Adapting an Evidenced-based Weight Management Intervention and Testing Strategies to Increase Implementation in Community Mental Health Programs

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STUDY PROTOCOL

STRATEGIES TO INCREASE IMPLEMENTATION OF AN ADAPTED, EVIDENCE-BASED WEIGHT MANAGEMENT INTERVENTION IN COMMUNITY MENTAL HEALTH PROGRAMS: THE ACHIEVE IMPLEMENTATION AND DISSEMINATION PILOT TRIAL

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Version 1.0 – February 23, 2021

Version 1.4 1.8.2025
- Change in PI to Gail Daumit, MD, MHS due to original PI leaving JHSOM.

Changes from version 1.3-10.18.2022
- Adding interviews six-month post project completion for staff coaches and administration
- Adding in $25 for both completion of focus group and for a six-month post project interview for coaches and peer leaders
- Adding in $25 for completion of focus group for other staff

Changes from version 1.2-March 8, 2022
- Adding Perceived Usefulness (motivational interviewing avatar platform) survey to coach participant six-month follow-up data collection

Changes from version 1.1- December 13, 2021
- Added Avatar Motivational Interviewing (MI) satisfaction survey to the coach participant six month follow-up data collection

Changes from version 1.0

Version 1.1- September 23, 2021

- Modified consumer participants eligibility criteria for BMI from ≥30 kg/m^2 to ≥25 kg/m^2
- Increased flexibility of program delivery by changing the number of groups offered each week from 3 groups/week to a minimum of one group/week
- Modified the curriculum to allow for the inclusion of group exercise during in-person groups, if permitted by the sites' COVID-19 safety protocols
- Modified the curriculum to allow for virtual exercise groups facilitated by a trained peer leader and study team

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1. ABSTRACT

Prevalence of obesity is significantly elevated in people with serious mental illness (SMI)[1-3], and obesity is a leading cause of preventable death in this population directly through its effects on cardiovascular disease (CVD) and indirectly by contributing other CVD risk factors[4-10]. In general populations, behavioral weight-loss interventions have been demonstrated to improve CVD risk by reducing blood pressure and glucose, as well as improving lipid profiles[11]. However, behavioral interventions targeting changes in diet, exercise and weight loss need to be tailored to the particular needs of people with SMI, such as memory impairment and limited executive function[12,13].

The NIMH-funded Achieving Healthy Lifestyles in Psychiatric Rehabilitation (ACHIEVE) trial tested a behavioral weight-loss intervention for consumers with SMI who attended community-based psychiatric rehabilitation programs[14]. This randomized controlled trial (RCT) demonstrated clinically significant weight loss (mean 7 lbs. at 18 months)[15]. ACHIEVE included group and individual weight-management and group exercise sessions, which was led by trained study interventionists. Given the obesity epidemic in persons with SMI, there is an urgent need to "scale-up" or expand ACHIEVE to similar settings and populations as those included in the RCT, which we posited could be accomplished by enabling the psychiatric rehabilitation program staff to deliver the sessions[16]. Using the Enhanced Replicating Effective Programs Framework for translating evidence-based interventions into community settings[17], our scale-up strategy considers this model's three stages: pre-implementation, implementation, and dissemination.

As part of the pre-implementation stage, we adapted the format of the original intervention to increase ease of adoption and sustained implementation of ACHIEVE by program staff in these community-based programs. (IRB00194122). We retained the core components, but modified the curriculum schedule (e.g., combined exercise and weight management group sessions) and enhanced the delivery format (e.g., video-assisted content) to support efficient, staff-led delivery. We pilot tested this adapted curriculum (ACHIEVE-D) where a trained study interventionist implemented 2 months of programming at a community-based psychiatric rehabilitation program[18], and we then further refined the adapted curriculum based on feedback from program staff and participating individuals with SMI.

In the implementation stage, the objective of this study is to develop and test innovative interventions to give community-based psychiatric rehabilitation program staff the knowledge, self-efficacy, and skills to deliver the adapted ACHIEVE curriculum (ACHIEVE-D) with high fidelity. Training of the ACHIEVE study interventionists required significant in-person initial and ongoing training, as well as performance feedback with particular emphasis on motivational interviewing skills[14,15]. Time and other logistical constraints prevent community-based psychiatric rehabilitation program staff from participating in such intensive training. By leveraging novel strategies that incorporate advances in training and feedback modalities (e.g., online training, virtual training environments), staff training could facilitate adoption and sustained implementation of the ACHIEVE curriculum. To prepare for dissemination, we will also determine the acceptability, appropriateness, and feasibility of both the ACHIEVE-D curriculum and the standard and enhanced strategies among coaches and program directors to direct further refinements of these products.

Strategies to increase implementation of an adapted, evidence-based weight management intervention in community mental health programs: The ACHIEVE Implementation and Dissemination Pilot Trial is an RCT testing the hypothesis that an enhanced intervention will be superior to a standard intervention in increasing program staff knowledge, self-efficacy, and skill to deliver the adapted ACHIEVE curriculum with high fidelity. We will randomly assign 10 community-based psychiatric rehabilitation programs in Maryland to the standard or enhanced intervention for ACHIEVE, and we will enroll 2 staff members per program to participate as coaches. A peer leader will assist them. The standard intervention will combine real-time onboarding training via Zoom, ongoing online training, and online avatar-assisted motivational interviewing practice[19,20] for coaches, as well as organizational strategy meetings to garner the leadership support for ACHIEVE implementation[21]. The enhanced intervention will include all standard strategies and will add performance

coaching for ACHIEVE staff coaches. All enrolled coaches will deliver the adapted ACHIEVE curriculum to consumers with SMI at each study site. We propose the following Aims:

2. SPECIFIC AIMS

Primary Aim: Conduct a pilot randomized clinical trial testing two implementation interventions designed to support delivery of ACHIEVE-D at community-based psychiatric rehabilitation programs.
H1.1. Both the standard and enhanced interventions will increase knowledge of and self-efficacy to deliver ACHIEVE-D, and result in high-fidelity delivery of ACHIEVE-D.
H1.2 Compared to the standard intervention, the enhanced version will lead to greater knowledge, self-efficacy, and ACHIEVE-D fidelity.

Secondary Aims:
1. Assess the acceptability, appropriateness, and feasibility of the adapted ACHIEVE curriculum to coaches, peer leaders, program directors and other staff.
2. Assess consumer outcomes of self-reported diet and physical activity, weight, attendance and satisfaction.

This study will lead to a refined intervention that will contribute to the future development of a certified ACHIEVE-D training program for mental health staff and peers, and thus facilitate future widespread dissemination of an evidence-based behavioral weight-loss program for individuals with SMI.

3. BACKGROUND & SIGNIFICANCE

Public health burden of CVD, obesity, and other CVD risk factors in persons with SMI
CVD is the leading cause of preventable death among persons with SMI[4-10], and this population has high prevalence of CVD and CVD risk factors[22-26]. Notably, obesity is extremely common[1-3]. For example, 60% of women with SMI have obesity[2,27,28] as compared to 41% of women in the general population[29].

Factors that contribute to obesity in individuals with SMI
Several factors contribute to the high obesity prevalence. First, the vast majority of individuals with SMI take at least one long-term psychotropic medication, and these drugs promote weight gain due to increased appetite along with metabolic abnormalities such as elevated glucose and lipids[30-36]. A shared decision-making process that provides patients with the expected weight and metabolic effects of these medications has been the recommended strategy to clinicians to make an informed decision about choice[37]. Unfortunately, initial selection of or changes to a weight-neutral alternative medication may not be an option for many individuals with SMI; therefore, medications are unlikely to be a modifiable risk factor.

Second, diet and physical activity are typically poor in this population. Studies of individuals with SMI demonstrate high calorie and fat intake, as well as low intake of fruit and vegetables[38-43]. Physical activity levels are low in this population[44-48]. For example, persons with SMI report 50% higher leisure time inactivity than the general population[45], and an accelerometry study showed only 4% of individuals with SMI met recommended moderate to vigorous physical activity in bouts of ≥10 minutes[48]. These lifestyle habits also contribute to obesity and CVD risk among individuals with SMI, and unlike psychotropic medications, represent a modifiable CVD risk factor.

Challenge of behavioral weight-loss interventions among persons with SMI
In general populations, behavioral weight-loss interventions have been demonstrated to improve CVD risk by reducing blood pressure and glucose, as well as improving lipid profiles[11]. Behavioral interventions promoting healthy diet, exercise, and weight loss are critically needed, but must be adapted to challenges particularly to the SMI population. In particular, memory impairment, limited executive function, and residual psychiatric symptoms[12,13].

A successful behavioral weight-loss intervention tested in an RCT within the SMI population
The NIMH-funded ACHIEVE trial was the first to demonstrate that an adapted behavioral intervention leads to clinically significant weight loss at 18 months among persons with SMI (mean 7 lbs. weight loss, net 3% loss)[15]. The magnitude of weight loss among individuals with SMI participating in ACHIEVE was similar to the

magnitude observed in efficacious weight-loss trials in general populations[11]. The ACHIEVE intervention combined group and individual weight-management sessions with group exercise sessions delivered in community mental health programs[14,15]. To address some of the noted challenges in this population[12,13], the intervention focused on repeated delivery of six key messages: avoid sugary drinks, avoid junk food, eat 5 servings of fruits/vegetables per day, portion control, smart snack habits, and regular physical activity. The ACHIEVE intervention was predominantly delivered by trained study interventionists, though mental health program staff delivered some video-assisted group exercise sessions[14,15]. Given the obesity epidemic in persons with SMI, there is an urgent need to "scale-up" or expand ACHIEVE to similar settings and populations as those included in the RCT, which we posited could be accomplished by enabling the psychiatric rehabilitation program staff to deliver the sessions[16]. Using the Enhanced Replicating Effective Programs Framework for translating evidence-based interventions into community settings[17], our scale-up strategy considers this model's three stages: pre-implementation, implementation, and dissemination.

Scaling up ACHIEVE – pre-implementation stage

We have already completed the pre-implementation stage, during which we adapted the format of the original intervention to increase ease of adoption and sustained implementation of ACHIEVE by program staff in these community-based programs. (IRB00194122). To realize the full public health potential of ACHIEVE, the curriculum needed to be modified for delivery by community mental health staff[16]. We retained the core components, but modified the curriculum schedule (e.g., combined exercise and weight management group sessions) and enhanced the delivery format (e.g., video-assisted content) to support efficient, staff-led delivery. We pilot tested this adapted curriculum where a trained study interventionist implemented 2 months of programming at a community-based psychiatric rehabilitation program[18], and we then further refined the adapted curriculum based on feedback from program staff and participating individuals with SMI. First, we defined the role for a peer leader within ACHIEVE, where a consumer would be recruited to serve as the peer leader from the group of participating consumers and the duties would include encouraging other enrolled consumers to attend ACHIEVE groups, actively participate in the group exercise sessions to act as a role model, as well as assist the ACHIEVE coach with set up and management of curriculum materials. Second, we identified the need for an assessment of readiness to make the necessary lifestyle behavior changes among consumers to ensure that we enroll individuals who are at an appropriate stage of change to engage in the intensive ACHIEVE curriculum.

In addition, we developed implementation strategies such as organizational strategy meetings with program directors and coaches to support the adoption of ACHIEVE in community-based psychiatric rehabilitation programs. We also refined procedures and assessment measures for grading coach fidelity to ACHIEVE, as well as adapted measures to assess acceptability, appropriateness, and feasibility.

Scaling up ACHIEVE – implementation and dissemination stages

The ACHIEVE Implementation and Dissemination Pilot Trial represents the next stages of the Enhanced Replicating Effective Programs Framework – implementation and dissemination[17], which has a particular focus on testing innovative interventions to enable psychiatric rehabilitation program staff to deliver ACHIEVE-D.

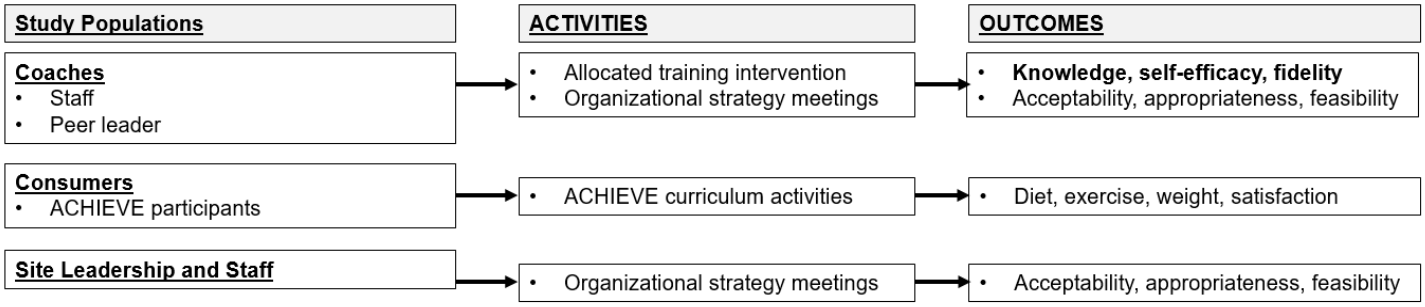
The ACHIEVE trial interventionists, who all had bachelor's or master's degrees in health-related fields, required significant in-person initial and ongoing training on intervention content and motivational interviewing (MI) [14,15]. MI is an evidence-based patient-centered communication method shown to help people make positive diet and exercise changes[49-51], and considered a key aspect of ACHIEVE. Traditional MI training includes two days of in-person training, followed by repeated post-training feedback and coaching by a master trainer. While the community-based psychiatric rehabilitation program staff have valuable experience working with people with SMI, they typically have different educational backgrounds and less experience with lifestyle content as well as MI communication skills. In real-world community mental health settings, time constraints prevent most program staff from participating in the intensive training used among ACHIEVE trial interventionists. Therefore, new strategies need to be developed that incorporate advances in training modalities (e.g. online training, virtual training environments) to enable psychiatric rehabilitation program staff to deliver ACHIEVE-D. Given that training alone is often insufficient to increase wide-spread adoption of new evidence-based interventions[52-55], the ACHIEVE-D curriculum will be supplemented with additional implementation strategies (e.g.,

organizational strategy meetings with program directors and coaches, peer leader identification and training to aid coach) to support future implementation and dissemination of ACHIEVE-D in community mental health settings. Unless effective interventions like ACHIEVE are translated into real-world settings, obesity and CVD disparities among the population with SMI will likely persist or even worsen.

4. DESIGN SUMMARY

The core design is a randomized, two-arm, parallel, pilot clinical trial where 10 psychiatric rehabilitation program sites will be randomized to a 6-month standard or enhanced intervention. This trial will recruit and enroll participants at each site – staff, peer leaders, and mental health consumers, (Figure 1). The primary outcome variables will be coaches' knowledge, self-efficacy, and fidelity to the ACHIEVE curriculum.

Figure 1. Study Populations with Corresponding Activities and Outcomes for Each Site



We estimate up to 280 mental health organization staff and peer leaders will participate in data collection including program directors, coaches, and other psychiatric rehabilitation program staff. Two coaches and one peer leader per study site will be randomized to the standard or enhanced intervention. Up to 120 mental health consumers across all sites will be enrolled, and all will receive group weight-management sessions delivered by the trained coaches at their site.

The ACHIEVE-D curriculum is designed to fit into and will be part of the regular psychiatric rehabilitation programming that is already being conducted.

Randomized groups:

Standard intervention: At those sites assigned to the standard group, two staff and one peer will receive training and approximately 8-12 consumers with SMI will participate in the ACHIEVE weight loss program. The standard intervention will combine onboarding training, ongoing online training, and online avatar-assisted motivational interviewing practice[19,20] for all coaches, as well as organizational strategy meetings to garner the leadership support for ACHIEVE implementation[21].

Enhanced intervention: At those sites assigned to the enhanced group, the implementation intervention will include all standard strategies and will add performance coaching for the coaches.

Trainings and meetings will be remote during the COVID-19 pandemic.

We outline the eligibility criteria sites in Section 5. Then, we describe the eligibility criteria as well as data collection and measurements for each study population separately in Sections 6-8.

5. SITE ELIGIBILITY

We will recruit approximately 10 community psychiatric rehabilitation programs across Maryland as study sites. (Table 1).

In general, sites will need 1) to be an adult psychiatric rehabilitation program. 2) Willing to implement the ACHIEVE curriculum; 3) Willing to support 2 staff members being trained as coaches and implementing the curriculum; 4) Willing to have a peer leader assist.

Table 1. Criteria for study sites

- Adult psychiatric rehabilitation program with willingness to implement the ACHIEVE curriculum at least one time per week for 6 months.
- Willingness to support 2 staff members to be trained and serve as ACHIEVE coaches
  - Training: ~16 hours of onboard training; ~2-4 hours per month of additional online training; ~1.5 hours per month for performance coaching if site is randomized to the enhanced training intervention arm
  - Coach duties: Lead at least one (and up to three) 1-hour sessions per week of the ACHIEVE curriculum to enrolled consumers
- Willingness to support a peer leader to assist with the curriculum.
  - Training: ~16 hours of onboard training; ~2-4 hours per month of additional online training
  - Peer leader duties: Assist staff coaches
- Organizational leaders and staff to participate in organizational strategy meetings with the study team. ~1 meeting every month
- Anticipated ability for study team to recruit consumers to participate in the ACHIEVE curriculum
- Ability for study staff to collect data from coaches, consumer participants, and other staff members

6. STUDY POPULATION: COACHES AND PEER LEADERS

6.1 Eligibility criteria

To be eligible to be a coach, the person must be age 18 or older and a staff member at a psychiatric rehabilitation program, as well as be willing to do the following: complete all training activities as part of the ACHIEVE intervention, deliver all components of the ACHIEVE curriculum to consumers at the program, work with a peer leader as part of the ACHIEVE curriculum, and complete data collection procedures as a study participant. We will exclude staff who plan on leaving their position or taking a leave of absence from the psychiatric rehabilitation program within the next 12 months.

For peer leaders, we will seek individuals 18 years and older who are or are in training to become a Maryland Certified Peer Recovery Specialist, or who are mental health consumers with interest who the psychiatric rehabilitation program staff and study team believe would be a good fit (e.g., in a vocational program). The peer leader must be willing to do the following: complete training activities as part of the ACHIEVE intervention, deliver components of the ACHIEVE curriculum to consumers at the program, work with the staff coaches as part of the ACHIEVE curriculum, and complete data collection procedures. We will exclude peers who plan on leaving their position or taking a leave of absence within the next 12 months.

6.2 Data collection procedures

Data collection is outlined in Table 2. Data collection for coaches and peer leaders will occur remotely via telephone or Zoom and/or online RedCap survey or delivered paper questionnaires. We will collect follow-up measures at 3 months and 6 months at completion of ACHIEVE curriculum.

Participant reimbursement for data collection for staff coach participants is estimated at $160 total for completing all data collection. Participant reimbursement for data collection for peer leader participants includes $75 for completing data collection, up to $320 ($20/hour) for participating in trainings and up to $1500 ($20/hour) per site for participating in delivery of the curriculum.

Table 2. Data Collection Schedule For Coaches and Peer Leaders				
	Baseline	Follow-up		
		During	6M Post	6M Post project completion
Primary Outcomes				
ACHIEVE curriculum weight management knowledge	x		x	
ACHIEVE curriculum exercise knowledge	x		x	
Self-efficacy to deliver ACHIEVE curriculum	x		x	
ACHIEVE Fidelity Document Assessment Form		x		
ACHIEVE Fidelity Video Assessment Form		x		
Other Measures				
Demographics & prior training	x			
Attitudes towards individuals with obesity	x			
Calculated BMI	x		x	
CARDIA/EARLY Q – sedentary behavior	x		x	
Block Dietary Fat Q	x		x	
Block Dietary Fruit/Vegetable Q	x		x	
EARLY Eating Away from Home Q	x		x	
EARLY SSB Consumption Q	x		x	
Perceived Stress Scale	x		x	
Self-Efficacy recall			x	
Beliefs about Motivational Interviewing	x	x	x	
Importance and Confidence of Using MI	x	x	x	
Avatar MI Performance Measurements	x	x	x	
Avatar Motivational Interviewing (MI) satisfaction survey			x	
Perceived Usefulness (motivational interviewing avatar platform)			x	
Fidelity to Motivational Interviewing	x	x	x	
Implementation Measures				
Acceptability of training	x		x	
Feasibility of training	x		x	
Appropriateness of training	x		x	
Motivation for implementation	x		x	
Implementation Climate	x			
Qualitative Assessment				
Focus Group			x	
Interviews				x

Abbreviations: BMI – body mass index; Q – questionnaire; SSB – sugar-sweetened beverage.

6.3 Measurements

Measurements for coaches and peer leaders will be conducted using standardized operating procedures and quality control methods. Specific study forms (RedCap or paper) will be used to collect data.

Primary Outcomes

Knowledge of the ACHIEVE curriculum. We will assess knowledge about key elements of the ACHIEVE curriculum using two measures: A 22-item *ACHIEVE Curriculum Weight Management Knowledge* measure and a 16-item *ACHIEVE Curriculum Exercise Knowledge* measure The study team created these questions

using best practices recommended by the National Board of Medical Examiners for item writing[56]. These measures will be assessed at baseline and 6 months.

Self-efficacy to deliver the ACHIEVE curriculum. We will assess self-efficacy to deliver key elements of the ACHIEVE curriculum, where participants rate their confidence to deliver each element on a 10-point scale. The study team used principles from other related self-efficacy measures in creating our measure[57,58]. This measure will be assessed at baseline and 6 months. Given that this type of self-report measure may be subject to response shift bias[59,60], we will also have coaches reflect upon their baseline ability to carry out these elements at the 6-month point, which will enable us to determine whether response shift bias may be present.

Fidelity to the ACHIEVE curriculum (ACHIEVE fidelity video assessment form and ACHIEVE fidelity documentation assessment form). To determine fidelity to the curriculum, we will use two data sources. First, coaches will video-record two ACHIEVE group sessions each month at each site, one per coach. Two study team members will view each recording and use a rating tool to assess fidelity to key elements of the ACHIEVE curriculum. We will calculate inter-rater reliability between coders. Second, a study team member will examine documentation practices of the coaches on the same day that video tapes are obtained. The study team has identified elements from both data sources that will be summed to create a composite score. Numerical values from all items will be used. For Y/N items, 'Yes' will equal a numerical score of 2 and 'No' a numerical score of 1.

<u>Other Measures</u>

Demographics and prior training. We will collect demographic information such as age, sex, race and ethnicity. We will assess educational level and employment status. We will determine prior training in nutrition, exercise and weight loss at baseline, as well as their proficiency in using computers and online education. We will assess this at baseline, as prior training in these areas may influence our primary outcomes.

Attitudes towards individuals with obesity. We will determine attitudes towards individuals with obesity using elements from a previously validated measure[61]. We will assess this at baseline, as attitudes towards individuals with obesity may influence our primary outcomes.

Physical activity. We will administer the CARDIA-EARLY Sedentary Behavior questionnaire, which is the measure recommended by the NIH for this outcome within weight loss trials[62,63].

Dietary change. We will administer Block Fat, Fruit, Vegetable and Fiber Screener Questionnaires as the food frequency measures[64,65]. These screeners provide a reasonably valid assessment of intake of these foods and have the advantage of being very brief. We will also administer the EARLY Eating Away from Home and Sugar-Sweetened Beverage questionnaires, which are the measures recommended by the NIH for these outcomes within weight loss trials[62,63].

Stress. We will administer the perceived stress scale[66] , which is the measure recommended by the NIH for this outcome within weight loss trials[62,63].

Self-efficacy recall. This instrument asks participants to recall their self-efficacy before training.

Beliefs about Motivational Interviewing. We will administer a 7-question survey assessing the extent to which each person agrees with statements about motivational interviewing.

Importance and Confidence of Using Motivational Interviewing. We will administer a 6-question survey assessing the importance and confidence each person has with motivational interviewing.

Avatar Motivational Interviewing Performance Measurements: Participants will use the avatar platform and conduct 15-minute practice conversations where they practice use of motivational interviewing techniques in

simulated conversations about weight loss with consumer avatars on the Kognito platform. An online dashboard will give them an individualized report on their performance each time they practice.

Avatar Motivational Interviewing (MI) satisfaction: Participants will respond to their use and satisfaction of the Motivational Interviewing (MI) training and practice simulations provided during the course of the six month project.

Perceived Usefulness (motivational interviewing avatar platform): Participants will respond to their perceived usefulness of the motivational interview avatar platform during the course of the six-month project.

Fidelity to Motivational Interviewing: Standardized Actor Interviews will be conducted to assess fidelity to motivational interviewing for coaches. Coaches will conduct 30-minute audio-recorded phone interviews with standardized patient actors. These standardized patient actors are trained actors playing consumers with SMI who are overweight or obese.

Implementation Measures

Acceptability, Feasibility and Appropriateness. We will determine perceptions of acceptability, feasibility and appropriateness of the ACHIEVE curriculum and the training that they received to deliver this curriculum. These measures were adapted from previously validated measures[67].

Motivation and Implementation Climate. We will assess these constructs by adapting previously validated instruments[68,69] .

Qualitative Assessment

Focus Groups. Focus groups will be conducted with select staff, staff coaches, and peer leaders at the end of the study. The focus group is designed to elicit measures in the following domains: perceptions of the acceptability, appropriateness, and feasibility of the ACHIEVE curriculum and the implementation of the intervention; barriers to ACHIEVE implementation; strategies to overcome barriers; and suggestions for further refinement. The focus groups will inquire about perceptions of the acceptability, appropriateness, and feasibility of the ACHIEVE curriculum and the implementation of the intervention; barriers to ACHIEVE implementation; strategies to overcome barriers; and suggestions for further refinement. They will be conducted by Zoom video-conference and will be approximately 90 minutes in length. Participants will receive $25 for participation.

Interviews. Interviews will be conducted at least six months post project completion with staff coaches and/or administration. The interviews are designed to understand if/how the organization has continued implementing the ACHIEVE curriculum. We will assess which aspects of the curriculum were liked and helpful, which aspects were changed and why those changes were made, and what, if any, training was provided to staff to continue delivery of the ACHIEVE program. We also aim to understand if changes were made at the organizational level to support continued delivery of the ACHIEVE program. Interviews will be conducted by Zoom video-conference and will be approximately 30 minutes in length. With permission, they will be recorded and transcribed. Participants will receive $25 for completing the interview.

7. STUDY POPULATION: CONSUMER PARTICIPANTS

7.1 Eligibility criteria

To be eligible to be an ACHIEVE participant, the person must be a consumer with SMI enrolled in a psychiatric rehabilitation program, age 18 or older, have a body mass index (BMI) ≥ 25 kg/m^2, and willing to make changes in diet and exercise to lose weight, as well as: willing to participate in all activities in the ACHIEVE curriculum at least 1 day per week, competent to give informed consent, and complete all data collection procedures. We aim to be generalizable while including individuals safe to participate in a weight loss program that includes moderate intensity exercise. Table 3 provides eligibility criteria for consumers.

Table 3. Eligibility Criteria for Consumers as ACHIEVE Participants
Inclusion criteria

• Age 18 and older
• Enrolled in a psychiatric rehabilitation program
• BMI ≥ 25 kg/m^2
• Willing to make changes in diet and exercise to lose weight
• Willing to attend the ACHIEVE group sessions virtually or in-person at least once per week
• Ability to use a computer or tablet
• Competent and willing to give informed oral consent
• Completion of baseline data collection
Exclusion criteria
• Any underlying medical conditions that could seriously reduce life expectancy, ability to participate in the study, or for which dietary change/physical activity/weight loss may be contraindicated e.g., o Lung disease requiring supplemental oxygen o Liver failure o History of anorexia nervosa or bulimia o Stage V kidney disease on dialysis o Cardiovascular event in the last 6 months including unstable angina, myocardial infarction, congestive heart failure, transient ischemic attack, or stroke
• Insulin dependent diabetes
• Inability to walk unassisted (e.g., uses a cane, walker, etc)
• Pregnant, breastfeeding, or planning a pregnancy during study period
• Prior or planned bariatric surgery
• Use of a prescription anti-obesity medication or over-the-counter orlistat within the past 3 months
• Self-reported weight loss of >20 lbs in the last 3 months
• Active substance use disorder, alcohol use disorder, or problem drinking (more than 14 drinks per week for women, more than 21 drinks per week for men)
• Planning to leave mental health program or move out of geographic area within 12 months
• Weight greater than 440 pounds (so as not to exceed capacity of study scale)
• Investigator judgment (e.g., for concerns over safety, adherence or follow-up)

7.2 Data collection procedures

Our study team has worked with several hundred persons with serious mental illness as study participants in intervention trials for more than 15 years.

For this study, when possible, data collection will occur at psychiatric rehabilitation centers, with all appropriate precautions in place to remain safe during the pandemic. If the participant cannot come to the center (e.g., kf the center is not open) measures will be collected over the phone/zoom and with participants self-measuring weight on a scale the team provides for them.

Participant reimbursement for data collection for all participants is estimated at $60 total for completing all data collection points.

Participant eligibility is determined by a combination of information provided by psychiatric rehabilitation program staff prior to consumer consent (with HIPAA waiver) and from several baseline measures after consent.

In response to the pandemic, several safety measures will be in place when meeting in person:

- Community mental health programs are regulated by the state of Maryland and currently have COVID safety protocols in place.
- Participants will be required to wear a mask at all times. One will be provided by the study team if needed.
- Research staff will wear PPE during in-person data collection.
- All equipment will be cleaned and disinfected before and after data collection using appropriate cleaning methods.
- Prior to an in-person visit, we will screen consumers by phone for virus/disease symptoms and exposure with the Ambulatory Screening Algorithm for COVID-19. Screening will occur the day prior to the visit. If symptoms or exposure are reported, we will not conduct the visit, we will alert mental

health program staff and also advise consumer to contact their primary care provider. In addition, mental health programs conduct their own screening prior to in-person attendance.

- During the in-person visit, study staff will instruct the consumer how to use a tablet to complete data collection and how to use Zoom. The study tablet will already be set up for the consumer.
- We plan to then discuss and obtain consent and survey data via videochat/Zoom with the participant in the next room. Study staff will review surveys with the consumer via Zoom. If the consumer is not able to follow along, study staff may sit in the same room, more than 6 feet apart, and read questions to the participant.
- We plan to collect weight, height, and blood pressure in-person. Research staff will take appropriate precautions when coming within 6 feet of participants and will minimize in-person time. We estimate that research staff will need to come within 6 feet of participants for a total of 13 minutes: Taking weight and documenting: 3 minutes; Taking height and documenting: 3 minutes; Taking measurements of the arm and wrapping of blood pressure cuff: 4 minutes; Documenting blood pressure and unwrapping cuff: 3 minutes.

We will assess eligibility in the following ways.

1. We will measure weight and height.
2. We will assess pre-participation health screening in preparation for a moderate intensity exercise program that includes the modified 2018 Physical Activity Readiness Questionnaire (2018 PAR-Q), a checklist of medical conditions for health screening, and blood pressure measurement.
    - The ACHIEVE curriculum emphasizes the achievement of moderate, not vigorous, intensity physical activity. The safety of moderate intensity physical activity in properly screened subjects is well established. We will follow the American College of Sports Medicine (ACSM) recommendations for health screening and risk stratification in preparation for starting a moderate intensity exercise program[70]. The ACSM exercise pre-participation health screening process focuses on 1) the individual's current level of physical activity, 2) presence of signs or symptoms of known cardiovascular, metabolic, or renal disease, and 3) the desired exercise intensity, as these variables have been identified as risk modulators of exercise-related cardiovascular events.
    - If potential participants endorse high risk symptoms on 2018 PAR-Q (e.g., chest pain or dizziness) or have a medical condition where physical activity and/or weight loss may be contraindication, we will communicate with their primary care provider to assess appropriateness for the program.
    - For patients with hypertension and non-insulin-dependent diabetes mellitus, we will send a letter to their primary care physician alerting these physicians to their patients' interest in participating in a weight loss program and their need for medical supervision. This letter will request that the physician agree to monitor and manage the patient's hypertension and/or diabetes mellitus during participation in the program.
    - For other participants, we will send a letter to primary care physicians alerting these physicians to their patients' participation in a weight loss program. Due to state regulations, almost all consumers will have primary care physicians; we will work with rehabilitation program staff to facilitate referral to primary care for those who do not.
3. We will review consumer medical records and medications for any exclusion criteria.
4. We will assess readiness to make changes needed to lose weight.
5. We will discuss with consumers and staff plans to remain at the rehabilitation center and be available to participate either in-person or remotely.

7.3 Measurements

Measurements will be conducted using standardized operating procedures and quality control methods. Specific study forms either in RedCap or paper will be used to collect data.

Table 5. Data Collection Schedule for Consumers		
		Follow-up

	Screening/ Baseline	During	6M Post
General Assessments			
Evaluation to Give Consent	x		
Demographics	x		
Exercise pre-participation screening (modified 2018 PAR-Q)	x		
Medical history	x		
Medications	x		x
Readiness rulers	x		
Physical Measurements			
BMI	X		x
Blood pressure	x		
Physical Activity			
CARDIA/EARLY Q – sedentary behavior	x		x
Diet			
Block Dietary Fat Q	x		x
Block Dietary Fruit/Vegetable Q	x		x
EARLY Eating Away from Home Q	x		x
EARLY SSB Consumption Q	x		x
NHIS Screener	x		x
Satisfaction			
Consumer Satisfaction & Helpfulness Q			x
Other Measures			
Palatable Eating Motives Scale (PEMS) – Coping Subscale	x		x
Reward-based Eating Drive (RED) Scale	x		x
Important Others Q	x		x
Medical Events			x
Perceived Stress Scale (PSS)	x		x
Ambulatory Screening for COVID-19	x		x

General Assessments

Demographics. We will collect demographic information such as age, sex, race, and ethnicity. We will also assess how often they attend the program.

We will use several measures and data sources to assist in determining eligibility for the study. *Exercise pre-participation screening (modified 2018 PAR-Q):* This modified physical activity readiness questionnaire will be used to assess if consumer is able to participate in exercise classes. *Medical History:* We will collect medical history information from each consumer to assess ability to participate in the ACHIEVE program and the staff. *Medications:* We will list all of the consumer's current medications. We will use the *Readiness Rulers* survey to assess participant's readiness to lose weight and willingness to participate in the ACHIEVE program.

Anthropometrics – blood pressure, weight, height and BMI. We will assess blood pressure, height and weight at baseline. Weight will be measured to the nearest 0.1 lb. by a high-quality digital scale with participants wearing light indoor clothes without shoes. Weight will be measures in lbs. for ease of interpretation by participants and converted to kg for calculation of BMI, calculated as the Quetelet index (kg/m^2). Height will be measured to the nearest 0.1 cm using a wall-mounted stadiometer. Blood pressure will be determined by the OMRON 907 XL, a validated device that records BP using an oscillometric technique[71]. One blood pressure with 3 measurements (each separated by 30 seconds) will be obtained on the right arm of participants after

they rest quietly in the seated position for at least 15 minutes[72]. If measures cannot be in person, participants will self-measure weight on a scale the team provides for them.

Physical activity. We will administer the CARDIA-EARLY Sedentary Behavior questionnaire, which is the measure recommended by the NIH for this outcome within weight loss trials[62,63].

Dietary change. We will administer Block Fat, Fruit, Vegetable and Fiber Screener Questionnaires as the food frequency measures[64,65]. These screeners provide a reasonably valid assessment of intake of these foods and have the advantage of being very brief. We will also administer the EARLY Eating Away from Home and Sugar-Sweetened Beverage questionnaires, which are the measures recommended by the NIH for these outcomes within weight loss trials[62,63]. We will also administer the NHIS Dietary Screener Questionnaire with 26 questions.

Satisfaction. We have adapted a prior measure used to assess helpfulness of various elements of another behavioral weight loss intervention[73], as well as adapted a measure previously validated among consumers with SMI to assess satisfaction with care[74].

Eating habits. We will administer two measures -- Palatable Eating Motives Scale (PEMS) – Coping Subscale and Reward-based Eating Drive (RED) Scale, which assess emotional factors that influence eating habits. We will also administer the Important Others Questionnaire that assess social factors that influence eating habits. All of these measures recommended by the NIH for these outcomes within weight loss trials[62,63].

Stress. We will administer the perceived stress scale[66], which is the measure recommended by the NIH for this outcome within weight loss trials[62,63].

Medical events. We will also capture any medical events that occur during the 6-month intervention.

Important others. We will capture information about support systems and people in the consumer's life that can assist in healthy weight management behaviors.

Intervention process measures. During the weight management curriculum, attendance, participation and weight measurements will be collected.

8. STUDY POPULATION: OTHER STAFF

8.1 Eligibility criteria

To be eligible as other staff, the person must be a staff member at a psychiatric rehabilitation program and age 18 or older, as well as willing to do the following: review waiver of documentation of informed consent with study staff and complete data collection procedures.

8.2 Data collection procedures

Data collection timeline is outlined in Table 6. Data collection will occur with study forms either in RedCap or paper. Focus groups will be conducted by Zoom. Participant reimbursement for data collection for other staff participants is estimated at $45 total for all data collection points, divided over each time point.

Table 6. Data Collection Schedule for Other Staff

	Baseline	Follow-up	
		During	6M Post

	x		
Other Measures			
Demographics & prior training	x		
Implementation Measures			
Motivation for implementation	x		x
Implementation Climate	x		
Qualitative Assessment			
Focus Group			x

Demographics and prior training. We will collect demographic information such as age, sex, race, and ethnicity. We will assess educational level and employment status. We will determine prior training in nutrition, exercise and weight loss at baseline, as well as their proficiency in using computers and online education.

Motivation and Climate for Implementation. We will assess these constructs by adapting previously validated instruments[68,69].

Qualitative Assessment

Focus Groups. Focus groups will be conducted with select staff, staff coaches, and peer leaders at the end of the study. The focus group is designed to elicit measures in the following domains: perceptions of the acceptability, appropriateness, and feasibility of the ACHIEVE curriculum and the implementation of the intervention; barriers to ACHIEVE implementation; strategies to overcome barriers; and suggestions for further refinement. Focus group participants will be represent all study sites. The focus groups will inquire about perceptions of the acceptability, appropriateness, and feasibility of the ACHIEVE curriculum and the implementation of the intervention; barriers to ACHIEVE implementation; strategies to overcome barriers; and suggestions for further refinement. They will be conducted remotely by Zoom video-conference and will be approximately 90 minutes in length. Participants will receive $25 for completion of focus group.

9. QUALITY ASSURANCE AND QUALITY CONTROL

Quality Assurance pertains to activities that promote collection of high-quality data, and Quality Control refers to activities that detect emerging data issues with sufficient time to implement appropriate corrective actions. Our approach to Quality Assurance includes: 1) preparing a manual of operations; 2) implementing a master trainer model to train and certify other staff; 3) train and certify all data collectors on in-person and remote procedures; 4) recertify data collectors at least annually; 5) routinely calibrate equipment; 6) maintain logs of certified staff and calibrated equipment. Our approach to Quality Control includes: 1) monitoring counts of completed data collection items; 2) monitoring distribution of trial outcomes, overall, by data collector and site; 3) record lag time in data entry; 4) issue queries on missing data, out of range values or illogical data relations; 4) review types and distribution of data entry errors; and 5) prepare reports for staff, investigators, and an independent study monitor on Quality Control.

10. RANDOMIZATION AND BLINDING

Following baseline data collection, sites will be randomized to the standard or enhanced arms. Randomized blocks of 2 in random order will be used to create the randomization sequence. The random sequence and allocation groupings will be stored in RedCap, only the data analyst will distinguish the treatment assignment to sites. Due to the nature of the intervention, both participants and interventionists will be aware of the assignment. Data collectors measure study outcomes. Investigators, staff and participants are masked to outcome data, with the exception of trial statistician, study coordinator, data analyst and independent study monitor.

11. INTERVENTION GROUPS

An overarching principle of the adapted ACHIEVE-D curriculum is that it is designed to fit into and will be part of the regular programming that psychiatric rehabilitation programs are already providing for their clients with mental illness. The psychiatric rehabilitation program staff trained as ACHIEVE-D coaches will have the support of their leadership for ACHIEVE-D program delivery. Based on discussions with and requests from the study sites, each site will decide how they will deliver the ACHIEVE-D curriculum during COVID, taking into consideration how they are delivering their other programming, their priorities, and resources. If psychiatric rehabilitation programs are delivering in-person programming, then they will likely plan to deliver ACHIEVE-D in-person at least once per week. For persons with serious mental illness, in-person programming is preferred due to psychiatric symptoms, cognitive impairment, and potential challenges using smartphones and computers. To support sites that prefer to offer remote groups, we will be providing clients with Grandpads (tablets). Our study team will train consumers to use the devices during baseline data collection and Coaches will troubleshoot technology issues that arise during groups. We expect most sites will use a hybrid method of delivery during COVID with both in-person and remote sessions. Sites follow Maryland Medicaid and other regulatory guidelines for safety and operating procedures. Sites will have the flexibility to change their delivery method during the study. (We have discussed these plans with Megan Singleton). Peer leaders will assist staff coaches as appropriate including considering COVID restrictions at each site.

In-person group exercise classes may be held during COVID-19 depending on each site's COVID safety protocol. Exercise classes may be delivered via Zoom video-conferencing as part of the ACHIEVE group or offered as a supplemental session led by a trained peer leader with support from the study team.

11.1 *ACHIEVE Curriculum*

All sites will use the ACHIEVE curriculum, a six-month behavioral weight loss program delivered by trained coaches with the assistance of peer leaders to enrolled mental health consumers at the 10 PRPs. ACHIEVE classes will be offered at least once per week (up to 3 days per week) for about 1 hour. Classes may be delivered in person or virtual depending on COVID restrictions in place at each PRP. Obesity is a chronic condition which benefits from ongoing intervention, and the curriculum is designed to be integrated into regular PRP programming. The curriculum includes six monthly core modules and seasonal modules that can be incorporated into the curriculum depending on the time of year the program is delivered (Exhibit 1). Within each monthly module, the topic varies by week. When sites are delivering more than one weight management class each week, the content will be repeated ; repetition of messages is a key tenet of intervention tailoring for persons with SMI. Coaches will use motivational interviewing communication techniques in all interactions with consumers. This curriculum was adapted from the behavioral intervention previously tested by Daumit and colleagues[15]. We have also previously tested two months of this adapted curriculum at one PRP in a proof-of-concept study, which found that the format was feasible and acceptable to consumers and staff.

Exhibit 1. 6-Month ACHIEVE Curriculum Overview
Type and Frequency of Contact
Multipurpose group weight management class: 1-3 times per week for 50-min class (30 min weight management and 20 min exercise (see above)) led by trained ACHIEVE staff and peer coaches
Weigh-ins: occur on the day of each class (10 min) (or virtually)
Curriculum Delivery Modality
Weight management: Facilitated session with short videos Exercise: Video-assisted group exercise
Goals and Recommendations
Weight loss goal 5% in 6 months
Behavioral recommendations: 6 Core Modules **Weight loss success** • **No sugar drinks** • **No junk food** • **Eat smart portions** • **Eat more vegetables** • **Putting it all together**
Seasonal modules available to tailor experience • **A New Start in the New Year** • **Heart Healthy Valentine's Day** • **Maintain Don't Gain during Celebrations** • **Spring into Walking** • **Halloween Fun without the Sugar** • **Maintain Don't Gain during the Holidays**

In-person group exercise classes may be offered during COVID-19 with appropriate safety protocols (e.g., social distancing, proper room ventilation). Exercise classes may also be delivered via Zoom video-conferencing as part of remote groups. For remote sessions, exercise class will occur during the first 20 minutes of the session via Zoom. The coach may play an exercise video over Zoom. If the site is using a hybrid model of delivery with some weight management sessions

occurring in-person, the coach may offer additional physical activity classes to be delivered via Zoom or recommend online exercise videos for participant. The coach will recommend daily physical activity for at least 20 minutes, whether in an ACHIEVE session or not, specifically emphasizing low impact moderate intensity aerobic exercises such as going on walks.

Video-based virtual exercise classes may also be offered as a separate group that is facilitated by the peer leader and study team staff. The peer leader will be trained to co-lead these groups using an ACHIEVE-approved low-impact moderate intensity aerobic video (e.g., Walk Away the Pounds). Groups will last 20 minutes and include a warm-up and cool-down. To ensure participant safety, the study team member will confirm each participants' contact information at the beginning of each class (e.g., name, address from which they are joining the exercise class, phone number and emergency contact). The peer leader will facilitate the class, and the study team member will monitor participants via video. These groups will be scheduled at times that do not conflict with the Coach-led ACHIEVE groups. When sites are delivering in-person groups and are not able to incorporate group exercise into the curriculum (due to COVID safety protocols), these virtual exercise classes provide an option for clients to engage in exercise from the safety and convenience of their home while also benefiting from the support of their peers.

11.2 Standard Intervention Group

The standard intervention components are described in Exhibit 2. Staff Coaches and Peer Leaders will participate in all trainings.

[12]

Exhibit 2. Overview of Standard Intervention Components		
	Component	**Elements**
Standard	**On-Board Training**	During training sessions, a mix of didactic content and role play are used. Materials needed to implement all components the ACHIEVE weight-loss curriculum is covered. More detail on how to discuss each weight-loss subject is introduced in a stepwise fashion. Training on motivational interviewing (MI) techniques is also provided. Master trainers who have expertise in health coaching and MI training conduct the initial on-board training.
	Online Training Modules	Monthly online didactic training modules (15-20 min) are an efficient method for coaches to observe and learn how to deliver the ACHIEVE weight-loss topics. Each training module includes both relevant didactic content and examples of experienced ACHIEVE staff providing real-world examples of delivering the content in groups. Coaches view the online modules each month before teaching that specific component of the program.
	Online Avatar MI Practice Module	At the end of the on-board training, coaches are given access to an online avatar MI practice module, which includes a 15-minute didactic component and 15-minute virtual practice conversations with consumers with SMI. These simulated conversations allow coaches to practice (a) providing feedback about weight-loss progress and (b) increasing participant engagement in exercise classes. The avatar module includes built-in MI performance feedback. Coaches are encouraged to use the module weekly for the first three months and as needed (e.g., monthly), repeating practice until they receive a "good" score.

Our training approach provides interactive opportunities for coaches to practice the skills needed to implement the ACHIEVE curriculum, a strategy more effective than didactic education.

At minimum, each Coach will be video-recorded delivering an ACHIEVE group during months 1, 3 and 6; each coach may be recorded monthly. These recordings will be for research purposes only and will not be shared with the site supervisors. Recordings will be shared with master trainers on the study team who are responsible for assessing fidelity to the ACHIEVE curriculum (master trainer grading will not be used in outcome scoring).

To enhance the uptake of ACHIEVE we will meet with leadership for organizational strategy meetings to increase leaders' engagement with evidence-based practice implementation. These meeting will be held approximately monthly and will include the PRP director and ACHIEVE coaches. These meetings support development, adoption, and sustainment of organizational strategies needed for program implementation (e.g., changes to class schedules to maximize attendance) as well as implement strategies that demonstrate leadership buy-in to ACHIEVE.

11.3 Enhanced Intervention Group

The enhanced intervention includes all components of the standard intervention along with the addition of performance coaching. Performance coaching may be particularly beneficial when, as in the present case, the evidence-based practice is new to most implementers. Each month a master trainer on the study team will meet with the Coach to provide tailored feedback and performance coaching session. The feedback will be used to 1) promote curriculum fidelity; 2) facilitate motivational interviewing skill development; and 3) help coaches plan for improved ACHIEVE curriculum delivery.

12. DATA MANAGEMENT and SECURITY

Quantitative Data. Each participant will be assigned a unique study ID number for data collection, instead of name or other identifying information. The link between identifying information and the study ID will be kept in a separate database with password access available only to the data analyst, statistician and principal investigators. Study team members are trained to protect integrity and confidentiality of the data. Data will be published only in aggregate, with no identifying characteristics of individuals published or presented. We will store data in a Johns Hopkins REDCap database. REDCap data is housed on secure servers at the Johns Hopkins Biostatistics Center under firewall protection. Database access is password protected and restricted to authorized personnel only and REDCap provides audit trails for tracking data manipulation and user activity. Any paper records will be kept in locked file cabinets. Kognito, a health simulation company, developed the avatar simulations for this project and hosts the avatar training platform and dashboard. Avatar performance measurement data for motivational interviewing practice conversations is accessible only by the individual study participant (provider) and the study team, not shared outside Kognito. Kognito stores data securely behind two firewalls.

Built-in range and logic checks will prompt data checks and confirmation in real-time during data collection. The analyst will routinely conduct thorough checking and cleaning, examining distributions and data patterns and evaluation to detect inconsistencies. Outliers (e.g., extreme weight changes) will be identified using Rosner's extreme Studentized deviate (ESD). Every effort will be made to determine correctness of outliers in a timely manner. Confirmed outliers will be flagged and set aside in the principal secondary analyses. Those removed will be treated as all other missing data; sensitivity analyses will be conducted to assess influence of outliers on results. The analyst will create detailed variable documentation and conduct analysis per protocol under direction of Dr. Wang, statistician.

Qualitative Data. Focus groups will be audio or video-recorded and recordings will be transcribed using Production Transcripts, Inc or another approved Johns Hopkins vendor. Names will be removed from transcripts. Recordings will be stored in a Johns Hopkins secure network drive and will be destroyed when analyses are complete. Standardized actor interview recordings will be reviewed by experts in motivational interviewing for fidelity to motivational interviewing practices and stored in a Johns Hopkins secure network drive or OneDrive.

13. DATA ANALYSIS

We will assess the effects of the implementation intervention on providers' knowledge self-efficacy, and fidelity to the ACHIEVE curriculum, as well as consumer outcomes using generalized linear mixed-effects models under the intent-to-treat approach. Mean models will include a binary intervention group indicator, time indicators, intervention by time interaction terms, and fixed effects for the 10 study sites. The time indicator coefficients estimate time-specific mean outcome changes in the "standard" group and interaction coefficients estimate the between-arm differences of time-specific outcome changes from baseline. The linear combination of these time-specific coefficients captures the time-specific mean outcome changes in the "enhanced" group. The model will use an unstructured variance covariance matrix for the repeated outcome measurements over time within individuals. To assess whether knowledge and self-efficacy mediate implementation intervention

effects, we will estimate the magnitude of attenuation on intervention effects in the consumer outcome models with vs. without these measures. We will also examine potential moderators, e.g. study sites' implementation intervention fidelity and/or implementation climate, by adding appropriate interaction terms to the models. We will analyze survey data on our implementation measures prior to conducting focus groups in order to explore survey findings in depth (e.g., if providers' rate performance coaching as having mediocre acceptability, we will explore reasons why in the focus groups). We will use descriptive statistics to analyze survey measures of perceptions of acceptability, feasibility and appropriateness of implementation intervention and ACHIEVE-D. Point estimates and corresponding 95% confidence intervals will be obtained.

14. HUMAN SUBJECTS

All study staff will complete the web-based Collaborative Institutional Training Initiative (CITI) for Basic Human Subjects Research, Conflict of Interest Training and training in the Health Insurance Portability and Accountability Act (HIPAA). All study participants have a waiver of documentation of written consent using procedures reviewed and approved by Johns Hopkins Institutional Review Boards. The consent scripts cover all procedures done as part of data collection and the intervention.

Sources of materials

Data collectors will conduct assessments in-person and/or remotely. Eligibility will be determined through baseline data collection procedures for each study population. To determine eligibility for the study for consumer participants, we will also obtain permission from potential subjects to talk with mental health program staff and clinicians and contact their primary care physician and psychiatrist concerning any medical or psychiatric reasons for study exclusion. We will communicate with these physicians to ensure there are no contraindications to participating in the intervention. We will document assessments in each subject's study chart.

Safety Monitoring for Consumer Participants

Consumer participant safety will be closely monitored. Protection of these research participants begins with the eligibility criteria, which are designed to exclude individuals with a serious medical condition or psychiatric instability that would make it unsafe for them to take part in a weight-loss program. During the study, regular mental health and primary care will be provided by the participant's usual mental health and primary care providers, not by the study. Participants will be made aware of this delineation of responsibility.

We will carefully monitor the safety of enrolled participants. If a participant develops a medical or psychiatric issue, the safety of continuing or resuming participation in the weight-loss program will be ascertained by the study clinician in collaboration with the participant's regular providers. Surveillance for serious adverse events and other relevant clinical events will occur at the six-month mark.

A study clinician, Dr. Murphy (independent study monitor), with appropriate expertise will be responsible for reviewing medical eligibility criteria and clinical measures, and will be the primary contact for staff, participants and physicians for medical issues. This clinician will review and report any serious adverse events and will have appropriate coverage during absences to provide 24/7 medical safety coverage for the study.

15. POTENTIAL RISKS

Potential risks differ by study population.

All research studies have some degree of risk or discomfort. Time burden in responding to surveys and discomfort during interviews using sensitive questions are common risks and discomforts of minimal risk studies that use an oral consent process.

Staff participants may become tired or bored during surveys, interviews or focus groups.

There are risks related to physical activity and nutrient intake, including hypoglycemia and symptomatic hypotension related to diet and exercise interventions. Protections against these risks are described below. We have also set alert values for baseline blood pressure data collection, we have procedures in place for surveillance and reporting, and our exclusion criteria is meant to exclude people for safety reasons.

Consumers will be screened for orthopedic or rheumatologic problems that might limit their ability to participate in the physical activity component of the intervention. Exercise will focus on mild to moderate intensity aerobic exercise using progression of intensity and duration appropriate for sedentary individuals. If there is any question about the etiology of an injury or the need for treatment, the consumer will be referred to a physician for further evaluation.

Surveillance for serious adverse events and other relevant clinical events that may be associated with study participation will occur at the six month mark. This is done using a standardized questionnaire. In addition to the end of study report participants may report events in other settings (e.g., intervention contacts). A study clinician will review the completed forms, will classify the event according to several dimensions (expectedness, relatedness and type) and will take appropriate action. Safety-related events will be reported in a timely fashion as required by the IRB and NIMH.

Expected events
Over the duration of the six month project a number of medical events may be expected to occur in overweight or obese adults, including routine surgeries and procedures, the development of cancer and other chronic conditions, increased symptoms from a chronic condition, musculoskeletal problems and motor vehicle accidents.

Importance of knowledge to be gained
Persons with SMI have high burdens of each major cardiovascular risk behavior, yet persons with SMI have been systematically excluded from interventions to decrease cardiovascular risk. If successful, this proposed program and curriculum could be disseminated widely. The minimal health risks to participants are offset by the potential benefits to participants and to the greater population with chronic mental illness.

16. ADEQUACY OF PROTECTION AGAINST RISKS

Organization staff will be appropriately recruited and informed of the study by study team with waiver of documentation of informed consent. They study team will inform them that they do not have to answer any questions they do not want to, and that their employment or evaluations will not be affected by their responses. This is a minimal risk study.

There will not be a Data Safety Monitoring Board (DSMB) for this project. Participant safety will be closely monitored. We will have an independent study monitor who is experienced in clinical trial lifestyle interventions Dr. Appel, a practicing internist, who will work with Drs. Daumit to promote and monitor safety throughout the study. The safety officer does not provide direct medical care and is not involved in the intervention.

Protection of research participants begins with the eligibility criteria, which are designed to exclude individuals with a serious medical condition that would preclude their ability to lose weight or to exercise safely. This will be done in collaboration with the participant's primary care physician. During the study, clinical care will be provided by the participants' usual specialty mental health providers and the primary care physician, not by the study. Participants will be made aware of this delineation of responsibility. We will carefully monitor the safety of enrolled participants. If a participant develops a medical problem, the safety of continuing or resuming the intervention will be ascertained by the participant's primary care physician in collaboration with a study clinician.

Physical activity: The small risk during physical activity will be minimized by emphasizing moderate activity, and by following American College of Sports Medicine guidelines regarding need for medical examination prior to beginning an exercise program. Trained exercise interventionists will supervise all exercise sessions.

Nutrient intake: Calorie restriction could theoretically lead to inadequate nutrition or excessive, rapid weight loss. Intervention subjects will be encouraged to eat a variety of foods from all food groups and maintain an adequate caloric level. Those who have a sudden, marked weight reduction will be interviewed to determine if extreme measures have been taken. The issue of adequate nutrient intake and the importance of safe weight loss will be discussed in the group and individual sessions. If a problem is suspected, the participant will be counseled.

Hypoglycemia related to diet and exercise interventions: For patients who may be susceptible to hypoglycemia due to use of anti-diabetic medications, weight loss interventions have the potential to increase the risk of hypoglycemia, especially during the time when diet and/or physical activity interventions are implemented. To minimize the risk of hypoglycemia, we will require primary care physician approval prior to enrolling individuals with diabetes.

Symptomatic hypotension related to diet and exercise interventions: For patients who may be susceptible to hypotension because they are using medications that lower blood pressure, weight loss interventions have the potential to increase the risk of hypotension. Participants are educated about symptoms of hypotension and urged to contact their primary physician if they have symptoms suggestive of hypotension. In addition, staff will notify primary physicians for participants who develop symptomatic hypotension while on anti-hypertensive medications.

Alert Values for baseline blood pressure data collection

Blood pressure: Alert level 1: For any systolic blood pressure (SBP) measure of >= 180 mmHg or diastolic blood pressure (DBP) of >=110, the participant is notified during the visit, the study clinician is contacted and the subject is referred to their personal physician for further evaluation within one week. Alert level 2: For any systolic blood pressure (SBP) measure of >= 160 mmHg or diastolic blood pressure (DBP) of >=100, the participant is notified during the visit, the study clinician is contacted within 1 week and the subject is referred to their personal physician for further evaluation within one month. Alert level 3: For any systolic blood pressure (SBP) measure of >= 140 mmHg or diastolic blood pressure (DBP) of >=90, the participant is notified during the visit, the study clinician is contacted per routine reporting and the subject is referred to their personal physician for further evaluation within two months. For any elevated blood pressure values, if the participant is symptomatic with chest pain, headache or shortness of breath, the study clinician and primary care physician are notified immediately. For any systolic blood pressure (SBP) measure of <90 mmHg or diastolic blood pressure (DBP) of <50, the participant is notified during the visit, the study clinician is contacted per and the subject is referred to their personal physician for further evaluation within one week. If the participant has symptoms of lightheadedness or feeling faint, the study clinician and primary care physician are notified immediately.

Mental Health

If a participant is hospitalized for psychiatric reasons during the study, he/she will be reassessed by rehabilitation program staff and study personnel after return to the rehabilitation program for the ability to continue in the curriculum. We have enrolled over 800 people from a similar population in clinical trials, and we expect these occurrences to be rare.

Pregnancy and other exclusions

If a participant becomes pregnant during the study, she is then excluded. If a participant develops cancer, unstable angina, or another condition for which weight loss or exercise might be contraindicated, further participation will be determined by the participant's primary care physician in conjunction with a study clinician.

Surveillance and Reporting Procedures

Serious adverse events include the following: death, life-threatening experience, inpatient medical or surgical hospitalization, persistent or significant disability or incapacity. Important medical events that do not result in death or require hospitalization may be considered serious adverse events if they jeopardize the participant or require medical or surgical intervention to prevent one of the outcomes above.

Breach of confidentiality
All participant information will be considered confidential. This confidentiality will be assured through several mechanisms. For the study, each participant will be assigned an anonymous study ID, which will be used on all study forms. In addition, all study forms and paper records that contain participant information will be kept in secured, locked areas when not in use. During active data collection, any hard copies of data collection forms will be stored in locked areas. Only authorized personnel will have access to these locked areas. Finally, neither the rehabilitation program nor participants will be identified by name in any publications.

For qualitative data, no focus group participants will be individually identified; a site identifier will be used. The link to the site ID will be held in a locked file. Focus group transcripts will have names (if mentioned during the group) removed, and no participants will be identified by name in any publications. The tapes will be kept for 7 years and then destroyed. Furthermore, data will not be presented in such a way that identity can be inferred. Transcripts of focus groups will have names removed. Employees will be assured that their participation in the study and information shared in the interviews will not affect their employment or their evaluation. As described in Data Management and Security, data will be stored in Johns Hopkins secure drives.

17. BENEFITS

There may be no benefit to individual participants. The research will help us understand the effets of the pilot implementation intervention on mental health program staff delivery of the curriculum in psychiatric rehabilitation program settings.

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