Official Title:	Peer Support and Mobile Technology Targeting Cardiometabolic Risk Reduction in Young Adults with Serious Mental Illness
NCT number:	NCT02815813
Document Type:	Study Protocol and Statistical Analysis Plan
Date of the Document:	Version Date: 5/8/2020 IRB Approval date: 5/20/20

SOCIAL, BEHAVIORAL, and NON-CLINICAL RESEARCH PLAN

CPHS template v. 11/19/2015

Please complete: CPHS# STUDY00029586 **PI: Kelly Aschbrenner, PhD**

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1. Introduction and Background

Obesity is nearly twice as prevalent in people with serious mental illness (SMI) compared with the general population[1] and is associated with cardiometabolic disorders and a reduced life expectancy of up to 32 years in this population.[2,3] Young adulthood, ages 18 to 35, is a critical window for interventions to reduce this early mortality health disparity as young adults are at the greatest risk of weight gain of any group.[4] The onset and progression of mental illness in young adults can have devastating consequences on major life domains, including education, employment, and social relationships, resulting in low self-esteem and a sense of hopelessness that can create a high vulnerability for engaging in poor health behaviors. Effective behavioral interventions to reduce cardiometabolic risk factors associated with obesity and sedentary lifestyles exist for adults with SMI, but there is a lack of research on health promotion specifically targeting younger adults ages 18 to 35 with SMI. The proposed research is expected to make a substantial contribution to advancing knowledge about the treatment of cardiometabolic health risk factors in young adults with SMI by rigorously testing the effectiveness of a group-based lifestyle intervention supported with mobile health (mHealth) technology and social media in young adults with SMI that is ideally suited for wide dissemination.

2. Objectives and Hypotheses

This 12-month study will recruit 144 young adults ages 18 to 35 with SMI. Participants will be randomly assigned to receive either the PeerFIT lifestyle intervention or to receive a comparison condition including **B**asic fitness and nutrition **E**ducation supported by a wearable **A**ctivity **T**racking device (BEAT). The goals of the PeerFIT program are to reduce the cardiometabolic risk within the target population of young adults ages 18 to 35 with SMI who have overweight or obesity (BMI ≥25) by achieving a 5% weight reduction and increasing physical activity gradually to 150 minutes per week over a 6-month period.

Specific Aims and Hypotheses

The specific aims are as follows:

Specific Aim 1: To compare the effectiveness of the PeerFIT group lifestyle intervention to BEAT with respect to weight loss, cardiorespiratory fitness, and A1c and lipid parameters in overweight and obese young adults with SMI.

(H1a) Hypothesis: PeerFIT compared to BEAT will be associated with greater weight loss and improvements in cardiorespiratory fitness at 6 and 12 months follow-up.

(H1b) Hypothesis: PeerFIT compared to BEAT will be associated with a greater proportion of participants who achieve cardiovascular risk reduction at 6 and 12 months follow-up as indicated by either clinically

significant weight loss (5% or greater) or increased fitness (>50 m on the 6-Minute Walk Test).

(*H1c*) *Hypothesis:* PeerFIT compared to BEAT will be associated with greater improvements in A1c and lipid profiles at 6 and 12 months follow-up.

Specific Aim 2: To investigate two theoretical mechanisms of action hypothesized to account for greater weight loss and increased cardiorespiratory fitness among participants assigned to PeerFIT: 1) improved self-efficacy for exercise and 2) increased peer social support for health behavior change.

(H2) Hypothesis: The relationship between PeerFIT and weight loss and improved fitness will be mediated by improved self-efficacy for exercise and peer support for health behavior change.

3. Study Design

Describe all study procedures, materials, and methods of data collection:

DESIGN SUMMARY

This randomized controlled trial will be conducted in real-world mental health settings providing services to clients within the Massachusetts Department of Mental Health (DMH) community-based system of care, the Mental Health Center of Greater Manchester (MHCGM) in Manchester, NH, the Greater Nashua Mental Health Center of Community Council (GNMHCCC) in Nashua, New Hampshire, and the Community Mental Health Affiliates (CMHA) in New Britain, CT. A total of 144 young adults with SMI and overweight/obesity (BMI ≥25) will be recruited from the MHCGM, GNMHCCC, and CMHA, as well as from sites within DMH to participate in a randomized controlled trial. The study will be referred to as the "Fit Forward Lifestyle Trial for in Young Adults." Participants will be randomized 1:1 to PeerFIT or to Basic Education in fitness and nutrition supported by a wearable Activity Tracking device (BEAT), resulting in approximately 72 clients randomized to PeerFIT and 72 clients randomized to BEAT. Recruitment will occur on a rolling basis with the PeerFIT group intervention starting once at least 2 new people have been randomized to PeerFIT. Thus, we will run open PeerFIT groups in which up to 18 new members are welcome to join at any time during the life of the group. The BEAT individual intervention will begin as soon as 2 participants are randomized to that intervention. This rolling recruitment process combined with open PeerFIT groups is an adaptation to the study design intended to reduce the participant burden of waiting to start the intervention until a full cohort of participants is recruited, which typically takes many months.

INTERVENTION AND CONTROL CONDITION

PeerFIT Intervention: The 12-month PeerFIT intervention consists of a 6-month intensive phase including: (a) once weekly 90-minute group weight management and exercise session led by a lifestyle coach; (b) once weekly one-hour physical activity session delivered in community settings; and (c) Facebook and mHealth technology (i.e., Fitbits, text messaging support) to increase motivation and facilitate self-monitoring and peer social support for health behavior change. Participants then transition to a 6-month lower intensity phase in which the 90-minute weight management sessions are discontinued. During the low intensity phase, participants will have continued access to the physical activity sessions, social media, and mHealth support described below. A total of 10-18 participants will be enrolled in each of the in-person groups with participants from all groups invited to join the secret PeerFIT Facebook group. The groups will be conducted as open groups with a minimum of 2 and maximum of 18 participants at any given time to offer more diversity and perspective from peer members. After 2 participants are enrolled, each new participant who joins the group will receive an orientation called the "Start Up Session" prior to the group session. The orientation session will be done individually or in a small group setting. The orientation session will last about one hour and will be conducted within one week prior to joining an existing PeerFIT group when possible.

Weight Management and Exercise Sessions. The PeerFIT weight management and physical activity component is adapted from the evidence-based Diabetes Prevention Program designed for individuals at risk for diabetes and cardiovascular disease in the general population. PeerFIT goals are to achieve 5% weight reduction and to increase physical activity gradually to 150 minutes per week over a 6-month period. A private and confidential weigh-in is conducted at the beginning of each session to track participants' progress. Participants are taught to achieve their weight loss and fitness goals by lowering calorie intake by reducing their consumption of sugar-sweetened beverages and junk foods that are high in sugar and fat and eating fewer processed foods, while adding more fruits and vegetables and lean protein into their diets, and by

participating in moderate-intensity physical activities. Daily self-weighing and physical activity trackers are used as self-monitoring strategies to promote and reinforce desired behavioral changes. Each 90-minute session includes up to 30-minutes of light to moderate physical activity (e.g., brisk walking) and weight management education and experiential learning activities taught at a beginner level. The PeerFIT lifestyle coach will be trained to deliver basic exercise instruction in a group format for overweight and obese young adults (e.g., walking groups). A certified fitness trainer will be hired as a consultant to the program 1-2 hours per month to develop a structured protocol for conducting the physical activity sessions and provide ongoing supervision for the lifestyle coach. The lifestyle coach will also be trained to lead team building activities, games, and problem solving exercises.

Physical Activity Sessions. In addition, we will offer a one-hour physical activity session each week delivered in community settings over the 12-month study. Due to the current COVID19 social and physical distancing guidelines, the weekly exercise sessions will be moved from community settings to an online format using Zoom technology during the social and physical distancing period. Participants currently enrolled in the study and randomized to the PeerFIT intervention will be notified of this change in the format of the intervention. At the beginning of each week, the PeerFIT coach will call each participant individually to invite them to join the group exercise session. If the participant expresses interest in joining the group the PeerFIT coach will send them Zoom meeting information via text message. This group will follow the same format each week consisting of a warm up, physical activity and cool down lasting no longer than 60 minutes. The group leader and program participants will decide together which activities to pursue each week (e.g., team sports, walking/jogging group, dancing, scavenger hunt). In the event the social and physical distancing restrictions are lifted at the agency prior to the end of this study, the PeerFIT coach may decide to resume conducting the exercise sessions in person.

PeerFIT mHealth Technology Component**.** PeerFIT includes mobile health (mHealth) technology to facilitate and reinforce self-monitoring and collective problem solving that are taught and practiced during weight management sessions, and to allow participants to connect and support each other as peers towards achieving healthy lifestyle goals. Participants who do not own a smartphone or do not want to use their personal smartphones for the study will be provided basic smartphones to use throughout the 12-month study so that they can access the "secret" PeerFIT Facebook group, use Fitbit wearable activity trackers, and receive supportive text messages from the lifestyle coach.

Facebook Group. The secret PeerFIT Facebook group supports an online peer network in which participants can interact and share personal successes and challenges with meeting weight loss and physical activity goals outside of regular face-to-face meetings. It is called a "secret" Facebook group because only PeerFIT participants can view or share content such as text, or photos, click 'like' to show that they enjoy a post, or post comments. On the Facebook platform, the secret group cannot be viewed by anyone except those who are invited to join the group. Participants are instructed to only post content related to healthy eating and exercise that is supportive and encouraging. The lifestyle coaches and study staff will regularly post content related to topics covered in the group sessions, reminders to exercise, and tips for healthy eating. To make the PeerFIT Facebook group fun and engaging, participants will be encouraged to share relevant jokes or stories, cartoons, or other interesting photos, tips, or suggestions that might be of interest to the group. The lifestyle coaches and study staff will monitor the Facebook group multiple times each week to ensure that content is appropriate and related to the PeerFIT program objectives.

Fitbit Wearable Activity Trackers. Participants are provided Fitbit Zip, Flex 2, or Inspire wearable activity trackers for self-monitoring physical activity and instructions for downloading the free Fitbit mobile application to track progress over time. Participants will be provided with basic smartphones to access the Fitbit mobile application if they do not own a smartphone. The Fitbit Zip (see Figure 1A) is a wearable accelerometer that clips onto clothing and tracks number of steps walked each day. Participants can view their steps on the LCD display and connect wirelessly to the mobile application to track their

Figure 1A. Fitbit Wearable Activity Tracker

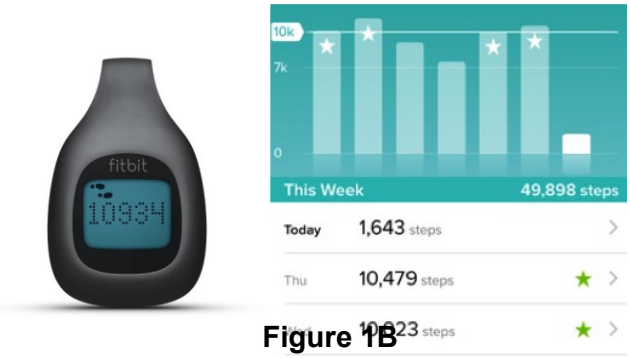

Figure 1B

progress over time and earn rewards for reaching daily step goals. The Fitbit Flex 2 and Fitbit Inspire is worn as a wristband and also tracks number of steps each day. As a wristband, it is hard to misplace and it is also waterproof. Step goals are set through the Fitbit app and progress towards those goals can be tracked by the number of LCD lights that light up on the wristband of the Flex 2. Other progress can be checked on the Fitbit app. Participants can also compare steps and progress by connecting with each other through the mobile application. In our pilot work participants expressed high satisfaction with using the Fitbit Zip, found it easy to understand, and valued using it to track their steps each day.

Supportive Text Messages. The text messaging component of the PeerFIT intervention is intended to increase participants' self-efficacy for health behavior change according to principles of Social Cognitive Theory. Participants receive encouraging messages and reminders about opportunities to meet the program healthy eating and exercise objectives. The PeerFIT lifestyle coaches send participants text messages 3-5 times per week over the 12-month intervention period. Text messages contain content to promote attendance, and to increase motivation for small goal changes related to healthy eating and being physically active (see Figure 1B). The text messages are structured the same way for each participant, with only minor customizations according to name, gender, and other personal characteristics. This approach is well suited for reaching young adults and promoting engagement in the PeerFIT intervention because text messaging is a ubiquitous form of communication in this age group. In our pilot work text messaging emerged as highly acceptable and useful for easily and quickly conveying practical information such as session times or scheduling, and providing encouragement and helpful reminders. Participants have expressed high satisfaction, ease of use, and appreciation with receiving supportive text messages and reminders.

Fidelity Measurement: Brief and parsimonious fidelity assessments will focus on the extent to which the delivery of the intervention adheres to the program model. Once per month, the lifestyle coaches will be asked to complete a web-based fidelity checklist that covers core components of the intervention. Specifically, the checklists will assess: (1) content covered; (2) activities conducted and time spent conducting the experiential activities; (3) methods for delivering the intervention; and (4) participant attendance at sessions. The research team will collect fidelity data to be analyzed as a potential covariate in the study, while program supervisors hired at the local level will provide continuous feedback to the lifestyle coaches for quality improvement purposes. This approach to turning over quality improvement efforts to agency staff is designed to be practical and feasible in real world settings.

Comparison Condition: Basic **E**ducation supported by wearable **A**ctivity **T**racking (BEAT)

Participants in the comparison condition will receive monthly individual lifestyle sessions delivered by a lifestyle coach including education, guidance, and support for self-monitoring behaviors (i.e., daily self-weighing and tracking daily steps) during the first six months of the study, plus text message reminders and encouragement for self-monitoring weight loss behaviors (3-5 text messages per week) during the entire 12-month study period. During the initial session, information about psychiatric medications and health behaviors associated with obesity in young adults with mental illness are presented as well as information about the role of healthy eating and exercise in improving physical health and mental health outcomes. Self-monitoring behaviors including daily self-weighing and physical activity monitoring are introduced as strategies for weight loss and increasing cardiovascular fitness. Participants will receive materials with tips and strategies for healthy eating and increasing physical activity. They will also be given a wearable activity tracker (i.e., Fitbit Zip, Flex 2, or Inspire) to use throughout the study with instructions for using the device and connecting it with their personal smartphone, tablet, or computer. The Fitbit Zip and Inspire are equipped with an LCD display that can be used to observe daily step counts without connecting to a smartphone or computer if participants do not own one. The Fitbit Flex 2 indicates progress towards step goals with LCD lights that light up on the wrist band, and more data such as exact steps can be monitored through the Fitbit app on participants' phones. Participants in the comparison condition will also receive routine access to technical assistance for using the Fitbit during the

monthly lifestyle sessions. The lifestyle coach providing the sessions will make sure the Fitbit is working properly, answer any questions about the device, and show participants how to check their progress by synching the Fitbit to a personal computer or smartphone. Participants may contact the lifestyle coach during business hours for one-on-one phone based technical assistance for using the device, but no active assistance is provided during these telephone contacts for behavioral strategies for weight loss.

Study Sites.

Mental Health Center of Greater Manchester (MHCGM)

The Mental Health Center of Greater Manchester (MHCGM) is a large community mental health center in New Hampshire offering comprehensive behavioral health services. Providing services to over 11,000 consumers each year, the MHCGM will participate in the identification and recruitment and enrollment of up to 60 eligible study participants who will be randomly assigned to either receive PeerFIT or BEAT. The MHCGM's CEO, Bill Rider, Sue Guarino, Director of Research at the MHCGM, fully support the project. Dr. Aschbrenner (PI) and Dr. Bartels (Co-I) have collaborated with the MHCGM on multiple research projects continuously since 2004, including an R01 and an R34 project funded by NIMH, and a projected funded by the Centers for Medicare and Medicaid, and several pilot projects, all of which have provided resources to develop and evaluate innovative mental health services for people with serious mental illness. Ms. Guarino will serve as site PI on the project, and Ms. Guarino will serve as the program supervisor.

Greater Nashua Mental Health Center at Community Council (GNMHCCC)

The Greater Nashua Mental Health Center at Community Council (GNMHCCC) is a large mental health center in New Hampshire offering behavioral health services to children and adults in Nashua and surrounding areas. They will participate in the identification and enrollment of up to 36 eligible consumers for this study. The GNMHCCC's CEO, Craig Amoth, Chief Medical Officer Dr. Marilou Patalinjug Tyner, and Research Manager Susan Flynn, RN, fully support this project. Research staff from Dartmouth (Veronica Pelletier) and the MHCGM (Jason Welsh) will recruit and enroll participants at GNMHCC. Although eligibility screenings and research interviews will take place at the GNMHCCC, intervention activities will take place at the Nashua Senior Activity Center due to space limitations at the GNMHCCC. The centrally located Senior Center offers private classrooms which may be rented by outside groups when not in use by their constituents. Their rooms are ideal for groups and will be used regularly for BEAT and PeerFIT sessions, including exercise sessions. Our Dartmouth team worked with the Nashua Senior Activity Center for the PeerFIT pilot. Participants and study staff found the Center welcoming, comfortable, and convenient.

Community Mental Health Affiliates (CMHA)

Community Mental Health Affiliates (CMHA) is headquartered in New Britain with 11 locations in three cities and towns throughout northwest and central Connecticut. They have more than 40 years' experience as one of the largest behavioral health care providers in the state. Dedicated to improving the quality of life for Connecticut's residents, CMHA offers a continuum of programs for approximately 6,100 children and adults annually. CMHA is the state's first fully Joint Commission accredited Behavioral Health Home. CMHA's Marie Mormile-Mehler, VP of Planning and Performance Improvement, and Director of Outcomes and Compliance, Dr. Heather Paluso, fully support the project. They have agreed to offer Fit Forward at their main location in New Britain. Research Staff (Lisa Daley) will recruit and enroll participants at CMHA. Currently, CMHA is partnered with Dr. Aschbrenner (PI) on a pilot study of PeerFIT to offer the intervention to clients at a residential intensive acute care facility in New Britain. CMHA has proven to be a hands-on, committed partner with strong organizational support for the successful implementation of a research study.

Massachusetts Department of Mental Health (DMH)

This study also includes sites within the Massachusetts Department of Mental Health (DMH) operated by the Massachusetts Mental Health Center and Vinfen Behavioral Health Care Organization. DMH provides services to over 21,000 individuals with SMI across the state. Most DMH clients (over 90%) are served in the community. Dr. Bartels (Co-I) has a long history of collaborating with the study sites on NIH-funded studies. This includes an RCT of a fitness coaching intervention for obesity in adults with SMI (R01 MH078052, PI: Bartels).[5] This study enrolled 210 individuals with SMI, including young adults ages 18 to 35, and demonstrated that over half of participants in the intervention achieved clinically significant reduction in cardiovascular risk. The Dartmouth team also enrolled 183 middle-aged adults with SMI across these sites in

a study of skills training and health management (R01 MH62324, PI: Bartels).[6] Both projects have benefited from strong support of key leaders at DMH. The strong partnership between the Dartmouth team and DMH will help ensure the success of implementing this study.

Massachusetts Mental Health Center (MMHC)

The Massachusetts Mental Health Center (MMHC) in Boston, MA, provides comprehensive services to DMH eligible adolescents and adults with SMI, including a large outpatient clinic that provides ongoing care to more than 1200 individuals. MMHC is home to a SAMHSA Primary and Behavioral Health Care Integration Program with on-site primary care and wellness services that provide assessment and education regarding the risks of medical morbidity associated with major mental illness. Mark Viron, MD, Attending Psychiatrist and Director of Home Health Services at MMHC, will serve as the site liaison for this study. Dr. Viron helped lead MMHC's transformation into a Health Home with integrated wellness and primary care services, a model that is designed to reduce early mortality for people with SMI. Dr. Viron oversees MMHC's Wellness and Recovery Medicine (WaRM) Center, which serves over 200 young adult clients per year. Dr. Viron will be a site PI who will work with the study PI to monitor and promote recruitment, and to ensure successful implementation of this study. MMHC leadership and Dr. Viron fully support the project.

Vinfen of Greater Boston

Vinfen, a private nonprofit 501(c)(3) organization provides services and support to people with SMI and is the largest vendor of services for DMH. Vinfen provides evidence-based services including supported living, employment, clinical, and peer support, covering more than 20 teams across 8 sites and over 2500 people with major mental illness. Over 500 young adults ages 18 to 35 are served through Vinfen's Psychiatric Rehabilitation Division. Dr. Bartels (Co-I) has collaborated with Vinfen for over 12 years, including on 3 RCTs. The Vinfen Director of Project Management (Ms. Cella) will be a site liaison for this study, working closely with the PI and the research coordinator to monitor and promote recruitment, and to ensure successful study implementation. The research staff hired to implement this project, including the lifestyle coaches, research interviewer, and research project manager will be Vinfen employees co-supervised by Ms. Cella and the study PI, Dr. Aschbrenner. The CEO (Dr. Bird) and Ms. Cella fully support this project.

Bay Cove Human Services, Solomon Carter Fuller Mental Health, Lindemann Mental Health Center

Bay Cove Human Services (Bay Cove) and Lindemann Mental Health Center (LMHC) are CMHCs providing comprehensive outpatient mental health services to people with SMI in the Metro-Boston area. Participants enrolled from this site will be supervised by Vinfen Project Manager, Ms. Cella.

Study Participants

Research staff (employees of the Vinfen organization, MHCGM, GNMHCCC, CMHA, and Dartmouth) will complete a brief pre-screen with potential participants in person or over the telephone. The pre-screen will ask participants to self-report whether they meet the age criteria (18 to 35 years old) and psychiatric diagnosis criteria (chart diagnosis of SMI using diagnostic criteria as defined in the DSM-V for schizophrenia and psychotic disorders, mood disorders, anxiety disorders, and borderline personality disorder) for the study. In addition, participants will be asked to indicate whether they are interested in working on weight loss and fitness goals. If the participant meets the initial eligibility criteria based on the pre-screen, they will be invited to attend a screening session during which the study inclusion and exclusion criteria will be reviewed. Participants will be asked to give written consent to participate in the screening session by signing an information sheet. In addition, they will be asked to complete a two-way authorization form giving permission for the research staff to review their medical records to verify their psychiatric diagnosis.

Inclusion criteria	**Note: All of the following inclusion criteria must be met at the time of written consent to enroll in the study**
Demographics	▪ Male, female, or transgender (no exclusion criteria based on gender or sexual orientation) ▪ Ages 18 to 35 years old ▪ Any race or ethnicity ▪ English speaking
Mental health diagnosis	▪ MA DMH, MHCGM, GNMHCCC, or CMHA client with a qualifying chart diagnosis of SMI using diagnostic criteria as defined in the DSM-V for

	schizophrenia and psychotic disorders, mood disorders, anxiety disorders, and borderline personality disorder
Body mass index	▪ Overweight, defined by Body Mass Index at least 25.0 kg/m^2
Informed consent	▪ Able and willing to give written informed consent to participate in the study or able to assent with guardian consent
Psychiatric Medications	▪ Client must not have started (discontinuation and dose changes OK) the psychiatric medications olanzapine or clozapine in the last two months based on self-report.
Medical clearance	▪ If screening indicates CVD risk, diabetes, a positive PAR-Q screening, or angina, able and willing to obtain a medical clearance letter from a primary care provider prior to enrolling in the study.
Program Participation	▪ Willingness to be randomized to either of the two conditions ▪ Able and willing to attend the weekly 90-minute weight management session, participate in the weekly 1-hour physical activity sessions, and use the Facebook and mHealth (i.e., Fitbits and text messaging) components of the PeerFIT program

Exclusion criteria	
Contraindication to weight loss	▪ Self-report of any of the following medical conditions will require medical clearance by a primary care provider to participate in the study: -Heart condition -History of anorexia nervosa -Past diagnosis of or treatment for anorexia nervosa or bulimia nervosa -Cardiac event within the past 6 months, for example: -Arrhythmias -Heart valve disease -Cardiomyopathy (enlarged heart) -Carotid or coronary artery disease ▪ Self-report of any of the following medical conditions will result in exclusion from participating in the study: -Liver failure -Cancer requiring active treatment (except for non-melanoma skin cancers) -Chronic use of steroid medication -Unable to walk for physical activity -History of weight loss surgery or planning weight loss surgery during study period -5% or greater weight loss in 3 months prior to screening session as indicated by self-report -Pregnant, breastfeeding, or planning a pregnancy during study period because reduction in calorie intake may be contraindicated
Substance Use	▪ Active substance use, with the exception of marijuana/synthetic cannabinoids, determined to be incompatible with participation in the intervention identified by screening questionnaire that assesses for excessive use according to intake limits by gender ▪ Use of anabolic steroids with the drug taken at least "most days of the week for the previous month"
Stroke	▪ History or stroke
Cognitive impairment	▪ Cognitive impairment sufficient to interfere with participant's ability to provide informed consent, complete study questionnaires, or participate in a group

	intervention as indicated by a Mini Mental Status Examination score less than 24.
Visual or hearing impairments	▪ People who are non-English speakers or who have major visual or hearing impairment will be excluded given the need to read the program materials and interact with technology
Participation in lifestyle studies	• Concurrent participation in the InSHAPE program or another commercially available weight loss program or physical activity study
Geography	▪ Planning to leave agency or DMH/MHCGM/GNMHCCC/CMHA services or move out of geographic area within 12 months

There will be no exclusion criteria for prior, current, or future use of weight loss medications in this study. This study is a pragmatic randomized controlled trial designed to be feasible and scalable within public mental health systems. Because pharmacotherapy can often be an adjunct to lifestyle modification we will not interfere with participants' ability to use both types of treatment to support their weight loss efforts.

Individual Screening Session: Study staff will schedule private screening sessions with potential participants to determine their eligibility for the study. Potential participants will be asked to give written consent to participate in the screening session on an information sheet. In addition, they will be asked to complete a two-way authorization form giving permission for the research staff to review their medical records to verify their psychiatric diagnosis. Either the research coordinator or research assistant at Vinfen, Dartmouth, CMHA, or the MHCGM will conduct the private screening sessions using a structured protocol designed by the study team. During the screening visits we will determine enrollment eligibility by using the following measures:

1) Self-reported age
2) Psychiatric diagnosis to be verified by medical record review
3) Measure height and weight using standard procedures to calculate BMI
4) Discuss with client his/her plans to remain in DMH/MHCGM/GNMHCCC/CMHA provider services and be available to participate in the study activities over the next 12 months
5) Review self-report of psychiatric medications over the past two months by reviewing a medication list with the participant.
6) Assess current ability to walk for physical activity.
7) Assess transportation to attend study activities.
8) Confirm willingness to be randomized and participate in either PeerFIT or BEAT.
9) Confirm willingness to participate in weekly activities if randomized to PeerFIT.
10) Discuss any plans of moving out of catchment area in the next 12 months.
11) Discuss upcoming surgeries that would prevent participation.
12) Assess for any scheduling conflicts that would prevent participating in study activities.
13) Discuss with client his/her current participation in other lifestyle programs with a focus on weight loss and fitness (e.g., InSHAPE, Weight Watchers)
14) Assess pregnancy, plans for pregnancy, or breastfeeding.
15) Assess for frequent use ("most days of the week for the previous month") of anabolic steroids to build muscles.
16) Assess for any past or planned weight loss surgery.
17) Determine whether participant has lost 5% or more weight loss in the last 3 months.
18) Assess any speaking, major visual, or hearing impairments that could interfere with ability to participate.
19) Use Mini Mental Status Examination to determine whether client has cognitive impairment sufficient to interfere with their ability to provide informed consent, complete study questionnaires, or participate in a group intervention as indicated by a MMSE score equal to or greater than 24.
20) Current alcohol and substance use will be assessed with a series of screening questions assessing use over the past month
21) Assess for present or history of anorexia nervosa or bulimia nervosa
22) In addition, we will use the PAR-Q[20]—a widely used physical activity appraisal questionnaire—and a

medical condition checklist to assess contraindications to participating in a moderate intensity exercise program. The intervention emphasizes the achievement of moderate, not vigorous intensity physical activity; the safety of moderate intensity physical activity in subjects with no prior cardiac event and no anginal symptoms is well established. If potential participants screen positive to any of the PAR-Q items, a prior history of cardiovascular disease, cardiac event, or have diabetes mellitus, they will need a signed approval letter from their primary care provider.

The screening process will cease if a potential participant fails to meet any of the inclusion criteria listed above. Similarly, if a potential participant meets any of the exclusion criteria listed above the screening will be stopped and the participant will be deemed ineligible for the study. If an approval letter from the primary care provider is needed, all other questions in the screener will be completed and the screening session will be tracked as "pending" until clearance is obtained. It will also be tracked as "pending" in instances where based on a participant's response, it is not clear if he/she meets study criteria, and the study team member must review the case with the study team to determine eligibility.

Verbal Consent for Modification to Interview Format
In the case that an assessment will be conducted over the phone due to social and physical distancing restrictions verbal consent will be collected prior to the interview. A study staff member will contact the participant by phone up to two weeks before the assessment is due and read the Information Sheet to the participant. During this time the study staff member will be able to address any questions or concerns the participant has about the phone-based interview. Staff will confirm the participant can be available for up to two hours for the interview and has access to a reliable phone for this amount of time. Once the participant has given verbal consent to conduct the interview, the study staff and participant will work together to schedule the phone interview at a time that is mutually convenient.

DATA COLLECTION AND MEASUREMENT

Data Collection for Aims 1 and 2

Trained research interviewers blind to group assignment will administer research assessments that include primary outcome data to consented participants at baseline, and at 6 and 12 months after randomization. Participants will receive $50 or receive a $50 gift card of their choice for completing each of the primary assessments at baseline, 6-and 12 months, for a total of $150. In addition, at 6 and 12 months, an unblinded research interviewer will conduct a brief 30-minute telephone assessment with PeerFIT participants to collect data on secondary measures specific to the experimental condition. PeerFIT participants will be paid an additional $15 or given a $15 gift card of their choice for participating in the interview.

Qualitative interviews: At the 12-month assessment, a subset of study participants will be invited to participate in a one-time telephone interview exploring their experiences participating in the intervention (either BEAT or PeerFIT). We will purposively sample participants based on their participation in the intervention as either "no engagement," "low engagement," or "high engagement." "No engagement" is defined as not attending any intervention sessions (PeerFIT or BEAT) during the 6-month intensive phase of the study. "Low engagement" is defined as attending less than 50% of the intervention sessions during the 6-month intensive phase. "High engagement" is defined as attending 50% or greater of the intervention sessions during the 6-month intensive phase. The study PI, Dr. Aschbrenner, will conduct these telephone interviews with up to 36 participants across three study sites (approximately 12 participants per category and per site): GNMHC, MHCGM, and CMHA. The interviews will last approximately 45 minutes and will explore in depth engagement in the interventions, including participants' perceptions, preferences, and experiences with the interventions and barriers and facilitators to participation, and will follow a semi-structured interview guide. Participants will be paid $30 to complete the telephone phone interview. With participants' permission, the interviews will be audio recorded and transcribed for data analysis.

Research interviewers will undergo comprehensive training on administration and rating of the study measures consistent with established procedures at Dartmouth. Reliability will be established prior to administration of the battery. The data collection supervisor (Kinney) will lead a bi-weekly supervision meeting with the

interviewers to answer questions, monitor data collection and minimize rater drift. Assessments will include baseline and follow-up measures required for Aims 1 and 2 as well as participant characteristics and covariates, as displayed in Table 1. Note: Participants' weight will be taken on day 1 of treatment for both conditions and this value will be used as the participant's baseline weight. Participants' baseline BMI will be calculated based on this value.

Table 1. Study Variables and Measures for Aims and Hypotheses

Physical Measures	**Instrument**	**Source**	0	6	12	
Height	Stadiometer	Interviewer	✓			Stadiometer
Weight	Digital Scale	Interviewer	✓	✓	✓	Digital Scale
BMI	Weight (kg)/height $(m)^2$	Interviewer	✓	✓	✓	BMI: Body Mass Index
Cardiorespiratory Fitness	6-MWT	Interviewer	✓	✓	✓	6-MWT: 6-Minute Walk Test
Lipid profile	Cardio Check	Interviewer	✓	✓	✓	Cardio Check Testing Device
Hemoglobin A1c	A1c Now	Interviewer	✓	✓	✓	A1c Now Testing Device
Waist circumference	Tape measure	Interviewer	✓	✓	✓	Guilick tape measure
Blood pressure	Cuff	Interviewer	✓	✓	✓	OMRON Hem-907 devic
Dietary Measures						
Sugar sweetened beverage consumption	Early Trials	Self-report	✓	✓	✓	Measure adapted from the EARLY trials
Eating away from home	Early Trials	Self-report	✓	✓	✓	Measure adapted from the EARLY trials
Daily meal patterns	Early Trials	Self-report	✓	✓	✓	Measure adapted from the EARLY trials
Physical Activity Measures						
Sedentary behaviors	Early Trials	Self-report	✓	✓	✓	Measure adapted from the EARLY trials
Vigorous exercise	IPAQ	Self-report	✓	✓	✓	IPAQ: International Physical Activity Questionnaire
Psychosocial Measures						
Exercise Self-Efficacy	ESE	Self-Report	✓	✓	✓	Self-efficacy for exercise scale
Peer Social Support (PeerFIT arm only)	SPS	Self-Report		✓	✓	SPS: Social Provisions Scale
Group Climate (PeerFIT arm only)	GCS-Q	Self-Report		✓	✓	GCS-Q: Group Climate Questionnaire
Group Cohesion Scale (PeerFIT arm only)	GCS	Self-Report		✓	✓	GCS: Group Cohesion Scale
Perceived Social Support (both arms)	MOS	Self-Report	✓	✓	✓	MOS-Social Support Survey
Other Questionnaires						
Demographics	CDI	Self-Report	✓	✓	✓	Client Demographics Instrument
Psychiatric Diagnosis	Med Record Dx	Staff	✓			Review of participant's chart
Medication Use	Med List	Self-Report	✓	✓	✓	Self-reported medications
Smoking and Alcohol Use	BRFSS	Self-Report	✓	✓	✓	BRFSS: Behavioral Risk Factor Surveillance System
Weight history	WHQ	Self-Report	✓			Weight History Questionnaire
Self-weighing	Self-weigh	Self-Report	✓	✓	✓	Self-weighing
Depressive Symptoms	CES-D	Self-Report	✓	✓	✓	Center for Epidemiologic Studies Depression Scale
Sleep Quality	PSQI	Self-Report	✓	✓	✓	Pittsburgh Sleep Quality Index
Neighborhood Environment	PANES	Self-Report	✓			Neighborhood Environment for Physical Activity
Technology use	CTUS	Self-Report	✓			Consumer Technology Use Survey
Treatment Covariates						
WM Attendance	WMS Log	LC		✓	✓	Adherence to weight management sessions
GE Attendance	GES Log	LC		✓	✓	Adherence to group exercise sessions
BEAT Attendance	BEAT Log	PM				
Fitbit Adherence	Device	Fitbit App		✓	✓	Proportion of days participant wore the device
Facebook group use (PeerFIT arm only)	Facebook	Facebook			✓	Number of participants who used the Facebook group and number of interactions (including posts, comments, or likes) in the Facebook group

- Assessments may be conducted over the phone due to social and physical distancing restrictions put in place related to COVID-19. Twelve-month assessments scheduled while these restrictions are in place will not include physical measurements, including weight, BMI, cardiorespiratory fitness, lipid profile, hemoglobin A1c, waist circumference and blood pressure.

The National Institute of Mental Health Data Archive (NDA)

As a requirement for NIH-funded investigators, this study will share the de-identified data collected from study participants with the National Institute of Mental Health Data Archive (NDA). The NDA makes available human subjects data collected from hundreds of research projects across many scientific domains. As a general rule, for NIH Grants, the NDA expects data from the same number of subjects as those reported on the NIH Inclusion Enrollment Report, including subjects eventually excluded from research analysis. Data will be submitted cumulatively every 6 months during data collection. Participants will be asked to sign a "Consent to

Data Sharing" consent form that is separate from the consent to participate in the study. Participants will not be excluded from participation if they refuse permission to share their data with the NDA. During the baseline, 6, or 12-month assessment, the following information will be collected from each study participant: legal name at birth, date of birth, sex at birth, and city/municipality of birth. This personally identifiable information will be linked with their study ID on a REDCap survey that is administered by the research interviewer. REDCap is a secure web application for building and managing online surveys and databases. Only the research team and data manager will have access to the survey. The data manager will then use the "GUID Tool" provided by the NDA to take the personally identifiable information and use it to securely create a global unique identifier (GUID). Using this tool, participant data can be linked across studies and laboratories while always maintaining the participant's privacy.

3.6.2 Study Variables and Measures

Variables and Measures for Aim 1 (Primary Outcomes)

Primary Hypothesis (H1a). Weight will be measured as the change in body weight over time, and BMI will be calculated by the formula: Weight (kg)/Height(m)^2. Participants' weight will be measured in pounds (lbs.) on a flat, even surface with the use of a high-quality, calibrated professional digital scale, with the participant wearing indoor clothing and no shoes. Weight will be measured to the nearest 0.1 pound (lb) and duplicate measurements will be made. If the two measurements are more than 0.5 lbs apart, then a third measurement will be collected and the three measurements will be averaged. Scales will be calibrated quarterly by study personnel using standard weights. Weight will be measured in pounds (lbs) for ease of interpretation by participants. Weight will then be converted to kilograms (kg) for calculation of BMI. Participants' height will be measured to the nearest 0.1 cm using a calibrated, mobile stadiometer. The participant stands shoeless on a firm, level surface, with head in the horizontal (Frankfort) plane. Duplicate measurements of height will be collected. If the two measurements are more than 0.1 cm apart, then a third measurement will be collected and the three measurements will be averaged.

Cardiorespiratory fitness will be assessed by the 6-Minute Walk Test (6-MWT), a performance based measure of exercise capacity.[7] After a baseline pulse has been obtained, participants are asked to walk a measured distance as far as they are able in 6 minutes. Standardized instructions are used to instruct the individual to reach a maximum comfortable pace without running. It is a reliable and valid measure of cardiovascular fitness in diverse populations. We have extensive RCT experience using the 6-MWT in persons with SMI.

Primary Hypothesis (H1b). Clinically significant cardiovascular risk reduction will be assessed by either a ≥5% weight loss or an increase in walking distance of >50 meters on the 6-MWT, both criteria are well-established indicators of clinically significant cardiovascular disease risk reduction.

Secondary Outcomes:

Lipids and A1c: We will test participants' non-fasting cholesterol, triglycerides, and A1c levels via a finger stick blood test done at the baseline assessment. The blood test requires only a tiny sample of blood (40µl) and is performed using the Cardio Check and A1c Now Polymer Technology Systems testing devices.

Blood Pressure: We will record blood pressure using the OMRON HEM-907 device, which records blood pressure using an oscillometric technique.

Waist Circumference: We measure waist circumference using an anthropometric tape, in a horizontal plane 1cm above the navel.

Dietary Measures

Sugar Sweetened Beverage Consumption: This tool measures the amount of sugar-sweetened beverages consumed by the respondent in a typical week. Specific beverages are included in the screener instrument to understand what types of beverages are commonly consumed and the consumption frequency of these specific beverages.

Eating Away from Home: The Eating Away from Home questionnaire is a self-report tool that assesses the frequency with which an individual consumes fast food, food prepared at a sit-down restaurant, food in an all-you-can-eat buffet, and food prepared at home. Respondents indicate their frequency of consuming food outside the home in the past 30 days (e.g. once per month, once per week, once per day). Respondents also report the number of days over the past week that they prepared breakfast, lunch, or dinner at home.

Daily Meal Patterns: Respondents are asked to indicate the number of times during a typical week they: (a) eat

breakfast; (b) eat a mid-morning snack; (c) eat lunch; (d) eat a midafternoon snack; (e) eat dinner; (f) eat an evening snack; (g) eat within an hour of bedtime, using either 0, 1-2, 3-4, 5-6, or 7 times.

Physical Measures

Sedentary Behavior Questionnaire (SBQ): The SBQ assesses the number of hours participants spend doing 9 behaviors (watching television, playing computer/video games, sitting while listening to music, sitting and talking on the phone, doing paperwork or office work, sitting and reading, playing a musical instrument, doing arts and crafts, sitting and driving/riding in a car, bus, or train).[9] The 9 items are completed separately for weekdays and weekend. Response options are none, 15 minutes or less, 30 minutes, 1 hour, 2 hours, 3 hours, 4 hours, 5 hours, or 6 hours or more. The time spent on each behavior is converted into hours (eg, a response of 15 minutes was recoded as .25 hours). For the total scores of sedentary behavior, hours per day for each item are summed separately for weekday and weekend days. To obtain weekly estimates, weekday hours are multiplied by 5 and weekend hours are multiplied by 2 and these are summed for total hours/week.

International Physical Activity Questionnaire (IPAQ) – vigorous questions only: The IPAQ is a measure of physical activity used to assess days in the past week and number of hours or minutes in one of those days doing physical activity across four domains: work, transportation, caring for the home/family, and recreation. Each domain is divided into categories including time spent walking, being moderately active, and being vigorously active. The IPAQ also assesses time spent sitting in a "usual" week day and weekend day in the past week.[19] For this study, we are only collecting time spent being vigorously active.

Variables and Measures for Aim 2 (Mediators)

Exercise Self-efficacy: The Exercise Self-efficacy measure will be used to assess participants' confidence in their ability to persist in exercising in various situations. Five items represent the following the following areas: negative affect, negative affect, resisting relapse, and making time for exercise. Respondents rate their confidence on a five-point Likert scale ranging from 1 = "Not at all Confident" to 5 = "Extremely Confident." Scores range from 1 to 25 and higher overall scores suggest higher exercise self-efficacy.

Social Provisions Scale: We will measure participants' level of perceived peer group support from the PeerFIT intervention with the 24-item Social Provisions Scale (SPS).[10] The SPS consists of six subscales to measure the availability of social support: emotional support or attachment, social integration, reassurance of worth, tangible help, orientation and opportunity for nurturance. The items are scored on a 4-point Likert scale from 1 = *strongly disagree* to 4 = *strongly agree* as it pertains to relationships with group members. Higher scores indicate greater perceived support from group relationships. The SPS has documented reliability and validity within social networks of young adults,[11] and has been used to study the influence of group dynamics on weight loss outcomes in a prior weight loss study.[12]

The Group Climate Questionnaire – Short form (GCQ-S) will be used to assess how participants regard the climate of the PeerFIT group intervention.[13] The GCQ-S consists of three subscales: engaged, conflict, and avoiding. The 12-item self-report questionnaire assesses the positive working group atmosphere, anger or tension of the group, and behaviors that indicate avoidance of personal responsibilities of group work by the members.

Group Cohesion Scale: The Group Cohesion Scale-Revised (GCS-R) will be used to measure group cohesiveness within the PeerFIT group intervention. The GCS is a 25-item multidimensional scale rated 1=strongly disagree to 4 = strongly agree assessing domains such as interaction and communication, member retention, decision making, vulnerability among group members, and consistency between group and individual goals.[14]

Medial Outcomes Study Social Support Survey: The 19-item Social Support Survey will be used to assess four components of perceived availability of social support among participants in both conditions, including (1) Emotional support/Informational support, (2) Tangible support (including material support), (3) Positive social interaction (does person have friends that are available to have fun), and (4) Affectionate support (including loving and nurturing relationships). A total score and subscale scores are calculated. Higher scores indicate more social support.[15]

Participant Characteristics and Covariates

Demographic Characteristics: Demographic characteristics will be collected with a client demographics instrument (CDI) developed by our research group. Socio-demographic information will include age, sex,

gender, race/ethnicity, living situation, education, employment status, and other basic characteristics.
Psychiatric Diagnosis: Psychiatric diagnosis will be verified using the diagnosis in the chart at the agency providing mental health services.
Medication Use: Because medications can directly affect weight gain and level of physical activity, we will collect self-report data on the type of prescribed psychiatric medications (e.g., antidepressant, antipsychotic) and all other medications taken by participants at the time of assessment. We will ask participants to bring their current mediations with them to the assessment appointment. The research interviewer will document all current prescription and non-prescription medications taken by participants. In addition, the research interviewer will review a list of psychiatric medications and FDA-approved and non-approved weight loss medication to assess whether participants are currently taking any of the medications on the list.

Smoking and Substance Use: We will use questions from the 2016 Behavioral Risk Factor Surveillance System to ascertain smoking history, frequency, quantity, and cessation attempts. We will also ask about participants' alcohol consumption during the past 30 days.

Weight History: We will use select items from the Weight History Questionnaire developed for the National Health and Nutrition Survey to assess both lifetime weight loss attempts and weight loss attempts made within the past 12 months.

Self-Weighing: Participants will be asked to report how often during the past month they weighed themselves with response categories ranging from: 0 = never weighed myself to 6 = several times a day.

Sleep Quality: The Pittsburgh Sleep Quality Index (PSQ) measures sleep quality and disturbance retrospectively over a 1-month period using self-reports.[16]

Depressive Symptoms: The Center for Epidemiologic Studies Depression Scale (CES-D) is a 20-item self-report scale that is sensitive and specific in detecting depressive symptoms.[17] The CES-D has scores ranging from 0 to 60, where higher scores represent greater depressive symptoms. The CES-D has well-documented psychometric properties in psychiatric populations.

Technology Use: We will use the consumer mHealth survey to assess participants' use of the Internet, social media, mobile devices, mobile applications, and text messaging. This questionnaire was developed by our research team to assess how people receiving services at mental health centers use these technologies.

Treatment-related Covariates. The lifestyle coaches will document the number of weight management and exercise sessions attended.

Fitbit. In this study, participants in the PeerFIT intervention and BEAT comparison condition will use Fitbit Zip, Flex 2, or Inspire wearable activity tracking devices. Participants will receive instruction to wear this device daily and to focus on collecting steps each day and meeting daily step goals. We will collect data on the number of days enrolled in the study that participants wore their Fitbit. This will indicate whether participants used the device or not. Additionally, we will collect hours of sleep, as well as physical activity data which includes step count, activity intensities, metabolic equivalents, and energy expenditure. We have observed in our pilot work that increasing number of steps walked each day was significantly correlated with greater weight loss. Therefore, we intend to explore whether this relationship between number of steps and weight loss is consistent in this larger randomized controlled trial. Participants' Fitbit accounts will be connected by research staff to a secure data management platform called Fitabase. Fitabase allows researchers to analyze data from wearable and internet-connected devices. All data associated with the Fitbit devices will be assigned de-identified study IDs and linked to the Fitabase platform. Participants will have full access to their Fitbit accounts but will not be able to access Fitabase. By consenting to use the Fitbit device as part of this study, the participants also consent to allow the research team to register their Fitbit accounts on Fitabase. Only data collected during study participation will be shared with Fitabase and analyzed, and de-identified Fitbit accounts will be deleted from Fitabase 90 days following the completion of data analysis.

Facebook. In this study, participants in the PeerFIT intervention arm can choose to access a secret Facebook group. Participants will be encouraged to post content, comments, or like other participants' posts to help support the PeerFIT program goals focused on healthy lifestyle change. We will collect data on the frequency of use of the PeerFIT Facebook group. In our pilot study we observed that greater use of the secret Facebook group was associated with clinically meaningful weight loss, suggesting that participants who use the Facebook group may be more engaged in the overall PeerFIT program and may benefit from support and encouragement from each other. We plan to collect the frequency of use of the Facebook group measured as

the number of posts, number of comments, and number of likes for each participant over the 12-month study duration. This data will be exported directly from the secret Facebook group to an excel document at 6-months and 12-months follow-up.

4. Analysis

Describe any qualitative tests and measures as well as quantitative methods:

Data Analyses

Analysis of data from the RCT will answer research questions associated with Specific Aims 1 and 2. Careful examination of frequency distributions and descriptive statistics for all variables will precede inferential statistical analysis. When necessary due to high skew, transformations will be used to normalize continuous data, or continuous variables will be recoded to ordinal or dichotomous scales.

Evaluation of Randomization. We will evaluate the effectiveness of random assignment by comparing the PeerFIT and BEAT groups on baseline measures of demographic characteristics, key outcome variables, and key covariates using chi-square tests and t-tests.

Handling of Missing Data. Based on our prior studies we do not expect attrition to exceed 20% over 12 months. The proposed method of analysis, mixed effects models, have been shown to produce unbiased estimates of treatment effect in the presence of data that is missing completely at random or missing at random even when dropout differs between treatment arms.[18] We will also perform sensitivity analyses to examine stability of treatment effect under different missing data assumptions as recommended in case data are not missing at random (i.e., missingness depends on the value of the missing observation).

3.6.5 Analyses for Study Aims and Hypotheses

Specific Aim 1 (Effectiveness): Mixed effects models will be fit to longitudinal weight, BMI, and cardiorespiratory fitness data. Models will include fixed effects for treatment arm, time and an interaction between treatment arm and time. Additionally, random individual-level intercept and slope terms will be included to account for individual variation in trajectory and simultaneously account for repeated observations within individual. A significant treatment effect of PeerFIT would be indicated by a significant time by treatment interaction accompanied by a mean reduction in weight or BMI or increase in fitness in the PeerFIT group that exceeds the reduction or improvement in the BEAT group (H1a). Similar, non-linear mixed effects models (i.e., longitudinal logistic models) will be fit to the binary cardiovascular risk reduction outcome data (H1b).

Power Analysis for Aim 1. Assuming a range of within-person, across time correlations (0.1-0.7), with 144 participants (72 per arm), there will be 80% power, at the two-sided 0.05 significance level, to detect a difference between arms in slope of at least 0.030-0.052 SD units per month, or equivalently, 0.36-0.62 SD units over 12 months. If SDs of weight, BMI, and 6-MWT are similar to those observed previously (approximate weight SD 60, BMI SD 9, and 6-MWT SD 350) with the InSHAPE intervention and active control, these standardized effect sizes are equivalent to difference between arms of 21.6-36.0 lbs, 3.20-5.40 BMI units, and 6-MWT of 126-210m over 12 months. With attrition, power will be slightly lower, or equivalently, detectable differences slightly larger. To provide information on detectable differences if maximum attrition is experienced we also provide detectable differences assuming data from only 115 participants (80% of proposed sample size). In this case, the detectable difference increases to 0.034-0.059 SD units per month or 0.41-0.70 over 12 months yielding detectable weight of 24.6-42.0 lbs, BMI of 3.69-6.30, and 6-MWT of 143-245m over 12 months. True power/detectable difference likely lies in between for 144 vs. 115 participants. In the InSHAPE trial, 38% of participants in the active control arm and 51% of participants in InSHAPE achieved a clinically significant change in cardiovascular risk reduction. Because InSHAPE likely had a strong intervention effect with one-on-one personal fitness training and a gym membership for the active control, we estimate that percentages achieving clinically significant change in cardiovascular risk reduction in this study will be 20% for BEAT and 40% for PeerFIT. Assuming these proportions, there will be 86% power to detect a difference between arms in cardiovascular risk reduction, assuming measures of this outcome at 2 time points and within-person correlation of 0.5. With maximum attrition, the power is reduced to 77%.

Specific Aim 2 (Mechanism of Action): To test the mechanism hypotheses, parallel process latent growth curve models will be fit within a structural equation model (SEM) framework. These models allow for testing mediation of the treatment effect on weight and fitness by changes in self-efficacy (H2a) and peer social support (H2b). It is hypothesized that PeerFIT will have a greater effect on the change over time (slope) of

self-efficacy than BEAT, and this change in self-efficacy will impact change in weight and fitness over time (slopes). PeerFIT is hypothesized to have a greater effect on peer social support slope than BEAT, and this change will also impact the change in outcomes. The product of coefficients (coefficient associated with path between treatment and mediator x coefficient associated with path between mediator and outcome) will be estimated along with bias-corrected bootstrap confidence intervals to determine the significance of the effect.

Power Analysis for Aim 2. The mechanism to be tested is the indirect effect of treatment on changes in weight and fitness (outcomes) through changes in self-efficacy and changes in peer social support (proposed mediators). The power for detection of the indirect effect depends on the size of each effect in the pathway.

The proposed parallel process growth curve analysis proposes mediation of the individual latent slopes, so power is computed at the individual-level although the individual-level latent slopes are estimated using data from observed mediators and outcomes measured at three time points (0, 6, and 12 months) improving precision. To compute power for detecting the mediated effect, we use results of a simulation study conducted by MacKinnon et al. In the simulation, indirect effects composed of effect of treatment on mediator and mediator on outcome were varied in size and significance was repeatedly tested via bias-correct bootstrap confidence intervals to obtain estimates of empirical power. This study showed that with 144 participants there will be approximately 80% power to detect a significant effect if the mediated effect is made up of two effects that are halfway between small and medium as defined by Cohen (explaining about 6.3% of the variance). For example, if treatment explains at least 6.3% of the variance in changes in self-efficacy, and changes in self-efficacy explain at least 6.3% of the variance in changes in weight, then there will be 80% power to detect this effect via bias-corrected bootstrap confidence intervals constructed around the indirect effect of treatment on changes in weight. If at least one of the effects (treatment to mediator or mediator to outcome) is larger (at least a medium effect explaining 13% of the variance), power is greater than 80%.

Qualitative Interviews Analysis. A semi-structured interview format will be used to allow flexibility in sequencing of questions and to allow for additional probing to clarify responses. Interviews will be audio-recorded. Audio files will be transcribed and de-identified by a professional transcription company. Transcripts will then be uploaded into a qualitative coding software program, Atlas.ti. Qualitative data analysis will include coding the data and identifying themes and salient points that illustrate the experiences of no engagement, low engagement, and high engagement participants in the study.

5. Study Progress Monitoring

Note: appropriate monitoring may include periodic assessment of the following:

- data quality
- timelines
- recruitment and enrollment

Provide a description of the methods which will be used to determine the progress of the study, including periodic assessments of data quality, timelines, recruitment, and enrollment as appropriate:

The trial consists of three main phases: planning, implementation (recruitment, intervention and data collection) and data analysis and dissemination. Hiring and training research coordinators, interviewers, and lifestyle coaches, and planning for implementation of the study protocol at research sites will occur during the first 6 months. Recruitment of participants will begin in month 6 and will conclude in month 33 or earlier, depending on when recruitment targets are met. We plan to recruit 144 participants. Participants will be enrolled on a rolling basis. The 12-month follow-up assessments will be completed by month 42, allowing 6 months for data cleaning, analysis, and manuscript preparation (months 42-48). The study timeline and enrollment milestones are shown below:

	YEAR 1				YEAR 2				YEAR 3				YEAR 4			
Month	0-3	3-6	6-9	9-12	12-15	15-18	18-21	21-24	24-27	27-30	30-33	33-36	36-39	39-42	42-45	45-48
Hire/Train Personnel																
Finalize Study Procedures																
Prepare Agency for Implementation																
Study Recruitment																
Recruitment Milestones				24	48	64	80	96	112	128	144					

Assessments																
Data Analysis																

To monitor study recruitment and enrollment, the PI (Aschbrenner) will lead a weekly supervision call with the research coordinator and research interviewers to monitor progress and regularly address questions and problems that arise during recruitment. Our approach to assessing data quality includes: 1) monitoring counts of completed data collection items; 2) monitoring distribution of trial outcomes, overall, by data collector and site; 3) record lag time in data entry; 4) issue queries on missing data, out of range values or illogical data relations; and 4) review types and distribution of data entry errors. Weekly research team conference calls, including assessment supervision, will help identify quality control issues early and allow consensus solutions to be reached.

Data Safety and Monitoring Plan: Although there is a low risk of adverse events (AE) associated with gradual, supervised weight loss and moderate exercise in young adults, an independent data safety monitoring process will be implemented for the proposed clinical trial. An independent Data Safety Monitoring Board (DSMB) will conduct reviews of the study every 12 months to ensure the safety of participants and data validity and integrity. The established DSMB that will be used for this study consists of several federally funded, highly experienced clinical researchers in the Department of Psychiatry at the Geisel School of Medicine at Dartmouth. Current members of the DSMB consist of researchers who are not co-investigators or collaborators on this proposal. This independent board will follow the policy for data and safety monitoring published by NIH.

The DSMB will be responsible for reviewing the following information: adverse consequences (whether serious or minor) to any participant and actions taken to remedy the problem; data quality, completeness, timeliness; performance of the study site; recruitment and retention; adherence to protocols; maintenance of confidentiality; external factors impacting safety or ethics of the study; and new or evolving information regarding the expected effectiveness and/or safety of the PeerFIT intervention. Summary reports of the meetings will be sent at the time of annual reviews to the Dartmouth Committee for the Protection of Human Subjects (CPHS).

6. Risks & Benefits

Note: Risks may be physical, psychological, social, legal, economic, to reputation, or others.

a. Describe any potential risks, their likelihood and seriousness:

Physical activity. The intervention emphasizes the achievement of moderate, not vigorous intensity physical activity; the safety of moderate intensity physical activity in young adults with no prior cardiac event and no anginal symptoms is well established. The small risk of physical activity will be minimized by emphasizing moderate (as opposed to vigorous) activity, and requiring participants who screen for elevated CVD risk to obtain medical clearance prior to beginning an exercise program. Risk of injury is further minimized by instruction on proper exercise technique, the importance of warm-up and cool-down exercises, and proper stretching techniques. If there is any question about the etiology of an injury or the need for treatment, the participant will be referred to a physician for further evaluation. We will continuously reinforce our recommendation to engage in moderate physical activity throughout the program duration.

Nutrient intake. Calorie reduction for weight loss could theoretically lead to inadequate nutrition or excessive, rapid weight loss. Intervention subjects will be encouraged to eat a variety of foods from all food groups and maintain an adequate caloric level. The lifestyle coach will conduct a private weigh-in at the beginning of each weight management and exercise session. Participants who have a sudden, marked weight reduction will be interviewed to determine if extreme measures have been taken. The issue of adequate nutrient intake and the importance of safe weight loss will be discussed in the group sessions. If a problem is suspected, the participant will be referred to their primary care physician and their primary mental health provider at the MA DMH, MHCGM, GNMHCCC, or CMHA study sites for follow-up.

Group activities. The potential minimal risks of participating in groups include potential stress surrounding sharing personal information in a group setting and hearing about the life experiences of others. The group leaders will lay out the ground rules for participating in the groups, such as not sharing personal or sensitive information about group participants with people outside of the group, and treating each other respectfully and cordially. Intervention staff will receive regular supervision and training from the PI (Aschbrenner) that will provide opportunities to address any concerns or ongoing problems associated with group dynamics. For more acute situations requiring immediate assistance, intervention staff will be instructed to contact the site coordinator and site PI. Additionally, intervention staff will be given a list of study participants' names and their respective primary mental health providers in case a problem arises that requires intervention by the mental health agency. These latter protections were used in our PeerFIT pilot study and were very rarely needed, but promptly and safely resolved any issue.

Text messaging. The text message component of this study poses minimal risk to participants. Participants are sent text messages from the PeerFIT lifestyle coach and BEAT lifestyle coach 3-5 times per week over the 12-month intervention period. PeerFIT related text messages contain content to promote program attendance to the weekly group sessions and exercise classes, and to increase motivation for small goal changes related to healthy eating and being physically active. The BEAT related text messages will include reminders and encouragement for self-monitoring weight loss behaviors. The text messages are structured in the same way for each participant, with only minor customizations according to first name, gender, and other personal characteristics. The text messages will not contain any personally identifying information (except for participants' first names) or any information pertaining to participants' specific mental health conditions or diagnosis.

Fitbit activity tracker. The Fitbit activity tracker poses minimal, if any, risks to participants. The device is worn on the wrist or by attaching it to participants' clothing, or keeping it in participants' pockets, and is designed to monitor steps walked and overall participation in physical activity. The device itself does not collect or contain any personal information. Each participant will create an online Fitbit account that will only contain participants' names, email address (which is their Fitbit username), gender, age, height, and weight. No other personally identifying information regarding each participant is stored within the online profile. Individual usernames and passwords for the online profile will only be known by research staff and respective participants. Fitness data will be collected from the device over a secure electronic connection and will be stored in the user's online account that synchs with the device through the smartphone application. Participants will also have the option to use other features on the Fitbit smartphone application such as viewing physical activity over time, tracking sleep, or tracking dietary intake. Using the app is optional but encouraged. Research members will not share Fitbit data from participants with other study participants. However, participants can choose to connect with other participants using the Fitbit smartphone "friend" feature built into the Fitbit app to share information such as step count and distance traveled. Participants can also choose to share their steps or progress meeting their step goals with other participants using the secret Facebook group.

Fitbit account usernames (i.e., email address), Fitbit account passwords, and study IDs will be stored on a password-protected spreadsheet that is maintained by and accessible to only the research team. This information will be used by research staff to connect Fitbit accounts on a data management platform called Fitabase. Fitabase is fully hosted, cloud-based software that follows industry standards to maintain secure databases and keep data private. Once a Fitbit account is connected to the Fitabase platform by research staff by registering the user's Fitbit username and password, it will be assigned a unique study ID – the participant's ID in the study – along with a "start" and "stop" synch date so that data will be synched only during the participant's 12-month participation and available for viewing and downloading by research staff in de-identified form. Fitabase does not collect or retain any identifiable information, such as the Fitbit user's email address, "Friends" list, IP address, or any GPS data. When participants synch their devices to their Fitbit accounts, Fitabase will collect this new information automatically. Given that participation in this study is voluntary, participants can also choose not to connect their Fitbit accounts with Fitabase. If participants choose not to connect their Fitbit account with the Fitabase data management platform, it will not affect their participation in the study or their access to using a Fitbit wearable device as part of their participation.

Data collected by Fitabase is housed in secure Azure (Microsoft) servers. Windows Azure runs in data centers managed and operated by Microsoft Global Foundation Services (GFS). These geographically

dispersed data centers comply with industry standards, such as ISO/IEC 27001:2005, for security and reliability. Furthermore, Fitabase database servers are IP firewalled and whitelisted such that they refuse any connection from IP addresses not preprogrammed as acceptable. Fitabase does not sell, release, or make collected data available to third parties. The data collected for a research team is only made available to that research team. In circumstances that dictate it, Fitabase staff may access participant data in order to provide technical support. Fitabase uses Secure Sockets Layer (SSL) for all logins, billing, and administration of the site. Fitabase stores passwords in encrypted form. Fitabase logs all site usage, including attempts to access restricted data or repeated erroneous logins. Fitabase will freeze accounts that appear to be compromised until they are able to make contact via the email address used to set up the administrator account. Per Fitabase's security policy, participants' de-identified accounts will be deleted from the Fitabase platform 90 days following the completion of data analysis for the study.

Secret Facebook Group. The secret Facebook group created for this study also poses minimal risk to participants. The Facebook group will be secret and only visible and accessible to participants who are invited to join by the research staff. Participants will have the choice to access the secret Facebook page using either their own smartphone, or if they do not have one, a smartphone provided by this study. All participants in this study randomized to the PeerFIT intervention, regardless of their prior experience using Facebook, will be provided with a basic overview of the Facebook website and mobile smartphone application, as well as safety precautions with using this online platform. Participants will be provided with safety recommendations, such as not sharing personally identifying information online that they do not wish other people to see, including phone number, address, financial information, or detailed health information. Participants will also receive recommendations about not responding to friend requests from strangers, ways to block or unfriend Facebook users that appear to be spam or junk accounts, and how to report content viewed as inappropriate to the Facebook website. For participants who are not familiar with Facebook or who do not have Facebook accounts, research staff will provide training about how to create a free account and how to use the website safely without disclosing personal health information or other personal information.

Participants will be oriented to the safety resources available from the Facebook website. Participants will be provided a live demonstration of the Facebook safety website at: https://www.facebook.com/safety.

On this page, participants will be guided through a ways to stay safe while using Facebook. This will include instruction about 1) Sharing; 2) Friending; and 3) Reporting.

1) Sharing:
"Every day, people around the world share things on Facebook that result in new and incredible ideas, opportunities, friendships and collaborations."

"We ask people to consider their audience when sharing on Facebook. It's important to be thoughtful about how and what you share. We make it easy for everyone to decide who can see the content they share, and we have policies that prohibit hateful, violent or sexually explicit content."

Before you share, ask yourself:
- Could somebody use this to hurt me?
- Would I be upset if someone shared this with others?
- What's the worst thing that could happen if I shared this?

"Always remember that the things you share with your friends can end up being shared with others."

2) Friending
"Facebook is a place for you to connect with the people and things you care about. Before accepting someone as a friend, you might want to take a look at the person's profile. Have you ever met them in person? Do you have friends in common?"

Following
“When you follow someone, you can see their posts in your News Feed. You automatically follow people you’re friends with. You can also follow the posts of public figures (ex: journalists, celebrities, political figures) even if you’re not friends.”
Unfollowing
“*When you unfollow someone, you won't see their posts in your News Feed, but you'll still be friends with them.”*

“To unfollow a person, Page or group directly, hover over "Following" (on a profile) or click "Following" (on a Page or in a group) near their cover photo and select "Unfollow".”

Unfriending
“*To unfriend someone, go to that person's profile, hover over the "Friends" button at the top and select "Unfriend". If you choose to unfriend someone, Facebook won't notify the person but you'll be removed from their friends list. If you want to be friends with this person again, you'll need to send a new friend request.”*

Blocking
“*You can block someone to unfriend them. This will prevent them from starting conversations with you or seeing things you post on your profile. In addition, people you block can no longer tag you, invite you to events or groups, or add you as a friend. Blocking is reciprocal, so you also won't be able to see things they post or start conversations with them. When you block someone, we don't notify them.”*

“To block someone, click  *at the top right of any Facebook page, click "How do I stop someone from bothering me?", enter the name or email address of the person you want to block and click "Block.""*

3) Reporting
“Facebook includes a link on nearly every piece of content for reporting abuse, bullying, harassment and other issues. Our global teams work 24 hours a day, 7 days a week, to review things you report and remove anything that violates our Community Standards. To report a post, click on the top right of the post and choose the option that best describes the issue, then follow the on-screen instructions. Learn more about reporting other types of content. If you've reported something, you have the option to check the status of your report from your Support Inbox. Only you can see your Support Inbox. We don't include any information about the person who filed the report when we reach out to the person responsible.”

Next, participants will be provided with general recommendations for securing their Facebook account. This includes instruction about the importance of 1) passwords; 2) tips for logging in and out of Facebook, which is especially important for participants who use public computers to access their account; 3) being aware of scams; and 4) hacked accounts. These recommendations are from the Facebook website.

1) Passwords
“Passwords help to protect your accounts.”

“Use passwords that are hard to guess. Make sure they are at least 6 characters long and use a combination of numbers, letters and special characters.”

“Use a different password for each of your accounts. That way, if someone learns your password, they don't have access to all your accounts.”

“Don't share your passwords with other people.”

2) Logins
“Facebook offers you tools to make your account more secure.”

Login alerts
"*When you turn on login alerts, Facebook will send you a notification if someone tries logging into your account from a new place."*

"To turn on login alerts, go to your "Security Settings", click on "Login Alerts", choose the type of alert (ex: email alerts) that you'd like to receive and click "Save Changes"."

Login approvals
"*When you turn on login approvals, you'll be asked to enter a special security code each time you try to access your Facebook account from a new computer, phone or tablet."*

"To turn on login approvals, go to your "Security Settings", click on "Login Approvals", check the box and click "Save Changes.""

Logging out
"*The "Where You're Logged In" section of your "Security Settings" shows you a list of computers and phones that have been used recently to log in to your account. To log out of Facebook on another computer, phone or tablet, go to your "Security Settings", click on the "Where You're Logged In" section, find the session you want to end and click "End Activity.""*

3) Being aware of scams
"The Internet allows many different people to communicate with you. You may receive messages telling you that you've won money or a prize. These messages may sometimes say that someone needs your help or needs you to look after their money. They usually will ask you for personal details like your bank account or identification number. These kinds of suspicious messages are scams. It's very unlikely that you've won something, even if you did enter a competition."

To protect yourself from scams, watch out for the following:

- People who you don't know asking for money
- People asking you for advance fees to receive a loan, prize or other winnings
- People claiming to be a friend or relative in an emergency
- Messages or posts with poor spelling and grammar errors

4) Hacked accounts
"Requiring people to use their authentic names on Facebook helps motivate all of us to act responsibly, since our names and reputations are visibly linked to our words and actions. If we discover that people have multiple personal profiles, we might ask them to close any additional profiles. We also remove accounts that impersonate other people. If you believe someone has created a Facebook account pretending to be you or someone you know, please use this form to file a report. If you believe your account has been compromised, please secure your account."

Next, participants will be provided an overview of tips for protecting their information. This involves recommendations for 1) posting; 2) profile updates;

1) Posts
"Whenever you update your status, share photos or post anything on Facebook, you can select who sees what you share by using the "Audience Selector" tool. You can choose to share with everyone, just your friends or even a customized audience. When you create a customized audience, you can selectively share with specific people. Remember, when you post something on another person's profile, that person controls who can view the post. Additionally, anyone who gets tagged in your posts may see them, along with their friends.

2) Profile

“When you log in to Facebook on a computer, you can see what your profile looks like to other people by using the “View As” tool.”

“To use "View As", click  on your profile, click "View As..." and follow the on-screen instructions. Using the tool, you can see what your profile looks like to the public or to a specific person.”

3) Tagging
“Tag review and Timeline review are options that help you control who sees what you post and what posts appear on your Timeline. Tag review lets you approve or dismiss tags friends add to your posts. Once you approve a tag, the person tagged and their friends may see your post. Remember, when people you’re not friends with tag you in a post, you're automatically asked to approve or dismiss the tag. Timeline review lets you choose whether posts you're tagged in appear on your Timeline. When people you’re not friends with tag you in a post, they automatically go to Timeline review. If you'd also like to review tags by friends, you can turn on Timeline review for tags from anyone.”

Tag review – *Tag review lets you approve or dismiss tags added to your posts:*
“To turn on Tag review, click ▾ at the top right of any Facebook page and select "Settings." Click "Timeline and Tagging", look for "Review tags people add to your own posts before they appear on Facebook?" and click "Edit." Select "Enabled" from the dropdown menu.”

Timeline review – *Timeline review lets you choose whether posts you're tagged in appear on your Timeline:*
“To turn on Timeline review, click ▾ at the top right of any Facebook page and select "Settings." Click "Timeline and Tagging", look for "Review posts friends tag you in before they appear on your timeline?" and click "Edit." Select "Enabled" from the dropdown menu.”

Lastly, participants will be provided an overview of other resources available from Facebook. This includes:

- An overview of the instructions for conducting a security and privacy checkup on your Facebook account.
- An overview of the Bullying Prevention Hub on Facebook (https://www.facebook.com/safety/bullying).
- How to access a suicide hotline for oneself or a friend through Facebook (https://www.facebook.com/help/103883219702654).
- And where to find instructions for reporting suicidal content or threats (https://www.facebook.com/notes/american-foundation-for-suicide-prevention/how-to-report-suicidal-contentthreats-on-facebook/10150090259398144/). And where to report suicidal content found on Facebook (https://www.facebook.com/help/contact/305410456169423).

All participants randomized to the PeerFIT intervention will receive a detailed handout with these instructions. Additionally, these instructions and relevant links will be posted in the secret Facebook group. Study staff and the lifestyle coaches will be available at any time throughout the study duration to assist participants with any concerns that they may have about using Facebook or updating the security and privacy settings of their personal Facebook accounts. All participants will receive instruction about the ground rules for using the secret PeerFIT Facebook group to ensure that participants understand that the Facebook group is intended for the purposes of supporting each other towards achieving shared healthy eating and exercise goals as part of the PeerFIT program. Participants will learn that the PeerFIT Facebook group is intended to serve as a platform where participants can support and encourage each other, and share personal successes or challenges with making healthy lifestyle changes. The Facebook group is a great way for participants to get to know each other outside of the weekly in-person sessions, and to keep in touch with each other. The lifestyle coaches will also regularly post content in the Facebook group that extends on the discussions from the group sessions. This content is aimed at stimulating discussion in the Facebook group, and to help participants feel more connected and engaged in the PeerFIT program and to support motivation for adopting healthy eating and exercise behaviors. The PeerFIT Facebook group will mainly contain information related to nutrition and exercise covered in the group sessions, as well as tips and strategies for overcoming common challenges or barriers that get in the way of adopting a healthy lifestyle. Participants will be specifically instructed not to

discuss personal health crises or medical emergencies in the PeerFIT Facebook group. Participants will receive instruction to seek emergency help and to contact their mental health provider in the event that they have any thoughts about self-harm or harming others.

The Facebook group will be visible and accessible only to individuals involved in the study, including participants, PeerFIT lifestyle coaches, and research staff. The name of the Facebook group will be generic and broadly related to wellness, and will contain no identifying information related to mental health diagnosis or weight loss. Through the Facebook group, participants will have the option to access diet and exercise content, post comments, share successes and challenges with making healthy lifestyle changes, and connect with, encourage, and support other participants. The Facebook group will be monitored for content by research staff and the lifestyle coaches, and in the event that content is posted that deviates from the PeerFIT program aims, such as hostile posts, personally identifying information, hurtful or derogatory comments or images, or intentions for self-harm or harming others, the lifestyle coaches will be informed and the purpose of the Facebook group will be explained again to responsible participants. Participants who post offensive or otherwise abusive content will be removed from the secret Facebook group by the moderator and banned from further participation. We do not anticipate that this will occur, and if so it will be very uncommon. Through our pilot studies consisting of roughly 12-months of active use of a secret Facebook group and over 1400 posts, comments, or likes from participants, we did not encounter one single hostile or derogatory comment, or any posts that deviated from the spirit and goals of the PeerFIT program. Additionally, actively posting content or engaging in the Facebook group is optional for participants. Participants may choose to use the group as often or as little as they wish based on their level of interest.

b. Confirm that risks to subjects have been minimized, by use of procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk:

The protection of risk described above have been used and evaluated in three separate pilot studies conducted by our group on the PeerFIT pilot model and have been employed in prior lifestyle intervention studies for people with serious mental illness conducted by our Dartmouth research team and elsewhere.

The additional risk of breach of confidentiality with respect to the study data will be minimized by using code numbers instead of names on the data. The code will be unavailable to anyone outside of the research team, and it will be destroyed at the conclusion of the data analyses. The code-name crosswalk will be kept in a password-protected file on a password-protected computer and stored on a secure network. Identifiable information, such as a copy of the participant's signed consent form, medical release of information form, MMSE results, and medical clearance letter will be stored in separate file folders in a locked filing cabinet at the offices of the research coordinator. Qualitative interview audio files will be stored on the data collection supervisor's (Kinney) password-protected computer until they have been transcribed and will not be stored with other study data. No medical records or protected health information shall be re-disclosed. A certificate of confidentiality will not be required. Other confidentiality protections include confidentiality training for all new employees and refresher seminars annually for all employees; removing or obscuring names from data forms; using an acronym in return addresses on correspondence to participants; and password-protected computer database.

c. Describe why all the risks to subjects are reasonable in relation to both anticipated benefits and the knowledge expected to be gained from the study:

This study has the potential to substantially enhance the quality of life of individuals with SMI. PeerFIT will use a group-based lifestyle intervention enhanced by peer support, mHealth technology, and social media to advance a scalable approach to addressing cardiometabolic risk in an urban population of young adults with mental illness served within a community-based system of care. PeerFIT leverages peer support and mHealth technology, including a wearable physical activity tracker (e.g., Fitbit Zip) and its companion mobile application, text-messaging support and reminders, and social media (i.e., Facebook) to promote health behavior change in this young adult population. By incorporating these approaches in a group lifestyle intervention that involves minimal and time-limited professional resources, PeerFIT provides a practical and scalable population-based

approach to reducing cardiometabolic risk in young adults with SMI within real world mental health settings.

Individuals with SMI experience excess morbidity and reduced life expectancy largely attributed to modifiable cardiometabolic risk factors. The proposed study will inform new approaches and policies to intervening early to reduce cardiometabolic risk in young adults ages 18 to 35 with SMI within community-based mental health care settings by determining the effectiveness of the PeerFIT lifestyle intervention— aimed at increasing self-efficacy and peer support for health behavior change to promote weight loss and cardiorespiratory fitness in overweight and obese young adults with SMI. This study will leverage a novel opportunity afforded by over a decade of partnering with an entire mental health care system (Massachusetts Department of Mental Health) to implement and evaluate innovative models of care for the highest risk people with SMI. There is significant potential for widespread dissemination and long-term sustainability of the PeerFIT intervention if proven to be effective.

7. Unexpected Events or Incidental Findings

Note: It may be important to consider the potential for certain unanticipated events to occur, for example:

- finding an anomaly in a MRI
- discovering child abuse
- causing distress in interviews of a sensitive nature

Describe potential events and provide a plan of action:

As with any behavioral weight-loss intervention study, there is a potential for unexpected events and incidental findings (e.g., participants showing up for group sessions under the influence of substances, uncovering signs of potential eating disorders during research interviews). With the exception of the GNMHCCC, the primary intervention activities and research interviews will take place at the MHCGM, CMHA, or DMH operated sites where the young adult clients enrolled in the study receive services. Recruitment, enrollment, and research interviews will take place at the GNMHCCC, but intervention activities will take place at the Nashua Senior Activity Center due to space availability. A clinical supervisor at the MHCGM, GNMHCCC, CMHA, or Vinfen will be actively involved in the overall supervision of the lifestyle coaches delivering the intervention along with the study PI (Dr. Aschbrenner) and site PIs (Bird, Viron, Guarino, Patalinjug Tyner, and Mormile-Mehler). If an unexpected clinical event occurs, the interventionists and/or research team will notify the on-site clinical treatment team immediately and the best course of action regarding medical or mental health treatment will be determined. With regard to unexpected research findings, the research team will carefully review the data, summarize the case, and share the findings with the site PI for further evaluation and discussion to determine the best course of action.

8. Deception

Does any part of this study involve deception or withholding of information from participants?

☐ **Yes** ☒ **No**

If Yes, provide an explanation which addresses the following:

- A description of the deception being used
- Why the deception is necessary
- A plan for debriefing, or providing subjects with the pertinent information after participation

9. Equitable Participant Selection

a. Estimated number of participants at Dartmouth CPHS reviewed sites:

This study will recruit 144 young adults ages 18 to 35 with SMI.

b. Provide a justification of the proposed sample size

We expect to enroll and randomize 144 participants in the Fit Forward Lifestyle Trial at study sites within the MA Department of Mental Health, Mental Health Center of Greater Manchester, Greater Nashua Mental Health Center at Community Council, and the Community Mental Health Affiliates. Given our stratified randomization procedure, the intervention allocation should be evenly divided between the experimental and control groups, at approximately 72 each. We chose this sample size because it is sufficient to detect weight loss that has public health significance. The proportion of participants who achieve clinically significant weight loss of ≥5% and ≥10% will be calculated because modest weight loss contributes to reduction in cardiovascular risk among overweight and obese individuals.

c. Define the target population:

This 12-month randomized controlled trial will recruit 144 young adults ages 18 to 35 with serious mental illness (SMI), defined by a chart DSM-V Axis I diagnosis of a qualifying SMI using diagnostic criteria as defined in the DSM-V for schizophrenia and psychotic disorders, mood disorders, anxiety disorders, and borderline personality disorder. Participants will be recruited from real-world settings providing services to clients within the Massachusetts Department of Mental Health community-based system of care, the Mental Health Center of Greater Manchester, the Greater Nashua Mental Health Center at Community Council, and the Community Mental Health Affiliates.

d. Vulnerable populations

Note: Certain populations are considered vulnerable to coercion and undue influence and are provided with additional protections when participating in a research study.

Identify any of the below populations which you plan to recruit for this study. In addition, complete the form(s) linked with each population as necessary and upload on the 'Supporting Documents' page in Rapport.

☐ Pregnant Women, Fetuses and Neonates
☐ Children
X People with impaired decision-making capacity

The following populations may also be considered vulnerable to coercion or other undue influence:

- Prisoners
- People who are economically disadvantaged
- The elderly
- People who are illiterate or do not speak English
- Students and employees

Describe any other potentially vulnerable population(s) and the additional protections provided to them:

This study will enroll young adults ages 18 to 35 with a qualifying SMI using diagnostic criteria as defined in the DSM-V for schizophrenia and psychotic disorders, mood disorders, anxiety disorders, and borderline personality disorder. Young adults with SMI represent a vulnerable subgroup given the elevated obesity rates, increased cardiometabolic risk, and resulting significantly reduced life expectancy affecting these individuals. Additionally, the onset and progression of mental illness in young adults can have devastating consequences on major life domains, including education, employment, and social relationships, resulting in low self-esteem and a sense of hopelessness that can create a high vulnerability for engaging in poor health behaviors. The current study represents a significant and important effort aimed at reducing the cardiometabolic risk factors

affecting the vulnerable subgroup of young adults with SMI by offering a scalable intervention that incorporates evidence-based strategies for achieving clinically significant weight loss and changes in fitness along with participatory learning activities with peers supported by mHealth technology and social media to engage and activate young adults with SMI in health behavior change. The primary intervention activities and research interviews will take place at the MHCGM, GNMHCCC, CMHA, or DMH operated sites where young adults in the study receive their services. A research supervisor, Ms. Cella (DMH)/Ms. Guarino (MHCGM)/Ms. Flynn (GNMHCCC)/Dr. Paluso (CMHA), will be actively involved in the overall supervision of the project along with the study PI (Dr. Aschbrenner) and site PI (Bird and Viron – DMH; Guarino – MHCGM; Patalinjug Tyner – GNMHCCC; Mormile-Mehler – CMHA). Concerns regarding any of the young adult participants will be discussed during weekly supervision calls with the study interventionists, and major concerns will be discussed among the study PI, site PI, and clinical supervisors to determine the best course of action.

10. Recruitment

Describe method(s) of recruitment. Associated advertisements and other materials to be used for recruitment should be uploaded to the 'Consent Forms and Recruitment Materials' page in Rapport.

The research staff hired to manage and conduct recruitment at DMH study sites will be employees of the Vinfen organization co-supervised by the study PI (Aschbrenner) and Vinfen Director of Project Management (Cella). Research staff (Guarino and Jason Welsh) hired to manage and conduct recruitment at the MHCGM will be employees of the MHCGM supervised by the study PI (Aschbrenner). Research staff, Pelletier and Welsh, will be employees of Dartmouth the MHCGM, respectively, and supervised by the study PI. Research staff (Paluso and Daley) will be employees of the CMHA supervised by the study PI (Aschbrenner). Administrative databases operated by DMH sites and the MHCGM and GNMHCCC will be used to identify potentially eligible participants based on age, diagnosis, and BMI (if available). In addition, individuals will be referred for participation by psychiatrists and other clinical providers at each agency, and by self-referral. Treatment teams will review their caseloads to identify eligible individuals.

We will use a multi-pronged approach to informing potential participants about the study that includes posters and brochures, and telephone and electronic communication (e.g., emails and text messages). Printed recruitment advertisements will provide details about the study and contact information for the research staff. This information will be distributed throughout study sites and also given to clinicians and staff at regularly occurring team meetings. During team meeting presentations, study staff will describe the study, eligibility criteria, and potential benefits of participating. Clinicians will be given recruitment materials and may take some "Fit Forward" branded giveaways such as pens and water bottles to distribute to interested clients. To make the presentations more interactive and memorable, study staff may "quiz" clinicians on their understanding of the study and their role in making referrals; winners will receive a small prize (<$25 in value). Clinicians and staff at each agency who have direct contact with young adults who may be eligible for the study will present them with a consent to contact form that they can complete if they wish to learn more about the study from the project team via telephone, email, and/or text messaging. Clinicians and staff will share client's contact information to research staff once clients have signed the consent to contact form. Personalized emails and text messages will not identify the potential participant as being an individual with a mental or physical health condition nor will they identify them as recipients of mental health care services. Rather, they will advertise a study of a lifestyle intervention for young adults enhanced by mHealth technology and social media.

To boost clinician and staff referrals, incentives may be used as both reward for referring potential participants and to increase awareness of and excitement for the study among study site staff. If referrals are low for an upcoming cohort, weekly raffles will be implemented. Clinicians and staff may receive raffle entries for each referral given to study staff or for assisting the study team in making contact with a participant. Incentives will include a Fitbit giveaway or a smaller reward, such as a $25 gift card. Each week, the winner at each study site will be announced via internal email.

In addition to these traditional recruitment methods, we will use novel channels and venues to recruit young adults with SMI. **First,** information about the study will be posted to the Vinfen, MHCGM, and CMHA Facebook groups. **Second,** we will equip 3-4 peer providers at each site with Fitbits to demonstrate and role model the use of the devices, which may incentivize young adults to learn more about the study. **Third,** we will

use experiential marketing strategies involving a series of live events with music and fun and engaging activities to give members of the target audience opportunities to experience firsthand the mobile technology used in the study. Healthy and flavorful foods will be served at each event and young adult clients will have the opportunity to socialize with one another, see a Fitbit demonstration and tryout the device for themselves, pick up "Fit Forward" branded giveaways like pens and wristbands, and win door prizes (e.g., water bottles or gym bags). **Finally,** young adults who enroll in the study will have the opportunity to refer other young adults in their social networks who also receive services at the study sites.

Individuals who meet initial pre-screen criteria for age and SMI diagnosis will be invited to attend a group orientation session prior to formal screening, consent, and randomization. If necessary, individual informational sessions will be conducted in lieu of group orientation sessions for potential participants who are unable to attend the group sessions for whatever reason (e.g., scheduling conflicts, weather related absences, lack of transportation). During these sessions, potential participants will learn about the health benefits of modest weight loss and improved fitness as well as trial design, the importance of a control condition, random assignment and the impact of dropouts. These sessions will also address ambivalence about adopting a healthier lifestyle through healthy eating and engaging in regular exercise, ambivalence about joining a trial, and unrealistic weight-loss and fitness expectations. An overview of trial design will be provided, including randomization to treatment conditions and follow-up assessments. Potential participants will have the opportunity to ask questions about the treatment conditions and the overall study. Introduction meetings have been successfully used by our research group, and interactive group orientation sessions have helped to minimize attrition in prior studies. A private and confidential formal screening will be conducted following the information session. As compensation for their time, potential participants will receive $10 for the information/formal screening session.

11. Informed Consent, Assent, and Authorization

All forms discussed in this section should be uploaded to the 'Consent Forms and Recruitment Materials' page in Rapport

a. Please describe the consent and/or assent process, addressing the following:

- Who will obtain consent/assent from participants
- Where the consent/assent process will take place
- The timeframe for providing information to potential participants about a study, having the consent form signed, and beginning study activities
- Any precautions taken to minimize the possibility of coercion or undue influence
- The forms which will be used as well as any aids used to simplify scientific or technical information
- How comprehension will be ensured?

A two-part consent procedure will be used for this study: (1) consent to participate in the screening; and (2) consent to enroll in the study. Potential participants will be asked to give written consent after reviewing an information sheet to participate in the screening session. In addition, they will be asked to complete a two-way authorization form giving permission for the research staff to review their medical records to verify their psychiatric diagnosis. At this point, potential participants will be consenting to participate in the screening (not to enroll in the study). Eligible and interested individuals who do not have a legal guardian will be given the opportunity to complete the informed consent session to enroll in the study during the same appointment or before beginning the baseline assessment. Eligible and interested individuals who have a legal guardian, and those who require medical clearance will be asked to complete a second consent session to enroll in the study as participants.

During the screening sessions the research coordinator and research assistant will conduct the sessions using a structured protocol designed by the study team. Once it is determined that the participant meets all study criteria (including medical clearance if necessary), he or she will meet with study staff who will review the written consent form to enroll in the study. The consent meetings will take place in a private space at the mental health

center or other community-based sites. During the consent process, sections of the consent form that are important to comprehend the nature of the study, what participation involves, and the rights of the participant, will be read aloud by a research team member. After each section, comprehension will be assessed by discussing the following questions:

1. What does “voluntary” participation mean?
2. In the participant’s own words, what is the purpose of this study? What are we trying to learn?
3. What does “randomization” mean?
4. How long is participation? What does participation involve?
5. How many study assessments are there?
6. What are the risks of participating? What are some of the perceived benefits?
7. Does the participant understand that we cannot guarantee benefit? I.e., This is NOT treatment?
8. Has the participant passed the MMSE (during screening)?
9. If there is a legal guardian, has the legal guardian given consent?

We will also obtain permission to audio record study assessments for research interview monitoring and intervention sessions for intervention fidelity monitoring purposes. Given the innovative nature of the trial, it is possible that ancillary studies will be proposed before or after the study begins recruitment. For this reason, during the informed consent process, we also will seek permission to contact the participant in the future about other related research opportunities. Participants will be provided a copy of the consent form with contact information for the research coordinator if they have questions.

People with guardians who have adequate decision-making capacity will be eligible to participate. In these instances, assent will be obtained from the participant and consent will be obtained from the guardian. Guardians will be mailed a consent request letter, the study consent form and Authorization to Release Health Information Form to review and sign. They will be asked to return the signed forms using a stamped envelope provided to them. Participants will not be enrolled in the study nor will they complete the baseline assessment until the consent process is finalized. Both the participant and the guardian will be provided a copy of the consent form.

Participants will be informed in the consent form that the research team will use a number of different strategies to reach them with reminders and information about upcoming study assessments and program activities, including phone calls, text messaging, email, and direct Facebook messages to the private Facebook group. They will be asked to provide the name, address, telephone number, and email address of at least two family members or close friends whom they give us permission to contact in the event we cannot reach the participant.

Participants will experience up to five study visits prior to starting the intervention; however, we will make every attempt to condense this process when possible to reduce participant burden (e.g., conduct the written consent and baseline assessment at same time). Participants will be told about their treatment assignment over the telephone when possible.

Consent to Share Data with the NDA

Additionally, participants will be asked to give separate “Consent to Data Sharing” to allow the research team to share their de-identified study data with the NDA. To share this data, the consent form will state that their legal name at birth, date of birth, sex at birth, and city/municipality of birth will be collected during one of the research assessments and used to create a Global Unique Identifier (GUID) code that will be linked with their de-identified data for submission to the NDA. Participants will not be excluded from participation if they refuse permission to share their data with the NDA, but extra care will be taken by research staff to ensure that the participant understands that personally identifiable information will not be protected with their research records and not shared, and only de-identified data will be shared with the NDA. This consent will be sought when participants are enrolled (randomized) in the study. It will be sought by the research assistant or research coordinator. For participants with legal guardians, the process for getting consent/assent described above will be followed.

Visit #1	Visit #2	Visit #3	Visit #4	Visit #5	Intervention Begins
Informational Session	Written Consent to Participate in Screening Session	Written Consent	Baseline Assessment within 6 weeks of Intervention	Randomization Assignment and Technology Set-up	PeerFIT Group Intervention
					BEAT Group Intervention

An information sheet will be used for qualitative interviews. The research coordinator will review the information sheet with participants at their 12-month assessment. For participants who agree to participate in the one-time phone interview, the study coordinator will assist them in scheduling a phone interview with the PI of the study. If an interested participant has a legal guardian, the information sheet will also be sent to the guardian and the participant will be asked to complete the telephone interview once permission is received by the legal guardian.

b. Waiver(s) or alteration(s) may be requested for research that involves no more than minimal risk. Indicate requested waiver(s) or alteration(s) below. In addition, complete the corresponding section of the Waivers and Alterations Request Form and upload it to the 'Consent Forms and Recruitment Materials' page in Rapport.

- ☐ For the informed consent *process*
- ☐ For the *documentation* of informed consent
- ☐ For the HIPAA Authorization to use and/or disclose PHI
- ☐ For a waiver of the requirement for medical record documentation

12. Compensation or Gifts

Please describe any payments, gifts or reimbursements participants will receive for taking part in the study:

Participants will not receive incentives for participating in the intervention or control group sessions. However, potential participants will receive $10 for their time in completing an information/formal screening session, regardless of whether or not they are eligible to be enrolled. Once enrolled, participants will receive $50 or receive a $50 gift card of their choice for completing data collection at each of the following time points: baseline, and 6 and 12 month follow-up, for a total of $150. In addition, at 6 and 12 months, an unblinded research interviewer will conduct a brief 30-minute telephone assessment with PeerFIT participants to collect data on secondary measures specific to the experimental condition. PeerFIT participants will be paid an additional $15 or given a $15 gift card of their choice for participating in the interview. Participants will also be allowed to keep the Fitbit wearable activity tracking devices once the study ends.

Participants will be paid $30 for completing a qualitative phone interview. Once the phone interview has been conducted, the research coordinator will contact the participant to arrange a convenient time to give them the $30 in person.

Participants receiving money/gift cards paid for directly through Dartmouth-Hitchcock ("DH") for research activities will be asked to complete a W-9 as a requirement of DH. If a study participant receives more than $600 in one calendar year from DH, DH will report this to the IRS as required by law.

13. Privacy of Participants

Note: Methods used to obtain information about participants may have an effect on privacy. For example:

- Consent discussions or interviews held in public which concern sensitive subjects or behaviors
- Observations of behavior, especially illicit behavior, in quasi-public settings

Describe any activities or interactions which could lead to a breach of privacy and provide a plan to protect participant privacy:

There are potential risks to privacy associated with using the Facebook social networking site. For example, there are potential risks concerning the data that users choose to share with others when they create a personal Facebook account (e.g., sharing telephone numbers, personal email, date of birth, and other personally identifying information). These are some of the risks associated with using Facebook, and these risks are apart from the use of the secret Facebook group that will be formed for this study. It is expected that most of the young adults in this study will be active Facebook users and will have existing personal Facebook accounts prior to enrolling in the study. This assumption is based on the findings from a recent survey conducted in inpatient and outpatient mental health settings in New York that found that over 96% of young adults with serious mental illness were Facebook users. Further, these individuals reported using social media including Facebook for about 2.6 hours each day on average. Therefore, the young adult participants in the current study will likely be comfortable and familiar with using Facebook, and will have agreed to the terms and conditions of using this social media platform, and thus will be aware of potential risks associated with daily use of social media. We are able to mitigate potential risks by using the secret group feature on Facebook. The secret group can only be accessed by study participants who are invited to join by study staff, and the Facebook group will be monitored several times each week to ensure that the content posted by participants is consistent with the goals of the PeerFIT program.

Several measures will be implemented in order to minimize potential risks to participants with using the secret Facebook group component of the PeerFIT program. Importantly, in the secret group feature on Facebook, study staff will be able to maintain administrative control over the Facebook group at all times throughout the study duration. This means that study staff can invite or remove participants at any time, and can delete comments or posts from different group members. Study staff will follow a protocol where they will monitor the content of the Facebook group at least 3 times each week. Study staff will ensure that the content posted in the group does not deviate from the spirit and goals of the PeerFIT program. Primarily, study staff will be checking to make sure that there are no hostile or derogatory posts directed at other participants, or any posts describing urgent health concerns or emergencies. Participants will be informed of the ground rules for using the secret Facebook group, and that if they post any hurtful comments or inappropriate content then they will be removed from the group by study staff. Participants will also be informed that if they post any content related to a medical emergency or related to self-harm or harming others, then the study staff will call 911 and will inform the participant's mental health provider immediately. We anticipate that it will be highly unlikely that participants will discuss any medical emergencies in the secret Facebook group.

In addition, the lifestyle coaches will have continuous access to the secret Facebook group through their study smartphones. The lifestyle coaches will be provided with smartphones connected to the Facebook application so that they can easily access the secret Facebook group and view content or respond to participants' posts. The lifestyle coaches' smartphones will be setup to receive automatic updates and push notifications whenever any content or comments are posted in the secret Facebook group. The lifestyle coaches will be instructed to check the notifications and content posted in the Facebook on a daily basis (Mon-Fri). The lifestyle coaches will be instructed to follow a protocol where they will inform study staff immediately if participants post any hurtful, derogatory, or inappropriate content. The lifestyle coaches will be instructed to call 911 immediately and to also contact the study staff in the unlikely event that a participant posts comments related to self-harm or harming others. In our prior experiences using Facebook as part of the PeerFIT program, we have not had any concerns related to the content or types of posts from participants. Participants in this study can use their personal Facebook account to join the secret PeerFIT Facebook group. Use of the secret group feature will minimize any risk of a loss of privacy experienced by sharing personal information with other participants. Participants will also be asked not to share any information or content posted in the secret Facebook group with people who are not enrolled in the intervention arm of the study. The secret Facebook component of the PeerFIT program is entirely voluntary, and participants can choose to stop using the Facebook group at any time, or they can choose to use it as often or as little as they would like.

14. Confidentiality of Data

Note: Any person engaged in research collecting information about illegal conduct may apply for a Certificate of Confidentiality from the National Institute of Health.

a. If disclosed, could any of the data collected be considered sensitive, with the potential to damage financial standing, employability, insurability, or reputation?

☐ **X No** ☐ **Yes**

If Yes, describe the data or information, the rationale for their collection, and whether a Certificate of Confidentiality will be obtained:

b. Describe the safeguards employed to secure, share, and maintain data during the study, addressing any of the following which may apply:

- Administrative, ie. coding of participant data
- Physical, ie. use of locked file cabinets
- Technical, ie. encrypted data systems

Our research team is experienced in training, instrument construction, editing, and data management. We will use the same procedures for data acquisition and management used in prior studies, including: (1) a common core of initial and refresher training for interviewers; (2) continuous team feedback to the sites; and (3) final data editing and management at our office in Merrimack, NH. Weekly research team conference calls, including assessment supervision, will help identify quality control issues early and allow consensus solutions to be reached. At the study sites, in a locked cabinet, single files will be maintained containing signed informed consent, participant contact information, and a study flow sheet. We will use a direct-entry, web-based system for data collection, which provides entry validation range tests for all fields, as well as default (missing) values. We have conducted several studies with this web-based system, including a state-wide intervention that has enrolled over 2,000 participants; therefore, we have confidence in its reliability and have had no problems with data safety, quality, or loss. All study data will be identified only with study ID numbers. The database will be protected by daily backup. Prior to analyses, data will be exported from the entry database into statistical analysis packages (SAS and SPSS) with complete labeling intact (variable names, variable labels, value labels, and missing value declarations). Data will be monitored and maintained by the Data Manager, who will review it weekly for accuracy and completeness.

Receipts of payment for the completion of research activities (e.g., information sessions, research assessments) as well as W-9s (if applicable) from study participants will be scanned by the study coordinator and thereafter shredded. Electronic receipts and W-9s will be stored on the study coordinator's password-protected computer to which only she has access. Electronic receipts and W-9s will also be sent to the grant manager via secure, encrypted email, and uploaded to a secure server to which only grant managers have access. W-9s will be kept separate from participant receipts, and neither will contain the name of the research study, only a project ID number.

Participants' Fitbit usernames (i.e., email address) and passwords, as well as their study ID, will be maintained by and accessible to only research staff. One password-protected spreadsheet will contain Fitbit emails, passwords, and the study IDs created for Fitabase accounts. This spreadsheet will be stored primarily for the purpose of registering the Fitbit accounts on the Fitabase platform. Fitbit data downloaded from Fitabase is de-identified and will only be shared among members of the research team. Only key research members with administrator accounts on Fitabase, such as the data manager, PI, and project manager, will be able to view and download the data. When participants go through informed consent and provide written consent, they will be giving the research team permission to maintain their Fitbit account username (i.e., email address) and Fitbit account password, as well as register their Fitbit accounts on Fitabase for the duration of their participation in the study. Participants can choose not to connect their Fitbit accounts with Fitabase and not to share their Fitbit data. For any participants who choose not to connect their Fitbit account with the Fitabase data management platform, it will not affect their participation in the study or their access to using a Fitbit wearable device for the duration of study participation.

Qualitative interview audio files will be deleted from audio recorders once they have been transferred to the data collection supervisor's computer and the transcription company's secure online portal. Instructions will be

given to the company to remove all identifiers from the transcript, such as names, locations, diagnoses, and any protected health information. De-identified transcripts will be stored in a password-protected online database that is accessible only to the PI and data collection supervisor.

c. Describe the plan for storage or destruction of data upon study completion:

The study team is aware of and agree to abide by the principles for sharing research resources, as described by NIH in "Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Programs." As a means of sharing knowledge, NIH encourages grantees to arrange for publication of NIH-supported original research in primary scientific journals. We therefore will strive to publish our findings in a timely manner and acknowledge that the research was supported by the NIH. All primary and secondary publications will be completed within 3 years following completion of data collection. After this 3-year period, data without identifiers, including all indirect identifiers that might lead to deductive disclosure of individual participants, will be available under the auspices of the PI (Aschbrenner). Following a request to the PI to access data, a data sharing agreement will be established and a CD containing the de-identified data will be sent to the requesting institution or investigator. We will also share analytic code and variable creation and restructuring information with researchers who request it for sound scientific purposes aimed at the public well-being. All protected health information (PHI) data collected during this study will be destroyed by June 1st, 2030.

Paper W-9s and receipts signed by study participants that are maintained by the study coordinator will be shredded, and electronic W-9s and receipts will be destroyed using an encrypted data shredder, after they are entered electronically by grant managers onto a secure server maintained by DH. Grant managers will destroy electronic W-9s using an encrypted data shredder a) if they are replaced by a new version of the W-9 for that study participant, or b) after 7 years of no DH-originated payments made to the participant. Grant managers will destroy electronic receipts using an encrypted data shredder 7 years from the date of the receipt.

At the conclusion of data analysis, the spreadsheet of Fitbit account usernames (i.e., email address), Fitbit account passwords, and study IDs will be destroyed using an encrypted online data shredder. De-identified Fitbit accounts on Fitabase will also be deleted 90 days following the completion of data analysis per Fitabase's security policy.

Qualitative interview audio files stored on the data collection supervisor's computer will be destroyed using a PGP-encrypted data shredder once de-identified transcripts have been received.

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