In Shape Together

Program Evaluation Proposal

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Understanding the Health Problem

Serious mental illness (SMI), which includes severe depression, bipolar disorder, schizophrenia, and schizoaffective disorders, affects four percent of American adults, or 9.8 million people (National Institute of Mental Health, 2015). Although SMI can occur at any point in life, most cases are diagnosed between the ages of 19 and 30 (NIMH, 2015). Results from the 2015 SAMHSA National Survey on Drug Use and Health reveal that 9.5% of biracial or multiracial Americans, 6.3% of Native Americans, 6.1% of Whites, 2.9% of African Americans, 2.3% of Native Americans, 5.0% of females, and 3.0% of males have SMI (NIMH, 2015). However, due to cultural and social stigmas against mental illness, minorities and males are much more likely to underreport SMI (McGuire & Miranda, 2008). Accounting for stigma against reporting would yield a comparable Prevalence of SMI across these groups (Miller et al., 2016).

While mental health care has improved substantially over the last few decades due to advancements in medicine, technology, and research, these improvements have not been reflected in the physical health of individuals with SMI. Individuals with SMI on average die 15-20 years earlier than those without SMI with the majority of deaths related to cardiovascular disease (CVD) (Druss et al., 2011; Kisely et al., 2005; Leucht et al., 2007). Not only are these individuals three times more likely to die from CVD, they are also twice as likely to develop CVD and at younger ages than those without SMI (Osborn et al., 2007). These inequalities can be attributed to a combination of factors including systemic issues, such as the separation of mental and primary care services from other medical services, healthcare provider issues such as stigma against individuals with mental illness, consequences of mental illness itself, and side effects of its treatment.

Mental disorders and psychiatric symptoms are independent risk factors for CVD and consequences of SMI, like glucose intolerance, hyperlipidemia, and increased visceral fat mass, further increase the risk (Björntorp, 1995; Björntorp & Rosmond, 2000; Malik, 2004). Compared to individuals without SMI, those with SMI are more likely to smoke heavily and have substance use disorders, unhealthy diets, diabetes, physical inactivity, poor cardiorespiratory fitness, and be overweight or obese (Ross, 2014; Scott et al., 2012; Stapelberg et al., 2011). Taken together, individuals with SMI are more susceptible to both developing and dying from CVD and steps must be taken to improve the cardiovascular health of this population.

Need for Better Solutions and Strategies

Several different interventions that aim to improve the cardiovascular health of this population have been implemented. Knowledge-based interventions aimed at physicians to reduce stigma against individuals with SMI and improve awareness of the increased CVD risk for those with SMI have been implemented (Knaak & Patten, 2016; Corrign, 2014; Modgill et al., 2014; Friedrich et al., 2013). A systematic review revealed that on average, these interventions increased knowledge of the higher CVD risk associated with SMI by 54% and reduced stigmatizing attitudes by 26% among physicians (Mehta et al., 2015). However, this reduction in stigma is likely to be a temporary, short-lived impact of the interventions (Gronholm et al., 2017). Additionally, at this time there is no evidence that these

interventions improved the quality of care that physicians provided to individuals with SMI (Gronholm et al., 2017).

Several interventions have focused on improving the overall physical health of individuals with SMI by increasing physical activity and promoting weight-loss (Alvarez-Jiménez et al., 2008; Faulkner et al., 2007; Lowe & Lubos, 2008). A systematic review of more than 24 studies that evaluated community-based dietary and exercise interventions by tracking weight loss for overweight and obese individuals with SMI found that participants of only two interventions achieved clinically significant mean weight losses of at least 5% of body weight (Verhaeghe et al., 2011). Most of these interventions focused on increasing knowledge about the importance of exercise and failed to make any significant changes in the physical health of this population. The two successful interventions, both of which integrated exercise into the program, were high cost interventions that could not be sustained (Verhaeghe et al., 2011).

All of the aforementioned studies have used weight loss as a measure of program success. Compared to individuals without SMI, individuals with SMI significantly more likely to be overweight (BMI ≥ 25) or obese (BMI ≥ 30), which doubles the risk for developing CVD (Daumit et al., 2013). It is also more difficult for this population to lose weight (Mcelroy, 2009). Medications to help control mental illness symptoms can increase appetite, leading to weight gain, which interestingly, is one of the most common side-effects of medications for SMI (Shrivastava & Johnston, 2010). Individuals with SMI are also less likely to be physically active than individuals without SMI due to consequences of their SMI on life-functioning and motivation as well as the lack of resources and facilities to engage in physical activity, that cater to this population (Naslund et al., 2017). Tracking weight has also been shown to lower self-esteem and increase depressive symptoms among individuals with SMI (Mcelroy, 2009). Therefore, tracking weight loss is not an appropriate method to assess the physical health for this population.

Tracking changes in cardiorespiratory fitness (CRF) is a much better option because improving the CRF of overweight or obese adults contributes to significant reductions in CVD risk, independent of a change in body weight (Ross & Janiszewski, 2008). Additionally, improved CRF is strongly associated with reduced CVD risk, whereas weight loss is insignificant after adjusting for CRF (Lee et al., 2011).

Only one study has aimed to improve the CRF of individuals with SMI. The study found that the physical health of individuals with SMI successfully improved after the implementation of a year-long intervention, In SHAPE (Bartels et al., 2013). The intervention entailed providing participants with a free year long pass to go to a gym along with meetings with their own free personal trainer for an hour once a week under whose supervision participants engaged in mostly aerobic and bodyweight exercises, after which they were told to complete the series of exercises twice more in the week on their own. Although In SHAPE was effective in increasing physical activity levels of participants by 75.2% and improving their CRF by 50.3%, the program could not be maintained due to the cost of hiring a personal trainer for each participant. Therefore, there is a need for a sustainable, exercise program.

Research has shown that interactive environments may improve retention, mental health, maintenance of healthy behaviors and thus physical health of individuals with mental illness (Firth et al., 2016). However, no studies to date have used a group-based design for which the reasoning is thought to revolve around misconceptions that individuals with SMI would be uncomfortable in social settings (Hyland, 2012). Therefore, the program to be

evaluated, In SHAPE Together, is modelled after In SHAPE and modified based on the latest research in the area, lessons learned from previous interventions, and the input of mental health care providers, individuals with SMI, and exercise physiologists, to utilize a novel cost-efficient, group-based approach to improve the CRF of individuals with SMI.

Description of the Proposed Intervention

In SHAPE Together is a year-long intervention designed with the goal of improving the cardiovascular health of individuals with SMI in Prince George's County (PGC), Maryland. The objectives are to: (1) increase the amount of moderate-intensity exercise among 75% of participants to at least 150 minutes per week and (2) improve the CRF of participants by 50% as measured by the 6-Minute Walk Test (6MWT)

The entire project (Table 1) will be a year and a half-long because mental health care providers in the county will be asked to refer patients with SMI between the ages of 19 and 30 who are overweight/obese (i.e. have a BMI ≥ 25) to the program from six months to one week prior to the start of the program. The main component of the program is a 75-minute weekly group session held at a local facility, such as a recreation center or school gym. It will be delivered three times each week by a physical trainer, who has received basic psychoeducation on SMI. All three sessions will have the same exercise routine. However, different routines will be used across weeks so that sessions do not become repetitive and cumbersome. Participants will be asked to attend at least one session each week.

During the first week, each participant will be given a book that they will bring to one session each week, in which they will be asked to record their weekly physical activity. The first 10 minutes of each in-person session will be a Record Sharing activity, during which participants pair up and discuss their progress from the previous week up to this session with one another, including whether they were able to complete the required in-person and video sessions, how closely they follow routines, any tips and suggestions they want to give each other to improve adherence to the activities of In SHAPE Together. Each participant must then sign-off in the book of the other participant to acknowledge that they have seen the record and discussed the progress leading up to that session.

During the next 10 minutes, the trainer will lead the group through warm-up exercises, followed by 45 minutes of moderate-intensity exercise incorporating cardio and strength training exercises, and a 10-minute cool down. At the end of each session, participants will be told to complete the exercise routine at least two more times that week and continue recording their physical activity in their notebooks. To help participants follow this instruction, at the beginning of every week, the physical trainer will upload a video of the him/her completing the weekly routine on the In SHAPE Together Website. Participants will sign-up for the free website and use their accounts to access and follow along to these videos. Participants can also attend the other two sessions each week, if they prefer.

Target Population

In SHAPE Together will be delivered in PGC because it includes several institutions of higher learning and thus 26% of the population lies in the age range of 19 and 30, 4.4% of residents within the county have a SMI (compared to the 4% national average), and 24.9% of deaths in the county are due to CVD, of which nearly two-thirds are individuals with SMI (Prince George's County Health Department, 2015). For the reasons described above, In

SHAPE Together will be targeted to individuals with clinically diagnosed SMI being treated through the health care system who have a BMI greater than or equal to 25 and are between the ages of 19 and 30, who will be referred to In SHAPE Together by mental health care providers in PGC.

Table 1: Project Outline

Event	Length/Time	Explanation
Recruitment	6 months to one week prior to intervention	Mental healthcare providers in PGC refer patients with SMI who have a BMI ≥ 25 and are 19-30 years old.
In SHAPE Together	1 year	Intervention, delivered by physical trainer(s)
In-Person Sessions	75 min., three times a week	The main component of the intervention. Participants attend (at least) one each week. Each session has different Exercise Components.
Physical Activity Tracking	Ongoing	Participants record number of exercise session, date, duration, and any comments in their record books (provided during Week 1).
Record Sharing	First 10 min. of each session	Participant discusses progress with another participant.
Sign-Off	At the end of Record Sharing component of each session	Each participant sign-offs in the book of the other participant.
Warm-up	Second 10 minutes of each session	Exercises to help participants stretch and prepare for exercise.
Exercise Component	45 min. after Warm-Up at each session	Moderate intensity exercise incorporating cardio and strength training exercises. These exercises use bodyweight and do not use any additional exercise equipment.
Cool Down	Last 10 min. of each session	Exercises to help participants cool and relax.
Video Sessions	One per week	Prerecorded videos of the physical trainer completing the weekly routine, to which participants can follow along and complete weekly routine two times each week. It will be uploaded to the program website after the first in-person session of each week.
Evaluation of Progress	First 10 min. of sessions of Week 1 and of sessions 6 and 12 months after Week 1.	Participants will complete a short survey on the amounts/levels of physical activity and take the 6MWT to measure CRF instead of Record Sharing activity.

Goals of the Evaluation

Serious mental illness (SMI) doubles the risk of developing CVD and triples the risk of dying from CVD due to complications of SMI itself, side effects of medication and treatment, systemic issues such as the separation of mental health and primary care and stigma against SMI among providers, and the low physical activity levels among this population. Both behavioral changes associated with SMI as well as side effects of medication makes it difficult for individuals with SMI to attain proper levels of physical activity, which leads to poor cardiorespiratory fitness (CRF) and increased CVD risk (Figure 1).

Therefore, the program to be evaluated, In SHAPE Together, aims to improve the CRF of overweight and obese individuals with SMI in PGC by increasing their physical activity in order to promote better cardiovascular health and decrease the risk of CVD among this population. In SHAPE Together will be evaluated using an experimental design to compare physical activity levels, CRF, and CVD risk among In SHAPE Together participants and a comparison group of overweight and obese individuals with SMI who will be given the American Heart Association Commit to Fit Brochure.

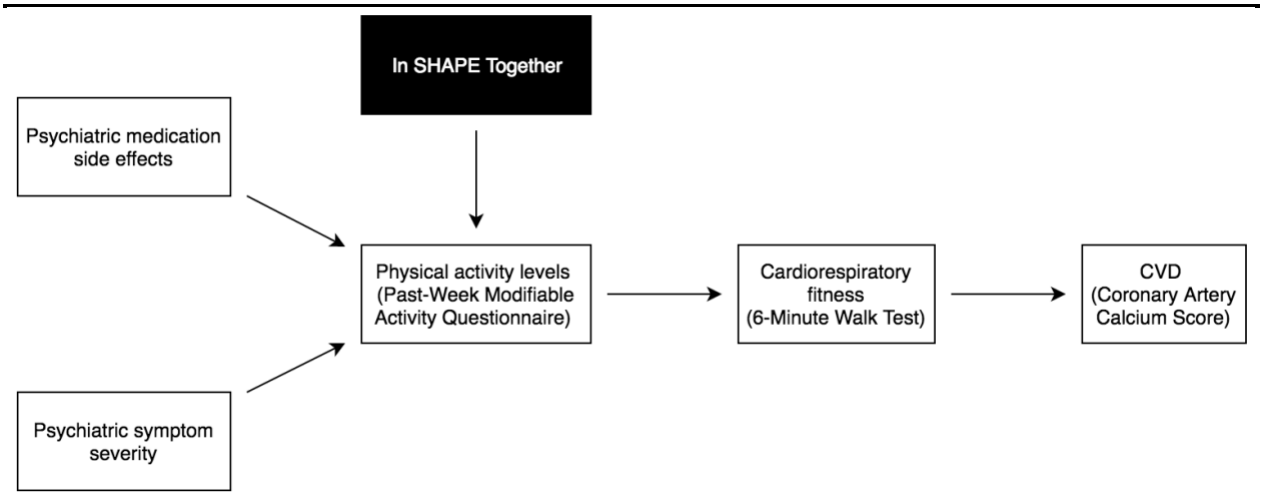

Figure 1. Conceptual model of the mechanisms of effect of In SHAPE Together

Process Goals

The first process goal of the evaluation will be to measure attendance of individuals with SMI at the weekly In-Person Session. The second process goal of the evaluation will be to measure the extent to which individuals with SMI followed or utilized the Video Sessions.

Intermediate Goals

The first intermediary goal of the evaluation will be to compare the change in the amount of physical activity from baseline to Time 1 (at 6 months) and Time 2 (at 12 months) for both individuals with SMI who received In SHAPE Together (Group 1) and individuals with SMI who received the brochure (Group 2). The second intermediary goal of the evaluation will be to compare the change in CRF from baseline to Time 1 and Time 2 for

participants in Group 1 and Group 2. It is hypothesized that both the change in amount of physical activity and change in CRD will be greater for individuals with SMI in Group 1.

Longer-term Goals

The long-term goal of the evaluation will be to compare the CVD risk among individuals with SMI who received In-SHAPE Together (Group 1) with individuals with SMI who received the brochure (Group 2) at the end of the year-long intervention. It is hypothesized that CVD risk will be lower among individuals with SMI in Group 1. Additionally, the extent to which attendance at the In-Person Sessions mediates the change in CVD risk will be evaluated. Similarly, the extent to which engagement with or utilization of the Video Sessions mediates the change in CVD risk will also be evaluated.

Evaluation Measurement Plan

Evaluation Design

Individuals with SMI who are referred to the program will be randomly assigned to either receive the intervention, In SHAPE Together (Group 1), or the American Heart Organization Commit to Fit brochure, which provides information on the importance of exercise for cardiovascular health (Group 2). Because individuals with SMI will be randomized to groups, an experimental evaluation design will be used. Individuals with SMI who are overweight or obese will be referred to program by mental health care providers in PGC. An organization-based, consecutive series, purposive sampling procedure will be used to identify mental health care providers in PGC. Providers will then be asked to refer patients with SMI who are overweight or obese to the program.

Sample

One hundred and fifty individuals with SMI in PGC will be recruited through mental health care providers within the healthcare setting to participate in In-SHAPE Together (Figure 2). A consecutive series purposive sampling strategy will be utilized to identify the mental health care providers employed through a large mental health care hospital or organization in PGC. This sampling strategy will be used because the goal is to get all mental health care providers employed through this hospital or organization to participate and refer patients with SMI to the program. Because providers are identified based on employment at the hospital or organization, an organization-based sample will be obtained.

Because individuals with SMI are a vulnerable population, IRB approval to access this population through mental health care providers and implement the intervention must be obtained before recruiting providers. Permissions from the hospital or organization director and/or supervisory board will be needed to contact mental health care providers employed. Mental health care providers themselves must then decide whether they will be willing to refer patients to the program. Patients referred to the program who are interested in participating will be contacted through the content information provided by the mental health care providers at referral, and sent a copy of the informed consent form to review. All information on the form will then be read to individuals over the phone and they will be given the opportunity to ask questions.

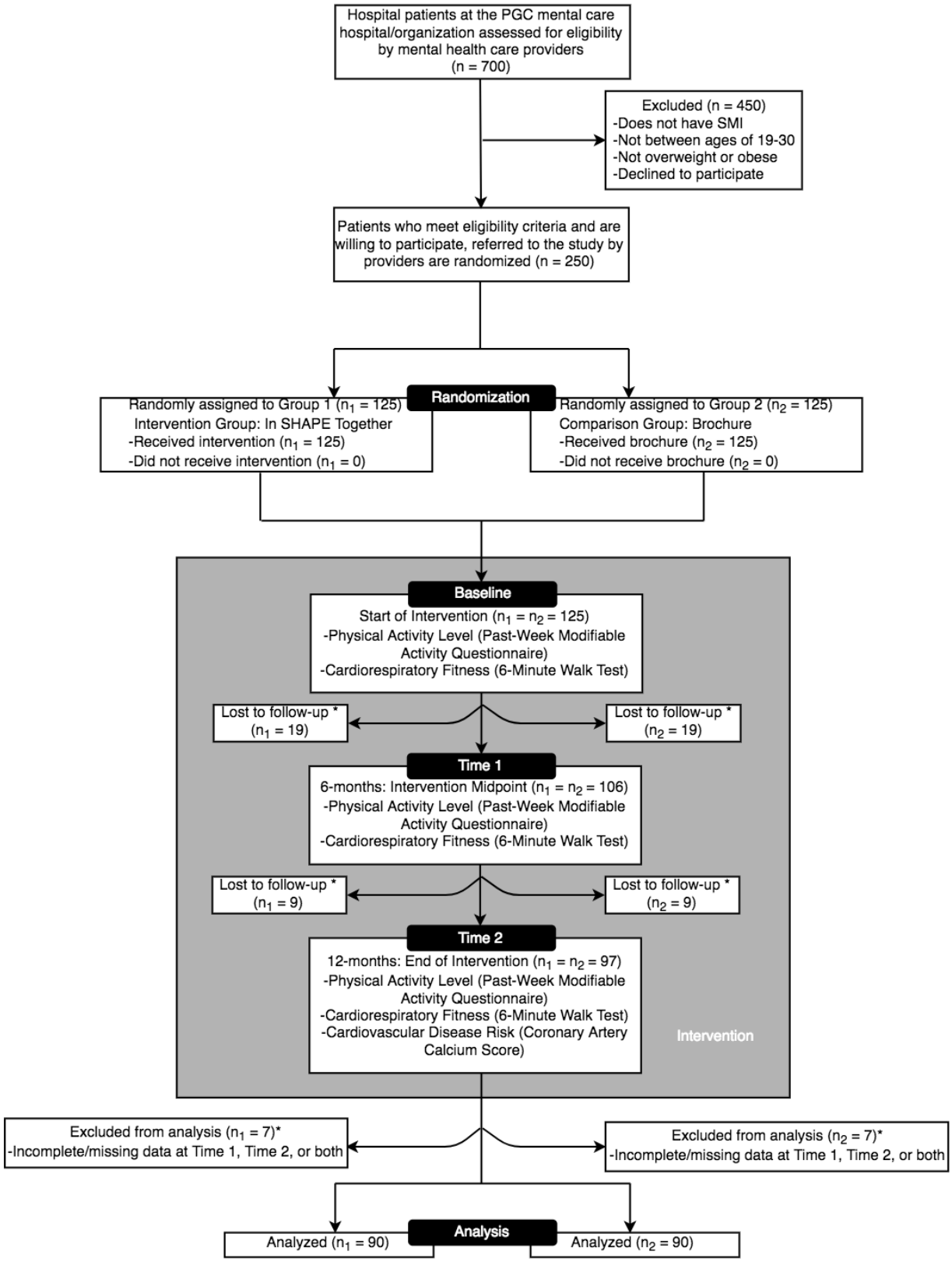

Figure 2. Anticipated flow of participants in In SHAPE Together. *Note: Follow-up rates at each wave of measurement anticipated based on follow-up rates in In SHAPE.

A teach-back technique will also be utilized to determine that individuals with SMI understand the information on the consent form and are providing truly informed consent. Only individuals who sign the consent form will be randomized to the two groups and allowed to participate in the program.

All patients referred to the program will be randomized to either receive In SHAPE Together or the brochure. The analytic sample will consist of individuals with SMI for whom complete data regarding physical activity levels, CRF, and CVD risk have been obtained at all three waves of measurement: baseline, 6-months, and 12 months. As stated previously, the program to be evaluated is modelled after In SHAPE and thus the analytic sample is expected to be 72% of total participants at baseline (Figure 2). Again, as in In SHAPE, no differences in demographics or severity between the target population and the analytic sample is anticipated in In SHAPE Together. Like In SHAPE, in the program to be evaluated, while no incentives will be offered to participants for attending the program, a $15 incentive will be provided to each participant at baseline, 6 months, and 12 months for completing the necessary assessments at each of those time periods (Table 2).

Some attrition is expected over the course of the program. Because In SHAPE Together is very similar to and modelled based on, In SHAPE, the response rates at each wave of measurement are anticipated based on the observed response rates at the three measurement waves in the In SHAPE intervention (Bartels et al, 2010). As such, at baseline, all participants are expected to respond because all participants in In SHAPE responded. In the In SHAPE intervention, 85.5% and 78% of total participants at baseline responded at six and twelve months. Therefore, 85% and 78% of participants can be expected to respond in In SHAPE Together at the 6-month and 12-month measurement waves (Figure 2). Additionally, equivalent attrition, retention, and response rates were found among individuals with SMI in both the experimental group and the comparison group. Thus, the response rates among participants in Group 1 and Group 2 is also expected to be equivalent.

Measures

A detailed description of all relevant variables, assessment measures, data collection methods, and waves of assessment is provided in Table 2. A paper and pencil survey will be used to gather personal characteristics and demographic information from participants. CRF will be assessed through the 6-Minute Walk Test (6WMT), a reliable and valid measure of CRF with favorable test-retest and discriminant validity (Larsson & Reynisdottir, 2008). It has also been used to assess CRF of adults with a variety of chronic health conditions, including mental illness (Bartels et al., 2013; Sciurba et al., 2013).

Compared to all the risk factors and predictors of CVD like hypertension and cholesterol levels, the Coronary Artery Calcium (CAC) score, obtained by conducting a computerized tomography of the heart, has been found to predict CVD most accurately (Joshi et al., 2017). Additionally, unlike other CVR risk indicators, CAC scores change rapidly to reflect changes in cardiovascular health status and thus can be used to determine CVD risk at earlier time periods and at younger ages than other indicators (Joshi et al., 2017). Therefore, the CAC score, will be used as the indicator for CVD risk.

Table 2. Intervention Measures

Variable	Assessment Measure	Data Collection Method	Wave of Assessment			Operationalization/ Analysis Methods
			Baseline	Time 1: 6 months	Time 2: 12 months	
Outcome Variables						
Physical Activity -Short Term	Past-Week Modifiable Activity Questionnaire (PWMAQ): Paper & Pencil	Self-report	✓	✓	✓	Continuous: number of minutes exercised in the past week
Cardiorespiratory Fitness -Short Term	6-Minute Walk Test (6MWT)	Direct measurement of distance, participant walks in 6 minutes	✓	✓	✓	Continuous: distance walked in feet
CVD risk -Longer Term	Coronary Artery Calcium (CAC) Score: X-ray	CT scan of heart			✓	<1: No identifiable signs of CVD 1-10: Mild CVD risk 11-100: Moderate CVD risk 101-400: High CVD risk >400: Severe CVD risk
Predictor Variable						
Intervention Group	Whether randomly assigned to Group 1 of Group 2	Access administrative list of group to which each participant is assigned	✓			Group 1: In SHAPE Together Group 2 (American Heart Association Commit to Fit Brochure)
Process Variables (Operationalization of Predictor Variable)						
Dose: Attendance at In-Person Sessions	-Attendance roster/ checklist -Attendance Sign-in sheet	-Research staff takes attendance by checking off names on a roster -Participants sign-in on sign-in sheet	Throughout the intervention			0 weeks: No attendance 1-13 weeks: Sporadic attendance 13-26 weeks: Occasional attendance 26-39 weeks: Regular attendance 39-52 weeks: High attendance

Dose: Engagement with or utilization of Video Sessions	**-Clicks per video on In SHAPE Together website -Duration of stay on video page after clicking it**	**Personal account usage on In SHAPE Together website tracked using Google Analytics™**	**Throughout the intervention**			**Continuous: Sum of (Number of clicks per video x Duration of stay on video page in minutes) for each weekly video**
Covariates						
Baseline physical activity level	**Past-Week Modifiable Activity Questionnaire (PWMAQ): Paper & Pencil**	**Self-report**	✓			**Continuous: number of minutes exercised in the past week**
Baseline CRF	**6-Minute Walk Test (6MWT)**	**Direct measurement of distance participant walks in 6 minutes**	✓			**Continuous: distance walked in feet**
Severity of SMI	**SF-12 Health Survey: Paper & Pencil**	**Self-report**	✓			**Categorical 0-20: Very high severe 20-40: High severity 40-60: Moderate severity 60-80: Mild severity 80-100: Very low severity**
SMI Diagnosis	**Adapted from Standard Demographic and Health Survey**	**Self-report**	✓			**Categorical (nominal) -Bipolar Disorder -Schizophrenia -Schizoaffective Disorder -Severe Depression**
Baseline BMI	**Calculated from self-reported height & weight at baseline on the adapted Standard Demographic and Health Survey**	**Calculated from self-reported height and weight at baseline**	✓			**Categorical (dichotomous) 25 ≤ BMI < 30: Overweight BMI ≥ 30: Obese**
Control Variables						
Age	**Standard Measure -Census Category**	**Self-report**	✓			**Continuous**

Gender	**Standard Measure -Census Category**	**Self-report**	✓			**Categorical (dichotomous) -Male -Female**
Race	**Standard Measure -Census Category**	**Self-report**	✓			**Categorical (nominal) -African American -White -Asian American -Native American -Native Hawaiian/Pacific Islander**
Ethnicity	**Standard Measure -Census Category**	**Self-report**	✓			**Categorical (dichotomous) -Not Hispanic -Hispanic**
Education	**Standard Measure -Census Category: Highest level of education completed**	**Self-report**	✓			**Continuous Recoding scheme: number associated with the highest grade completed in school -Elementary (0-8) -High school (9-12) -GED (18) -College/technical school (13-16) -Graduate and above (17)**
Height	**Standard Measure**	**Self-report**	✓			**Continuous**
Weight	**Standard Measure**	**Self-report**	✓			**Continuous**
Total Household Income	**Standard Measure -Census Category**	**Self-report**	✓			**Categorical (ordinal) Total Household Income/ Number of persons supported on income: -Less than $20,000 -$20,000 - $39,999 -$40,000 - $59,999 -$60,000 - $79,999 -$80,000 or more**

Physical activity levels will be assessed through the Past-Week Modifiable Activity Questionnaire (PWMAQ) which participants will complete using paper and pencil (Gabriel et al., 2009). Similarly, the baseline severity of SMI will be assessed through the SF-12 Health Survey, administered using paper and pencil (Ware et al., 1966). This instrument was found to have high reliability and validity. Specifically, test-retest reliability and content, concurrent, and criterion validity were established through respective coefficients in follow-up studies (Gabriel et al., 2010; Gandhi et al., 2001). Further, this instrument has been utilized to assess SMI severity in numerous studies (Huberty et al., 2017; Seib et al., 2015; Younsi, 2015; Andrianosolo et al., 2015).

Intervention Fidelity Monitoring

Several steps will be taken to ensure that In SHAPE Together is implemented as planned. Physical trainers are responsible for modelling and walking participants through the weekly exercise routine during in-person sessions and uploading a video of the same routine every week after the first in-person session during the week. In order to ensure that physical trainers are delivering the program properly during the in-person sessions, research staff will observe three randomly selected in-person sessions each month using a fidelity observation checklist aimed at identifying implementation issues, adapted from a fidelity observation checklist used in an evaluation study of In SHAPE conducted by the Dartmouth-Hitchcock Medical Center (2015).

To ensure that physical trainers are uploading videos on time, research staff will record time stamps of when videos are uploaded each week. Physical trainers are also asked to complete an in-person session checklist, adapted from a checklist used in another exercise-based intervention (Palmer et al., 2016). At the end of each session where they can check out what activities were completed according to the project outline and include notes and comments on any changes made from the project outline. They are asked to then scan or take a picture of this checklist and email it to the research staff.

Additionally, once every three months, participants will be asked to complete an anonymous online survey on the In SHAPE Together website, wherein participants will be asked to reflect on their experience with In SHAPE Together thus far, with specific questions to help assess intervention fidelity, such as whether physical trainers are carrying out in-person exercise sessions according to the schedule for these sessions provided in the project outline (Table 1), whether weekly videos were uploaded on time etc. At the end of the survey, participants are asked to provide additional comments on what is working, what could be improved and how, and any other comments, which can then be used to make changes to the intervention during implementation to better benefit the target population.

Every three months, physical trainers will also be asked to complete a survey online wherein they will be asked to describe how weekly sessions are going, whether any changes were made from the project outline during implementation, why changes were made, and finally any additional comments including comments on what is working, what could be improved, and how. Like the input from participants, results from the survey given to physical trainers will be used to make necessary changes to the intervention during implementation.

Follow-up Procedures

The day before each in-person session, participants will receive a text reminder, email, as well as a pop-up notification on their online accounts when they log on to the In SHAPE Together website, about the upcoming session. Participants are required to attend at least one in-person session each week. At the end of each session, physical trainers are asked to scan or take a picture of their attendance roster, participant sign-in sheets, and as mentioned earlier, the in-person session checklist they completed, and email it to the research staff.

The day before the first weekly session, in addition to the text reminder and notification on the website, research staff will call all participants to remind them about the upcoming session. The day before the second weekly session, all participants who did not attend the first weekly session, determined from the sign-in sheets from the first session, cross-checked against attendance taken by the physical trainer during the in-person session, to remind them about the upcoming session. Finally, on the day before the third and final weekly session, all participants who did not attend the first or second sessions for that week, are called by research staff to remind them about the least session for the week.

Methods to Minimize Attrition

Several methods to minimize attrition are employed throughout the program. First, before the beginning of the intervention, each participant will be asked to provide their email address and phone number, along with the phone numbers of three other individuals who could be contacted if the participant cannot be reached by the research staff. The contact information of each participant and the three other individuals will be uploaded and stored in their personal accounts on the In SHAPE Together website. Every three months, when the participant logs into the website, there will be a pop-up window asking if their contact information and the contact information provided for the three others are correct. If incorrect, participants can easily make changes to the contact information in the pop-up window itself before proceeding onto the website. During the middle on the program (6 months), physical trainers will be asked to remind participants at the beginning on the in-person sessions for that week to update their contact information if it has changed through the website or on note-cards made available during those sessions, which can be turned into the training at the end of the session.

Although participants are only required to attend one in-person session each week, three in-person sessions are offered each week to make it more convenient for participants to attend. Calling and sending text reminders, emails, and online notifications to participants before each session, will allow research staff to build trust and rapport with participants. Additionally, participants are encouraged to contact research staff with any concerns or questions throughout the program, which could help corroborate staff-participant relationships. Finally, to encourage participants to continue attending sessions during evaluation time-points, a $15 incentive will be provided to each participant at baseline, Time 1, and Time 2 for completing the necessary assessments at each of those time periods.

Statistical Analyses

Statistical analysis will be only be conducted on the analytic sample of program participants who have no missing data at any of three time-points: baseline, Time 1, and Time 2. Univariate descriptive statistics will be used to determine the frequency distributions of all variables, including process, outcome, control, and covariate variables, for both the intervention and control groups.

Summarizing Process Outcome Measures

Descriptive statistics will be used to summarize the process outcome measures. To measure attendance of individuals with SMI at the weekly in-person sessions, the total number of weeks attended by each participant will be calculated, and then categorized into five different categories based on total attendance, ranging from no attendance to high attendance (Table 2). To measure the extent to which individuals with SMI followed or utilized the video sessions, for each weekly video, the number of clicks and the duration of stay on the video page in minutes per each click, obtained using Google Analytics™ for each participant, by analyzing their online account use. Then the computations for each weekly video would be summed for each participant.

Impact of Process Outcome Measures on Outcome Variables

Additionally, An ANOVA test will be used to determine if there are significant differences in the continuous variables, physical activity and CRF, at the end of the intervention based on the regularity of attendance. A Chi square test will be then used to determine if there are significant differences in CVD risk, a categorical variable, at the end of the intervention based on the regularity of attendance. Similarly, ANOVA and Chi square tests will be used to assess whether there are significant differences in physical activity and CRF, and CVR risk, respectively, based on the extent of video session utilization.

Group Comparisons on Key Characteristics at Baseline

The statistical procedures utilized in this study are similar to the procedures used in In SHAPE (Bartels et al., 2013). The intervention and control group will be compared at baseline to determine if there were any differences on key characteristics, specifically on the type of SMI and severity of SMI using Chi squared tests, as well as differences in baseline physical activity and CRF using t-tests.

Key Group Comparisons on Outcome Variables

Physical activity and CRF are both continuous variables. Therefore t-tests will be used to compare the physical activity and CRF of Group 1 and Group 2 at the end of the intervention to determine if any significant differences exist between groups. Because CVD risk is a categorical variable, a Chi-square test will be used to compare the CAC scores of Group 1 and Group 2 at 12 months to determine if there is a significant difference in CVD risk between the two groups.

Group 1 and Group 2 will be compared with one another with respect to the covariates and control variables provided in Table 2. Then, the relative contributions of the group variable (Group 1 versus Group 2) on the outcome variables will be assessed after adjustment for covariates and controls. Specifically, linear regression will be used for

physical activity and CRF, which are both continuous dependent variables, similar to the example provided by Seber & Lee (2012). In contrast, an ordinal logistic regression will be used for CVD risk, an ordinal variable, similar to the example provided by Warner (2008).

Examining Mediation Effects

The intervention, which increases physical activity is expected to decrease CVD risk by increasing CRF. In other words, CRF could be a mediator. Multiple regression analysis will be conducted to determine if mediation by CRF is present between In SHAPE Together and CVD risk (Baron & Kenny, 1986; Kim, 2017). Then the Preacher and Hayes bootstrapping method will be used to determine if the mediation is statistically significant (Preacher & Hayes, 2014).

Limitations

All participants for the intervention are referred to the program by mental health care providers employed through a large mental health care hospital or organization in PGC, meaning all participants are patients at this one particular hospital or organization in PGC. As a result, the sample of participants in this study may not be representative of the total population of overweight or obese individuals with SMI between the ages of 19 and 30, and thus the results obtained from this evaluation may not be generalizable to other populations of individuals with SMI in places other than PGC or the overall population of individuals with SMI.

In SHAPE Together is expected to directly change physical activity levels. Physical activity is only measured through the PWMAQ survey, and is thus self-reported by participants. Therefore, the possibility of participants overestimating their physical activity cannot be ruled out. However, participants are given a record book in which they are told to record their physical activity. During the first 10 minutes of in-person sessions, they are asked to share information about their progress with another participant. This Record Sharing Activity is used to motivate participants to exercise. Although it is possible that participants may overestimate and report socially desirable levels of physical activity, hearing their partner describe their progress may encourage participants to keep up by engaging in the required amount of physical activity. Additionally, because participants are required to bring in their record book to the in-person sessions, they will have access to their records while taking the PWMAQ survey, which may encourage participants to report amount of physical activity completed accurately.

Another limitation is that In SHAPE Together is a relatively intense intervention, requiring participants to attend at least one in-person session each week and complete weekly exercise routines twice during their own time, by following along to the uploaded videos on the intervention website, whereas individuals in the control group are simply given the American Heart Association Commit to Fit Brochure. Therefore, differential attrition between the two groups is possible, which could impact the findings of this evaluation. However, in the In SHAPE study, attrition across the two groups was similar. As a result, because In SHAPE Together is modelled based on In SHAPE, attrition in the present study is also expected to be nondifferential. Additionally, multiple methods to maintain contact and minimize attrition are employed in the present study.

Outcomes are measured during the intervention and at the end of the intervention. In other words, possible changes in outcomes are not measured months or years after the intervention to determine if changes observed at the end of the intervention are sustainable. However, although In SHAPE Together is modelled based on In SHAPE, the present intervention utilizes several novel techniques, as described earlier. Therefore, it is important to determine whether In SHAPE Together works short-term before addressing sustainability. Because it is important to determine if In SHAPE Together works at all, it is imperative to maintain and many participants as possible throughout the study. As such, multiple methods to minimize attrition are employed in this study.

Another limitation is that the severity of SMI among participants may have influence their ability to exercise regularly, such that participants with more severe symptoms may have been less likely to complete required amounts of physical activity. Therefore, it is possible that SMI severity plays a moderating effect. However, the present study does not examine potential moderation by SMI severity.

Strengths

Because the sample is obtained from a hospital in PGC, a county known for its racial and ethnic diversity, compared to other studies conducted among this population that included predominantly white samples, the sample in In SHAPE Together is much more racially and ethnically diverse (Alvarez-Jiménez et al., 2008; Bartels et al., 2013; Faulkner et al., 2007; Lowe & Lubos, 2008, Prince George's County, 2015). Therefore, the results of In SHAPE Together, compared to previously implemented interventions, may be more generalizable to more racially and ethnically diverse populations.

Another strength of this study is that all surveys used to evaluate outcomes, including the PWMAQ survey, have high validity and reliability, as mentioned before. Additionally, other studies to estimate CVD risk among the general population as well as the In SHAPE study utilized self-reported measures such as hypertension, cholesterol levels, BMI and body weight to estimate CVD risk **(**Bartels et al., 2013; Department of Health and Human Services, 2013). The present study, however, measures CVD risk biologically, using a CAC test, which has been proven to be the best predictor of CVD risk, compared to all the other aforementioned CVD risk factors typically used to predict CVD risk (Joshi et al., 2017).

As stated previously, while In SHAPE Together directly addresses physical activity, it is expected to reduce CVD risk by increasing CRF based on the suggested mechanism of effect of In SHAPE provided by Bartels and colleagues (2013). Therefore, CRF likely mediates the relationship between physical activity and CVD risk. Specifically, statistical analysis will be conducted to determine if mediation by CRF exists and whether it mediation is statistically significant.

Finally, this study is expected to be more cost-efficient than the In SHAPE Study. Unlike In SHAPE, in which a personal trainer was hired for each participant to provide independent sessions, which was very costly and thus could not maintained long-term, In SHAPE Together uses a group-based approach wherein personal trainers work with a large group of participants. In general, among individuals with mental health, neurological, and substance use disorders, group-based interventions tend to be more cost-efficient and thus more sustainable over time than individual-based interventions (Levin & Chisholm, 2016).

Additionally, group-based interventions that encourage social interactions and allow participants to develop a sense of community, has been shown to increase adherence and participation in the intervention among individuals with SMI than individual interventions (Cabassa et al., 2010).

Significance and Implications for Public Health

The evaluation of In SHAPE Together has important implications for multiple audiences. Regardless of whether the present intervention is successful, it has several implications for researchers. If the intervention failed, researchers could use this finding to determine why the intervention did not work. Because this intervention is modelled on In SHAPE, a successful intervention, researchers could determine which of the components that are used in this intervention but not in In SHAPE worked and which components did not work.

If In SHAPE Together was successful, it would lay down a foundation for researchers to uncover the mechanisms of effect. For instance, researchers could determine how physical activity improves CRF and how improved CRF reduces CVD risk. Researchers could also determine whether increased physical activity decreases CVD risk through some mechanism other than CRF or whether there is direct relationship between physical activity and CVD. Because maintenance of outcomes over time are not examined in this study, researchers could also evaluate whether the observed changes in outcomes are sustainable after the intervention is over. They could then use the findings from this sustainability evaluation to uncover potential mechanisms of the long-term nature of observed effects.

Researchers could also determine whether this intervention might be successful when implemented among SMI populations at other places. Although the sample size used in the present study is based on the sample size in In SHAPE, In SHAPE Together could be implemented among a larger sample of individuals with SMI to determine if there are any differences in findings. Additionally, because a potential moderating effect by SMI severity is not examined in the present study, researchers could determine if SMI severity is a moderator and whether its moderation effect is statistically significant.

Researchers could also work with program developers to try to identify the active ingredients of the program. For example, new interventions that contain different combinations of, but not all, components of In SHAPE Together could be implemented among this population to see which of these interventions are successful. This would help highlight which components are necessary to increase physical activity and reduce CVD risk among this population. Even if In SHAPE Together was not successful, program developers could incorporate the components of this intervention into other interventions to determine if new combinations of intervention components successfully reduce CVD risk among this population.

Both mental healthcare providers and primary care providers provide care to individuals with SMI. Based on the findings of In SHAPE Together, mental health care providers could provide guidance to patients with SMI on what strategies they could use to exercise based on the components in In SHAPE Together. For instance, if the present intervention was successful, healthcare providers could tell their patients to exercise within a group setting so that others can motivate them to exercise, to follow along to exercise videos that show them exactly what movements to do and when instead of just relying on

their knowledge to come up with best ways to exercise, and/or to keep a record of their exercise habits and then consistently share their progress from this record book with another person, preferably someone who will also start exercising with the patients, to help keep them motivated. Currently, many primary care providers do not recommend exercises or exercise programs to individuals with SMI, because many providers believe that individuals with SMI will not be able to exercise regularly and thus, it is of little use to recommend exercising to this population (Ross et al., 2015).

These providers can be shown that it is possible for individuals with SMI to exercise properly and that they should therefore, encourage their patients to exercise regularly. If In SHAPE Together is successful, it would provide additional proof that this population can exercise regularly and that it significantly reduces their risk of developing CVD. Even if the present intervention was not successful, it could still be used to help health care providers understand that it is difficult to get individuals with SMI to exercise and thus, providers should spearhead efforts to encourage their patients to participate in other interventions and attend nearby exercise and fitness classes to help get them started.

Finally, if In SHAPE Together proves to successfully reduce CVD risk among this population of individuals with SMI, this program may be used to successfully reduce CVD risk among a population of individuals with milder symptoms, such as individuals with non-serious mental illness like anxiety. Therefore, In SHAPE Together has broader implications for individuals with milder symptoms.

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