A Skills-based RCT for Physical Activity Using Peer Mentors

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**Research Protocol : A Skill-Based RCT for Physical Activity Using Peer Mentors**

## I. Objectives/Aims of the Study:

The long-term goal of this study is to positively impact the physical activity patterns to improve health outcomes including the high rates of obesity in Appalachian teens. For this RCT, we will train peer mentors to deliver the culturally appropriate intervention and provide social support that is critical for facilitating and sustaining health behavior change. Our objective is to compare the efficacy of an innovative healthy lifestyle skills mentoring program (*Mentored Planning to be Active [MBA]*) to a teacher led program (PBA) for increasing physical activity in Appalachian high school teens. Our specific aims are:

**Aim 1:** Compare the efficacy of peer-led delivery **(MBA)** to teacher-led delivery **(PBA)** on health outcomes.

a. Examine the relationship between health behaviors (sugar sweetened beverage consumption, sleep patterns, and health outcomes (body mass index, body fat at baseline)

**Aim 2:** Compare the efficacy of peer-led delivery **(MBA)** to teacher-led delivery **(PBA)** on physical activity behavior outcomes of Appalachian teens.

**Aim 3:** Examine the behavioral impact of the mentoring approach on teen mentors and teachers.

**Aim 4:** Examine the usefulness, ease of use, general satisfaction, and suggested refinements of the approach by the teen mentors and teachers.

**AIM 5**: Determine if self-regulation skills and exercise self-efficacy mediate the relationship between health outcomes and moderate/vigorous physical activity.

## II. Background and Rationale:

### Background

Rural Appalachian populations have poorer health and fewer positive health-related behaviors[1-4] compared to other United States populations .[5-6] Appalachians are the most sedentary population in the U.S.,[7-8] and teens are particularly sedentary. Only 13.6% of adolescents reported 60 minutes of daily moderate activity, while 38% reported no moderate physical activity in the past week and 78.2% reported no vigorous physical activity in the past week.[1,2,9] Obesity prevention through improving physical activity is a top priority in Rural Healthy People 2020.[13] The prevalence of obesity among Appalachian teens exceeds national rates and is greater than 25%.[10-12]

In academic underperforming schools such as those prevalent in Appalachia, the primary educational focus is to meet core academic mandates. To meet academic mandates, despite school-based health education and physical education programs, most Appalachian schools no longer require health and physical education. Low rates of physical activity and high rates of obesity persist in Appalachia. Efforts to improve physical activity in school-aged adolescents residing in Appalachia have relied on organized sports and school-based curricula delivered by teachers. These approaches have not been effective for Appalachian teens.[19] One explanation may be **unique circumstances** present within Appalachia. Opportunities to participate in organized sports are limited due to inadequate school resources, lack of available transportation, and limited availability of school teams. As a result, most adolescents residing in Appalachia are unable to participate in organized sports. Further, school-based health interventions are limited in their scope and impact on obesity prevention.[22-25] School-based interventions typically deliver content as part of a regular course such as health or physical education via teachers in classroom settings (this is the proposed comparison intervention). Low efficacy of these programs may be due to unique cultural challenges: a preference for informal sharing of information among local residents rather than health content delivered by formal teachers. Rarely do adolescent obesity prevention programs use peer mentoring. Though school-based interventions increase health knowledge, there is less evidence of the effectiveness for health behavior changes leading to **obesity prevention**.[24-26] Longer-term follow-up of health behavior and health status outcomes in intervention studies are lacking.[24,27]

### Rationale

*Planning to be Active* (PBA)[2-4] is a theory-based program for promoting regular physical activity in high school teens in Appalachia. In pilot studies, PBA was delivered by classroom teachers and showed efficacy in producing short-term increases in physical activity. Additionally, the research team has developed and tested a peer mentoring program based upon similar theoretical constructs used in PBA to successfully promote daily physical activity changes in Appalachian youth.[14-15] Building upon these successes and our experience in this highly vulnerable population, we propose to expand the PBA intervention to be delivered in an after school program by trained high school mentors from Appalachia. We predict that peer mentors will be more effective than classroom teachers and will improve their own health behaviors, providing a double-edged intervention.[16] Employing high school mentors as agents of change further addresses a unique need of Appalachian residents who often lack access to or trust in health professionals.

## III. Procedures:

### A. Research Design

Our approach is to randomize participants to one of two groups: (1) intervention: Peer Mentoring (MBA), and (2) comparison: Teacher-Led (PBA). We will test the hypothesis that, compared to delivery by teachers in a classroom setting (usual care), an innovative delivery format of PBA by local peer mentors (trained 11$^{th}$ and 12$^{th}$ grade teens) will promote the adoption of healthier physical activity and regular exercise among 9$^{th}$ and 10$^{th}$ grade teens not engaged in organized sports by combining (a) peer mentoring by trained high school students to younger adolescents with (b) a tailored self-regulation lifestyle program. We propose a **group-randomized controlled trial** (G-RCT) to evaluate mentored delivery of a school-based intervention to improve physical activity behaviors and health outcomes among high school students in Appalachian Ohio. G-RCTs are characterized by random assignment of identifiable social groups (rather than individuals) to study conditions, with measurements taken on members of those groups to assess the impact of the intervention.[44,45]

Prior to the intervention (baseline data), we plan to complete a sub-analysis of the relationship between health behaviors from lifestyle behavioral scale (sleep patterns reported and sugar sweetened beverage consumption rates and measured body mass index and body fat percentage).

### Sample

We conducted a careful analysis of sample size calculations for primary analysis of the primary outcome: BMI in adolescents at 6 months post intervention. As discussed further below, we will use a mixed model ANCOVA in our primary analysis. Power calculations for this approach are given by Murray.[42] Power in a G-RCT is influenced by five factors: number of groups (schools), number of individuals in each group (adolescents in each school), similarity of outcomes within clusters (school-level intra-class correlation [ICC] for BMI), similarity of outcomes within individuals (correlation of BMI measurements on the same student over time), and percentage of the variance that can be explained by the regression model. Using data from the **Ohio Family Health Survey**, we estimate that the school-level ICC for BMI among 9th graders in Appalachian Ohio counties is 0.023. We further estimate the over-time correlation of BMI measurements is 0.70 and that adjusting for age and gender will explain approximately 30% of the variance in BMI. With these assumptions, 10 schools per condition, and 75 students per school, we will have 82% power to detect a modest intervention effect (0.2 standard deviation difference between groups). This effect size would correspond to a difference in mean BMI between groups of 1.04 kg/m $^{2}$ if the observed variation in BMI is similar to that of all Appalachian 9th graders from the Ohio Family Health Survey (mean BMI = 23.41, *SD* = 5.2).

With an average of 75 mentee participants per school (50% participation rate of eligible students based on our preliminary work), we estimate that a total of 1,500 9$^{th}$ and 10$^{th}$ grade participants will be recruited over 2 years (750 per year). Further, 190 older teens will be recruited to serve as peer mentors (19 per school x 10 schools) in the MBA condition, for a study total of 1,690 high school-aged children. Recruitment of mentor and mentee participants will occur during the start of the school year (September).

At the end of the academic year, we will randomly select at least 1 PBA teacher and 5 teen mentors from each school that delivered the curriculum that year to participate in cognitive interviews. These semi-structured interviews will be conducted individually and will be audio-recorded . Audio recordings will be transcribed verbatim . Each interview will last approximately 30 minutes and will be held in a private room at each school.

**Participant Recruitment and Retention**

Nine school districts from 9 rural Appalachian Ohio counties have agreed to participate; an excess of 10 schools needed for Wave1. Wave 2 schools will be recruited during Year 1 of the study (with amendment to IRB protocol once letters of support are received). Peer mentors will be recruited based on interest in working with peers, supporting others, and striving to cultivate their own health-supportive behaviors. Eleventh and 12th graders attending the target high school at the study's start will be eligible to participate as mentors if they are not expected to move from the participating school before the conclusion of the study; can speak English; and are recommended by a teacher, school advisor, or counselor. Teens interested in serving as mentors will complete an application form; selection will be based on: study needs, motivation to serve, and recommendations. Teen mentors with a BMI (for age and gender) above the 85th percentile or below the 5th percentile at the start of the study will be excluded because of concerns about those not classified as having a healthy weight serving as role models for healthy lifestyle behaviors. These exclusionary criteria will be clear in recruitment materials so those excluded understand why. All teen mentors will attend the same school and reside in the same local community as study participants. Each peer mentor will be assigned up to 4 adolescents (2 per session; 2 possible sessions each week); we will recruit 19 peer mentors per school. We will attempt to match mentors and mentees by gender.

School health teachers at participating schools will provide the comparison delivery method. With approximately 25 students per classroom, we anticipate 3 classrooms to participate in each comparison school. Based on preliminary studies, an 80% retention rate is expected, resulting in 82.5% power to detect a modest intervention effect. To aid retention of subjects, monetary incentives at each data collection time-point and booster kits for use during the summer months will be provided. In addition, attendance will be taken at all sessions; the PI will contact all subjects missing a session within 48 hours.

## IV. Measurement/Instrumentation

**Measures.** Our measures are comprised of items adapted from published studies and preliminary studies. All measures have been used with adolescents residing in rural or Appalachian settings and show acceptable psychometrics: internal consistency reliability α of .75-.94; face validity, predictive validity, and content validity, and/or construct validity are established (See Table 1).

**Table 1. Variables, Instruments, Reliability, Validity and Data Collection Times for the Teens**

| Variable from Theoretical Framework | Instrument/ Source of Data | Cronbach's Alpha | Type of Validity | Data Collection Times | | | | Measure Used in Statistical Analysis |
|---|---|---|---|---|---|---|---|---|
| | | | | Pre | | 3 mo | 6 mo | |
| **Demographics** (potential covariates/ moderators) | Demographic questionnaire | NA | NA | X | | | | Item ratings/answers |
| **Behavioral Outcomes** | Healthy Lifestyle Behaviors Scale | .84 and ↑ | Face, Content Construct | X | | X | X | Total score on the Healthy Lifestyle Behaviors Scale |
| | Accelerometer Activity | | | X | | X | X | 7 days of daily activity |
| **Behavioral Outcomes** | Daily Lifestyle Patterns | | Content, Construct | X | | X | X | 4-item questionnaire |
| **Primary Health Outcomes** | Body Mass Index, BMI%, Body Fat% | NA | NA | X | | X | X | BMI, BMI%, Bio Electronic Impedance |
| **Psychological Determinants** | Physical Activity Outcome Expectations | .86-.97 | Construct Predictive | X | | X | X | Total Score on each of 8 sub-scales: relaxation, fitness, competition, social growth, social continuation, health Total Score |
| | Self-Efficacy for Physical Activity | 85-.94 | Predictive | X | | X | X | |
| **Self-Regulation** | Self-Regulation for Physical Activity | .89-.95 | Content and Construct | X | | X | X | Total score on each 6 subscales: goal setting, self-monitoring, overcoming barriers, time management, self-reward, planned support |
| | Social Support | .75-.88 | Face and Construct | X | | X | X | Total Score |
| **Environmental Determinants** | Perceived Environment for Physical Activity | Test-retest (59%-74%) | Construct | X | | X | X | Total score on each of 1 subscale: neighborhood |

## Demographics

**Demographic Questionnaire.** Participants and peer mentors will complete a demographic questionnaire with: age, birthdate, grade in school, gender, race and ethnicity, zip code, and household members.

**Primary Health Outcomes**

**Body Mass Index (BMI)**: The primary outcome of BMI will be computed by measuring height and weight for each participant. BMI measurement procedures are further described in Appendix A. We propose actual BMI as the primary outcome because this is a long-term trial. BMI z-scores are widely used and recommended for cross-sectional comparisons because they take into account differences in age and gender that may confound those comparisons. Recently, however, several authors have cautioned against the use of BMI z-scores for research using longitudinal designs, citing concerns that their use could result in spurious differences between groups.[55,56] One reason for this problem is that children at the extreme ends of BMI distribution require substantially greater changes in weight than their thinner counterparts for the same change in z-score. Because the BMI z-score curves were constructed using only data between the 3rd and 97th percentiles, the CDC recommends caution when using growth curves outside this range.[57] Berkey et al. noted that the difference between z-scores reflect larger differences in BMI in older compared to younger children.

Using CDC guidelines by age and gender, we also will calculate BMI percentiles with healthy weight status is defined as between the 25th and 85th percentile; overweight status is defined as between the 85th and 95th percentile; and obese is defined as above the 95th percentile.[54]

**Body Fat Percentage**: Body fat percentage readings will be obtained by a portable body electronic impedance (BEI) device. During each data collection cycle, two measures using BEI will be obtained. The average percentage from the readings will be recorded.[58,59] Room will be a normal ambient temperature (about 72$^0$ F). Participants will lie supine on a mat with non-conductive surface. with arms and legs abducted at 30-45 degree angles from the trunk.[89] Electrode skin sites will be cleansed with alcohol wipes prior to application. Two distal current-introducing introducing electrodes will be placed on the dorsal surfaces of the hand and foot proximal to the metacarpal phalangeal and metatarsal phalangeal joints, respectively.[89] Two voltage-sensing electrodes will be applied at the pisiform prominence of the wrist and between the medial lateral malleoli of the ankle.[89] BEI measurements will be taken in the morning hours and prior to engagement of MVPA for that day. Participants will be instructed to be normally hydrated and urinate within 30 minutes of test.[89] See Appendix A for measurement procedures. BEI data will be adjusted for height to allow for the estimation of total body water (TBW), relating height$^2$/impedance to TBW.[90] TBW will be converted to total fat-free mass (FFM) from which body fatness will be estimated using equation accounting for height, resistance in ohms, body weight in kg and age.[91] See Appendix A for complete equations.

**Behavioral Outcomes**

**Daily Physical Activity**: Student, peer mentor, and teacher participants will wear **accelerometers** for 7 straight days (1 week) of physical activity data collection measures for each data collection cycle (described above). The data will be used to estimate time spent in sedentary, moderate, and vigorous activity. Readings at or above 3962 counts per minute will be treated as vigorous physical activity.[61,62,92] Moderate physical activity cut points are between 1535-3961 counts per minute.[92] Readings between 100-1534 counts per minute are light activity.[92] Readings less than 100 counts per minute will be treated as sedentary activity.[87,88,92] Two or more hours of zero counts suggests that device as not worn and will be excluded from sedentary analysis.[92]

**Healthy Lifestyle Behaviors Scale:** Student and peer mentor participants will respond to 8 items on a 5-point Likert scale. Face and content validity are established for physical activity and sedentary behaviors (8 items) when used with teens.[63] Internal consistency reliability has been reported at α =.78 when used with teens.[63]

**Daily Lifestyle Patterns:** A 4-item questionnaire will be given to ask participants to estimate their daily SSB consumption, water consumption, and hours of sleep per day during the past 4 weeks. Internal consistency reliability has been reported (α > .80) when used with teens residing in rural Appalachia (Smith & Holloman, 2014). .

**Psychosocial Determinants**

**Outcome Expectations for Physical Activity:** The outcome expectancy values instrument in this study assesses outcome expectations and their associated expectancies for physical exercise by requesting information on six dimensions: relaxation, fitness, competition, social growth, social continuation, and health Each of the eight dimensions is measured by five items. Previous studies demonstrated internal consistency, reliability coefficient ranging α = 0.86-0.97 when used with Appalachian teens.[64,65] Construct validity has also been demonstrated through three confirmatory factor analyses using data from our previous work.[64,65]

**Self-Efficacy for Physical Activity:** Self-efficacy will be measured using a previously developed instrument with 14 items.[65] The instrument has demonstrated predictive validity for boys and girls: 0.23 and 0.27.[65] Re-test reliability of this scale has been reported to be 0.82.[64,65] This instrument has been refined by adding three additional items and altering the response scale from dichotomous to a five-point Likert-type scale, with internal reliability consistency ranging α = .85-.94.[64,65]

**Self-Regulation**

**Self-regulation for Physical Activity Questionnaire** contains six subscales: Behavioral Goal Setting, Self-Monitoring, Overcoming Barriers, Time Management, Self-Reward, and Planned Social Support.[66] The instrument was developed by Co-PI Petosa using a three-stage expert panel review to establish content validity. Internal reliability ranged from 0.89 to 0.95.[66] Construct validity has been demonstrated through confirmatory factor analyses.[66]

**Social Support:** Social support is measured using a self-report questionnaire containing 13 items originally developed by Reynolds et al.[67] and refined by Trost et al.[68] This instrument measures instrumental social support, social encouragement, and social expectations that are provided by friends and family members for physical exercise. In order to increase the internal reliability of the instrument, the original reporting scale was expanded to a five-point Likert-type scale.[37] This instrument has previously been demonstrated to have construct validity.[177,178] Internal reliability ranged α = .75-.88, and re-test reliability ranged R = 0.78-0.93.[64,65]

**Environmental Determinants**

**Perceived Environment for Physical Activity:** Perceived environment is measured by one Likert scale. The 8-item subscale focuses on the perceived neighborhood environment. Construct validity and test-retest reliability have been established for this scale when used with adolescents residing in rural communities.[69]

**Acceptability, Ease of Delivery, and Usefulness of Curricula Delivery Approach**

**Cognitive Interviews**: Semi-structured interviews will be conducted on a randomly selected subset of mentor and teacher participants. Questions focus on acceptability, ease of delivery, and usefulness of curriculum.

## B. Detailed Study Procedures

Anthropometric and other quantitative data will be in a designated private room at each participating high school at all data-collection time-points ($T_1$, $T_2$, and $T_3$). Questions will be read aloud to accommodate any reading difficulties and be available to answer questions. Prior to baseline data collection, a series of training sessions will be held to train data collection staff responsible for taking measurements, including physical activity using Actical accelerometers (Actical, Bio-Lynx Scientific Equipment, Montreal), BMI, body fat, and administration of the data collection instruments. The measurement team training will held at the Project Office located on the OSU campus. In order to assure standardization and quality of data collection, this training will include a review of the eligibility criteria and consent procedures; overview of the measurement protocol; demonstration of the measurement methods; and an opportunity to have each measurement team mock data collect on several subjects and gain expert feedback on their ability to follow protocol. This training will occur prior to each data collection time period ($T_1$, $T_2$, and $T_3$). The accelerometer data collection training will be done by Dr. Petosa. Dr. Petosa is an expert in accelerometer use and accelerometer data processing. Body fat analysis measurement training will be conducted by Dr. Smith an advanced practice registered nurse and expert in the collection of anthropometric data in community settings. The survey data collection training will be conducted by Petosa and Smith. The Project Office will ensure that the measurement teams perform only those functions for which they are certified, and that re-certification activities are implemented as planned in a timely manner.

Participants will receive $15 at each data-collection time-point. Anthropometric measures (height, weight, and body fat) will be collected from each privately. BMI will be calculated by: weight (lb)/[height (in)]$^2$ x 703 (Measures). Pilot testing found anthropometric data collection will take 10-15 minutes. BMI percentiles for children will be calculated via computer using CDC guidelines. Data from peer mentors will be collected by an RA at completion of mentor training ($T_1$), at the end of the academic year ($T_2$), and beginning of the following academic year ($T_3$). See Table 5 (next page) for the data collection plan and process.

In adherence to school and district policies, teacher participants will not be provided any financial incentive for their participation.

Informed consent will be documented on a participant tracking form. This form allows linkage of the participant to their study identification number. For subsequent data collection, the identification number will be used instead of any identifiable information. All databases will be encrypted and password-protected. We will use a registration and tracking number that is randomly generated to document all measurement activities within individuals. Once informed consent is given, information on physical activity levels will be collected using the Actical accelerometer. Collection of the physical activity variable requires that the Actical be worn by the study participant for seven study days, and requires two school visits by the measurement team for each participant. Participants will be informed of the procedure used to wear the Actical monitor as outlined in the Actical user manual. There will be a demonstration of the correct right iliac crest placement of the monitor using a belt provided by the study. Each subject will receive a belt that allows for the correct placement of the monitor and written directions for the subject and parent to assure correct placement of the device in subsequent days. The subject will receive a reminder daily from their classroom teacher during the monitoring period to make sure that they are wearing the monitor and to answer any questions they may have. After seven days of monitoring, the measurement team will return to the school collect the devices, debrief the participant, and provide an incentive. Actical monitor data will be downloaded to a laptop PC at the school site by the measurement team. This requires the use of the download device and software provided by the vendor. The monitor will then be reset and redistributed for use by another subject in that school. This process will be repeated weekly for three weeks at each school, representing three waves of data collection in a different one-third of the participating students each week.

One week prior to implementation of the intervention, a measurement team will go to the school for another data collection day that involves survey instrument and data collection. Each data measurement team will read explicit directions regarding how the survey will be filled out. With each instrument the measurement team will read the directions, answer questions, and then allow the students to fill out each instrument. When the entire battery is completed, the measurement team will collect the data, count the surveys, and record the count on a data sheet that is placed in a box and sealed. This box will not be opened until it reaches the project office to be counted to verify there are no missing forms.

The questionnaire will administered in a group setting each day for a week at the beginning of the health class period using a paper-and-pencil format. Filling out the survey takes approximately 10 minutes, and each day it gets easier and faster to fill out as the students become accustomed to it. On Friday, the students are given two questionnaires to be filled out as homework each night before bed and to be signed by a parent as completed on that date. This will provide for a seven-day total of activities the student recalls. Again, when the entire group of questionnaires is completed, the measurement team will collect the data, count the surveys, and record the count on a data sheet that is placed in a box and sealed. This box will not be opened until it reaches the project office to be counted to verify there are no missing forms. Questionnaires and data forms will be kept in a locked cabinet in the project office. Demographic information or identifiable data will be removed immediately from the questionnaire, transported, and stored separately from the questionnaire.

**Table 5: Data Procedures and Process**

| Time | Process: (Data Provided By) | Team Member |
|---|---|---|
| **YEAR 1** | | |
| | Finalization of data collection protocols<br>Finalization of participating schools to Waves 1 or 2<br>Training of PD and RAs: protocols, use of accelerometers<br>Randomization of Wave 1 schools to either intervention or comparison | Smith & Petosa<br>Smith & Petosa<br>Smith & Petosa<br>(Shoben) |
| **WAVES 1,2** | | |
| Consent | Consent/Assent of Peer Mentors and School Participants | Smith or Petosa |
| End of Recruitment | 1. Assignment of identification numbers to subjects, mentors, and teachers<br>2. Demographic Questionnaire (Peer Mentor, Subjects | Szalacha<br>Team |
| Baseline ($T_1$) | Subject Survey Questionnaire: Self-Report (Subjects)<br>Height, weight, BEI (Subjects)<br>Accelerometer – one week of data[a] (Teachers, Peer Mentors, Subjects)<br>Health Behaviors Questionnaire: (Peer Mentors, Subjects) | Team |
| $T_1$: Follow-Up | Collection of accelerometer data (7 days) | Team |
| Weekly | Debriefing sessions: observations and notations: mentors and teachers<br>Measures of Fidelity (mentors and teachers)<br>Data Interim Reports | Smith & Petosa |
| Monthly | Measures of Fidelity (mentors and Teachers) | Smith & Petosa |
| 3 Months Post Intervention ($T_2$) | Subject Survey Questionnaire: Self-Report (Subjects)<br>Height, weight, BEI (Subjects)<br>Accelerometer – one week of data[a] (Teachers, Peer Mentors, Subjects)<br>Health Behaviors Questionnaire (Peer Mentors, Subjects) | Team |
| $T_2$: Follow-Up | Collection of accelerometer data (7 days)<br>Reinforcement (Booster) Session | Team |
| 6 Months Post Intervention ($T_3$) | Survey Questionnaire: Self-Report (Subjects)<br>Accelerometer – one week of data[a] (Teachers, Peer Mentors, Subjects)<br>Health Behaviors Questionnaire (Peer Mentors), Subjects) | RA (blinded to group) |
| $T_3$: Follow-Up | Collection of accelerometer data | Team |

BEI = bio-electronic impedance; [a]Accelerometer data collected over 3 weeks (1/3 of subjects each week to wear for 1 week)

## C. Internal Validity

To avoid study bias, schools will be randomized for study condition (PBA or MBA). The primary analysis will follow intention-to-treat principles.[77,78] Randomization carries the expectation that the study conditions will be equivalent at pretest with respect to known and unknown prognostic factors. As a result, removing randomized groups or members from the analysis runs the risk of tampering with this balance and introducing bias. Further, loss of one or more groups could create an unbalanced design at the group level and heighten the risk associated with heteroscedasticity in a G-RCT.[79] Based on our previous research, we estimate that no more than 20% of members measured at pretest will be missing at posttest, although we will make every effort to obtain posttest data on all individuals, including those who stop attending the sessions. Multiple imputation is now widely regarded as an effective method for replacing missing data,[78,80] and we will use this approach, adapted for use with a G-RCT.[81] We will employ SAS PROC MI and SAS PROC MIANALYZE to implement these multiple imputation procedures. Advantages of this analysis are that it carries the nominal Type I error rate across a variety of conditions found in G-RCTs;[47,50,70,73] it provides results that correspond to the standard ANCOVA, except that the standard errors and *df* for fixed effects are constructed to reflect the extra variation and limited *df* due to the G-RCT design; it often has good power compared to the alternatives;[82,83] and the analysis is simple to conduct and explain. The only disadvantage is that it provides results in the form of adjusted condition means rather than change scores; we do not consider this an important disadvantage.

### D. Data Analysis

We will use Linear Mixed Models (LMMs) and Generalized Linear Mixed Models (GLMMs) to account for various levels of correlation among participants.[75] Power for this study was based on power for the primary analysis comparing BMI outcomes at $T_2$ between the two groups, adjusting for baseline BMI values. Such an approach is also known as a "mixed-model ANCOVA."[75] We will implement these models using SAS PROC MIXED and GLIMMIX, Version 9.3.

Research questions guiding the analysis of cognitive interview data for this aim are: Were there specific components of the intervention that appealed more than others? Were there any specific components which were not liked or were objectionable in anyway? Was there an age- or gender-related difference in reactions to components of the intervention?

To analyze mediating effects of self-regulation and self-efficacy on health outcomes and M/V physical activity, we will use bootstrapping techniques to determine significant relationships between the potential mediating variables and outcomes of interest.

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