Peer-Led Healthy Lifestyle Program in Supportive Housing Agencies

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Columbia University Human Subjects Stand-Alone Study Description Document

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Protocol: IRB-AAAO7250
Title: Peer-Led Healthy Lifestyle Program in Supportive Housing Agencies
Abbreviated title: Peer-Led Healthy Lifestyle Program
Study Description

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1. Study Purpose and Rationale

The overall goal of this study is to test the effectiveness of a peer-led healthy lifestyle intervention (Peer GLB) in supportive housing agencies serving diverse clients with serious mental illness (SMI; e.g., schizophrenia, bipolar disorder) who are overweight or obese. The risk for obesity and related conditions (e.g., type 2 diabetes [T2D]) is twice as high in people with SMI compared to the general population.

Minority origin contributes additional risk. Compared to non-Latino whites with SMI, African Americans and Latinos with SMI are at higher risk of obesity, T2D, and cardiovascular disease (CVD). Modifiable lifestyle factors (e.g., lack of exercise, poor diet) that cause obesity add to these disparities, as they are prevalent among minorities and people with SMI. These health needs are exacerbated by the fact that minorities with SMI have poor access to medical care, are disproportionately enrolled in fragmented health care services, and are unlikely to engage in healthy lifestyle programs in their communities. These inequities justify the need to bring people with SMI established interventions to help them achieve clinically significant weight loss (5% weight loss), the single most important factor in reducing T2D incidence and critical for reducing CVD risk.

The Group Lifestyle Balance (GLB), derived from the Diabetes Prevention Program, is an established healthy lifestyle intervention that is efficacious in the general population for achieving clinically significant weight loss. Studies in the general population, including among racial/ethnic minorities, have shown that translating GLB to real-world settings is enhanced through the use of a group format and trained lay workers who deliver the intervention without compromising its effectiveness. Similar interventions that use GLB principles produce clinically significant weight loss among people with SMI, but their impact is limited as they tend to be delivered in clinical settings using healthcare professionals, making them prohibitive for community agencies. We aim to improve the reach of GLB in this study by: 1) bringing this intervention to people's doorsteps through its delivery in supportive housing agencies, and 2) using peer specialists (individuals with lived experience of SMI) as facilitators to address economic and staffing demands.

In this study, we aim to test the effectiveness of delivering a 12-month peer-led GLB (Peer GLB) intervention in supportive housing agencies. We will enroll up to 300 clients that are overweight or obese (BMI > 25) to participate in a randomized controlled effectiveness trial. Clients will be randomly assigned to either 1) the 12-month Peer GLB intervention (n=150) or 2) to usual care (n=150). GLB intervention fidelity will be monitored throughout the study through fidelity checklists, attendance logs, and trial records that capture participants' degree of completion of intervention activities. Outcomes will be evaluated through repeated assessments with participants via structured face-to-face interviews that will occur at baseline and 6, 12, and 18 months post-randomization. We will conduct 10 post- intervention focus groups with participants randomized to the Peer GLB group once they have completed the 12 month intervention to learn about their experiences with Peer GLB.

We have identified three supportive housing agencies that are participating in the project: [redacted] houses clients in apartments throughout the community, offers a variety of health, mental health and social services and employs peer specialists. The site at [redacted] will be at [redacted]

The second site is [redacted] located at [redacted]

The third site is [redacted] located at [redacted].

This study is part of a larger project that focuses on investigating the implementation and effectiveness of Peer GLB. The present protocol focuses on the effectiveness trial using the RCT study, which is represented by Aims 1-3 outlined in the grant proposal for the current NIMH funded study (1R01MH104574-01: see grant attached). A different IRB protocol for the mixed methods implementation study (Aim 4) was previously submitted and approved: IRB-AAAN5207. We will be submitting as a protocol modification all Spanish translation of study materials (e.g., consent forms, capacity-to-consent, structured interviews) once the English versions have been approved.

2. Study Design and Statistical Procedures

We will use a randomized controlled trial design in order to test the effectiveness of Peer GLB vs. usual care (UC) in supportive housing agencies. Peer GLB lasts 12 months and consists of weekly core group sessions (3 months.), bimonthly (twice a month) transitional group sessions (3 months.), and monthly maintenance sessions (6 months). Peer specialists in the housing agencies will be trained and supervised by the study team and the supportive housing agencies to deliver Peer GLB. Repeated participant assessments conducted by trained study staff (e.g., research assistants) will occur at baseline and at 6, 12, and 18 months post-randomization.

Primary Aim:

1. Compare the effectiveness of Peer GLB vs. UC in achieving clinically significant weight loss (5% weight loss) among overweight/obese (BMI 25) clients in supportive housing agencies. Primary Hypothesis: Peer GLB participants will have a higher proportion of persons achieving

clinically significant weight loss (5% weight loss) at 12 and 18 months than UC participants.
Secondary Aims:
2. Compare secondary outcomes: reductions in total weight, waist circumference, blood pressure, and improvements in physical activity, self-efficacy, recovery, and quality of life at 6, 12, and 18 months between Peer GLB and UC. Secondary Hypothesis: At 6, 12, and 18 months post- randomization, there will be significant reductions in average weight, waist circumference, blood pressure, and significant improvements in physical activity, self-efficacy, recovery, and healthrelated quality of life in Peer GLB compared to UC.
3. Explore whether client-level characteristics (e.g., socio-demographics, use of antipsychotic medications, attitudes toward Peer GLB) moderate Peer GLB's effectiveness.

We will use descriptive and multivariate statistics (e.g., logistic regression, generalized linear mixed effects models) to examine differences in primary and secondary outcomes between the Peer GLB intervention and UC groups. We will also explore interactions between treatment conditions and client- level characteristics (e.g., socio-demographics) to examine how these characteristics moderate Peer GLB's effectiveness.

3. Study Procedures

In this study, we will examine the effectiveness of Peer GLB among adult clients in supportive housing agencies who have SMI and are overweight or obese (BMI > 25), thus placing them at risk for cardiovascular disease. We will recruit clients through provider and self-referrals. We plan to recruit up to 300 clients to participate in this RCT. Eligible clients are: active supportive housing agency clients who are residing in supportive housing, are 18 years of age or older (18 to 90 years old), of any race/ethnicity, speak English or Spanish, have chart diagnoses of serious mental illness (e. g., schizophrenia, schizoaffective disorder, bipolar disorder, major depression), and have a BMI > 25, and willing to get a medical clearance letter from a primary care doctor with assistance from the study staff if randomized to the Peer GLB group. Additionally, participants who are randomly assigned to the Peer GLB intervention will have to have been cleared by their primary care physician to participate in light- to-moderate physical activity.

We will exclude clients who are in need of detoxification, are at acute risk of suicide or homicide, fail a capacity-to consent questionnaire, are cognitively impaired (as detected on the Mini-Cog Examination) and self-report contraindications to participating in a weight loss program, including: receiving active cancer treatment (radiation/ chemotherapy), have liver failure, have been told by a doctor that they had anorexia, had a cardiovascular event (e.g., unstable angina, myocardial infraction) within the past 6- months, ever had or planning to have weight loss surgery in the next 18-months, unable to walk, and (for female participants) currently pregnant or planning a pregnancy during the study period. Individuals who are 65 years or older will also be screened for cognitive impairments using the MiniCog examination (see a description of the Mini-Cog examination in the informed consent process section below). Those that fail the mini-cog will be excluded from the study because of possible cognitive impairment issues.

At the baseline assessment (and also at 6, 12, and 18-month), participants complete the BASIS-24 questionnaire which includes questions regarding potential psychiatric symptoms. If participants

indicate anything other than "never" to questions regarding "how often did you think about ending your life" and "how often did you think about hurting yourself", clients are taken for immediate in-person evaluation and counseling by a member of their treatment staff. A member of the treatment team is always on-site and researchers will accompany the participant to the treatment team's offices and a case manager (or other provider) will then conduct a formal assessment regarding their risk, per agency's protocols. No specific referral form will be used as participants are already receiving support services from the agency. A member of the treatment services team (e.g., case manager) will formally evaluate the participant, directly provide counseling, and make referrals to an appropriate treatment setting as necessary (e.g., emergency room, psychiatrist). Enrollment into the study will only proceed if the agency determines that the participant is not at acute risk of suicide. The supportive housing agencies directly provide extensive mental health treatment support and have close linkages to local hospitals, detox facilities, and other treatment settings to which participants can be routinely referred as needed.

We will use multiple methods to recruit clients. We will do presentations at staff and client meetings and host lunches/ dinners at the research sites to introduce the project to clients and staff and answer any questions they may have about the project. Interested participants will be asked to provide study staff with their names and contact information. We will also accept provider referrals. Study staff will then initiate contact with interested clients via telephone or in person at each site to further explain the project and set up a face-to-face meeting at the study site to screen potential participants for eligibility, and for those eligible conduct the written consent process.

Once a client has been screened for eligibility into the study and provided informed consent, the study staff will schedule the initial baseline interview based on participants' availability and preference. The baseline interview will last approximately 90-minutes and will be conducted by a trained research assistant (RA) in a private room at the study site in participants' preferred language (English or Spanish). Randomization will occur after participants have completed the baseline interview on a 1-to1 ratio to intervention or usual care condition by a computer-generated random number program with treatment assignment kept in sealed, opaque envelopes. For participants randomized to the Peer GLB intervention, study staff will provide each participant a copy of the approval letter that the participant can take to their primary care physician for review and signature. Participants will be required to bring their doctor's approval letter to the first Peer GLB group meeting in order to participate in the lifestyle intervention. The study staff, with assistance from the peer specialist at each study site, will help coordinate participants' visits to their primary care physician to obtain this medical clearance. Failure to obtain this approval letter will preclude the individual from participating in the Peer GLB intervention. For participants randomized to the intervention group, baseline interviews will occur at most two weeks before the first group session. After the baseline interview is completed, the study staff will provide the participant the date and time of the first group session meeting.

Peer-Led Group Lifestyle Balance Intervention

Peer GLB, is based on an established group-based lifestyle intervention adapted from the original Diabetes Prevention Program (DPP) lifestyle program26 by the DPP Lifestyle Resource Core at the

University of Pittsburgh's Diabetes Prevention Support Center (DPSC). Peer GLB is a goal-based behavioral intervention aimed to achieve loss and maintenance of 7% baseline body weight through modest dietary restrictions (e.g. reduce fat intake by <25%) and increase moderate physical activity (e.g., brisk walking) to 150 min/wk.21 GLB consists of weekly core group sessions (3 months), bi-monthly (twice a month) transitional group sessions (3 months), and monthly maintenance sessions (6 months.) delivered in community settings (i.e., supportive housing agencies.

Core features of Peer GLB include: integration of safe and appropriate nutritional education, physical activity and behavioral change, strong emphasis on the use of self-monitoring tools (e.g., food and physical activity logs) with regular feedback, and the incorporation of problem solving techniques to address barriers to healthy eating and physical activities. Examples of session topics and themes include: being a fat and calorie detective, healthy eating, move those muscles, problem-solving, four keys to healthy eating out, etc. The intervention includes a group facilitator curriculum manual and DVDs specifying session-by-session instructions, scripts, and group activities (e.g., portion size demonstrations, use of pedometers, problem solving steps) as well as participants' handouts for each session. Intervention materials are available in English and Spanish. Throughout the program, participants are given session handouts, commercially available fat and calorie-counting book, self- monitoring books to tracking food intake and physical activity, pedometers with instructions, program calendar, and a chart to self-monitor their weight twice a week over the course of the program. During session, participants are also shown the intervention DVD's to augment the educational content of the intervention. For English speaking participants, the Peer GLB groups will be delivered in English. For Spanish speaking participants, the Peer GLB groups will be delivered in Spanish.

Dr. Cabassa, study Principal Investigator, is a certified GLB group-facilitator having completed the 2- day facilitator training workshop provided by the DPSC and having facilitated GLB groups in previous studies. This training also provides ongoing implementation support through telephone conferences calls, on-line discussion board, GLB-listserv, GLB program directory, and Newsletters.

Description of Peer Specialists

Peer GLB will be facilitated by trained peer-specialists employed at the supportive housing agencies. According to SAMHSA, a peer specialist "is a person who uses his or her lived experiences of recovery from mental illness and/or addiction, plus skills learned in formal training, to deliver services in behavioral health [and other] settings to promote mind-body recovery and resiliency." The Peer Specialists will be employees hired by the supportive housing agency. They are individuals who are 18 and over, who have at least a high school education or GED equivalent, and who have completed prior training enabling them to become service providers. The qualifications of peer specialists hired at each study site include prior completion of extensive training in delivering services to populations with serious mental illness as well as certification, or in the process of receiving certification, for the delivery of peer specialist services per state regulations. These trainings to become a peer specialist include developing an understanding of the public mental health system, becoming integrated into the workforce, and intensive training in how to assist people with SMI in their recovery. As a result of these completed trainings, the peer specialists have expertise in 1) sharing their personal recovery experience to help others understand their experience of mental illness and treatment services, 2) assisting persons with SMI to identify

and overcome barriers to recovery and participation in services, and 3) assisting persons with SMI to develop skills that promote recovery, health, and wellness. Through the completion of this training and previous experience, peer specialists will have the ability to provide services either one-on-one or in groups. Each supportive housing agency will also provide peer specialists with its usual orientation and training that is required of all new employees prior to delivering services to clients.

Peer Specialist Intervention Training and Supervision

In addition to completing these general trainings, which is a prerequisite for being hired, peer specialists at each supportive housing agency will receive training conducted by the study team in the GLB intervention prior to beginning the clinical trial. Peer specialists will complete the intensive 2-day, standardized training in the GLB intervention offered by the DPSC (the developers of the intervention). This training will teach peer specialists how to properly deliver each session of the intervention stepby- step. Additionally, the research staff will also provide training to peer specialists in research fundamentals and collecting anthropometric measures (i.e., weight) and simple physical activity measures (e.g., how many minutes of physical activity participants engaged in weekly) in order to become proficient in standardized measurement consistent with the GLB intervention. As additional training in the intervention prior to the clinical trial, peer specialists will practice delivering weekly GLB sessions and collecting anthropometric and physical activity measures during mock workshops with the study PI and project director. Once the clinical trial begins, peer specialists will receive regular supervision and support from the supervisors at their agency, as well as from research staff. Supervisors from the supportive housing agencies will provide daily oversight and supervision regarding the peer specialists' job responsibilities and delivery of services. The peer specialists will also receive ongoing weekly to biweekly supervision and support from the PI, the project director, and expert consultants in both the delivery of peer services generally, and the GLB intervention specifically, as well as research processes, throughout the trial. These supervision meetings will include review of weekly sessions, discussion and group problem-solving of emerging issues, feedback on fidelity monitoring ratings, and support for the delivery of Peer GLB. Supervision meetings will be conducted via teleconference calls to accommodate everyone's schedules and facilitate communication across all study sites and in person, when necessary. We will also invite the supervisors of the peer specialists at their site to participate in these meetings.

To evaluate the fidelity of delivering Peer-GLB, we will audio-record all GLB group sessions with the participants' consent. These session recordings will be reviewed on a regular basis by a trained research assistant to rate the fidelity of the session using GLB fidelity rating scale, and these fidelity ratings will be used in supervision meetings with peer specialists and their supervisors to provide ongoing feedback and support for delivering Peer GLB and avoid intervention drift throughout the trial.

To evaluate the effectiveness of our intervention, clients will be assessed by a trained research assistant (RA) at baseline and at 6, 12, and 18 months after baseline through structured face-to-face interviews. All assessments will be conducted in person. For follow-up assessments, the study staff will contact the participant a week before their follow-up assessment via telephone and/or in person

at their respective study site to remind them of their follow-up assessment and to set up a time and date to conduct the interview. These follow-up assessments will be about an hour long.

Lastly, all participants randomized to the Peer GLB group will be invited to participate in focus groups once they have completed the 12 month intervention. We will conduct 15 focus groups in total. The focus groups will be conducted by Dr. Cabassa or the Project Director at the study sites. A research staff member will also be present to take notes and help with focus groups logistics. The groups will last 90 minutes and will consist of 8-10 participants who have participated in the Peer-GLB intervention. The focus group will be audiotaped and professionally transcribed. They will be conducted in English or Spanish. To protect participants' confidentiality, the focus group facilitator at the beginning of the group discussion will remind participants that they should not disclose information shared in the focus group with people outside of the group. Participants will also be reminded that the audio taping of the group discussion can be stopped at any time at their request. A focus group guide [redacted] with open-ended questions will be used to elicit participants' views about their experiences with the healthy lifestyle program and explore participants' views about the acceptability, feasibility and cultural appropriateness of the intervention including suggestions for improvement. Examples of questions include: What did you think about the program? What about the program did you find most helpful?
Why was this helpful? What was your relationship like with your group facilitators? If you were going to improve this healthy lifestyle program what kind of things would you want the group facilitators to do? What advice would you offer someone entering the healthy lifestyle program today?

Lastly, participants assigned to the intervention will be asked to complete one semi-structured qualitative interview that focuses on the participants' experiences with the group facilitator and explores specifically how intervention services were delivered from the participants' perspective. This semi-structured qualitative interview will be conducted after the transition phase of an intervention group has been completed. Participants who attended at least two intervention sessions will be asked to complete the interview and a total of 55 participants are expected to participate. The interviews last approximately 90 minutes and will be conducted in person by Drs. Cabassa (PI) & Stefancic (PD) and/or a trained research assistant at the study site. Examples of questions include: Is there anything that makes the healthy lifestyle peer specialist/facilitator unique from other provider staff that you have worked with? What are some of the peer specialist's/facilitator's best qualities? What kinds of things did your peer specialist/facilitator do to model or show you how to engage in a healthy lifestyle?

Criteria for Early Discontinuation

Early discontinuation from the study will be ascertained by the group facilitator in consultation with the participants' service providers (e.g., case managers) at the supportive housing agency. Participants who during the course of the project are in need of detoxification and are at acute risk of suicide or homicide will be referred for treatment and discontinued from the study. Moreover, participants that develop contraindications to participating in a weight loss program, such as receiving active cancer treatment (radiation/chemotherapy), develop liver failure, have a cardiovascular event (e.g., unstable angina, myocardial infraction) and become pregnant or are planning a pregnancy during the study period will be discontinued from the study.

4. Study Drugs or Devices: Not applicable.

5. Study Instruments

Structured Interviews: Baseline and 6, 12, and 18-month Follow-Up
The structured interview includes the collection of basic anthropometric measures and a simple physical activity measure by trained research staff:

- Weight will be measured to the nearest 0.1lb using a digital high quality scale with participants wearing light indoor clothes without shoes. Weight will be measured in pounds (lbs) for ease of interpretation by participants and converted to kg for calculation of Body Mass Index which will be calculated as kg/m2
- Height will be measured to the nearest 0.1 cm at entry into the project using an anthropometric tape. The participant stands shoeless on a level surface with head in the horizontal plane.
- Waist circumference will be measured to the nearest 0.1 cm with an anthropometric tape, in a horizontal plane 1 cm above the navel in light indoor clothing.
- Blood pressure will be assessed on the right arm of participants after they rest quietly in a seated position for at least 5-minutes, using a validated automated sphygmomanometer. We will take 2 measurements each separated by at least 30 seconds.
- 6-minutes walking test will be assessed by having participants walk in a normal relaxed passed for 6 minutes at the study site (e.g., long hallway and then measure the distance that they walked during these 6-minuted to the nearest meter.

The structured interview will also include a series of standardized instruments to collect information about client's demographics, self-reported mental and physical health conditions, and use of medical and mental health services in the past 12-months. We will also use the following standardized instruments: Self-Efficacy Exercise Scale and the Weight Efficacy Lifestyle (WEL) questionnaire to measure participants' levels of self-efficacy for engaging in physical activities and a healthy lifestyle behaviors, the International Physical Activity Questionnaire (IPAQ): Short Form to measure participants engagement in physical activity during the past seven days, the BASIS-24 to measure mental health symptoms, the Recovery Assessment Scale to measure the different aspects of recovery the SF-12 to measures participant health and mental health-related quality of life, the Perceptions of Food Environment Scale to measure the availability of health and unhealthy options in their neighborhood, the Client Satisfaction Questionnaire (CSQ) to measure participants satisfaction with our health lifestyle program (administered only at the 6 & 12-month follow-up), the Bidimensional Acculturation Scale to measure the acculturation-related changes in two languages (Only for Hispanic participants), the Addiction Severity Index to measure use of substances, the Block Food screeners to measure nutrient intake, and the Multidimensional Health Locus of Control to measure perceptions of control over health.

The baseline interviews will last approximately 90 minutes and the 6, 12, and 18-month interviews will be shorter (60 minutes) as they will not include the demographic, acculturation and mental health and health history sections. All interviews will be administered by trained research assistants

supervised by the Project Director, Ana Stefancic and the study PI. The structured interviews will be administered in English or Spanish, depending on participants' language preferences.

Focus Group

A focus group guide [redacted] is used to facilitate participants' post Peer GLB focus group discussions. In this guide, we use open-ended questions followed by probes to facilitate the groups' discussions. The focus groups last approximately 90 minutes, will be conducted by Dr. Cabassa or the Project Director at the study sites. We will have one of our research staff serve as a note taker. The focus group guide will be used to elicit clients' views about their experiences with the healthy lifestyle program and explore clients' views about the acceptability, feasibility and cultural appropriateness of the intervention including suggestions for improvement. Examples of questions include: What did you think about the healthy lifestyle program? What about the program did you find most helpful? Why was this helpful? What was your relationship like with your group facilitators? If you were going to improve this healthy lifestyle program what kind of things would you want the group facilitators to do? What advice would you offer someone entering the healthy lifestyle program today? What would you recommend they do to take full advantage of the program?

Semi-structured qualitative Interview

A semi-structured qualitative interview guide [redacted] will be used to conduct a post Peer GLB transition phase interview with participants who participated in the intervention. In this guide, we use open-ended questions followed by probes to facilitate an interview response. The interview guide will be used to solicit participants' views of the group facilitator and the specific approach used by the facilitator to deliver the intervention. Examples of questions include: Is there anything that makes the healthy lifestyle peer specialist/facilitator unique from other provider staff that you have worked with? What are some of the peer specialist's/facilitator's best qualities? What kinds of things did your peer specialist/facilitator do to model or show you how to engage in a healthy lifestyle?

Peer GLB Intervention Materials

Intervention materials that are given to study participants are attached (see GLB Program Materials Given to Participants). Participants will also receive a copy of the following book that is commercially available: Borushek, A. (2013). The Calorie King: Calorie, Fat, & Carbohydrate Counter. Costa Mesa, CA: Family Health Publications, as an additional resource to help participants keep track of their calories. This book largely consists of tables that list the calorie, fat, and carbohydrate content of numerous foods and beverages.

6. Study Subjects Description of Study

Site:

We have identified three supportive housing agencies that are participating in the project: [redacted]

The [redacted] study site is located at [redacted] This location has several conference rooms that are used for a range of support groups and activities. [redacted] is a supportive housing agency that provides housing, social and mental health services to adults with SMI and substance abuse conditions. [redacted] uses a scattered housing model in which tenants are housed throughout Philadelphia. Every [redacted] client has service providers who are part of an Assertive Community Treatment (ACT) Team or Case Management team. We plan to recruit 100 adult [redacted] clients, ages 18 to 90 years old to participate in this study. [redacted] is a licensed behavioral health provider and each participant is required to work with a multi-disciplinary treatment team that provides mental health treatment, rehabilitation, housing support, and crisis intervention 24 hours per day, 7 days per week. Participants work directly with the teams' case managers, social workers, nurse practitioners, and psychiatrists. [redacted] also has a Federally Qualified Health Center on-site (that is run by [redacted]) and that serves [redacted] clients' medical needs, including study participants.

The second site is [redacted] located at [redacted] provides housing and support services for clients with serious mental illness in Philadelphia. We plan to recruit 100 adult clients, ages 18 to 90 years old to participate in this study.

The third site is [redacted] located at [redacted] provides housing and support services for clients with serious mental illness in New York. We plan to recruit 100 adult clients, ages 18 to 90 to participate in this study.

Description of Study Sample

Based on supportive housing agency data, we expect that our study sample will be 70% male and 30% female. The average age of potential participants across the study sites is approximately 50 years old. Approximately, 85% of participants are 18-65 years old and the rest (15%) are older than 65 years old. Approximately, 57% of participants are expected to be African-American, 28% Hispanic, 9% non- Latino whites Caucasian, and 6% other racial identities. All will have a diagnosed SMI.

Inclusion Criteria

Eligible clients are: active supportive housing agency clients who are residing in supportive housing, are 18 years of age or older (18 to 90 years old), of any race/ethnicity, speak English or Spanish, have chart diagnoses of serious mental illness (e. g., schizophrenia, schizoaffective disorder, bipolar disorder, major depression), and have a BMI > 25, and willing to get a medical clearance letter from a primary care doctor with assistance from the study staff if randomized to the Peer GLB group. Additionally, participants who are randomly assigned to the Peer GLB intervention will have to have been cleared by their primary care physician to participate in light-to-moderate physical activity. Study staff and the staff at the study site (e.g., peer specialists, case managers) will assist participants in getting this medical clearance letter.

Exclusion Criteria

We will exclude clients who are in need of detoxification, are at acute risk of suicide or homicide, fail a capacity-to consent questionnaire, and self-report contraindications to participating in a weight

loss program, including: receiving active cancer treatment (radiation/chemotherapy), have liver failure, having been told by a doctor that they had anorexia, had a cardiovascular event (e.g., unstable angina, myocardial infraction) within the past 6-months, ever had or planning to have weight loss surgery in the next 18-months, unable to walk, and (for female participant) currently pregnant or planning a pregnancy during the study period Individuals who are 65 years or older will also be screened for cognitive impairments using the Mini-Cog examination (see a description of the Mini-Cog examination in the informed consent process section below). Those that fail the mini-cog will be excluded from the study because of possible cognitive impairment issues. These criteria will be ascertained by our study staff during the consenting process discussed in detail in the informed consent process section below.

7. Recruitment

We plan to recruit up to 300 supportive housing clients who are overweight or obese (BMI > 25) through provider referrals, presentations at consumer and staff meetings and hosting lunches at each site (See study flow chart attached). Supportive housing agency staff will help identify clients from their existing program roster who they think will be interested and motivated to participate in this study and who generally meet our study inclusion criteria and do not meet our exclusion criteria. Agency staff will then approach these clients and briefly introduce the project to them using the project information sheet [redacted] For those clients interested in the study, agency staff will then fill- out a project referral form [redacted] with the clients' name and contact information and whether the client meets study eligibility criteria using their knowledge of the client's status. Research staff will also provide a brief training to agency staff on how to fill-out this referral form. The agency staff will then give the referral form to our research staff who will be on-site at each study site. Project staff will also conduct presentations to staff and clients and host lunches/dinners at each site to introduce the project to potential interested participants. In these events, study staff will present the goals of the project and answer any questions or concerns clients may have about the project. Interested clients will then be asked to write down their name and contact information in a project referral list so that project staff can contact them.

Research staff will use the following script to contact interested clients via telephone and/or in person at each site in order to provide further details about the project, answer any questions the interested consumers may have, and schedule a face-to-face meeting at the site to initiate the screening. The following script will be used to explain the study to interested consumers in order to invite them to participate in a screening to determine if they would or would not be eligible to participate in the study.

"Thank you for your interest in our study. The purpose of this project is to evaluate a free group-based healthy lifestyle program to help [Agency] clients who are overweight or obese reduce and manage their weight. The goal of this program is help participants improve their eating habits and increase their engagement in physical activities. The study is being conducted through a partnership between [Agency] and the Columbia University School of Social Work. If you are eligible and you choose to participate, you will be randomly assigned to either 1) continue receiving your usual services or 2) to continue receiving your usual services plus participate in a 12-months healthy

lifestyle program that will be held at [site]. Random assignment is like a lottery and means that you have a 50/50 chance of being assigned to either group. If you are not randomly assigned to receive the healthy lifestyle program, you will continue receiving your usual services, but you will not participate in the healthy lifestyle program. If you are randomly assigned to receive the healthy lifestyle program, you will continue receiving your usual services and you will also be asked to attend the healthy lifestyle groups every week for 12 consecutive weeks. After you attend the program for 12 weeks, you will be asked to attend follow-up groups once a month for 9 months. Each group will last approximately 90 minutes and will be facilitated by a trained peer specialist.

All participants in this study will be asked to participate in four interviews with study staff to learn about your ongoing experiences with your health, weight, physical activity, and quality of life issues. This means that no matter what group you are assigned to, we would like to continue to conduct interviews with you. During these interviews, study staff will 1) measure your weight, height, blood pressure, and waist circumference and 2) ask you questions about various aspects of your life including your health, physical activity, mental health recovery, service use, and quality of life. These interviews will occur just before random assignment, and then every six months after that for 18 months. All interviews will be conducted at [site]. Participation in this project is completely voluntary and all of the information collected for this study will be kept confidential. In order to participate in the study, we first have to ask you some questions to determine if you are eligible. If you are interested in learning whether you are eligible, we would like to schedule a time with you so that we can ask you questions about certain medical or mental health conditions that you may have which may affect whether you are eligible to participate."

Project staff will then answer any questions, schedule a time to conduct the screening questionnaire, meet with the interested client in-person, read the screening eligibility information sheet, obtain verbal consent to complete the screening eligibility questionnaire, and complete the screening questionnaire for those who provide verbal consent. For those who are determined to be eligible, project staff will then administer the informed written consent process for participation in the effectiveness trial. Once clients have provided informed consent for the effectiveness trial, we will complete the baseline interview and carry out random assignment. For participants randomly assigned to the Peer GLB group, we will work with supportive housing agency staff to obtain the approval letter from the participants' primary care doctor. Participants who have been consented will be given the date and time of the first group session and a reminder card of this first session. Project staff will also call participants one or two days before each groups session to remind them of their group sessions. Failure to submit the medical clearance letter by the first group session will preclude the person from participating in the Peer GLB intervention.

How will project be advertised/publicized?
As we have done in our previous research projects at community agencies, the research staff (PI, project director, and/ or research assistant) will present the project at different staff meetings. With the permission of program staff, we will also present the study at client meetings where events and new initiatives are discussed with clients. We will also host lunches/dinners at each study site to introduce the project to clients and staff. We will distribute a one-page description of the study to agency staff so that they can also present the study to interested clients (see attached: Project Description for Staff).

Compensation

Participants will be compensated for completing study assessments (e.g., structured interviews) not for attending intervention sessions. Participants will receive $25 plus a round-trip transportation reimbursement (e.g., MetroCard in NY, two transit tokens in Philadelphia) for participating in each of the structured interviews at baseline, and 6, 12, and 18 months after baseline. The $25 compensation will be given in cash at the end of the individual interviews.

Whenever possible, we will provide travel compensation for potential participants that attend the screening eligibility appointment. Participants who participate in the Post Peer GLB focus groups will receive $25 plus a round-trip transportation reimbursement (e.g., MetroCard in NY, two transit tokens in Philadelphia). Participants who participate in the Post Peer GLB transition phase semi-structured qualitative interview will receive $25, plus a round-trip transportation reimbursement if they had to travel to the research site (e.g., two transit tokens in Philadelphia). Participants are being compensated for their time and effort in participating in the individual interviews and focus groups. Participants are being compensated for their time and effort in participating in the individual structured interviews.

8. Informed Consent Process

Trained research assistants (RA) with a BA and/or Masters under the supervision of the Project Director, Ana Stefancic and the Principal Investigator, Dr. Cabassa, will be in charge of obtaining informed consent from all participants. The RAs will complete the required CU IRB and CITI trainings. They will also receive the following consent training for this project. First, the Project Director will review the consent procedures with the RAs explaining each step and how to ascertain cognitive impairment and capacity-to-consent (see procedures in the following sections). Second, as part of their training the RAs will participate in a role play exercise in which they will get a chance to practice the informed consent steps and receive feedback from the Project Director and other trained research staff members. Third, they will observe the Project Director or another trained research staff member obtain informed consent from a potential participant. Fourth, the Project Director or another trained research staff member will observe the RA obtain informed consent from a potential participant and received feedback after worth. Lastly, as part of our project's weekly research staff meetings, we will discuss recruitment and informed consent procedures and troubleshoot any issues that may arise throughout the project, including reviewing informed consent procedures and providing a booster training to any RA, if needed.

Once interested clients have been referred to the study staff (via provider referral or self-referred), the RA will contact the interested consumer (e.g., via telephone or in person at the site) to arrange an-in person meeting to further discuss the study and invite the person to participate in the screening questionnaire which determines whether the person is eligible to participate in the effectiveness trial [redacted]. During the in person meeting, project staff will meet with the client, read the screening eligibility information sheet [redacted], obtain verbal consent to complete the screening eligibility questionnaire, and complete the screening questionnaire for those who provide verbal consent. Potential participants who do not wish to be asked the screening questionnaire will not be screened

and they will not be eligible to participate in the effectiveness trial. The screening instrument does not collect individual identifiers and data obtained during the screening will not be linked to identifiers. Only the overall eligibility determination (eligible or not eligible) will be linked to an identifier. For those who are eligible to participate in the study, the project staff will then initiate the informed consent process for participation in the effectiveness trial and ask participants to provide written consent. Details for each of these steps are described below.

Step 1: Ascertainment of Study Eligibility Criteria. The RA will read the screening eligibility information sheet [redacted] to participants and ask them to provide verbal consent to complete the screening questionnaire. For those participants who provide verbal consent, the RA will use a standardized screening form to ascertain study inclusionary and exclusionary criteria, including measuring participants' height and weight and using these measures to calculate potential participants' Body Mass Index (see PGLB RCT Screening Questionnaire attached). The screening instrument does not collect any individual identifiers and data obtained during the screening will not be linked to identifiers. Only the overall eligibility determination (eligible or not eligible) will be linked to an identifier.
To ascertain for possible cognitive impairment among potential participants 65 years old or older, the RA will use the Mini-Cog Examination [redacted] The Mini-Cog asks participants to draw a clock face, putting the hands at the correct time (e.g., 11:30), and are given a three-word recall task (e.g., apple, car, ball). The Mini-Cog is scored by assigning 1 point for each recalled word after the patient completes the clock drawing test (CDT). The CDT is considered normal if all numbers are present in the correct sequence and position and the hand readably display the requested time. Scores range from 0-3. A positive screen for cognitive impairment includes a score of 0 in which no words are recalled or a score of 1 or 2 in which one or two words are recalled but the CDT is abnormal. A negative screen for cognitive impairment includes a normal CDT plus 2-3 words are correctly recalled. We have used this instrument in previous studies with people with serious mental illness from diverse backgrounds and educational levels. This instrument has worked well in diverse settings as neither English nor Spanish language proficiency nor literacy is required. A positive screen for cognitive impairment will preclude the client from being able to provide informed consent and thus from participating in this study.

Step 2: Ascertainment of Capacity-to-Consent and Written Informed Consent for Eligible Participants. Once the RA has established participant's eligibility for the study, the RA will present eligible participants with a copy of the consent form in English or Spanish [redacted], depending on the participant's preference, and discuss the study purpose, alternative to participation, study procedures, study's risk and benefits, compensation, and how patient's confidentiality will be protected. At any time during this face-to-face meeting, participants are encouraged to ask questions and voice any concerns about the study and their participation.

The RA will also explain to the eligible participant that before he/she signs the informed consent form, the RA will be asking them questions about what is being discussed to determine if the participant understands the study, the consent process, and what they are consenting to using our Capacity-to- Consent screen instrument [redacted] This instrument is adapted from an established capacity-to- consent measure developed by Zayas, Cabassa, and Perez (2005). Dr. Cabassa is one of the researchers involved in developing and testing this capacity-to-consent screen.

The original instrument was tested with a sample of English and Spanish speaking Hispanic consumers receiving outpatient community mental health services for disorders, such as schizophrenia, bipolar disorder and major depression. We have also used this instrument in previous studies at supportive housing agencies. The attached measure includes procedures and eligibility cutoffs. The RA will then administer the capacity-toconsent screen instrument to ascertain consumers' capacity to consent. Only those clients who demonstrate that they have the capacity-to-consent based on the result of this screening instrument are then asked to sign the study consent form. We are requesting an exception to the requirement for having a licensed physician assess capacity to consent and have provided a separate document that includes a justification for this request that specifies the exact procedures for how we will assess capacity to consent, including who will determine capacity to consent and how they will be trained and supervised [redacted]. A summary is provided below.

While we are recruiting individuals with serious mental illness (SMI) in the research, the population of individuals we are recruiting from is generally presumed to meet the criteria of being autonomous agents – they are individuals who are maintaining independent living in the community. The informed consent process and the research protocols are being administered in community, not clinical, settings where the assistance of a licensed physician is not routinely required nor available. Further, as clients of community-based support services, they are regularly expected to make treatment decisions by their programs. Our decisional capacity to consent assessment process conforms to recommended strategies including the use of a structured interview, clear cut-points for passing/failing capacity, reliability training for those administering the assessment, and opportunities for education and repeated learning within the assessment to improve comprehension among potential participants. Such brief questionnaires that test an individual's understanding of a study's purpose, risks, benefits, and voluntary nature have been shown to be sensitive and reliable ways of assessing decisional capacity (Dunn et al., 2006; Sturman, 2005), including among populations with SMI when administered by trained research staff who are not physicians (Jeste, Palmer, Appelbaum et al., 2007). The PI and the project director will supervise the RAs in the capacity assessment process throughout the protocol. Initially, RAs will make decisional capacity determinations of potential participants while being observed by the project director or PI who will provide direct feedback as necessary. Only after the PI and project director have determined that the RAs have demonstrated reliability and adherence to the assessment protocol will RAs conduct independent assessments. If, during the course of conducting a capacity to consent assessment, an RA encounters an ambiguous situation, they will not move forward with the consent process and enrollment. They will discuss the potential participant's responses with the project director and PI who will then make a final determination regarding capacity. The project director will also review all capacity to consent assessments to ensure that all RAs are adhering to the established protocol and scoring algorithm. If a potential subject does not meet our capacity determination, they will be deemed ineligible and will not be enrolled in the study.

Participants who are randomly assigned to the Peer GLB group will also need to obtain a signed approval letter from their primary care physician [redacted] to give them a medical clearance to participate in our healthy lifestyle program. This letter specifies that the person can participate in a weight loss program that includes engagement in moderate physical activity (e.g., brisk walking for 30 minutes, 5 days a week). Participants will be asked to bring a copy of this letter or have the letter

faxed to the study staff by their first Peer GLB group session. Study staff and staff from the supportive housing agency (e.g., peer specialists, case managers) will assist participants in getting this medical clearance letter.

Participants who are randomly assigned to the Peer GLB group and who have participated in at least two intervention sessions will also be asked to complete one additional semi-structured qualitative interview post the Peer GLB transition phase. The RA will administer informed consent in person with the participant to seek permission to conduct a one-time semi-structured qualitative interview regarding the participants' experiences with the group intervention and with the group facilitator. The RA will present participants with a copy of the semi-structure qualitative interview consent form [redacted]; discuss the purpose, alternative to participation, procedures, risk and benefits, compensation, and how patient's confidentiality will be protected; and answer any questions the participant has regarding the qualitative interview.

9-10. Privacy Protection and Confidentiality of Study Data

All participants' data will be kept confidential to the extent permitted by law. Once participants have provided informed consent, they will be assigned an identification (ID) number. All data collected from participants will be recorded and stored using only their identification number. Any data containing PHI or PII will be stored in compliance with the IRB Data Security Policy effective 11/25/2013. Data containing PHI or PII will be stored on a single-user system and any endpoint devices storing these data are encrypted and protected with a strong password. Survey data will also be entered and stored on a multi-user Qualtrics system [redacted]. A master key file matching each participant to his/her identification number will be stored separately from the data and will be stored on single-user, password-protected, and encrypted computers. Only the PI, Project Director, and the Research Assistants will have access to this master key file. Data obtained during the screening will not be linked to identifiers. Only overall eligibility status (eligible/not eligible) will be linked to an identifier. Project data will initially be collected on paper (e.g., structured interviews) and/or on a digital audio file (e.g., recordings of intervention sessions, focus groups, and qualitative interviews).

Paper-based research records (e.g., structured interviews, focus groups transcripts) will be stored at each research site in a locked office and in locked file cabinets to which only research staff have access (i.e., RAs, Project Director, PI). Paper-based research data will be identified only by participants' ID numbers. The Project Director and PI will periodically audit each RA's files to ensure ongoing compliance with all protocols. The Project Director will conduct supervision check-in calls with each RA twice a week at minimum to monitor adherence and offer any additional training. Audio files will be labeled using participants' ID numbers and will be stored as password-protected computer files accessible only to authorized study personnel. Once these audio files have been successfully transferred from the digital recorders to the authorized computer, the audio file will be deleted from the digital recorder. Focus group and semi-structured qualitative interview audio files will be professionally transcribed and purged of any identifiable information (e.g., names, locations). All original and back-up audio files stored in the authorized, password protected computer will be destroyed 5 years after the completion of the study to provide sufficient time to review the audio files, transcribe the files, and before all the study analyses are concluded.

Transmission & Storage via Qualtrics: Survey data will be entered into the survey software Qualtrics, and stored on the Qualtrics [redacted] for the transmission and storage of sensitive data. Qualtrics is a survey program that allows users to create online surveys, conduct web-based data entry, and store responses. While the data entered into Qualtrics will not contain individual identifiers such as names, geographic locations, etc., the data will contain a participant ID code that allows the researchers to link the data back to participants. The survey will continue to be administered in person by Research Assistants who will record answers on paper-based copies; the Qualtrics program will only be used for data entry. Research assistants at each site will enter survey data using a single-user, password-protected computer into the project's survey on the [redacted] Qualtrics system. Qualtrics offers Transport Layer Security (TLS) encryption (HTTPS) which allows for the transmission of encrypted data to a secure database. The Project Director will download the database on a regular basis and save it on a single-user, password-protected, and encrypted computer at the Columbia School of Social Work.

The PI will be the Qualtrics survey account administrator for the project and will grant different levels of access to the Project Director and the research assistants who will be conducting data entry. The PI and each research staff member will use their UNI and password to access the Qualtrics survey account. User permissions are very specific and allow the PI to limit the research staff to view or enter data, as well as restrict access to download the entered data. Only the PI and Project Director will have permission and access to download the entered data.

E-mail transmission: Data that is encrypted will be transferred electronically via CU to CU e-mail only after the following CU e-mail usage policy steps have been followed: 1) All email communications of Sensitive Data or Confidential Data are encrypted before being transmitted. 2) Sensitive Data or Confidential Data are not transmitted in the "Subject" line of an email. 3) Before transmitting an email that contains Sensitive Data or Confidential Data, the User double-checks the message and any attachment to verify that no unintended information is included and that the proper document is attached. 4) Before transmitting an email that contains Sensitive Data or Confidential Data, the User doublechecks the identity of the recipients (CU email usage policy, 2014).

Data will also be stored on a single-user, password-protected, encrypted computer. A back-up copy of the data will also be stored on a password-protected, encrypted endpoint device (e.g., external drive) that will be stored at Columbia University School of Social Work. Any electronic data that is not entered into Qualtrics or sent via e-mail will be transferred from the research site to Columbia in person by research staff via a password-protected, encrypted endpoint device (e.g., external drive)

All research staff will be educated about the importance of strictly respecting participants' confidentiality and privacy as part of their training into the study. All participants' data will be kept confidential. Once participants have provided informed consent, they will be assigned an identification (ID) number. Participant interviews and focus groups will be conducted with only research staff present.
Participants' focus groups and Peer GLB sessions will be audio recorded using standard digital recorders. To protect participants' confidentiality, these audiotapes can be stopped at any time at the request of the participant. To protect participants' confidentiality, the focus group facilitator at the

beginning of the group discussion will remind participants that they should not disclose information shared in the focus group with people outside of the group.

Lastly, consent forms will also specify that if during the group discussions or the individual interviews the participant indicates that their health or mental health is worsening, or that he/she may hurt themselves or someone else, we will inform the clinician treating (e.g., case manager) them. If the participant is in need of immediate evaluation, research staff will also refer participant for evaluation and treatment with their mental health services provider, at study site, or an emergency room. The consent form also specifies the agencies which are allowed to access participant data under certain circumstances.

11. Potential Risks

A risk for all participants associated with the structured individual interviews and the semi-structured qualitative interview is that they may become upset by discussing topics related to their health or use of health services. Participants will be able to stop participation at any time and the RA conducting the interviews will be able to help them cope with emotional reactions, including referral for evaluation and treatment with their provider at the study site (e.g., case manager, etc). Participants could develop mild emotional discomfort or frustration associated with participating in the focus groups discussion or in the individual interviews. Study personnel will make efforts to help clients to feel as comfortable as possible (e.g., by offering encouragement). Clients in the individual interviews may also reveal that they are at acute risk of suicide. These clients will have access to immediate in-person evaluation by a member of their treatment staff. All screenings and interviews will be conducted at a program site where the participant's usual service providers are present. At each supportive housing agency site, participants found to be in need of further counseling or treatment, during or upon completion of an interview, will be immediately referred to a member of their treatment/services team (e.g., case manager). A member of the treatment team is always on-site and researchers will accompany the participant to the treatment team's offices and a case manager will then conduct a formal assessment, per agency's protocols. No specific referral form will be used as participants are already receiving support services from the agency. A member of the treatment services team (e.g., case manager) will formally evaluate the participant, directly provide counseling, and make referrals to an appropriate treatment setting (e.g., emergency room, psychiatrist). The supportive housing agencies directly provide extensive mental health treatment support and have close linkages to local hospitals, detox facilities, and other treatment settings to which participants can be routinely referred as needed.

Potential Risks and Procedures to Minimize Risks Associated with Participating in the Peer GLB Intervention: There is a small risk of injury while engaging in physical activity, but this will be minimized by recommending that participants in the Peer GLB intervention engage only in moderate physical activity (e.g., brisk walking 30 minutes a day), as opposed to engaging in more vigorous physical activity (e.g., running). There is a small risk of having inadequate nutrition or experiencing excessive, rapid weight loss due to changes in diets. For participants taking antidiabetic medications, changes in diet and physical activity may increase the risk of having low blood sugar levels, especially at the beginning when participants start making these changes. For

participants taking medication that lowers blood pressure, weight loss interventions have the potential to increase the risk of having blood pressure that is too low.

We will take several steps to minimize all of these risks. All participants randomly assigned to the Peer GLB intervention will be referred to a medical provider to determine whether it is safe for them to participate in the intervention prior to beginning Peer GLB. Only participants who obtain this medical clearance will be able to participate in the Peer GLB intervention. We will further minimize these risks through group sessions and individual counseling that will teach participants about: 1) the importance of properly engaging in moderate physical activity, warm-up and cool-down exercises, proper stretching and exercise techniques; 2) the importance of eating a variety of foods from all food groups, taking in enough calories, and losing weight safely and slowly as recommended and emphasized in the program; 3) and the importance of understanding and monitoring potential symptoms of low blood sugar and low blood pressure. Additionally, study staff and peer specialists delivering the intervention will also periodically (e.g., weekly basis) review participants' food logs, weight logs, self-monitoring tools and provide feedback to Peer GLB participants on whether they are taking in enough nutrients. If there is any question about the cause of an injury or the need for treatment, or if a participant experiences sudden, dramatic weight loss, or signs of low blood sugar or low blood pressure, we will refer them to their physician and stop the intervention as recommended by their physician. The project also has primary care physician, Dr. Richard Younge, readily available to provide consultation to study staff regarding any potential medical issues.

12. Data and Safety Monitoring

Describe how data and safety will be monitored locally to identify unanticipated problems (i.e., events, outcomes, or occurrences that are unexpected, at least possibly related to the research, and suggest an increase in risk of harm to subjects or others). Dr. Cabassa (PI) and Ana Stefancic (Project Director) will be responsible for data and safety monitoring. The following steps will be used for data and safety monitoring:

1. At Bi-monthly meetings (twice a month), the PI and Project Director will review rates of enrollment and study retention, any problems with participant safety, and the status of data collection. Protocol violations will be discussed and, if appropriate, the IRBs will be consulted and corrective actions devised.
2. Although the risks to participants from this protocol are likely to be low (given medically unstable participants are excluded), these risks will be continuously monitored and appropriate measures implemented in cases of unforeseen adverse events, including the removal of participants from the study protocol. For example, if participants became suicidal during the protocol, they would be removed from the study and given appropriate clinical care at the study site.
3. Every 2 months during the intervention phases of the study, the PI and Project Director will review the number of participants enrolled, the number who discontinued participation (and reasons why), the number who did and did not complete study procedures (and reasons why), any adverse events, procedures for assuring participant privacy and confidentiality, and the quality and integrity of the data collected. Corrective action will be taken if needed.

4. IRB protocols and informed consent documents will be reviewed annually by the CU IRB and respective IRBs (e.g., supportive housing agency IRB). Reports of enrollment and retention and reporting of adverse events are required with these renewals. Research Meetings for Data Safety and Monitoring: Throughout the project, frequent research staff meetings will be held with all study personnel to coordinate the study and to assess the progress and status of participants. The PI and Project Director will supervise the day-to-day operations of the study staff. Ad hoc meetings will be performed at Columbia University School of Social Work Offices or study sites with Co-investigators, in order to discuss and resolve any participant-specific issues. These meetings will be attended by the PI, Project Director and study staff. In addition, monthly regular project steering committee with the PI, study staff, representatives from study sites and Co-investigators will be performed to discuss general updates and performance of the project.

Adverse Events: In consultation with the DSMB and pursuant to Human Subjects Regulations and CU IRB protocol, the PI will adhere to the following protocol for adverse events.

1) Adverse events may be initially identified by RAs, the Project Director, PI, or other project staff, including staff reviewing audio recordings of Peer GLB sessions, or they may be reported by participants or their providers at the supportive housing agency.
2) Within 24 hours of an adverse event being identified, an Adverse Event Report form will be completed by the study staff member or supportive housing provider who identified the event. The report form will include date, description of the event, duration, severity, measures taken to ameliorate the adverse event, and disposition related information (e.g., time spent providing referrals and type of referral (e.g., mental health treatment, ER visit, etc.). The report form will be reviewed and signed by the immediate supervisor who will be responsible for ensuring that appropriate actions have been taken. 3) Once the PI becomes aware of an adverse event, he will, in consultation with the study physicians as necessary, assess the event to determine whether the adverse event was an unanticipated problem by evaluating 1) was it unexpected, and if so, 2) was it possibly related to study participation, and if so, 3) does it qualify as a serious adverse event or suggest that the research places subjects or others at greater risk of harm than previously recognized. In making this determination, the PI will consult with housing provider staff and the physician co-investigators on the study, as well as review any documentation or other sources to clarify the nature of the event and outcomes. The PI will report any events that meet the three criteria to the IRB as unanticipated problems within 1 week of the PI becoming aware of the event. The PI will consult with the investigative team, DSMB, and supportive housing provider to determine whether protocol changes are needed. The PI will maintain a log of all adverse events and present a summary report for the DSMB to review.
4) The investigative team and the DSMB will review all adverse event data every six months to determine if systematic trends exist among adverse event data to warrant changes to study protocols and procedures. Any proposed changes will be reviewed with staff at the study sites, and, if needed, external consultant (e. g., other senior investigators conducting federally-funded research on the physical health of people with SMI).

Approval for changes in study protocol or materials will then be obtained from the Columbia University IRB and other study site's IRB. After approval, the NIMH program official will be

notified, and changes will also be reported in the annual progress report submitted to NIMH. The investigative team will also conduct systematic analyses of adverse event data (e.g., associations among frequency, type, severity of adverse events; participant characteristics; and operational aspects of research such as time point) to inform future studies with participants in supportive housing as well as recognizing such activities represent a potentially under-researched area of inquiry and scientific endeavor unto itself.

Data and Safety Monitoring Board (DSMB)

In order to maximize the safety monitoring of this effectiveness randomized clinical trial, Dr. Cabassa will appoint an independent DSMB to review safety data. The DSMB will have three members who are not associated with the conduct of the study and will include experts in clinical trial methodologies, mental health and health interventions, and health disparities research. The following individuals have agreed to serve on the DSMB for this study [redacted]:

Lisa Dixon, MD, MPH is a Professor of Psychiatry at the Columbia University Medical Center and Director of the Center for Practice Innovation at the New York State Psychiatric Institute. She has been engaged in multiple clinical studies evaluating interventions and services to improve the health and well-being of people with serious mental illness and their families. She has chaired the DSMB for the NIMH Schizophrenia Trials Network and is the chair of the VA Health Services Research and Development DSMB.

Alex Kopelowicz, MD, PhD is a is Professor and Vice-Chair in the Department of Psychiatry and Biobehavioral Sciences, David Geffen School of Medicine at UCLA and Medical Director of the San Fernando Mental Health Center (SFMHC), a community mental health center operated by the Department of Mental Health of Los Angeles County. He brings substantial expertise leading clinical trials examining mental health treatments among vulnerable populations and studying racial and ethnic health and mental health disparities in the U. S.

Daniel B. Herman, MSW, PhD is a Professor and Associate Dean for Scholarship and Research at the Silberman School of Social Work at Hunter College, City University of New York. He brings to this role substantial research expertise in leading clinical trials and mental health services studies examining services and interventions among formerly homeless adults with serious mental illness.

Conflict of Interest: DSMB members will be asked to disclose any conflicts of interest prior to DSMB meetings. No DSMB members will have any role on the study.
Charge of the Board: During the trial, the DSMB will assess the performance of overall study operations and any other relevant issues, as necessary. Specific items that will be reviewed by the DSMB include:

- Interim/cumulative data for evidence of study-related adverse events
- Data quality, completeness, and timeliness
- Adequacy of compliance with goals for recruitment and retention, including those related to the participation of women and minorities
- Adherence to the protocol

- Factors that might affect the study outcome or compromise the confidentiality of the trial data (such as protocol violations, unmasking, etc.)
- Interim analysis

Meeting Format: The meetings may include both open and closed sessions. In the open sessions, the PI and the Project Director presents and discusses information with the DSMB on study progress and adverse events. In closed sessions, the DSMB chairperson leads the meeting with the board members and without participation of the PI or study investigators to discuss any concerns with the progress of the study or with risks to participants. The need for closed meetings is at the discretion of the DSMB chair. Meetings may be conducted by teleconference at the request of Board members.

Frequency of Meetings: The first DSMB meeting will take place before the enrollment of the first participant in the effectiveness study. During the first DSMB meeting, a chair for the board will be selected. Then, the DSMB will meet once a year until the completion of the study. Additional meetings will be convened quickly if problems arise that require addressing between reviews. Ad hoc DSMB meetings may be requested by DSMB members, the Project Officer (PO), Columbia University IRB, or Principal Investigator (PI) at any time to discuss safety concerns.

What is Monitored: The DSMB will evaluate the progress of the trial, recruitment rates, retention rates, adverse events, unanticipated problems, and other factors affecting safety or outcomes. The DSMB will review rates of adverse events in the study (in an unblinded manner if they wish) to evaluate any changes in participant risk. The PI, Project Director, and study statistician (Dr. Wall) will be available to the DSMB to provide summary data on recruitment, data quality, adverse events, and will provide requested data analyses. The DSMB also will review major proposed modifications to the study prior to their implementation.

Confidentiality: The DSMB will not have access to personally identifiable information of participants. DSMB members agree not to disclose the results of the data except as agreed by the PI. The report to the DSMB includes actual vs. projected recruitment rates (number screened, consents, randomized, etc.), summary of serious adverse events, and any modifications to the protocol.

Communication Plan: At the end of each DSMB meeting, the chair will provide the study leadership with written information concerning findings for the trial as a whole and any relevant recommendations related to continuing, changing, or terminating the trial. The chair will prepare a summary of the meeting along with any recommendations for changes to the protocol based on the meeting. The draft report will be reviewed and edited by all Board members prior to issuing the final report. This report will not include confidential information. The report should indicate whether the study should continue as originally designed, whether the study should be modified to protect patient safety or whether the study should be terminated. The PI will send the report to the Columbia University IRB, other study site's IRBs, and to the sponsoring NIH Institute.

13. Potential Benefits

The potential benefits to participants are direct (improved health and wellness) and indirect (helping to refine the appropriateness and promote the use of a promising group-based healthy lifestyle intervention). The study will test the effectiveness of Peer GLB to improve the physical health of culturally diverse consumers with serious mental illness who are overweight or obese receiving services at supportive housing agencies.

14. Alternatives

The alternative for participants is not to participate in this study and to receive the usual care services at their supportive housing agencies (e.g., case management, wellness groups).

15. Research at External Sites

We have identified two supportive housing agencies that are participating in the project: [redacted]. The site at [redacted] will be at [redacted] The second site is [redacted] in Philadelphia, PA. [redacted] does not have an IRB and does not require IRB review, but the Philadelphia Department of Public Health IRB has already approved the protocol locally and has approved [redacted] IAA request for the existing protocol.

In conjunction with the CU Morningside IRB, we have also obtained IRB approval from the City of Philadelphia Department of Public Health (PDPH) IRB (which requires review of studies involving consumers receiving services funded by PDPH, as is the case at [redacted]). [redacted] have obtained an IRB Authorization Agreement with the City of Philadelphia's Department of Public Health IRB so the PDPH IRB serves as the IRB of record for [redacted]

[redacted] does not have an IRB, and so we are requesting that the CU IRB consider entering into an IRB Authorization Agreement (IAA) so that the CU IRB can serve as the IRB of record for [redacted].

16. Columbia as Lead Institution

Not Applicable