Adapted ACHIEVE Curriculum for Community Mental Health Settings

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1. Abstract

Prevalence of obesity is significantly elevated and a leading cause of preventable death in people with serious mental illness (SMI) through its effects on other cardiovascular disease (CVD) risk factors and CVD. Behavioral interventions targeting changes in diet and exercise need to be tailored to the needs of people with SMI, such as memory impairment and limited executive function. The NIMH-funded Achieving Healthy Lifestyles in Psychiatric Rehabilitation (ACHIEVE) trial tested a behavioral weight-loss intervention for persons with SMI and demonstrated clinically significant weight loss. In light of the obesity epidemic in persons with SMI, there is an urgent need to scale-up interventions like ACHIEVE. To increase ease of adoption and sustained implementation of ACHIEVE in community mental health programs, the format needs to be adapted for delivery by community mental health staff. Based on our experience conducting the ACHIEVE trial, this study team has already made modifications to adapt the ACHIEVE intervention into ACHIEVE-Dissemination or "ACHIEVE-D" curriculum for community mental health settings. Therefore, we will pilot test two months of this ACHIEVE-D curriculum in a community-based psychiatric rehabilitation program (PRP) to determine whether this format is acceptable to participating PRP consumers with SMI as well as PRP staff and peer leaders.

This pilot study protocol is the first part of an NIMH R34 study that will test strategies to increase implementation of ACHIEVE. The second part of the R34 study, which will test the complete version of ACHIEVE-D in multiple study sites, will be submitted as a change in research or a separate protocol. This R34 is part of a P50, the NIMH Johns Hopkins ALACRITY Center.

2. Objective

To pilot test two months of the adapted ACHIEVE-D curriculum at a single PRP.

Hypothesis 1: The adapted ACHIEVE-D curriculum will be acceptable to individuals with SMI.

Hypothesis 2: The adapted ACHIEVE-D curriculum will be feasible and acceptable to PRP staff and peer leaders in promoting weight loss and lifestyle behavior change among consumers with SMI at their center.

3. Background

CVD and CVD Risk Factors among Persons with SMI. CVD is the leading cause of preventable death among persons with SMI. Diet and physical activity habits are typically poor in this population which contribute, along with metabolic side effects of many psychotropic medications, to high rates of obesity, other CVD risk factors, and CVD. Behavioral interventions promoting healthy diet, exercise, and weight loss are critically needed, but must be adapted to challenges particularly to the SMI population including memory impairment, limited executive function, and residual psychiatric symptoms.

The ACHIEVE Trial. 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). 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. The ACHIEVE intervention combined group

and individual weight-management sessions with group exercise sessions delivered in community mental health programs. The curriculum 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 curriculum was predominantly delivered by trained study interventionists, though mental health program staff delivered some video-assisted group exercise sessions. In light of the obesity epidemic in persons with SMI, there is an urgent need to scale-up interventions like ACHIEVE.

Considerations for Scaling up ACHIEVE. To realize the full public health potential of ACHIEVE, the curriculum needs to be modified for delivery by community mental health center staff. Adaptations should ease implementation, but maintain fidelity to the core content of ACHIEVE (Table 1).

Table 1. ACHIEVE vs. ACHIEVE-D Comparison

ACHIEVE Trial	Proposed ACHIEVE-D Dissemination
Type and Frequency of Contact	
Months 1-6: **Group weight management class:** 1x/wk, 45-min led by study interventionist; **Individual weight management visit:** 1x/month, 15-20 min with interventionist; **Group exercise classes:** 3x/week, 50-min led by interventionist. PRP staff delivered video-assisted classes 1x/wk in mo. 6-12, 2x/wk in mo. 13-18.	**Months 1-6:** **Multipurpose class: group weight management + exercise:** 3x/wk, 45 to 60-min class (~20-30 min weight mgmt, ~20-30 min exercise) led by a PRP staff member and peer leader trained as ACHIEVE-D coach/peer-leader.
Weigh-ins: weekly, 2 min	**Weigh-ins:** weekly, 2 min
Curriculum Delivery Modality	
Weight mgmt: In-person Exercise: Staff led or video-assisted	Weight mgmt: In-person with short videos Exercise: Video-assisted
Goals and Recommendations	
Weight loss goal 10lbs in 18 mo. (tailored to indiv.)	Weight loss goal 5lbs in 6 mo. (tailored to indiv.)
Behavioral Recommendations: 6 messages	Behavioral Recommendations: 6 messages

Modifications to the curriculum delivery and schedule – e.g. video-assisted, combined exercise and weight management sessions-could help support efficient, staff-led delivery. However, whether these adaptations will produce similar behavior change results have not yet been tested. Based on their experience conducting the ACHIEVE trial, the study team is making these modifications to adapt the ACHIEVE intervention into the ACHIEVE-Dissemination or "ACHIEVE-D" curriculum for community mental health settings. The curriculum adaptations are described in more detail below:

(1) **Class Format**: Group weight management and exercise will be combined into one multi-purpose class in ACHIEVE-D. To increase efficiency of delivery, ACHIEVE-D will be conducted in group sessions only; in lieu of the individual weight management sessions used in ACHIEVE, coaches and peers will be encouraged to set individualized behavioral goals related to the topic of the week during the discussion portion of group sessions.

(2) **Class Timing**: ACHIEVE-D multi-purpose classes will be held three times a week; this schedule will make it easier for consumers to receive the curriculum if they miss one of the groups, eliminating the need for make-up sessions. Within each monthly module (Table 2), topic varies by week. In the three group weight management + exercise classes each week, content builds gradually but is largely repeated; repetition of messages is a key tenet of intervention tailoring for SMI. This format will also provide frequent opportunities for on-site exercise.

Table 2. ACHIEVE-D Monthly Modules (and Example Weekly Topics)
Weight Loss Success (e.g., What Does it Mean to Watch What You Eat?)
Avoiding Sugar Drinks (e.g., Drinking Enough Water)
Avoiding Junk Food (e.g., Avoiding Junk Food by Making Smart Choices)
Eat more Fruits and Vegetables (e.g., Adding Fruits & Veg to Your Meals)
Eat Smart Portions (e.g., Slowing Down for Smart Portions)
Smart Snacking (e.g., Creating Smart Snack Habits)

(3) **Video-Assisted Content**: In the ACHIEVE trial, mental health program staff used videos to successfully deliver exercise classes; we will use the same exercise video approach in ACHIEVE-D. In addition, we have developed weight-loss content videos for each week of the curriculum. Each 5 to10-minute video segment will assist coaches and peer leaders in delivering the evidenced-based weight management content (e.g., video showing consumers reviewing the calorie and sugar content in various beverages). In class, the coach will introduce the weight management topic using the video, followed by discussion. Coaches will stop and start videos as-needed, emphasize repetition of content, and use motivational interviewing techniques to evoke consumers' confidence and competence to implement each ACHIEVE-D behavior.

(4) **Peer Leaders**: In ACHIEVE-D, peer leaders will support ACHIEVE-D coaches in curriculum delivery. Specifically, peers will role-model behaviors for the entire group, particularly during the group exercise sessions; help participants with SMI set realistic individualized behavioral goals; and encourage consumers' with SMI to consistently attend class. Because of their common SMI experience, peers are in a unique position to demonstrate empathy and support consumers in behavior change.

In this study, we will pilot test two months of the ACHIEVE-D curriculum in a community-based psychiatric rehabilitation program (PRP) to determine whether this format is acceptable to participating PRP consumers. The study team has prior experience collecting qualitative and quantitative data and delivering interventions among persons with SMI and has a long-term relationship with the study site (Prologue, Inc.) where this research will be conducted.

4. Study Procedures

a. Study design

We will conduct a pre/post study of two months (8 weeks) of the ACHIEVE-D curriculum. We will conduct a focus group among mental health consumers, as well as secondarily compare their outcomes pre- and post- intervention. The study will invite PRP staff as well as peer leaders to observe all the sessions during this pilot. We will conduct a focus group among PRP staff and peer leaders who observe the intervention sessions. Our primary outcomes will be to determine the acceptability and feasibility of the adapted curriculum.

Description of ACHIEVE-D Intervention

We will test two modules of the adapted video-assisted curriculum format (Tables 1 & 2). Consumers will participate in 45 to 60-minute multipurpose classes three times per week, which will include a segment on group weight management (~20-30 minutes) and group exercise (~20-30 minutes). Within each module, the group weight management topic varies by week, and within each week the content of the three weight management groups builds gradually and is purposely repeated. Within each module, the group exercise classes will focus on mild to moderate intensity aerobic exercise using an exercise video. The class will have a progression of

intensity and duration appropriate for sedentary individuals. Classes will start at a lower intensity for 10-15 minutes and gradually progress to moderate intensity aerobic exercise for 20-30 minutes per session across the two-month period. Participants will also be encouraged to engage in moderate intensity exercise, such as brisk walking, of similar duration on days when they are not at the PRP. In this pilot study, a trained study interventionist will deliver the ACHIEVE-D curriculum, as our aim is to determine acceptability of this new format with consumers, PRP staff and peer leaders prior to training the PRP staff and peer leaders to deliver the content, which is planned for a subsequent study.

Procedures related to Hypothesis 1 – Consumers with SMI

Recruitment. We will recruit participants from Prologue, which is a PRP based in Baltimore with whom the study team has a long-term relationship (see letter of support). We will use similar methods as in prior and ongoing studies. We will recruit consumers with SMI who are willing to participate and have no contraindications to participating in a diet and physical activity program (see eligibility criteria described in following section).

We will make presentations during regular consumer meetings at the PRP where we will provide information about the study. We will also display recruitment flyers in the PRP (Flyer). We will use a telephone script to handle all calls or in-person inquiries generated from these presentations and flyers (Screening Script). Consumers who are interested in participating will sign up to attend a consent/screening visit. To address privacy issues during recruitment, all participants who are contacted or who approach us for recruitment will be assured that the research staff at Johns Hopkins will be the only ones to see their information, and that the information we collected will be kept private and be used only for the research study we are discussing. If the potential participant chooses not to enroll in the study or does not qualify to be in the study, then his/her information will be destroyed.

Consent & Screening. We plan to screen a total of 20 consumers with the goal of enrolling approximately 10 into the study. Participant eligibility will be determined at the consent/screening interview (Table 3).

Consent

The study will be explained in detail to the potential participants in a one-on-one format onsite at the PRP in a private room. Informed consent for the study will be obtained from each eligible participant at the beginning of this visit (Consumer Written Consent). In particular, consumers will be advised of the voluntary and confidential nature of participation. Consumers will be asked questions about the study procedures to test their understanding. They will also be provided the contact information of the principal investigator. We will emphasize that their participation in the study will not affect their care at the PRP or Johns Hopkins. After consent is obtained, then potential participants will be screened.

Screening

The consumer will meet individually with a research staff member onsite at the PRP in a private room. Basic demographics will be assessed. A brief medical history will be taken and the 2018 Physical Activity Readiness Questionnaire+ (2018 PAR-Q+) will be administered as part of the exercise pre-participation health screening. Consumers will give permission for their primary care physicians to be contacted regarding medical eligibility for participation in moderate exercise and for review of Prologue on-site medical records. We will assess for alcohol and illicit substance use. Height and weight will be measured using standard procedures. We will

measure weight to the nearest 0.1 lb by a high quality digital scale with participants wearing light indoor clothes without shoes. Weight will be measured in lbs for ease of interpretation by participants and converted to kg for calculation of BMI. The scale will be calibrated quarterly using standard weights by trained study personnel. Height, without shoes, is measured once at baseline using a wall-mounted stadiometer. Body mass index is calculated as the Quetelet index (kg/m^2). Consumers who meet all eligibility criteria (see eligibility criteria described in following section) will be enrolled into the pilot study.

Primary Outcome – Consumer Focus Group Procedures. At the end of the preliminary pilot period, we will conduct one 90-minute focus group with consumers. The focus group will assess consumers' satisfaction, perceptions and attitudes regarding the ACHIEVE-D program. We will inquire with them regarding their satisfaction with the curriculum, including seeking feedback on feasibility of format, understandability of content, and likability of intervention materials, as well as challenges/issues that they experienced. We will also discuss whether members were successful in making diet and physical activity changes, as well as barriers and facilitators to making the change. This focus group will be held in a private room in the PRP. We will use a moderator guide for the focus group (Consumer Focus Group Moderator Guide). The group will be tape-recorded and conducted by a moderator. The focus groups will be transcribed by Production Transcripts.

Secondary & Other Outcomes – Survey, Anthropometric and Process Measure Procedures. This data will be collected during study visits at baseline and follow-up for enrolled particpants held onsite at the PRP in a private room. Surveys will be administered in-person by trained research assistants. All data will be collected on Johns Hopkins encrypted, password protected laptop computers and entered into a RedCap database. Because of consumers' generally low literacy and problems with cognition, all instruments will be interviewer administered to decrease the burden on participants and improve validity of data collection. Enrolled participants will complete baseline data collection measures (Table 3).

During the intervention, we will also collect data on participants regarding attendance, weight from weigh-ins during the sessions, hours per week each consumer participated in ACHIEVE-D exercise classes, as well as diet and physical activity via weekly self-reported logs.

We will video record each class session (3 classes per week for 8 weeks – 24 sessions total) and grade the sessions using a fidelity tool (ACHIEVE-D Fidelity Tool), which measures to what extent the coach implements the core components of ACHIEVE-D and uses a motivational interviewing delivery style. Once videos are evaluated for fidelity, any that are not needed will be destroyed; some will be stored on a Johns Hopkins secure network drive and used for future training in fidelity monitoring. In addition, short video clips from these sessions may be incorporated into materials for the larger R34 study including to train coaches.

After completion of the intervention, consumers will complete a survey including asking questions regarding satisfaction with the curriculum, self-reported sugar sweetened beverages and sedentary behaviors, and anthropometric measurements will be repeated at this time. We will also repeat other measures as described in Table 3.

Table 3. Data Collection Schedule	**Consent/ Screening**	**Baseline**	**Follow-up**	
			During	**Post**
Informed consent	x			
Demographics	x			
Medical history	x			
Medications	x			x
Substance use (ASI-Lite)	x			
Exercise pre-participation screening (2018 PAR-Q+)	x			
Weight	x	x	x	x
Height	x			x
<u>Primary Outcomes</u>				
Consumer focus group				x
PRP staff & peer leader focus group				x
<u>Secondary Outcomes</u>				
Diet				
EARLY Eating Away from Home Q		x		x
EARLY SSB Consumption Q		x		x
Physical Activity				
CARDIA/EARLY Q – sedentary behavior		x		x
Eating Behaviors				
Palatable Eating Motives Scale (PEMS) – Coping Subscale		x		x
Trait Food Craving Q – Reduced Form		x		x
Reward-based Eating Drive (RED) Scale		x		x
Psychological & Support				
Perceived Stress Scale (PSS)		x		x
Important Others' Q		x		x
Anthropometric Measurements				
Waist circumference		x		x
Process Measures				
Consumer attendance & exercise at group sessions			x	
Consumer food and physical activity logs			x	
Consumer Satisfaction Q - Nabati				x
Coach Fidelity to ACHIEVE-D			x	

Abbreviations: SSB – sugar-sweetened beverage; Q – questionnaire

Below we describe the planned secondary outcomes:

<u>Acceptability</u>

A 12-item Consumer Satisfaction Questionnaire based on the instrument developed by Nabati and colleagues will be used to determine acceptability. Following the intervention, in addition to the focus group, we will use this standard measure of satisfaction with the intervention. We will also examine participation as a reflection of acceptability. Participation in intervention sessions will be measured by attendance at the group classes, the number of sessions attended, and proportion attending at least 80% of sessions.

Diet
We will administer the EARLY Sugar-Sweetened Beverage (SSB) questionnaire at baseline and post-intervention, which has been selected by the NIH as Accumulating Data to Optimally Predict Obesity Treatment (ADOPT) Core Measures for diet.

Physical Activity
We will administer the sedentary behavior inventory from CARDIA/EARLY at baseline and post-intervention, which has been selected by the NIH as ADOPT Core Measures for self-reported physical activity.

Weight & Waist Circumference
Weight will be measured at baseline and post-intervention using standard procedures as described in the screening section above. Waist circumference is measured using a tape, according to a standardized protocol at baseline and post-intervention.

Below we describe the other planned survey measures in this study:
Demographics
Most demographic data will be obtained from Prologue's intake assessment, but we will obtain updated marital status and living arrangements as well as confirm educational level. This data will be collected at the screening visit.

Medical History
We will measure medical conditions with a short checklist of conditions. Each consumer is required to have a physical exam annually, and a list of medical conditions is kept in the Prologue chart. Potential participants will consent to allow us to review their medical records at Prologue. We will assess conditions by reviewing the medical chart and by interview. Any discrepancies will be confirmed by participants' primary care physicians. This data will be collected during screening.

Medications
Prologue tracks all medications and medication changes. We will measure medications including dose, route and frequency at baseline by compiling a list of medications from the medical chart. Potential participants will be asked to confirm this list with input from caregivers, as needed. Medication information will be updated at the end of the pilot intervention.

Diet and Eating Habits
We will administer the EARLY Eating Away from Home questionnaire and 3 questionnaires regarding eating habits as listed in Table 3, which have been selected by the NIH as ADOPT Core Measures for these domains.

Psychological & Support
We will administer 2 questionnaires regarding psychological and social support domains as listed in Table 3, which have been selected by the NIH as ADOPT Core Measures for this area.

Procedures related to Hypothesis 2 – PRP staff and peer leaders

We will recruit staff and peer leaders from Prologue, who will be invited to observe all the sessions during this pilot. We aim to recruit at least 4 PRP staff members and at least 1 peer leader to observe however, we have the capacity for up to 20 staff or peers.

At the end of the pilot period, we will conduct a 90-minute focus group with PRP staff and peer leaders who were able to observe at least two sessions of the ACHIEVE-D curriculum to explore their perceived feasibility of delivering such a program as well as their satisfaction with program content and format. Informed consent will be obtained from each participant on the day of the focus group (Staff & Peer Leader Oral Consent). We will use a private room in the PRP for this group. We use a moderator guide for the focus group (Staff & Peer Leader Focus Group Moderator Guide), and will show them video recorded of the pilot intervention session(s) to facilitate the discussion and prompt feedback. The focus group will be tape-recorded and conducted by a moderator. The focus groups will be transcribed by Production Transcripts. Names will be removed from transcripts and replaced with ID numbers. After transcription, recordings will be destroyed.

b. Study duration and number of study visits required of research participants.
We anticipate that the total duration for all study procedures to be 4 months, and the intervention will take 2 months. Consumers will participate in a focus group as well as complete baseline and post-intervention data collection visits. PRP staff and peer leaders will participate in a focus group. Study visits and focus groups will be held onsite at the PRP.

c. Blinding
Not applicable

d. Justification of why participants will not receive routine care or will have current therapy stopped.
Not applicable

e. Justification for inclusion of a placebo or non-treatment group.
Not applicable

f. Definition of treatment failure or participant removal criteria.
Not applicable

g. Description of what happens to participants receiving therapy when study ends or if a participant's participation in the study ends prematurely.
Not applicable

5. Inclusion/Exclusion Criteria

For consumers with SMI to participate in the pilot, they must be aged 18 and older and are consumers at Prologue psychiatric rehabilitation program. In addition, we will require that these consumers are 1) Expected to be in the rehabilitation program for at least 6 months after enrollment in intervention and able to attend the intervention classes 3 days per week, 2) Able and willing to give informed consent and participate in the intervention, 3) have a BMI over 25 kg/m^2 (overweight or greater), and 4) be interested in losing weight.

We will exclude consumers with any underlying medical conditions that could seriously reduce their life expectancy, their ability to participate in the study, or for which dietary change or physical

activity may be contraindicated and/or require medical supervision by a physician such as medication-dependent diabetes mellitus, cancer or malignant tumor, lung disease requiring supplemental oxygen, dementia or cognitive impairment, consumption of more than 14 drinks per week, eating disorders, angina, or diagnosis in the last 12 months of myocardial infarction, congestive heart failure, transient ischemic attack or stroke, liver disease or kidney disease. We will exclude women who are pregnant or breastfeeding. We will also exclude individuals with an inability to walk to participate in exercise class as demonstrated by walking up and down 2 flights of stairs.

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. 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. The intervention emphasizes the achievement of moderate, not vigorous intensity physical activity; the safety of moderate intensity physical activity in properly screened subjects is well established.

The 2018 Physical Activity Readiness Questionnaire (2018 PAR-Q+) will be administered to triage participants within the ACSM Exercise Pre-Participation Health Screening Logic Model. For persons who require medical clearance according to these ACSM guidelines, we will refer them to their physician and send a letter to this physician informing them that the patient is planning on enrolling in the study (Physician Approval for Exercise Letter). We will ask for a fax-back form with medical clearance from the physician for the individual to participate. The ACSM guidelines define medical clearance as approval from a health care professional to engage in exercise, on the basis of the presence of signs or symptoms and/or known cardiovascular, metabolic, or renal disease and physical activity status. The term ''medical clearance'' has replaced specific recommendations for a medical examination or exercise test because it should be the health care provider who decides what evaluation, if any, is appropriate before the initiation of a moderate-intensity exercise program as proposed in ACHIEVE-D.

For PRP staff or peer leaders to participate, they must be at least 18 years old and have observed at least two ACHIEVE-D sessions.

6. Drugs/ Substances/ Devices

Not applicable

7. Study Statistics

a. Primary outcome variables.

All focus groups will be audio recorded and transcribed verbatim. Research assistants will check the transcripts for accuracy. Two investigators will identify meaningful segments within the responses and assign codes using an editing style analysis technique for each focus group transcript. We will group codes into themes and discuss these themes among the entire team of investigators. We will use Atlas.ti 5.2 software to facilitate qualitative data management and analysis. The study team will also review the transcripts and make modifications to the intervention materials and study procedures for a future trial based on these results.

b. Secondary outcome variables.

We will conduct descriptive analyses of baseline data. Our acceptability outcomes among consumers will include their satisfaction with the intervention as well as program attendance. Our behavior change outcomes among consumers will include changes in dietary and physical activity measures pre-post. We will examine changes in diet and physical activity outcomes with t-tests and Chi Square tests, as appropriate. If these outcomes are not normally distributed, then we will use Wilcoxon signed-rank tests in lieu of t-tests.

c. Statistical plan including sample size justification and interim data analysis.
Not applicable to qualitative data collection

d. Early stopping rules.
Not applicable

8. Risks

a. Medical risks, listing all procedures, their major and minor risks and expected frequency.

ACHIEVE-D Intervention Risks.

The 2 month behavioral weight loss intervention sessions should be minimal risk for participants. Physical activity may pose a small risk of musculoskeletal injury. In addition, making dietary changes and engaging in moderate-intensity exercise may also pose risks such as needing to adjust the dose of certain medications (e.g., hypoglycemic agents) or may be inappropriate for people with certain medical conditions.

Focus Group Risks. This study involves focus group discussion. Every effort will be made to protect confidentiality. There is minimal risk to the participant. If a participant changes her/his mind and does not wish to complete the focus group discussion, s/he will be allowed to leave.

Data Collection Risks. Risks related to the data collection include loss of confidentiality, and potential discomfort, boredom or inconvenience from participating in a focus group and answering survey questions and undergoing anthropometric measurements.

b. Steps taken to minimize the risks.

Minimizing ACHIEVE-D Intervention Risks.

Participant safety will be closely monitored. 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. Participants will be educated about symptoms to look for (e.g., low blood sugar). 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.

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 classes will focus on mild to moderate intensity aerobic exercise using progression of intensity and duration appropriate for sedentary individuals. Staff will be trained to identify signs and symptoms of cardiovascular events in accordance with CPR training. In the case of illness or injuries during the intervention period (e.g., motor vehicle accident), interventionists continue to advise consumers on adapting

their physical activity program. 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.

Minimizing Focus Group Risks. We will minimize risk of group discussions by advising participants that by agreeing to be in this study, they are agreeing not to talk about any personal details that other individuals share in the focus group. Participants will be informed that they do not have to participate in any group discussion where they feel uncomfortable and can leave the session at any time.

Minimizing Data Collection Risks. There is a risk of the loss of confidentiality of medical information. We will ensure protection of the data and any personal health information. Only the study team will have access to participant's identifying information. Each participant will be assigned an identification (ID) number at the time of recruitment. The database that links the ID with the participant will only be accessible by the principal investigator and core investigative team. Data will be stored in RedCap and when exported on a Hopkins (JHMCIS managed) network drive which is password- protected and backed-up each night. If a participant changes her/his mind and does not wish to complete the study s/he may withdraw at any point.

Participants will be aware through the consent process that videos will be taken of the group sessions and that clips may be incorporated into future training materials or posted on Dr. Daumit's research website.

There is a risk of potential stress, discomfort, boredom or inconvenience from answering survey questions and undergoing anthropometric measurements. Participants will be informed that they do not have to answer any questions that they do not wish or have their waist circumference, height, or weight measured. There are risks related to interview location at the PRP. To ensure participants' privacy, we will conduct interviews in a private space.

c. Plan for reporting unanticipated problems or study deviations.
Unanticipated problems or study deviations will be reported to the IRB, the NIH, and if applicable to all study participants in a letter.

d. Legal risks such as the risks that would be associated with breach of confidentiality.
None

e. Financial risks to the participants.
None

9. Benefits

Consumers may benefit from participating to increase their knowledge about healthy diet and physical activity. This study may provide benefit to society at-large, as our results will help us determine whether the ACHIEVE-D curriculum is acceptable to consumers with SMI. We believe that the risks to subjects are minimal and reasonable given the knowledge to be gained. There are no direct benefits to the PRP staff or peer leaders; however, their input is likely to improve the design and implementation of the ACHIEVE-D curriculum in a future trial.

10. Payment and Remuneration

We will offer all consumers an incentive to complete the screening ($10), baseline ($20) and follow up assessment ($30), as well as an incentive to participate in the focus group ($25). Total possible compensation for data collection for consumers is $85. PRP staff and peer leaders who participate in the focus group session will receive a $25 at the conclusion of the session to compensate for their time

11. Costs

There are no costs to participants.