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Exercise videogames for physical activity and fitness: Design and rationale of the *Wii Heart Fitness* trial

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Abstract

Introduction: Despite numerous health benefits, less than half of American adults engage in regular physical activity. Exercise videogames (EVG) may be a practical and attractive alternative to traditional forms of exercise. However there is insufficient research to determine whether EVG play alone is sufficient to produce prolonged engagement in physical activity or improvements in cardiovascular fitness and overall health risk. The goal of the present study is to test the efficacy of exercise videogames to increase time spent in moderate to vigorous physical activity (MVPA) and to improve cardiovascular risk indices among adults.

Methods: *Wii Heart Fitness* is a rigorous 3-arm randomized controlled trial with adults comparing three 12-week programs: (1) supervised EVGs, (2) supervised standard exercise, and (3) a control condition. Heart rate is monitored continuously throughout all exercise sessions. Assessments are conducted at baseline, end of intervention (week 12), 6 and 9 months. The primary outcome is time spent in MVPA physical activity. Secondary outcomes include changes in cardiovascular fitness, body composition, blood lipid profiles and maintenance of physical activity through six months post-treatment. Changes in cognitive and affective constructs derived from Self

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Determination and Social Cognitive Theories will be examined to explain the differential outcomes between the two active treatment conditions.

Conclusion: The Wii Heart Fitness study is designed to test whether regular participation in EVGs can be an adequate source of physical activity for adults. This study will produce new data on the effect of EVGs on cardiovascular fitness indices and prolonged engagement with physical activity.

Keywords

Exercise videogames; Physical activity; Cardiorespiratory fitness; Adults

1. Introduction

1.1. Physical activity and active video games

Physical inactivity is one of the leading preventable causes of death among Americans [1]. The guidelines issued by the U.S. Department of Health and Human Services recommend that adults should engage in at least 150 min of moderate-intensity or 75 min of vigorous-intensity aerobic activity per week [2]. Participation in the recommended or more amounts of physical activity is associated with a significant decrease in the risk of cardiovascular and all-cause mortality [3–5]. However, despite numerous health benefits, less than half of U.S. adults currently engage in regular physical activity [6,7]. Even among those individuals who initiate a program of physical activity, long-term adherence is a challenge [8,9]. Approximately 50% of the individuals who begin an exercise program (e.g., supervised, community-based) stop within six months [10]. Therefore, there is a great need for effective approaches that not only promote physical activity adoption but also promote its maintenance.

A growing body of research has begun to examine physically interactive videogames that require substantial body movement and exertion for continued play. These exercise videogames (EVGs, also called “active videogames”) include products such as the Nintendo Wii, the Xbox Kinect, and dance simulation products (e.g., Dance-Dance Revolution). A number of research studies have demonstrated that playing EVGs elicits greater energy expenditure compared to rest and traditional inactive (sedentary) videogames [11–13]. The energy expenditure associated with some EVGs is similar in intensity to traditional moderate-intensity activities such as walking and cycling, at approximately 3–6 Metabolic Equivalents [14,15]. Thus, EVGs may present a viable, practical, and highly attractive alternative to traditional forms of exercise. However, most EVG research has been conducted with children. Research among adults has typically been limited to studies of the acute effects of EVGs on energy expenditure, often within single sessions [16,17].

The few existing longitudinal studies in adults have tended to focus on elderly populations and have examined the effect of EVGs on balance training [18–20], cognition [21], and depression [22]. Only one small study with college attending males (n = 14) has examined outcomes of interactive video games (combined with stationary cycling) in comparison with traditional aerobic training (stationary cycling alone) [23]. At the end of a 6-week intervention, program attendance and health related cardiovascular fitness (i.e., VO_2 max,

resting blood pressure) were significantly improved in the video game group [23]. Attendance mediated the relationship between condition and changes in health outcomes, indicating that EVGs may be more efficacious than traditional aerobic exercise through their effects on motivating people to maintain their exercise.

The goal of the present study is to test the efficacy of exercise videos games to increase time spent in physical activity and to improve cardiovascular outcomes among adults. This paper describes the design and rationale of this randomized controlled trial.

2. Methods

2.1. Study design

The *Wii Heart Fitness* study is a 3-arm randomized controlled trial with adults comparing (1) a supervised program of exercise videogames (EVG), (2) a supervised standard exercise program (Standard), using aerobic exercise equipment (e.g., treadmill, stationary bike), and (3) a health and wellness (Control) condition. Assessments are conducted at baseline, end of intervention (week 12), and 6 and 9 months follow-up. This design was chosen as the best method for answering the questions central to this study. The control condition allows testing the absolute effect of the EVG and Standard interventions relative to no physical activity intervention. This design also allows testing of the relative efficacy of EVG vs. Standard exercise within a single randomized study protocol. The use of a supervised program of standard aerobic exercise provides a stringent comparison between EVGs and the current standard of care while controlling for participant burden and contact with staff. This design will also provide information about the mechanisms that may underlie potential differences in efficacy or adherence between the different exercise formats. Twelve weeks of intervention was chosen, as it is the minimum duration of program that can reliably be expected to produce measurable changes in study outcomes [24–26]. The follow-up periods will allow us to compare whether either approach to physical activity promotes continued adherence through a six month maintenance period.

The Institutional Review Board (IRB) of the hospital where this study is conducted has approved all study procedures (The Miriam Hospital IRB registration #0000396) and a core group from the research team provides ongoing monitoring of the trial. The study is currently in the recruitment phase.

2.2. Theoretical framework

EVGs may increase motivation to persist in game play (and thus, physical activity), by their influence on certain cognitive and affective constructs that encourage increased adherence to physical activity. Social Cognitive Theory (SCT) and Self-Determination Theory (SDT) have been widely studied for the promotion of physical activity [27–30] and may provide a foundation from which we can examine the effects of EVGs. Research has shown that SCT concepts including self-efficacy [31–33], self-regulation [34,35], outcome expectancies for physical activity [36], and perceived enjoyment of physical activity [35,37,38] predict physical activity participation.

SDT proposes that decisions to engage in a behavior are based on needs for autonomy, competence and relatedness, and that behaviors are a result of an intrinsic motivation due to personal choices (autonomy) or extrinsic motivations due to external pressures [39–41]. People with greater intrinsic motivation for a behavior show increased dedication to goal attainment and tend to maintain that behavior over time [42]. These constructs may explain motivation to play videogames. Research on inactive (sedentary) videogames has shown that perceived in-game competence and autonomy predict game enjoyment, game preferences, duration of game play, and post-game feelings of well being [43]. This suggests that EVGs can be engaging, enjoyable and thus could lead to sustained physical activity participation. Consequently, EVGs could have significant effects on fitness and cardiovascular health indices. However, to date there is insufficient research to determine whether adults' EVG play alone is sufficient to produce improvements in cardiovascular fitness and overall health risk. In addition, no research has examined whether adults will continue to use EVGs over extended periods of time sufficient to constitute a source of regular physical activity.

2.3. Research goals and hypotheses

The primary outcome of this study is time spent in physical activity. We hypothesize that EVG and Standard participants will engage in significantly more minutes of physical activity than Controls at end of intervention (week 12). We will also examine maintenance of physical activity during a 6 month maintenance period in which Standard and EVG participants are given home-based programs (Months 4–9). We hypothesize that adherence to the recommended physical activity will be greater in the EVG arm than in the Standard arm at both 6 and 9 month follow-up assessments.

Secondary outcomes of the study are changes in cardiovascular fitness and health risk indices. These include changes in blood pressure, resting heart rate, peak exercise heart rate, waist/hip circumference, body composition, body mass index, and blood lipids. We hypothesize that EVG and Standard arms will show significantly greater improvement in cardiovascular fitness measures than Controls, and the EVG arm will show greater improvement in fitness measures than the Standard arm; provided our hypotheses are true that individuals spend more time in PA in the EVG arm vs. Standard.

Changes in theory-based cognitive and affective constructs that may explain the differential outcomes between EVG and Standard arms will also be examined. These constructs from the Social Cognitive Theory and Self-Determination Theory include Enjoyment, Outcome Expectations, Self-efficacy, Intrinsic and Extrinsic Motivation.

2.4. Sample size and power calculations

The primary outcome for this study is minutes spent in physical activity at week 12. Statistical power calculations were used to ensure that the final sample size would be adequate to detect between group differences. Effect size and power calculations for the primary outcome were as follows: Effect sizes for the EVG arm were based on data from our pilot study [44]. Effect sizes for the Standard and Control arms were based on previous studies [45–48]. Based on these prior studies, we anticipate the mean minutes of physical

activity reported at 12 weeks would be 124.6 (SD = 39.27) for EVG participants, 71.5 (SD = 67.3) for Standard participants, and 41.3 (SD = 41.6) for Controls.

For this study, with 83 participants randomized to each arm at baseline, would have sufficient power (> 80%) to detect a difference in physical activity minutes between all three arms, using a two-tailed significance level $\alpha = .05$. The total of 249 participants randomized at baseline includes adjustment for 20% attrition, similar to what has been seen in past studies [45,49,50]. In addition, since effect estimates for the EVG arm were based on pilot data [44] that involved a relatively small sample size, the targeted sample size for this study was increased to 100 participants per arm. This allowed for the possibility that standard deviations from the pilot data may be lower than those obtained in a fully-powered version of this intervention and it also ensures that the proposed study has adequate statistical power needed for all proposed analyses.

3. Study procedures

3.1. Participant recruitment and screening

Recruitment strategies include advertisements inviting healthy adults to participate in a "health and wellness program" using internet, newspaper, and radio advertisements as well as flyers posted in public venues. Individuals responding to advertisements can either call the study telephone to be screened by the Research Assistant (RA) or can complete an online screener to determine eligibility. To be eligible for the study, individuals must be age ≥ 18 years, in generally good health, currently sedentary (i.e., participating in <60 min of moderate or <30 min of vigorous physical activity per week), and willing to commit to the demands of the study protocol. Exclusion criteria include body mass index over 40, current or planned pregnancy, hospitalization from a physical or mental disorder in the past 6 months, hypertension (defined as: blood pressure ≥ 140/90), or taking anti-hypertensive medication or medications that may impair physical activity tolerance (e.g., beta blockers), current cardiovascular disease (i.e., physician diagnosed cardiac, peripheral artery or cerebrovascular disease), pulmonary disease, metabolic disease (i.e., physician diagnosed type 1 or type 2 diabetes mellitus, taking hyperthyroid medication), renal or liver disease, or orthopedic conditions that would prevent exercise. Individuals are also excluded if they have used an EVG at home 4 or more times over the past 3 months since this could contaminate study conditions and randomization. Individuals are also screened for safe participation in physical activity using the Physical Activity Readiness Questionnaire for Everyone (PAR-Q +) [51,52]. If one or more items are endorsed on the PAR-Q+, physician consent is required for participation. Recruitment began in January 2012.

3.2. Informed consent, enrollment and randomization

Individuals who are eligible following screening, are scheduled for an in-person orientation session in which the study RA describes the study protocol in detail and administers written informed consent. At this orientation visit it is emphasized that the individual should be willing to accept random assignment to any of the three groups. Consented individuals are then scheduled for a second visit to complete baseline assessments (Table 1). After all in-person and laboratory assessments are completed, participants are randomized to one of the

three arms using a permuted block randomization procedure, with small random sized blocks. This protocol of having two in-person visits before randomization provides the participant with sufficient time to determine their availability and commitment to the study requirements.

4. Overview of intervention

The goal for both EVG and Standard interventions is to increase physical activity to meet federal recommendations (i.e., 150 min of moderate intensity aerobic physical activity per week) [2]. The target heart rate range (i.e., moderate intensity) is calculated by using the Karvonen Formula [53]. Additionally, in both the EVG and Standard groups, participants are instructed to exercise in a perceived exertion range of fairly light to somewhat hard (11–13 on the Borg perceived exertion scale) [54].

4.1. Exercise videogames (EVG) condition

Participants randomized to this arm attend 12 weeks of thrice-weekly, 50-minute EVG sessions. Each session includes 5–10 minute warm-up and cool-down components and 50 min of moderate-intensity exercise, using a variety of EVGs available for the Xbox and Wii platform. The participant is allowed to select games to play and is permitted up to 2 changes of game if desired within each session. All games are focused on aerobic exercise training and produce a moderate or vigorous intensity exercise response during game play. All sessions are supervised by a trained research assistant (RA) who provides technical assistance with the EVG and records the games played, duration of each game, and total exercise time. The Study RA also continuously monitors the participants' heart rate throughout each session using a HR monitor (Polar RS400) and measures resting blood pressure once weekly prior to the start of the first session each week. Participants may play as many games as they choose. As needed the study RAs reminds the participants to maintain a moderate intensity of physical activity throughout the session. If heart rate falls below the moderate range, the RA instructs the participant to increase their speed and/or intensity, or choose another game. After week 12, participants are given a game console (XBox or Wii) and an EVG of their choice to facilitate their home practice.

4.2. Standard exercise program (standard)

The format for Standard exercise sessions follows the same protocol as EVG sessions: 12 weeks of thrice-weekly, 50-minute sessions. Participants are provided with a range of aerobic exercise equipment including treadmills and stationary bicycles. Each session is supervised by a trained RA and includes 5–10 minute warm-up/cool-down, heart rate monitoring throughout the session, and blood pressure recording once a week at start of session. Heart rate is continuously monitored and if it falls below the moderate intensity range the RA instructs the participant to increase their speed and/or intensity. After 12-weeks, participants in the Standard condition are provided with a print-based physical activity program, a list of local gyms, walking trails and other local physical activity resources, and a pedometer to help them maintain their participation in moderate-to-vigorous physical activity.

In both Standard and EVG conditions, participants completing less than two exercise sessions in a week are called by the project staff and encouraged to continue in the program and to schedule a make-up session within that same week if possible.

4.3. Health & wellness control (control)

Retention of participants in control conditions, such as the Health and Wellness arm used in this study, is often a challenge for physical activity interventions. Therefore, we have carefully planned our Control condition to maintain interest of the participants in the study while reducing their participation burden. The Control participants do not have contact time equal to the other two arms, but have sufficient contacts with the study staff to keep them engaged in the study. They receive print materials weekly for 12 weeks on a wide variety of general health & wellness topics (e.g., back health, sun protection, vitamin supplement, etc.). These materials include health-oriented books (e.g., *Eat This Not That*) and printed pamphlets from reliable sources (e.g., American Heart Association, American Diabetes Association) that address issues related to maintaining a healthy lifestyle. In addition, they receive health and wellness items (e.g., sun screens, stress ball, hand sanitizer.) throughout the study to encourage retention. No physical activity promotion materials are provided to the Control arm, and participants are asked to continue their normal activity levels. After the final follow-up assessment (month 9), participants in this arm are offered three 60-minute supervised exercise sessions at our facility and funds ($80) to help pay for a gym membership.

5. Data collection and blinding

Participants complete all assessments on the same schedule regardless of the treatment arm. Assessments are conducted at baseline prior to randomization, at week 12 (end of intervention) and at 6 and 9 month follow-up. In addition, other data including choice of videogames (EVG arm) and heart rate (EVG and Standard arms) are collected weekly during the 12-week program. Prior to each follow-up assessment, participants are mailed the questionnaire packet and an actigraph monitor. The follow-up visit is scheduled to occur after the 7th day of actigraph use.

5.1. Physical activity measures

Minutes of weekly physical activity as measured by the 7-day Physical Activity Recall interview (PAR) [55,56] is the primary outcome measure for this study. The PAR is administered at baseline, week 12, 6 and 9 months by a trained interviewer who is blinded to the participant's randomization assignment. The PAR is a valid, reliable instrument that is known to be sensitive to change in physical activity in interventions trials [57–61]. In addition, participants in all conditions are asked to wear an Actigraph Motion Monitor (model GTX3: Actigraph, LLC) for a 7-day period prior to each assessment point. Actigraph data will allow us to validate self-reported physical activity levels obtained from the PAR.

During the 12 week intervention the RA keeps a record of the games played and duration of each game (EVG) or exercise equipment used (Standard), and total exercise time and number of sessions attended for the EVG and Standard arms. Percent of physical activity

sessions attended will be calculated and compared between conditions. During the 6-month home maintenance program, participants in EVG and Standard arms are asked to maintain a physical activity log, which is collected by the study RAs monthly. Participants in the Health and Wellness condition are asked to complete monthly logs that record health habits not related to physical activity (i.e., hours of sleep, water intake).

5.2. Measures for cardiovascular outcomes

Resting blood pressure and resting heart rate are recorded by the RA at the baseline, 12-weeks and both 6 and 9 month follow-up visits for all participants and prior to the first exercise session of each week for those in the EVG and Standard arms during the 12-week supervised program. These readings are taken with the participant in the seated position. At each time point the study RA takes two readings of blood pressure and heart rate with the participant in the seated position after a 10-minute rest period. Heart rate is monitored by a Polar RS400 monitor that participants wear throughout the exercise session. Heart rate is monitored every second to ensure that participants stay in the prescribed moderate-intensity range. The monitor has a built-in alarm that beeps if the participant exceeds his/her threshold for target heart rate for vigorous exercise. We also record the peak heart rate achieved during each exercise session.

Dual energy X-ray absorptiometry (DXA) is used at baseline and week 12 to obtain body composition including muscle, fat, and bone mass measurements collected from whole body and regional (left arm, right arm, trunk, left leg, right leg, head) measurements at baseline and 12-week [62]. Height is measured at baseline, and body weight is measured at all four assessment times on a calibrated balance beam scale to evaluate any change in weight over the course of the study. Body Mass Index (BMI) is calculated as weight (Kg)/height (meters) squared. Waist and hip circumference are measured at each assessment point. Waist circumference is measured at the level of hip bone. The hip measurement is the largest horizontal girth between waist and thigh. Each measurement is obtained in the standing position at the end of normal expiration to the nearest 0.5 cm. Measures are obtained twice from each participant, and then averaged. A total lipid profile, including cholesterol, high and low-density lipoproteins, and triglycerides are also assessed at baseline and week 12.

At baseline and week 12, a sub-maximal exercise tolerance test is conducted to assess participant’s cardiorespiratory fitness level. During the exercise test, the initial speed of the treadmill is 1.7 mph with initial grade being 10% and then increasing speed and grade every 3 min. Heart rate and blood pressure are monitored throughout the test and recorded every 3 min (at each change in stage). Rating of perceived exertion (RPE) is assessed throughout the test and recorded every 3 min using the 15-point category scale. The test is terminated once the participant has reached his or her age predicted maximum, or exhibits signs or symptoms that call for termination (i.e., excessive rise in blood pressure, onset of angina or angina-like symptoms, etc.). Following the test, participants are given a 5 to 10-minute recovery period to ensure that heart rate and blood pressure have returned to pretesting levels [63].

5.3. Measures relevant to theory

Participants complete questionnaire packets at baseline, week 12, and 6 and 9 month follow-up that include instruments based on SDT and SCT theory. The Exercise Motivations Inventory (EMI) [64] is a 27-item scale developed to examine questions concerning the functional significance of exercise motives (i.e., external regulation, introjection, identification, and intrinsic motivation) from the perspective of Self-Determination Theory [36,65]. The internal consistency of this measure is acceptable with Cronbach's alpha reliability coefficients ranging from 0.63 to 0.90. Test-retest reliability coefficients over a 4 to 5 week period range from 0.59 to 0.88 [64,66]. The Behavioral Regulation in Exercise Questionnaire (BREQ-2) [67], a 19-item scale, is used to assess self-determined motivation in physical exercise. The BREQ-2 measures external, interjected, identified and intrinsic regulation. The BREQ has been used by numerous researchers [67–69] and has shown good psychometric properties with Cronbach alpha for all BREQ-2 subscales at 0.89 [70]. Self-Efficacy to become physically active is measured with a 5-item instrument [28] that has shown good reliability and validity with Cronbach's alpha at 0.92 [71]. Outcome Expectations for Exercise [72] is 9-item scale that assesses the individual's expectations regarding the likely outcome of exercising. This scale has shown good reliability (Cronbach alpha = 0.89) and has external validity [72]. The 8-item Physical Activity Enjoyment Scale (PACES) is used to examine perceived attributes of physical activity (e.g., *"it's very pleasant," "It's no fun at all"*). This scale has demonstrated high internal consistency and test-retest reliability in past studies [73]. The 12-item Exercise-Induced Feeling Inventory is used to assess four distinct feeling states (i.e., revitalization, tranquility, positive engagement and physical exhaustion) that occur in response to physical activity [74]. Readiness to engage in physical activity is assessed with the Stages of Change for physical activity questionnaire developed by Marcus and colleagues [28].

5.4. Other measures

Demographic information including age, gender, race/ethnicity, marital status, education, employment status and income are collected at baseline. The SF-36 is used to assess functional health and overall well being [75,76], and the 20-item Center for Epidemiological Studies-Depression scale (CES-D), is used to assess symptoms associated with depression such as restlessness, sleep, poor appetite and feeling lonely [77]. Dietary patterns are assessed using the Rate Your Plate (RYP) instrument [78], which is a simplified food-frequency questionnaire that focuses on foods contributing to the most fat, saturated fat, and cholesterol to the American diet.

5.5. Qualitative research

Qualitative methods are included to expand our knowledge about exercise maintenance after the end of supervised sessions. At the 9 month follow-up visit, semi-structured interviews are conducted by a trained interviewer with participants in the EVG and Standard arms. All interviews are audio recorded and interview notes are entered into a framework matrix for analysis. These brief, semi-structured interviews specifically explore barriers and facilitators of exercise during the maintenance phase providing an opportunity for participants to explain, in their own words whether, and how, the program had a role in shaping their

exercise choices. A framework matrix analysis [79] will explore the differences between the EVG and Standard participants, including reasons for stopping EVGs and/or maintenance of other forms of exercise. NVIVO 10 software, which includes a framework matrix tool [80], will be used to manage data and facilitate the qualitative analyses.

6. Participant incentives

Because this is a demanding protocol for participants in the EVG and Standard arms, and because individuals may be disappointed and less motivated to stay in the study if randomized to the Health and Wellness arm, incentives are used to encourage retention. At follow-up assessments all participants receive $50 compensation for each completed assessment (week-12, months 6 and 9). Participants receive $5 for each monthly log returned and are entered into a monthly drawing for $50. Participants in the Health and Wellness arm receive an additional $80 at month 9 toward the cost of a 6-month membership to a local gym.

7. Process evaluation/quality control

Standard exercise sessions are held in a separate room of the facility from the EVG room to avoid cross-contamination. Participant attendance is recorded for each session. All participant contacts, including reminder calls, session attendance and follow-ups are tracked through an electronic Microsoft Access database system. At the end of 12-week intervention, participants in EVG and Standard exercise arms complete a program evaluation form to provide their feedback on program satisfaction. PAR interviews are audio-recorded and audited on an ongoing basis to ensure appropriate administration and coding.

All data designated as primary outcome data are subject to a 100% cross-referencing with the original paper copy. All other entered data is subject to a 20% sample cross-referenced with the original paper copy. This audit must have an error rate less than 1%. If the verification fails the audit, all data will be reentered, the original computer files discarded, and the newly re-entered data audited. This process continues until the audit no longer exceeds the maximum allowable error rate.

8. Planned analyses

To test the primary and secondary study aims, the number of minutes of at least moderate intensity physical activity (measured by the PAR) is considered the primary outcome of interest. If needed, normalizing transformations will be applied to the response measure (e.g., taking the logarithm of physical activity minutes) before proceeding with analyses. This will serve to remove the effects of potential outliers. Analysis will be conducted using a repeated measures regression model implemented with generalized estimating equations (GEE) with robust standard errors. Specifically, standard errors are adjusted to account for repeated measurements [81]. To test the primary aim we will focus on the difference between treatment arms in mean minutes of PA from baseline to 12 weeks. To test the secondary aim, we will focus on difference between treatment arms in PA minutes from 12 weeks to month nine. Furthermore, using Spearman rank correlations, we will validate the

self-reported physical activity minutes (7-day PAR) with ActiGraph data at each follow-up time.

Similar analyses will be run for secondary outcomes including cardiorespiratory fitness (estimated VO_2max) and cardiovascular risk indicators (resting heart rate, peak exercise heart rate, and waist/hip circumference, blood lipids). Again, repeated measures regression models will be implemented with GEE's and resulting contrast estimates comparing treatment effects over time will be used to test tertiary aims.

It is anticipated that SCT and SDT constructs will mediate the difference in adherence to physical activity and thus differences are anticipated in outcomes (e.g., minutes of physical activity, cardiorespiratory fitness) between Standard and EVG interventions. However, the proposed sample size does not provide sufficient power to simultaneously test all possible mediators. Thus, our goal for this study is to examine differences in SCT and SDT constructs between intervention conditions (Standard, EVG, Control) over time using a repeated measures regression models [81]. This can be considered the first step in a mediation analysis.

Our primary approach to quantifying mediation effects will be the method of principal stratification [82], which was originally developed to model the causal effect of compliance with treatment, which is a post-randomization variable (as are mediators). Since measurement of the potential mediator precedes measurement of the primary outcome, principal stratification can be used to estimate the causal effect of the potential mediator on the outcome. We will compare the findings of the principal stratification analysis with the more traditional regression-based approaches. In most cases, we expect mediation to be partial and individual mediators might not meet the criterion of strict statistical significance. Since our intervention targets multiple theoretical constructs, it is unlikely that any of the individual constructs will completely mediate the intervention effect on their own. We will also explore whether treatment effects on program adherence, minutes of physical activity, and secondary outcomes differ between genders. These analyses will examine the potential of gender to act as a moderator of intervention efficacy.

All planned analyses will be conducted on the intent to treat sample, thus all randomized participants will be included in the analysis. We will compare results of different statistical approaches to handling missing data. First, we will use inverse probability weighting with propensity scores. This method involves first using logistic regression to model the probability of missingness as a function of baseline covariates and previous outcomes. The inverse of the resulting predicted probabilities (from the model) are then used as weights in our proposed regression model of the response (e.g., reported physical activity minutes at follow-up). This methodology assumes the data is missing at random (MAR). Since the MAR assumption may not hold, we will also use pattern mixture models, which assume that the distribution of the outcome (reported PA minutes) is different for those with missing data and those without. By varying the missing data assumptions, we can test how robust the findings are to these assumptions. We will compare these results to a more conservative intent to treat approach in which missing outcomes are imputed.

9. Discussion

The Wii Heart Fitness trial is innovative because it: 1) Tests the efficacy of EVGs for adoption of regular PA participation among adults; 2) Examines physiological changes in physical fitness and cardiovascular risk indices among adults using EVGs with rigorous contrast conditions (standard exercise program and contact-control); 3) Is the first to examine the potential of EVGs for helping adults to maintain longer-term physical activity; and 4) Explores the relative contribution of theoretically grounded constructs for their ability to explain potential differences in physical activity adherence between traditional physical activity formats and EVGs.

Most of the research on EVGs with adults has been conducted to examine its acute effects on physiological outcomes such as energy expenditure, heart rate or oxygen consumption [16,17]. A few longitudinal studies have been performed with older adults to examine their physical function including balance training, cognition and depression [18–22]. We found two pilot studies that have examined adherence to physical activity as a result of participation in EVGs [23,83]. However, these studies included a small sample (n = 14 to 29) of young men, were conducted for a short duration (i.e., 6 weeks), used attendance as a measure of adherence to physical activity, and did not assess long term follow-up. The Wii Heart Fitness study will examine the potential of EVGs for adoption of physical activity. It is anticipated that individuals in the EVG arm of the study will show greater minutes of physical activity participation during the 12-week intervention than Controls or those in the Standard condition (mediated by attendance).

This trial is also designed to test whether EVGs can be an adequate source of physical activity for adults comparable to a standard exercise program using more traditional equipment (e.g., treadmills, stationary cycles). In addition to determining whether adults will engage in continued EVG play (adoption), it is also important to determine whether EVGs provide sufficient increases in exertion sufficient to improve cardiovascular fitness and/or health benefits. Current research suggests that single sessions of EVG play can produce increases in heart rate similar to standard aerobic exercise [11–13]. This study adds to that literature by extending assessments to a series of regular sessions (3 times weekly for 12 weeks) and adding fitness outcome assessments as an exercise stress test, body composition and lipid analyses. It is anticipated that EVG and Standard arms will show significantly greater improvement in cardiovascular fitness measures than Controls, and provided our hypothesis that individuals spend more time in PA in EVG arm vs. Standard is supported, we anticipate that the EVG arm will show greater improvement in fitness measures than the Standard arm.

In addition, and equally important to achieving physical activity goals, it is also necessary to establish whether individuals will voluntarily engage in EVGs with frequency and duration sufficient to produce changes in health and fitness [84]. Population participation levels in physical activity are low, and among those who begin a program of physical activity, maintenance is also low, suggesting that physical activity has not proven to be an intrinsically motivating activity for the majority of the population [6–10]. EVGs are designed to be enjoyable, but their hedonic value does not rely on direct enjoyment of

physical activity per se. Thus, EVGs may contribute to increasing engagement in physical activity through other mechanisms such as intrinsic motivation. We will be able to measure whether this mechanism is operating in our sample. The Wii Heart Fitness trial is the first study to examine the potential of EVGs for longer-term maintenance of physical activity. It is anticipated that individuals randomized to the EVG arm will engage in more physical activity at follow-up compared to those in the Standard arm.

This study is also the first to explore the relative contribution of theoretically grounded constructs for their ability to explain potential differences in physical activity adherence between traditional physical activity formats and EVGs. This study will examine constructs posited by SDT and SCT for their potential to explain differential engagement in physical activity between a standard/traditional exercise program and a program of EVGs. These constructs include Enjoyment, Outcome Expectations, Self-efficacy, Intrinsic and Extrinsic Motivation. Drawing from Self Determination Theory [36,37], it is anticipated that the value of EVGs is that they present physical activity as a game, thus inspiring both entertainment/amusement and rewards which will serve to bolster intrinsic motivation for continued play. Findings that those randomized to the EVG condition engage in more minutes of physical activity than those in the standard arm would tend to support this hypothesis. It is hoped that this study will elucidate the mechanism(s) by which EVGs promote physical activity, and whether these are different than those seen in standard exercise protocols

As with all studies, there are potential limitations. It is possible that there may be differential dropout among individuals randomized to the non-physical activity (control) group. Efforts to minimize this risk of attrition include advertising the study as a health-promotion trial rather than an exercise/fitness trial, and providing monetary incentives to participants for completing assessments. We have had good adherence in the control arm in our other studies [45,47,50]. In addition, to test whether EVGs produce changes in cardiovascular fitness comparable to standard exercise protocols, it is necessary to ensure that participants engage in 3 sessions of 50 min weekly during the 12 week intervention period. EVGs used in other environments such as the home, or in a gym/fitness club would have different social and environmental influences than our laboratory, and may produce different results regarding adoption of EVGs that will be seen in this trial.

Physical inactivity is a significant public health issue that will require multifaceted approaches including innovative strategies to incorporate physical activity in daily routines. This study is an important and timely evaluation of EVG for physical activity adoption and cardiovascular outcomes among adults. To our knowledge, this is a first large scale rigorous RCT using objective measures and a long-term follow-up to establish the benefits of a technology that is rapidly growing. EVGs, if found to be effective, have potential for an important impact in the fight against obesity and cardiovascular diseases.

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Table 1

Measures and schedule.

	Baseline	Weekly (1–12)	Week 12	Monthly (4–9)	Months 6 & 9
Phone/DatSTAT (online) Screener	Screener				
Physical activity outcomes					
7-Day Physical Activity Recall	x		x		x
Actigraph	x		x		x
Stage of Change for Exercise	x		x		x
Physical Activity/Wellness Logs				x	
Cardiorespiratory fitness					
Stress test	x		x		
Body Composition (DEXA)	x		x		
Lipids (triglycerides, HDL, LDL)	x		x		
Resting BP, HR, Peak HR	x	x	x		x
Waist/hip circumference	x		x		x
Height/Weight	x		x		x
Physical activity covariates					
Exercise Motivations Inventory	x		x		x
Behavioral Regulation in Exercise Questionnaire	x		x		x
Self-efficacy for Exercise	x		x		x
Outcome Expectations of Exercise	x				
Physical Activity Enjoyment Scale	x		x		x
Exercise-Induced Feeling Inventory	x		x		x
Feeling/Felt Arousal Scale		x			
Other covariates					
Demographics	x				
SF-36	x		x		x
Center for Epidemiological Depression Scale	x		x		x
Patient Health Questionnaire	x		x		x
Rate Your Plate	x		x		x
Process measures and program evaluation					
Program attendance (Weeks 1–12)		x			
Games/Equipment used, duration		x			
Program Satisfaction Questionnaire			x		
Interviews (EVG + Standard groups)					x
Quality control					
Audit 10% of PAR interviews					quarterly
Audit 100% of primary outcome + 20% rest of the data entry					quarterly
IRB audit of consent documents					periodic

BP = Blood Pressure; HR = Heart rate; HDL = High density lipoproteins; LDL = Low density lipoproteins; trigly = triglycerides.