despite these benefits, less than 5% of overweight and obese adults meet national guidelines for PA.[44] Moreover, overweight adults spend less time in PA than normal weight adults,[44-48] and are more likely to discontinue PA programs.[49,50] Affect (feeling good/bad) is important for promoting regular PA, as those who respond with less positive affect **during moderate intensity PA** are less likely to adopt a program of regular PA.[23-28] Additionally, those experiencing lower positive affect and higher negative affect **outside the context of PA** are less likely to engage in PA.[29-34] Given the importance of positive affect for adoption and maintenance of regular PA, intervention componenents that focus on enhancing positive affect may be a valuable addition to standard PA promotion interventions. Specifically, interventions derived from positive psychology[55] have shown promise in reducing depressive symptoms and increasing positive affect and are beginning to be applied to other areas of behavioral health.[56-57] Consistent with the ORBIT model[52] for developing behavioral interventions, the **aims of this project** are to, **first**, translate positive psychology theory into a 6-week, group-based positive psychology for PA promotion (PPPA) intervention for low-active overweight or obese adults (≥18 years; BMI 25-40), delivered at **local YMCAs**, and supplemented with **text messaging**. We will deliver the intervention prototype among a cohort of 10 participants. Participants and investigators will provide ongoing feedback regarding their experiences with the intervention in an iterative development process to refine the protocol. Our **second aim** is to test proof-of-concept and feasibility of PPPA in the context of a randomized pilot study among 60 low-active overweight or obese adults at local YMCAs. In an **additive design**, participants will be randomized in a 2:1 ratio to **PPPA** versus a **control** intervention including only the standard PA promotion components of the PPPA intervention (i.e., PA education, self-monitoring, and goal-setting), with **equal frequency of staff contact and text message delivery**. All participants will be followed for 6 months, and will receive a 6-month YMCA membership to equate access to PA facilities. We **hypothesize** that participants in PPPA, relative to the standard PA intervention will: demonstrate **equal or greater session treatment retention and satisfaction** (**H1**); and **more min per week of PA** as measured by accelerometry at immediate post-treatment (week 7) and weeks 13 and week 26 (**H2**). As a secondary aim we will examine effect sizes for PPPA versus the standard PA intervention on putative mediators that may underlie the efficacy of PPPA in improving PA outcomes, including positive and negative affect, optimism, happiness, life satisfaction, social support for PA, and PA enjoyment. The proposed research will set the stage for an RCT to test a novel PA promotion intervention that can be readily disseminated.

Engaging in regular physical activity (PA) is an important cancer prevention behavior. A consistent inverse association has been shown for engagement in PA and risk and of breast and colon cancers, [3-17] with some evidence for endometrial,[18,19] pancreatic,[20] and lung[21,22] cancers. As a result of the large and growing evidence base showing the protective effects of PA, NCI has emphasized funding for research on the development of PA promotion interventions to reduce risk of multiple cancers.[2]

Despite the benefits of PA for cancer prevention, rates of regular PA are low, particularly among overweight and obese adults. Less than 5% of overweight and obese adults meeting national guidelines of expending 500-1000 MET-minutes (intensity in metabolic equivalents times minutes) per week through PA of at least moderate intensity (64-76% of maximal heart rate (HR))[35] and overweight adults spend less time in moderate-to-vigorous PA,[35-39] and are more likely than normal weight adults to discontinue PA programs.[40,41]

Affect (feeling good/bad) plays an important role in promoting regular PA, as those who respond with less positive affect during moderate intensity PA are less likely to adopt a program of regular PA.[23-28] Additionally, those experiencing lower positive affect and higher negative affect outside the context of PA are less likely to engage in PA.[29-34] Given the importance of low positive affect for adoption and maintenance of regular PA, interventions based on positive psychology offer a promising means of enhancing PA promotion interventions.

Positive psychology is a burgeoning area of research that may provide valuable and innovative directions for improving on PA promotion interventions.[55] Building from a focus on personal strengths and the value of positive emotions and cognitions, interventions derived from positive psychology have shown promise in reducing depressive symptoms and increasing positive affect and are beginning to be applied to other areas of behavioral health.[56-57] Most positive psychology interventions can be readily implemented with limited additional training and treatment resources and have the potential to appeal to a broad range of individuals given their emphasis on the near-ubiquitous human goal of enhancing personal happiness. Positive psychology interventions may increase levels of PA by emphasizing the potential physical and mental health gains associated with being more active, harnessing individuals' personal strengths to address challenges to maintaining a program of regular PA, and providing techniques to savor positive events, social interactions, and social support for PA. Such intervention targets may directly impact PA behavior, and set off reciprocal effects among increased PA behavior, enhanced general positive affect, and PA enjoyment.

The **Aims of this project** are consistent with the ORBIT model[42] for developing behavioral interventions:
Aim 1: Intervention development and refinement (ORBIT Phase 1): The first aim of the project is to translate positive psychology theory and research into a 6-week, group-based positive psychology for PA promotion (PPPA) intervention for low-active overweight or obese adults, delivered at **local YMCAs**, and supplemented with **text messaging**. The in-person session and text-messaging protocol will be based on the team's previous and ongoing work developing and implementing positive psychology and smoking cessation interventions (Kahler, Bock), as well as our expertise in exercise promotion interventions (Williams; Bock). We will deliver the intervention prototype among a cohort of 10 low-active (< 60 min/week of structured PA) overweight or obese adults (≥18 years; BMI 25-40). Participants and clinician-investigators will provide ongoing feedback regarding their experiences with application of the intervention in an iterative development process to refine the protocol, improve the utility of the intervention and modify intervention materials. The milestone for Phase 1 is a finalized PPPA intervention protocol by month 6 of year 1.
Aim 2: Preliminary testing (ORBIT Phase 2): The second aim of the project is to test proof-of-concept and feasibility of PPPA. This will be accomplished in the context of a randomized pilot study among 60 low-active overweight or obese adults at local YMCAs. In an additive design, participants will be randomized in a 2:1 ratio to PPPA versus a control intervention including only the standard PA promotion components of the PPPA intervention (i.e., PA education, self-monitoring, and goal-setting), with equal frequency of staff contact and text message delivery. All participants will be followed for 6 months, including the 6-week treatment period, and will receive a 6-month YMCA membership to equate access to PA facilities. We **hypothesize** that participants in PPPA, relative to the standard PA intervention will: demonstrate equal or greater session treatment retention and satisfaction (**H1**); and more min per week of PA as measured by accelerometry at immediate post-treatment (week 7) and weeks 13 and week 26 (**H2**).
Secondary Aim: As a secondary aim we will examine effect sizes for PPPA versus the standard PA intervention on putative mediators that may underlie the efficacy of PPPA in improving PA outcomes, including positive and negative affect, optimism, happiness, life satisfaction, social support for PA, and PA enjoyment. Putative mediators will be assessed at mid-treatment (week 3), immediate post-treatment, and follow-ups. The proposed research will set the stage for a randomized clinical trial, which would be powered to test main effects and mediational mechanisms of action. Ultimately, we expect this program of research will result in a well-specified, efficacious PA promotion intervention that could be readily disseminated.

A. SIGNIFICANCE

A.1. Health benefits of physical activity for cancer prevention. The benefits of physical activity (PA) for cancer prevention are significant. Numerous large cohort studies and systematic reviews have shown consistent evidence of an inverse relationship between engagement in PA and risk and of breast and colon cancers, [3-17] with some evidence for endometrial,[18,19] pancreatic,[20] and lung[21,22] cancers. Moreover, a recent pooled-cohort study of 1.44 million adults showed associations between leisure-time PA and 13 cancer types.[1] As a result of the large and growing evidence base showing the protective effects of PA, NCI has emphasized funding for research on the development of PA promotion interventions to reduce risk of multiple cancers.[2]

A.2. Low rates of PA among overweight adults. Despite the many health benefits of PA, rates of regular PA are low, particularly among overweight and obese adults. Studies based on accelerometer data show that less than 5% of overweight and obese adults meet national guidelines of expending 500-1000 MET-minutes (intensity in metabolic equivalents times minutes) per week through PA.[35] Moreover, overweight adults spend less time in moderate-to-vigorous PA than normal weight adults,[35-39] and PA promotion studies have shown that overweight adults are more likely to discontinue PA programs and discontinue them sooner.[40,41] Thus, there is an urgent need to improve adherence to PA programs among low-active overweight and obese adults.

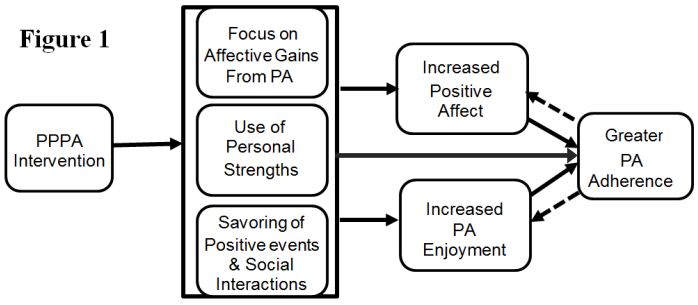
A.3. Importance of affect for PA promotion. Affect (feeling good/bad) is important for promoting regular PA. First, although both acute sessions of PA and participation in regular PA can result in increases in positive affect,[43,44] findings from our group[23,24] and others[25-28] have shown that those who respond with less positive affect during moderate intensity PA are less likely to adopt a program of regular PA as assessed 6 and 12 months later. Importantly, the latter effects have been shown even when controlling for affect assessed immediately prior to PA, thus illustrating that a less positive *affective response to PA* is predictive of poorer PA adherence. Second, research from our lab[29] and others[30-34] has shown that those experiencing lower positive affect and higher negative affect outside the context of PA are less likely to engage in PA. Thus, low positive affect and high negative affect experienced outside the context of PA are likely to be significant barriers to PA adoption. Given the importance of low positive affect for adoption and maintenance of regular PA, interventions based on positive psychology offer a promising means of enhancing PA interventions.

A.4. Positive psychology interventions. Positive psychology calls for a balanced approach to addressing behavioral health that focuses not only on ameliorating deficits and addressing psychological suffering but also building on strengths and promoting flourishing.[45] Accordingly, positive psychology interventions (PPIs) "aim to cultivate positive feelings, behaviors, or cognitions."[45] The majority of PPIs have been directed at decreasing depressive symptoms and enhancing positive affect and well-being.[46] A meta-analyses encompassing 51 studies, indicated that PPIs enhance well-being (r = .29) and decrease depressive symptoms (*r*=.31).[46] A second meta-analysis of PPIs including only RCTs with long-term follow-ups found standardized mean differences of .34 for subjective well-being, .20 for psychological well-being, and .23 for depression.[47]

PPIs are now being tested in the broader context of behavioral medicine, including trials of PPIs for family care-givers of people with dementia (R01, NINR), adolescents with Type I diabetes (DP3; NIDDK), youth substance abusers (R21; NIDA), people recently diagnosed with HIV (R01; NIMH), and cardiac patients (R01; NHLBI), including our research team's ongoing work applying PPIs to individuals with chronic pain,[48] and adolescents with suicidal ideation (R34MH101272). Promising results have been reported recently for positive affect-focused interventions to improve health behaviors in patients with hypertension and cardiopulmonary disease[49-51] and to reduce stress in healthcare practitioners.[52] As we describe below (Preliminary Studies), our team conducted a treatment development study[53] and pilot randomized controlled trial[54] of a smoking cessation treatment incorporating PPIs, with promising results, and we are now conducting an RCT comparing a PPI for smoking cessation plus text messaging versus a standard smoking cessation intervention (R01 CA201262).

A.5. Positive psychology for PA promotion. We propose to incorporate PPI techniques into a community-based PA promotion intervention: Positive Psychology for Physical Activity (PPPA). Our approach has a strong scientific premise, with multiple potential mechanisms of action specifically designed to target the low positive affect that is a barrier to PA promotion (Figure 1). **First**, evidence shows that engaging in regular PA is likely to result in significant affective gains outside the context of PA, including increased positive affect,[43] quality of life,[55] and happiness,[56] and reduced risk of depression,[57] depressive symptoms among healthy adults,[58] and anxiety.[59] On the other hand, many people, particularly those who do not engage in regular PA, experience an acute negative affective response

Figure 1



during PA.[24,60] A positive psychology-based approach to PA promotion can build upon these data by ***gain-framing PA as part of an effort to increase both physical and mental health***, while still acknowledging the challenges associated with acute negative affective responses during PA. This is similar to the approach we have taken with positive psychology and smoking cessation.[53,54] **Second**, a focus on ***accentuating individuals' strengths*** in the context of PA promotion may enhance intervention engagement. For example, positive self-affirmations[61] have been shown to reduce stereotype threat,[62] reduce biased evaluation of information,[63] and reduce defensiveness about health information leading to increased behavioral intentions.[64] **Third**, PPIs that ***focus on savoring of positive events*** and ***positive social interactions*** help to further enhance positive affect and provide a valuable counter to negative affect that may undermine PA adherence.[65] Emphasis on positive social interactions includes recruitment of social support and decreased loneliness, which are predictive of adherence to PA programs.[66,67] These three intervention targets are posited to directly impact PA adherence and to further increase PA behavior through ***enhancing overall positive affect*** and ***PA enjoyment***. Increases in positive affect outside the context of PA and PA enjoyment can improve efficiency of thinking and the ability to consider behavioral options for increasing PA, and build social and psychological resources that provide a buffer against future stress.[68-72] Indeed, an analysis of three clinical trials with patients with cardiovascular disease and asthma indicated that a positive affect intervention buffered against the effects of stress on reduced PA.[51] Thus, increases in overall positive affect and PA enjoyment will serve to increase adherence to PA programs. ***Increases in PA will, in turn, have a reciprocal effect on positive affect and PA enjoyment***, thus creating a feedback loop for positive affect, PA enjoyment, and PA adherence.

A.6. Community-based physical activity promotion. In order for PPPA to ultimately have high public health impact, the intervention must be ***readily conducted in community settings with an eye towards future dissemination***. For this project, we are focusing on delivering the intervention in the YMCA setting. The YMCA is a non-profit organization with a mission to increase the health of their clientele. There are 2,700 YMCA branches nationwide, which serve a diverse clientele in large part due to their sliding-scale policy for membership fees. Partnership with the YMCA at this stage of intervention development will ensure that the program is conducive to a community-based setting that will ultimately allow for widespread dissemination.

A.7. Use of text messaging to enhance compliance with positive psychology exercises. Development of PPPA must include easy-to-disseminate approaches to maximize participants' engagement in the ongoing exercises that must be completed outside therapy sessions—i.e., homework. In our team's prior work using PPIs for smoking cessation, a substantial portion of participants reported engaging only sporadically in homework, often citing "forgetting" as a key reason for nonadherence. Therefore, in our recent pilot work and now in our ongoing NCI-supported clinical trials, we have incorporated ***text messaging as a means of regularly prompting participants to complete PPI homework***. Text messaging is a relatively simple and low cost technology[73] that has widespread use and popularity.[74] Pew Research estimates that 95% of adults in the US own a cell phone, including 94% of non-Hispanic whites, 94% of Blacks and 98% of Hispanics; over 99% of those under age 50, 97% of those 50-64, and 80% of those 65 or older. Even among the lowest income groups, 92% own cell phones. Over 80% of all cell phone users regularly use text messaging.[75] Thus text messaging offers considerable reach across diverse populations. Moreover, text messaging has been increasingly used in health promotion research,[76,77] with meta-analyses showing favorable effects.[78-80]

B. INNOVATION

Positive psychology and the development of PPIs represents a shift from traditional social-cognitive-based PA promotion programs towards a focus on enhancing well-being and accentuating individual strengths.[45,81,82] ***We are not aware of any previous studies that have tested a positive psychology approach to PA promotion.*** Health behavior researchers have just begun to describe the potential innovative contributions positive psychology can make to health behavior interventions.[83] Moreover, use of PPIs to enhance PA is likely to have high appeal given that people across nations list happiness as a top priority in terms of life goals[84] and so such a focus may enhance treatment engagement.[81] We propose to integrate the framework of positive psychology throughout PA promotion counseling, creating a highly innovative protocol that builds from a clear ***conceptual model of intervention effects***. Additionally, while the use of text messaging is not innovative in its own right, this project is innovative in its ***use o*f ***text messaging to increase engagement and allow completion of homework exercises through texts***. Initial data suggest participants prefer to complete PPI homework exercises with text messages rather than traditional written forms. The text messaging program also is innovative in its ability to allow users to choose which PPI exercises to continue and to provide day-level data to counselors regarding homework completion. Use of text messaging is likely to enhance the effects of PPPA in a cost-effective and disseminable manner and provide valuable data on the extent to which participants engage in the PPI exercises and how this engagement predicts PA adherence.

C. APPROACH

C.1. Preliminary studies

C.1.a. Behavioral interventions for physical activity promotion. Bock (Co-I), Williams (PI), and colleagues have developed and repeatedly tested an individually tailored PA promotion intervention designed to help previously sedentary and low-active adults overcome barriers to regular PA. The intervention has been delivered through multiple media (e.g., print, internet, phone) and has repeatedly shown efficacy in increasing PA.[85-90] This research demonstrates our track record of PA promotion research among community volunteers, including extensive experience with recruitment, screening for PA contraindications, delivery of behavioral interventions, PA-related assessments (e.g., accelerometry), and participant retention.

C1.b. ***Development and evaluation of positive psychology interventions.*** Our consultant, Dr. Parks, was one of the early pioneers in the development and validation of PPIs. In her first study, a 6-week group-based PPI was delivered to college freshmen with mild to moderate elevations in depressive symptoms.[81] Participants showed significantly greater reductions in depressive symptoms than control participants through 1-year follow-up. Findings were replicated in a second study among a more age-diverse group including non-students.[91]

C.1.c. Positive psychology for smoking cessation. Kahler (Co-I) has an ongoing collaboration with Parks (Consultant) using PPI strategies for smoking cessation. In an initial study (1R01CA156241) Kahler and Parks developed a structured manual for Positive Psychotherapy for Smoking Cessation (PPT-S), which participants received favorably and which was modified based on patient and clinician-investigator feedback[53] prior to launching a successful pilot randomized trial (N=66).[54] Participants in PPT-S had significantly higher odds of abstinence (OR=2.75; p=.046) compared to those receiving standard treatment, and greater use of PPT-S strategies was associated with a less steep decline in smoking abstinence rates over time (OR=2.64; p=.04), suggesting that PPT-S had a positive effect on successful behavior change maintenance.

C.1.d. Text messaging and positive psychology. Over the past two decades, Bock (Co-I) has been conducting studies that use technology (e.g., videogames, mobile phones, expert systems, Internet, text messaging) applied to behavioral assessment and intervention. Kahler and Parks have recently partnered with Bock to develop a text-messaging component for their PPT-S intervention (i.e., PPT-S+). Based on feedback and pilot testing, the messages in PPT-S+ were reduced in frequency so that the number of messages does not become burdensome. Responses to piloting of PPT-S+ with 8 smokers have been positive. Participants responded to 83% of messages, with 7 participants indicating they prefer to complete exercises by text rather than using pen and paper, and one indicating no preference. Kahler, Bock, and Parks are currently testing PPT-S+ in an RCT. In the proposed research, we will use the same iterative methods used to develop PPT-S+.

C.1.e. Previous and ongoing partnerships with the Greater Providence YMCA. Williams (PI) has previous and ongoing collaborations with Ms. Taylor (Consultant), Vice President for Healthy Living and Membership for the Greater Providence YMCAs, including delivery of PA promotion and smoking cessation programs through multiple Greater Providence YMCA branches (R01 CA155381; R03CA188473; R01 DA21729).[92-94] Thus, the YMCA is a natural partner for development and preliminary testing of the PPPA program.

C.2. Procedures for Aim 1: Intervention development and refinement (ORBIT phase 1)

C.2.a. Overview. For Aim 1 (months 1-6), we will first develop a PPPA intervention prototype and corresponding treatment manual based on our existing PPT-S+ intervention and our extensive experience with PA promotion interventions. We will then test the preliminary 6-session PPPA intervention with 10 participants in a group format at two local branches of the Greater Providence YMCAs serving central (Kent County) and northern (Mount Hope) RI. The Research Interventionist (RI) will conduct the treatment sessions, which will be audio-recorded and reviewed by Kahler, Bock (Co-Is), and Parks (Consultant) to provide ongoing feedback and suggestions. We will also solicit feedback from participants at the end of each in-person session. Adaptation of the intervention and treatment manual will be ongoing during this stage.

C.2.b. Recruitment and screening. We will recruit 10 overweight or obese (BMI: 25-40) adults ($\geq$18y) through newspaper, internet, and radio advertisements. We will actively recruit minority women and men through targeted newspapers and radio stations. Participants must be sedentary or low-active, defined as < 60 min/week of structured PA. Exclusion criteria will be history of coronary artery disease, stroke, uncontrolled hypertension or asthma, COPD, diabetes, osteoarthritis or orthopedic problems that limit PA,. Adults with BMI > 40 will be excluded given the increased risk of unsupervised PA in these populations.[95] Only one participant per household will be permitted. Smokers will be eligible, with smoking status included as a covariate in a future RCT. Participants must be able to receive and respond to a text message at the time of screening.

C.2.c. Orientation, baseline assessment, and YMCA membership. Individuals who are eligible on an initial phone screen will be asked to attend an orientation session at the local YMCA where the Research Assistant (RA) will provide more information about the study, and the opportunity to ask questions prior to signing

consent. After orientation and consent, the RA will obtain height and weight, and observe participants use of YMCA aerobic exercise equipment to ensure adequate capacity for moderate intensity PA. Participants who remain eligible following baseline assessments will take with them an accelerometer to assess baseline frequency, duration, and intensity of ***moderate-to-vigorous PA (MVPA)*** over a one-week period. Orientations will be group-based and ongoing until 15 participants are eligible, thus allowing for a minimum of 10 participants in the PPPA intervention group. We expect to achieve this number within 2-3 weeks of recruitment. Participants will be provided a 3-month YMCA membership upon arrival at session 1 of the PPPA intervention. ***C.2.d. Primary treatment components.*** There will be 6 weekly one-hour PPPA treatment sessions consisting of core PA promotion content and positive psychology content. All participants will receive a treatment binder that contains information about each session. **Core PA promotion content** will be based on our previous PA promotion studies, and will focus on (a) health benefits of PA, (b) individualized PA intensity prescriptions based on age and resting heart rate, and instruction on how to gauge PA intensity, (c) goal-setting and self-monitoring, and (d) tips on overcoming barriers to PA, including time-management. Participants will be instructed to target 30-60 min/day 5 days/week of MVPA consistent with national guidelines.[96] PA content will be concentrated in sessions 1 and 2, but content on goal-setting, self-monitoring, and overcoming barriers will continue throughout the 6-week period. **Positive psychology content:** The exercises listed below begin in session 1 and will continue throughout the 6-week program, with PPPA homework completed via text-messaging. Specific content for each session will be determined upon development of the intervention manual. *PPPA model of PA promotion*. In the PPPA model, success in maintaining regular PA is influenced by perceived physical and mental health benefits of PA, overcoming negative associations with PA, social and environmental factors, and personal factors such as commitment to PA, optimism, satisfaction with the past, and positive emotions. Examples of how PPPA will address each of these areas will be provided. Participants will be told that the combination of positive psychology strategies and regular PA can help develop and enhance pleasure, happiness, and meaning in life. *Positive introductions.* PPPA will begin by introducing the concept of signature strengths and how those can be important in adhering to a program of regular PA. Participants are provided feedback about their 5 signature strengths based on the Values in Actions Survey[97] and asked to share (via texting) how they demonstrated one of their strengths. *Using signature strengths*. Treatment providers highlight the role that signature strengths play in leading an engaged life and assign participants to find new ways to employ their signature strengths in their daily life. This treatment element has been empirically demonstrated to decrease negative affect and increase happiness.[82] In PPPA, participants are also asked to consider how they can employ their signature character strengths to help them manage barriers to regular PA. *Three good things*. Participants are instructed to text about three good things that happened each day and their causes. This exercise has been shown to have rapid and lasting effects on reducing negative affect and increasing happiness[82] and has been employed successfully via text messaging.[98] *Savoring.* Treatment providers introduce the concept of savoring positive experiences. Participants are asked to savor at least two experiences each day for one week and text back their response to evening text prompts regarding homework completion. *Active/constructive responding*. Participants are instructed to listen carefully when people they care about report good events. They are instructed to stop and go out of their way to respond actively and constructively to these events and to keep a record of these experiences via nightly texting. *Commitment and gratitude discussion.* This exercise involves selecting an important support for PA, discussing with that person the reason one is grateful to them and the reasons they appreciate them, and asking for specific support for increasing and maintaining regular PA. [81,82] *Maintenance of happiness*. In the final session, participants discuss their experiences with PPPA and generate ways that they can modify these experiences in order to keep using them in their lives. They then choose one or two exercises to continue over the following months after treatment. **Text messaging:** Participants in PPPA will receive daily texts. Morning texts provide static messages relevant to a given PPPA exercise, while evening texts are interactive and ask for open-ended descriptions of what participants did to complete that day's PPPA exercise, with a reminder sent after 1 hour if no response is received. These responses are tabulated for the counselor. Text messages specific to a PPPA exercise are initiated at the respective counseling session at which that PPPA exercise is introduced by texting a key word, e.g., 'Savor' to initiate the savoring texts. The PPPA exercise continues each day following the session until that exercise is replaced by a new exercise. At session 6, participants choose which PPPA exercises they want to continue and receive texts based on their choice for an additional 2 weeks. Participants are also given forms for completing exercises on paper if they prefer to write longer responses or won't have cell phone access. *Text messaging platform*. We will build on the text-messaging platform developed by Co-I Bock and currently being used by Kahler and Bock.[99] This

program enables users to request additional support messages and uses two-way texting. This beta version has been successfully piloted, allowing us a quick time to start-up.

C.2.e. Interventionist characteristics and training. The characteristics of the interventionist have implications for ultimate dissemination of the Positive Psychology for PA (PPPA) program should it show initial efficacy. A bachelor's-level RI will conduct the treatment, with oversight from the investigative team. The RI will be similar in training and experience to the community-level staff that we expect would ultimately deliver the treatment in a future effectiveness trial and upon dissemination of the program. Treatment manuals will be developed to ensure consistent delivery of the PPPA and Standard PA promotion (SPA) interventions. The RI will practice the treatment protocol with other staff and students until it is delivered consistently.

C.2.f. Treatment fidelity. A treatment fidelity checklist will be created for each session and completed at the end of each session by the RI. Additionally, all treatment sessions will be audio-recorded. Review of recordings along with a second completion of the checklist will be split among Williams, Kahler, and Parks, who will meet weekly with the RI to discuss any deviations from the treatment protocol. Although we do not expect deviations from the protocol, any such deviations will be addressed by the PI, with the RI retrained as needed. Weekly meetings will also be used to assess strengths and weaknesses of treatment components and suggest revisions to the protocol that will be implemented in the next phase of research (see below).

C.2.g. Assessment timeline. Assessments will be conducted at baseline, ongoing during the 6-week PPPA program, at week 7 (one week after the final PPPA intervention session) and at week 13 (3-month follow-up).

C.2.h. Measures. **Demographics** will be collected at baseline, including gender, ethnicity/race, education, marital/relationship status, income, and employment. **PA outcomes:** Total volume of MVPA (i.e., min of MVPA weighted by intensity) expressed in MET minutes will be determined by *accelerometers* (Actigraph wGT3x-BT) worn during one-week periods at baseline (prior to the start of treatment), immediate post-treatment, and 3-month follow-up. Accelerometers will be worn on the right hip at the anterior axillary line using an elastic belt, consistent with standard practices.[100] Instructions, including proper positioning, will be provided in person at baseline and again at the final, week 6, PPPA session. As our team has done in previous studies,[101,102] we will use ActiLife software to determine PA intensity.[103] However, we will also be collecting raw accelerometry output data thus allowing for consideration of alternative cutpoints (e.g.[104-106]) and/or data processing approaches (i.e., pattern recognition[107]) as the literature develops. MVPA will also be *self-reported in diary form* over the 7-day accelerometer period. This procedure is standard in the field, as it helps to verify accelerometry outputs and also accounts for MVPA that is not easily recorded by the accelerometer (e.g., stationary bicycle). **Intervention feasibility and acceptability:** We will record PPPA session attendance and responses to the evening text-messages as objective indices of feasibility and acceptability. Retention will be coded as a dichotomous variable with participants who complete the sixth and final treatment session characterized as treatment "completers" and those not attending the final session as "non-completers." Participants will complete a Treatment Strategies Questionnaire at sessions 2-6, which will assess frequency of use of specific PPPA strategies in the past week such as planning opportunities for PA and completing the 3 Good Things exercise.[108] Responses to the questions will be used to inform the treatment feedback process. Satisfaction will also be assessed with the Client Satisfaction Questionnaire, an 8-item questionnaire that will be administered at the 7-week follow-up to assess participant satisfaction with provided services (CSQ-8).[109] **Positive psychology measures and putative mediators:** The Values in Action Survey[97] will be administered to all participants at baseline, and participants will receive feedback on their 5 "Signature Strengths" derived from this measure.[81,82] The following putative mediators will be assessed at mid-treatment (session 3), post-treatment (week 7), and 13-week follow-ups. Short-term changes in positive and negative affect will be assessed with the Positive and Negative Affect Scale.[110] Trait optimism will be assessed with the well-validated revised Life Orientation Scale.[111] Subjective happiness and subjective well-being will be assessed with the 4-item Subjective Happiness Scale[112] and the 5-item Satisfaction with Life Scale.[113] Social support will be assessed at baseline and follow-ups using the 13-item Social Support for Exercise Scale.[114] Finally, PA enjoyment will be assessed with the 18-item Physical Activity Enjoyment Scale.[115]

C.2.i. Intervention refinement. During the initial PPPA intervention group, the intervention manual and materials will be refined based on an iterative treatment development process. After each of the sessions is completed, participants will complete brief questionnaires on perceived session utility and their use of PPPA strategies in the past week. Open-ended questions will also assess the utility and acceptability of the treatment sessions and exercises. Intervention refinement will also be based on investigators' weekly reviews and discussion of the audio-recorded sessions. This will lead to a revised PPPA manual going into Phase 2.

C.3. Additional procedures for Aim 2: Preliminary testing (ORBIT phase 2).

Procedures for Aim 2 will be the same as Aim 1, with the following exceptions:

C.3.a. Recruitment, enrollment, and randomization. We will recruit 60 participants who will be randomized at a 2:1 ratio to PPPA treatment versus **standard PA promotion (SPA)** in order to focus resources on the PPPA program while still including a comparison for preliminary testing. We will run 4 groups of PPPA and 2 groups of SPA, with 10 participants per group. Urn randomization will be used to balance on sex and BMI.
C.3.b. PPPA condition. The PPPA condition will follow the revised treatment manual and text messaging program, based on feedback from Aim 1, but will follow the basic themes and procedures noted above.
C.3.c. SPA condition. The SPA condition will consist of the **core PA promotion content** (see above). To equate for session duration, additional information on health and wellness will be delivered by the staff, including topics such as skin care, alcohol use, and heart health. **Text messages** for the SPA condition will consist of reminders to engage in PA and other general motivational messages, thus controlling for total number of text messages. Because all of the PA-related content in the SPA condition will also be provided in the PPPA condition, this is essentially *an additive design, with an equal contact control*.
C.3.d. Additional 6-month follow-up and 6-month YMCA membership. For both conditions, YMCA memberships will be extended for 6 months, and an additional assessment will take place at month 6 (wk 26).

C.4. Participant retention, compliance, and incentives

We expect from our prior research experience to be able to contact 85-95% of participants at each follow-up assessment.[108,116,117] We will employ our previously successful procedures to maintain high follow-up rates.[108,116-118] Additionally, participants will be paid $25 for 7-week follow up, $25 for the 13-week follow up, and (in Study 2) $25 for the 26-week follow up. These payments are not contingent upon PA level. **C.5. Data analysis:** We will examine within-group changes from baseline in MVPA at 7 and 13 weeks. We will also tabulate scores on all treatment feasibility and acceptability measures, as well as baseline measures and putative mediators, to determine mean responses to these measures.
Aim 2. We will focus on determining **effect sizes** for PPPA rather than strict statistical significance testing. At the same time, we are well aware of the dangers of relying exclusively on small-scale pilots to determine the promise of novel treatment approaches,[119] as estimates from small samples tend to have large standard errors. Thus our hope is that we find a pattern of results that is supportive of the experimental treatment. Similar PPIs have shown medium to large effect sizes on depressive symptoms, positive affect, and happiness. Effect size estimates will include Cohen's *d* (for unadjusted between-group comparisons) and f^2 (for longitudinal multivariate models of treatment effect). For the purpose of estimating the effects of treatment on both MVPA and the putative mediators, we will fit a series of mixed effects regression models in which, for example, min/week of objectively measured MVPA at post treatment, and at 13 and 26 weeks will be simultaneously regressed on treatment group, baseline MVPA and variables not balanced by randomization. Models will allow for estimating both effects of treatment on MVPA post treatment, as well as maintenance of MVPA from 7 weeks through 6m. A similar strategy will be used to estimate effect sizes with respect to treatment effects on the putative mediators. We believe a sample size of 60 (40 intervention versus 20 control) should allow adequate examination of PPPA intervention effect sizes while staying within the scope of a developmental project. We recognize that only medium to large effect sizes will be likely to attain statistical significance with an unbalanced sample of this size. **Feasibility and acceptability:** Between-group differences for continuous measures (number of sessions attended and client satisfaction scores at post-treatment) will be conducted using analysis of variance and chi-squared analyses for dichotomous variables (treatment retention). We anticipate that treatment attendance and completion will either be equal or will be higher in the PPPA condition.
Missing data. Although our follow-up rates in previous studies have exceeded 90%,[108,116,117] some data will inevitably be missing. The proposed regression models use a likelihood-based approach to estimation and thus makes use of all available data (on the intent to treat sample) without directly imputing missing outcomes, to produce consistent estimates of the effects. However, we will compare the robustness of our findings using other statistical approaches for handling missing data, including propensity scores (in which we first model missingness as a function of observable data and then use the inverse predicted probability of drop-out as weights in the subsequent regression model). Provided the data is missing at random (MAR) or that the probability of missingness can be fully explained by observable data, this approach produces asymptotically unbiased estimates. To allow for the possibility that the MAR assumption may not hold, we will also use a second approach, pattern mixture models, in which the distribution of the outcome is assumed to follow a mixture of two distributions: one for those who complete follow up and another for those who do not.
C.6. Timeline: Given our experience with similar research, we expect to finalize the PPPA manual prototype within the first month of the study period and be ready for recruitment and enrollment in the initial study cohort (Aim 1) by month 2. This will give us two months upon completion of the 6-week program (and 7- and 13-week follow-ups) to refine and revise the treatment protocol prior to enrollment for Study 2 at the start of month 6.

Protection of Human Subjects

1. Risks to the Subjects

1.a. Human Subjects Involvement, Characteristics, and Design.

Procedures for Aim 1: Intervention development and refinement (ORBIT phase 1)

Overview. For Aim 1 (months 1-6), we will first develop a PPPA intervention prototype and corresponding treatment manual based on our existing PPT-S+ intervention and our extensive experience with PA promotion interventions. We will then test the preliminary 6-session PPPA intervention with 10 participants in a group format at two local branches of the Greater Providence YMCAs serving central (Kent County) and northern (Mount Hope) RI. The Research Interventionist (RI) will conduct the treatment sessions, which will be audio-recorded and reviewed by Kahler, Bock (Co-Is), and Parks (Consultant) to provide ongoing feedback and suggestions. We will also solicit feedback from participants at the end of each in-person session. Adaptation of the intervention and treatment manual will be ongoing during this stage.

Recruitment and screening. We will recruit 10 overweight or obese (BMI: 25-40) adults (≥18y) through newspaper, internet, and radio advertisements. We will actively recruit minority women and men through targeted newspapers and radio stations. Participants must be sedentary or low-active, defined as < 60 min/week of structured PA. Exclusion criteria will be history of coronary artery disease, stroke, uncontrolled hypertension or asthma, COPD, diabetes, osteoarthritis or orthopedic problems that limit PA,. Adults with BMI > 40 will be excluded given the increased risk of unsupervised PA in these populations.[95] Only one participant per household will be permitted. Smokers will be eligible, with smoking status included as a covariate in a future RCT. Participants must be able to receive and respond to a text message at the time of screening.

Orientation, baseline assessment, and YMCA membership. Individuals who are eligible on an initial phone screen will be asked to attend an orientation session at the local YMCA where the Research Assistant (RA) will provide more information about the study, and the opportunity to ask questions prior to signing consent. After orientation and consent, the RA will obtain height and weight, and observe participants use of YMCA aerobic exercise equipment to ensure adequate capacity for moderate intensity PA. Participants who remain eligible following baseline assessments will take with them an accelerometer to assess baseline frequency, duration, and intensity of ***moderate-to-vigorous PA (MVPA)*** over a one-week period. Orientations will be group-based and ongoing until 15 participants are eligible, thus allowing for a minimum of 10 participants in the PPPA intervention group. We expect to achieve this number within 2-3 weeks of recruitment. Participants will be provided a 3-month YMCA membership upon arrival at session 1 of the PPPA intervention.

Primary treatment components. There will be 6 weekly one-hour PPPA treatment sessions consisting of core PA promotion content and positive psychology content. All participants will receive a treatment binder that contains information about each session. **Core PA promotion content** will be based on our previous PA promotion studies, and will focus on (a) health benefits of PA, (b) individualized PA intensity prescriptions based on age and resting heart rate, and instruction on how to gauge PA intensity, (c) goal-setting and self-monitoring, and (d) tips on overcoming barriers to PA, including time-management. Participants will be instructed to target 30-60 min/day 5 days/week of MVPA consistent with national guidelines.[96] PA content will be concentrated in sessions 1 and 2, but content on goal-setting, self-monitoring, and overcoming barriers will continue throughout the 6-week period. **Positive psychology content:** The exercises listed below begin in session 1 and will continue throughout the 6-week program, with PPPA homework completed via text-messaging. Specific content for each session will be determined upon development of the intervention manual. *PPPA model of PA promotion*. In the PPPA model, success in maintaining regular PA is influenced by perceived physical and mental health benefits of PA, overcoming negative associations with PA, social and environmental factors, and personal factors such as commitment to PA, optimism, satisfaction with the past, and positive emotions. Examples of how PPPA will address each of these areas will be provided. Participants will be told that the combination of positive psychology strategies and regular PA can help develop and enhance pleasure, happiness, and meaning in life. *Positive introductions.* PPPA will begin by introducing the concept of signature strengths and how those can be important in adhering to a program of regular PA. Participants are provided feedback about their 5 signature strengths based on the Values in Actions Survey[97] and asked to share (via texting) how they demonstrated one of their strengths. *Using signature strengths*. Treatment providers highlight the role that signature strengths play in leading an engaged life and assign participants to find new ways to employ their signature strengths in their daily life. This treatment element has been empirically demonstrated to decrease negative affect and increase happiness.[82] In PPPA, participants are also asked to consider how they can employ their signature character strengths to help them manage

barriers to regular PA. *Three good things*. Participants are instructed to text about three good things that happened each day and their causes. This exercise has been shown to have rapid and lasting effects on reducing negative affect and increasing happiness[82] and has been employed successfully via text messaging.[98] *Savoring.* Treatment providers introduce the concept of savoring positive experiences. Participants are asked to savor at least two experiences each day for one week and text back their response to evening text prompts regarding homework completion. *Active/constructive responding*. Participants are instructed to listen carefully when people they care about report good events. They are instructed to stop and go out of their way to respond actively and constructively to these events and to keep a record of these experiences via nightly texting. *Commitment and gratitude discussion.* This exercise involves selecting an important support for PA, discussing with that person the reason one is grateful to them and the reasons they appreciate them, and asking for specific support for increasing and maintaining regular PA. [81,82] *Maintenance of happiness*. In the final session, participants discuss their experiences with PPPA and generate ways that they can modify these experiences in order to keep using them in their lives. They then choose one or two exercises to continue over the following months after treatment. **Text messaging:** Participants in PPPA will receive daily texts. Morning texts provide static messages relevant to a given PPPA exercise, while evening texts are interactive and ask for open-ended descriptions of what participants did to complete that day's PPPA exercise, with a reminder sent after 1 hour if no response is received. These responses are tabulated for the counselor. Text messages specific to a PPPA exercise are initiated at the respective counseling session at which that PPPA exercise is introduced by texting a key word, e.g., 'Savor' to initiate the savoring texts. The PPPA exercise continues each day following the session until that exercise is replaced by a new exercise. At session 6, participants choose which PPPA exercises they want to continue and receive texts based on their choice for an additional 2 weeks. Participants are also given forms for completing exercises on paper if they prefer to write longer responses or won't have cell phone access. *Text messaging platform*. We will build on the text-messaging platform developed by Co-I Bock and currently being used by Kahler and Bock.[99] This program enables users to request additional support messages and uses two-way texting. This beta version has been successfully piloted, allowing us a quick time to start-up.

Interventionist characteristics and training. The characteristics of the interventionist have implications for ultimate dissemination of the Positive Psychology for PA (PPPA) program should it show initial efficacy. A bachelor's-level RI will conduct the treatment, with oversight from the investigative team. The RI will be similar in training and experience to the community-level staff that we expect would ultimately deliver the treatment in a future effectiveness trial and upon dissemination of the program. Treatment manuals will be developed to ensure consistent delivery of the PPPA and Standard PA promotion (SPA) interventions. The RI will practice the treatment protocol with other staff and students until it is delivered consistently.

Treatment fidelity. A treatment fidelity checklist will be created for each session and completed at the end of each session by the RI. Additionally, all treatment sessions will be audio-recorded. Review of recordings along with a second completion of the checklist will be split among Williams, Kahler, and Parks, who will meet weekly with the RI to discuss any deviations from the treatment protocol. Although we do not expect deviations from the protocol, any such deviations will be addressed by the PI, with the RI retrained as needed. Weekly meetings will also be used to assess strengths and weaknesses of treatment components and suggest revisions to the protocol that will be implemented in the next phase of research (see below).

Assessment timeline. Assessments will be conducted at baseline, ongoing during the 6-week PPPA program, at week 7 (one week after the final PPPA intervention session) and at week 13 (3-month follow-up).

Measures. **Demographics** will be collected at baseline, including gender, ethnicity/race, education, marital/relationship status, income, and employment. **PA outcomes:** Total volume of MVPA (i.e., min of MVPA weighted by intensity) expressed in MET minutes will be determined by *accelerometers* (Actigraph wGT3x-BT) worn during one-week periods at baseline (prior to the start of treatment), immediate post-treatment, and 3-month follow-up. Accelerometers will be worn on the right hip at the anterior axillary line using an elastic belt, consistent with standard practices.[100] Instructions, including proper positioning, will be provided in person at baseline and again at the final, week 6, PPPA session. As our team has done in previous studies,[101,102] we will use ActiLife software to determine PA intensity.[103] However, we will also be collecting raw accelerometry output data thus allowing for consideration of alternative cutpoints (e.g.[104-106]) and/or data processing approaches (i.e., pattern recognition[107]) as the literature develops. MVPA will also be *self-reported in diary form* over the 7-day accelerometer period. This procedure is standard in the field, as it helps to verify accelerometry outputs and also accounts for MVPA that is not easily recorded by the accelerometer (e.g., stationary bicycle). **Intervention feasibility and acceptability:** We will record PPPA session attendance and responses to the evening text-messages as objective indices of feasibility and acceptability. Retention will be coded as a

dichotomous variable with participants who complete the sixth and final treatment session characterized as treatment "completers" and those not attending the final session as "non-completers." Participants will complete a Treatment Strategies Questionnaire at sessions 2-6, which will assess frequency of use of specific PPPA strategies in the past week such as planning opportunities for PA and completing the 3 Good Things exercise.[108] Responses to the questions will be used to inform the treatment feedback process. Satisfaction will also be assessed with the Client Satisfaction Questionnaire, an 8-item questionnaire that will be administered at the 7-week follow-up to assess participant satisfaction with provided services (CSQ-8).[109] **Positive psychology measures and putative mediators:** The Values in Action Survey[97] will be administered to all participants at baseline, and participants will receive feedback on their 5 "Signature Strengths" derived from this measure.[81,82] The following putative mediators will be assessed at mid-treatment (session 3), post-treatment (week 7), and 13-week follow-ups. Short-term changes in positive and negative affect will be assessed with the Positive and Negative Affect Scale.[110] Trait optimism will be assessed with the well-validated revised Life Orientation Scale.[111] Subjective happiness and subjective well-being will be assessed with the 4-item Subjective Happiness Scale[112] and the 5-item Satisfaction with Life Scale.[113] Social support will be assessed at baseline and follow-ups using the 13-item Social Support for Exercise Scale.[114] Finally, PA enjoyment will be assessed with the 18-item Physical Activity Enjoyment Scale.[115]

Intervention refinement. During the initial PPPA intervention group, the intervention manual and materials will be refined based on an iterative treatment development process. After each of the sessions is completed, participants will complete brief questionnaires on perceived session utility and their use of PPPA strategies in the past week. Open-ended questions will also assess the utility and acceptability of the treatment sessions and exercises. Intervention refinement will also be based on investigators' weekly reviews and discussion of the audio-recorded sessions. This will lead to a revised PPPA manual going into Phase 2.

Additional procedures for Aim 2: Preliminary testing (ORBIT phase 2).

Procedures for Aim 2 will be the same as Aim 1, with the following exceptions:

Recruitment, enrollment, and randomization. We will recruit 60 participants who will be randomized at a 2:1 ratio to PPPA treatment versus **standard PA promotion (SPA)** in order to focus resources on the PPPA program while still including a comparison for preliminary testing. We will run 4 groups of PPPA and 2 groups of SPA, with 10 participants per group. Urn randomization will be used to balance on sex and BMI.

PPPA condition. The PPPA condition will follow the revised treatment manual and text messaging program, based on feedback from Aim 1, but will follow the basic themes and procedures noted above.

SPA condition. The SPA condition will consist of the **core PA promotion content** (see above). To equate for session duration, additional information on health and wellness will be delivered by the staff, including topics such as skin care, alcohol use, and heart health. **Text messages** for the SPA condition will consist of reminders to engage in PA and other general motivational messages, thus controlling for total number of text messages. Because all of the PA-related content in the SPA condition will also be provided in the PPPA condition, this is essentially *an additive design, with an equal contact control*.

Additional 6-month follow-up and 6-month YMCA membership. For both conditions, YMCA memberships will be extended for 6 months, and an additional assessment will take place at month 6 (wk 26).

Participant retention, compliance, and incentives

We expect from our prior research experience to be able to contact 85-95% of participants at each follow-up assessment.[108,116,117] We will employ our previously successful procedures to maintain high follow-up rates.[108,116-118] Additionally, participants will be paid $25 for 7-week follow up, $25 for the 13-week follow up, and (in Study 2) $25 for the 26-week follow up. These payments are not contingent upon PA level.

1.b. Sources of Materials.

Telephone interview: Screening for eligibility criteria at baseline.

Questionnaires: Measuring demographics, and putative mediators of treatment effects at baseline, mid-treatment, post-treatment, and 13 week (3 month) and (for Study 2) 26 week (6 month) follow-ups.

Weekly questionnaires: Weekly questionnaires during the treatment period will assess frequency of use of specific PPPA strategies.

Accelerometers and physical activity diaries: For assessment of PA behavior at baseline, post-treatment, and 13 week (3 month) and (for Study 2) 26 week (6 month) follow-ups.

Text messages: Participant responses to open-ended text messages regarding intervention exercises (i.e., homework) for both assessment and treatment planning purposes.

1.c. Potential Risks.

Complications associated with physical activity. The likelihood of serious orthopedic injury or cardiac event from moderate intensity PA (as targeted in the proposed study) is low. We have had no serious injuries reported from field-based PA in our previous PA studies (HL69866, HL64342, CA137211), although there have been occasional reports of minor sprains or strains. Nonetheless, participants may suffer broken bones resulting from falls or other physical activity-related injuries that prohibit them from walking for transportation or engaging in daily activities.

Loss of Confidentiality. The likelihood of this is low and it has not occurred in our prior studies.

2. Protection against Risks.

Informed Consent: Potential participants will be recruited primarily through newspaper, radio, website, and email advertisements. Individuals who are eligible on the phone screen will be asked to attend an orientation session where they will be given more information about the study, and the opportunity to ask questions prior to signing consent. Those who agree to the procedures will provide written consent to participate. The study GRA will seek informed consent.

Complications associated with physical activity: Subjects will be screened for orthopedic problems particularly gait disturbances prior to enrolling. Subjects will also have demonstrated competence on YMCA aerobic exercise equipment as a condition of enrollment in the study (see above). Although we do not expect it will be necessary, both Brown research staff and YMCA staff have the capacity and training to deal with cardiac emergencies, with automated external defibrillators (AEDs) immediately available in each building.

Loss of Confidentiality: Confidentiality will be maintained by numerically coding all hard-copy data, by disguising identifying information, and by keeping all data in locked file drawers. All information obtained from participants will be accessible only to research staff. Data obtained from the text messaging protocol will be uploaded onto a secure server, with data coded by participant ID only. Previously entered data will be deleted following transmission to the secure server.

3. Potential Benefits of the Proposed Research to Human Subjects and Others.

The risks to participants in this study are judged to be minor (potential for sprains and strains) or of low likelihood (cardiac event, loss of confidentiality). However, participants will have the potential for great benefit in adopting a program of regular physical activity, which has been shown to enhance weight regulation and decrease risk of multiple cancers and all-cause mortality.

4. Importance of the Knowledge to be Gained.

The risks to participants in this study are judged to be minor or of low likelihood. The anticipated benefits are great, insofar as the results will be used to further understanding of the factors related to PA adoption and maintenance among previously inactive adults, which is a critical public health problem.

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