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Peer Support and Mobile Health Technology Targeting Obesity-Related Cardiovascular Risk in Young Adults with Serious Mental Illness: Protocol for a Randomized Controlled Trial

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Abstract

Background—Individuals with serious mental illness (SMI) such as schizophrenia and bipolar disorder face a higher risk of early death due to cardiovascular disease and other preventable chronic illnesses. Young adulthood is a critical window of development for lifestyle interventions to improve the long-term health and quality of life in this population. Fit Forward is an NIH-funded randomized clinical trial examining the effectiveness of a group lifestyle intervention (PeerFIT) enhanced with mobile health technology compared to one-on-one mobile lifestyle coaching with Basic Education in fitness and nutrition supported by a wearable Activity Tracking device (BEAT) in achieving clinically significant weight loss and improved cardiorespiratory fitness in young adults with SMI.

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Trial Status

Trial recruitment started in March of 2017 and is currently open.

Trials registration: ClinicalTrials.gov, NCT02815813

Disclosure statement

The authors have no competing interests to disclose.

Methods—Fit Forward targets 144 young adults (18 to 35 years) with SMI and a body mass index (BMI) of ≥ 25 receiving public mental health services. In a two-arm randomized clinical trial, participants will be randomly assigned with equal probability to PeerFIT or BEAT, stratified by birth sex and psychiatric diagnosis. Participants will be assessed at baseline, 6, and 12 months. The primary outcome is cardiovascular risk reduction indicated by either clinically significant weight loss (5% or greater) or increased fitness (>50 m on the 6-Minute Walk Test). Secondary outcomes include change in BMI, lipids, and hemoglobin A1c. Perceived self-efficacy for exercise and peer support will be evaluated as mechanisms underlying intervention effects.

Conclusion—If effective, PeerFIT will provide a potentially scalable approach to addressing health risks among young adults with SMI in mental health settings.

Keywords

Lifestyle intervention; Young adult; Serious Mental Illness; Peer support; Mobile health technology

1. Introduction

Individuals with a serious mental illness (SMI) such as schizophrenia and bipolar disorder have a life expectancy that is 8 to 32 years less than people without mental illness [1, 2]. High rates of cardiovascular disease and other preventable chronic illnesses among persons with SMI contribute to this early mortality disparity [3, 4]. Cardiovascular risk factors including obesity, prediabetes, and prehypertension are present early in the course of mental illness and likely related to many factors, including unhealthy lifestyles and psychiatric medications [5]. An estimated 48% of young adults with SMI are overweight or obese [5]. Although young adulthood (18-35 years old) is increasingly recognized as a critical time for lifestyle interventions to address obesity-related cardiovascular risk in individuals with SMI, the field lacks evidence-based interventions tailored to address health behaviors in this young age group.

Lifestyle interventions for adults with SMI have achieved clinically significant cardiovascular risk reductions in upwards of 50% of participants [6-9]. These trials, however, consist predominantly of middle-aged samples with very few young adult participants. Young adults with SMI are typically enrolled into standard adult programs that include adults ages 18 to 70 or older. This practice does not take into consideration the unique values, attitudes, and preferences for weight loss in younger vs. older adults that appear to influence treatment engagement and success [10, 11]. When overweight and obese young adults with SMI participate in lifestyle interventions they experience benefits comparable to other participants [12]. However, a secondary analysis of three trials of a lifestyle intervention for persons with SMI revealed adults under age 30 comprised 15% of the total sample [12]; thus, highlighting the need to design effective lifestyle interventions that are relevant and appealing to younger age groups with SMI.

Our research team has developed and pilot tested “PeerFIT,” a group-based lifestyle intervention supported by mobile health technology for adults with SMI [13]. Weight loss strategies are taught in creative and highly interactive peer groups involving collective

problem solving, accountability, and mutual support. Popular technologies including wearable activity trackers, text messaging, and Facebook are integrated into lifestyle sessions aimed at supporting self-efficacy and facilitating peer support for health behavior change [14, 15]. Pilot studies have demonstrated the feasibility, acceptability, and preliminary effectiveness of PeerFIT [16-18]. PeerFIT is especially suited for younger adults with SMI because the creation of a peer support network, access to engaging and results-oriented exercise classes, and the use of technology is consistent with the values and preferences of this age group [11, 19, 10].

This protocol paper describes the rationale, design, and methods of the Fit Forward Study. The goal of the study is to evaluate the effectiveness of PeerFIT compared to mobile lifestyle coaching with Basic Education in fitness and nutrition supported by a wearable Activity Tracking device (BEAT) in achieving clinically significant weight loss and improved cardiorespiratory fitness in young adults with SMI. The results of this study will inform intervention for cardiovascular risk reduction among young people with SMI, an area of mental health services currently lacking evidence-based practices.

2. Methods

Fit Forward is a randomized clinical trial funded by the National Institute of Mental Health (R01MH110965) that will be conducted at three community mental health centers in the Northeastern US. The principal investigator is affiliated with the Geisel School of Medicine at Dartmouth College. Fit Forward plans to enroll 144 young adults (18 to 35 years) with SMI and a body mass index (BMI) of ≥ 25 receiving state-funded mental health services. Participants will be randomly assigned with equal probability to PeerFIT or BEAT, stratified by birth sex and psychiatric diagnosis. Participants will be assessed at baseline, 6, and 12 months.

The primary hypothesis is that compared to participants in BEAT, a greater proportion of participants in PeerFIT will demonstrate 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). Secondary aims compare the two conditions on mean changes in BMI, weight, and cardiorespiratory fitness over 12 months. The two groups will also be compared on changes in behavior (e.g., physical activity, weight control strategies, daily meal patterns), psychosocial functioning (e.g., perceived social support), mental health (e.g., depression), and other cardiovascular disease risk factors (including blood pressure, lipids, hemoglobin A1C, and waist circumference).

Two theoretical mechanisms of action hypothesized to account for greater weight loss and increased cardiorespiratory fitness among participants assigned to PeerFIT will also be evaluated: 1) improved self-efficacy and 2) increased peer social support for health behavior change. The study will also explore demographic and other clinical and background factors that might predict weight loss over the average follow-up of 12 months and moderate the effect of the PeerFIT on weight loss and cardiovascular fitness outcomes, including initial BMI, medication use, ethnicity, age, smoking and alcohol use, sleep quality, and neighborhood environment.

This study was approved by the Institutional Review Boards at Dartmouth College, the Massachusetts Department of Mental Health, and the State of New Hampshire Department of Health and Human Resources.

Eligibility

The recruitment goal is to randomize 144 participants, with at least 50% men and 40% from racial/ethnic minority groups. Table 1 describes the eligibility criteria for this trial. As indicated, all participants must be 18 to 35 years old. The minimum BMI criteria of ≥25 kg/m^2 was selected to target individuals classified in overweight and obese weight categories. Participants will be required to be service recipients at a mental health center and have a qualifying mental health disorder using diagnostic criteria as defined in the DSM-5 for schizophrenia and psychotic disorders, mood disorders, or anxiety disorders. The exclusion criteria were developed to maximize the safety of the intervention and minimize the likelihood that a participant would complete the full trial while also taking into account the generalizability of the findings.

Recruitment

The Fit Forward study will be primarily advertised at participating mental health agencies using recruitment flyers and brochures and sponsored events with promotional items (e.g., water bottles, wristbands, smartphone wallet card holders). Members of the research team will regularly attend clinical team meetings where they present the study, answer questions, and seek referrals from clinicians and administrative staff. Participants will be encouraged to describe the study to other clients whom they think may be interested in it, and who can learn more about the study from research staff. Individuals will be self-referred or clinician-referred to research staff who provide them with basic information about the study and ask them to complete an initial eligibility screen reporting their age and whether they are interested in weight loss. Subsequently those who appear eligible upon phone screening will be asked to attend an informational meeting where, if interested and available to participate in the study, they will be further screened for eligibility. Eligible participants will then be scheduled to complete informed consent and a baseline assessment visit.

Randomization

A total of 144 clients will be recruited and randomized to either the PeerFIT or BEAT intervention at the three sites, with approximately the same number of clients at each site. Randomization within each will follow a simple, non-adaptive variable block length algorithm, and will be stratified by birth sex and psychiatric diagnosis (psychotic disorders, defined as schizophrenia, schizoaffective disorders, psychotic disorders not otherwise specific vs. all other diagnoses). PeerFIT groups at each site will begin once four new people have been randomized to PeerFIT. Thereafter, open enrollment of participants into ongoing groups will be used whereby new participants can join the PeerFIT group immediately following randomization.

PeerFIT Intervention (Experimental condition)

The 12-month PeerFIT lifestyle intervention consists of an initial 6-month intensive phase including: (a) once weekly 60-minute group lifestyle sessions; (b) once weekly 60-minute group exercise sessions; (c) a private Facebook group to reinforce lessons and facilitate peer-to-peer support for health behavior change outside of group sessions; (d) wearable activity trackers (i.e., Fitbits) to promote self-monitoring of physical activity; and (e) weekly text messages (3-5 texts per week) from a lifestyle coach with prompts for adherence to the behavioral intervention and reminders and encouragement for self-monitoring behaviors (i.e., daily self-weighing and physical activity tracking). A lifestyle coach leads the group sessions, moderates the private Facebook group, and delivers the text messaging component of the study.

At month 7, participants transition to a lower intensity phase in which the weekly lifestyle sessions are discontinued. Participants have continued access to the weekly exercise sessions, private PeerFIT Facebook group, Fitbit activity tracker, and weekly text messaging support through Month 12 of the study. A total of 10-18 participants will be enrolled in each of the groups with participants from all groups invited to join the private PeerFIT Facebook group.

Lifestyle Sessions—The PeerFIT lifestyle sessions are based on principles from the Diabetes Prevention Program designed for individuals at risk for diabetes and cardiovascular disease [22]. PeerFIT program goals are to achieve 5% weight reduction and to increase physical activity gradually to 150 minutes per week over a 6-month period. Participants are taught to achieve these 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.

PeerFIT participants are engaged in participatory and active learning through team building activities, games, and group problem solving exercises. For example, in the session “Lets Get Moving!” team learning stations use group card sorting games that challenge participants to sort different types of exercises by level of perceived effort to stimulate thinking about how to meet weekly physical activity goals. In an empowering session informed by photo voice techniques (“Know Your Neighborhood”), participants leave the classroom on a 10-minute walk during which they use their study smartphones to take pictures of barriers and facilitators to exercise and then present their photos to the group for discussion. Another session (“Making Friends with Food”) involves participants working in pairs to give presentations to the group on how food can be a positive (rather than a negative) force in overcoming obesity by making healthy food choices to boost energy and improve mood. Didactic instruction is kept to a minimum so that participants have optimal time to form group cohesion, empathy, and share physical activity and wellness goals among group members.

Exercise Sessions—The PeerFIT lifestyle coach also leads once weekly one-hour group exercise sessions designed to increase cardiorespiratory fitness and promote weight loss. The

group exercise sessions give participants an opportunity to reach their weekly physical activity goals by working out together in an engaging and supportive environment. The lifestyle coach modifies exercises during group sessions as needed, starting at a level appropriate for sedentary persons, with gradual increases in duration and intensity. The lifestyle coach delivers the exercise sessions with guidance and ongoing supervision from a certified personal fitness trainer who provides an initial 2-hour training and once monthly supervision covering physical activity, exercise, and sedentary behavior. The instructor-to-participant ratio is up to 20 participants per one-hour group. The sessions take place at the mental health agency (e.g., large conference room) or at a location in the community, depending on space availability. Minimal equipment is used during exercise sessions with a focus on bodyweight exercises to build strength.

Mobile Health Technology—PeerFIT includes mobile health technology to facilitate and reinforce self-monitoring and collective problem solving taught and practiced during lifestyle sessions, and to allow participants to connect and support each other as peers towards achieving healthy lifestyle goals. Participants use their smartphones to access a "private" PeerFIT Facebook group, use wearable activity trackers, and receive supportive text messages from the lifestyle coach. Participants who do not own a smartphone will be provided basic smartphones to use throughout the duration of the 12-month study.

Private Facebook Group—The "private" 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 "private" 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. Participants are instructed to only post content related to healthy eating and exercise that is supportive and encouraging. The lifestyle coach also regularly posts content related to topics covered in the group sessions, reminders to exercise, and tips for healthy eating. Participants are 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 coach monitors the Facebook group multiple times each week to ensure that content is appropriate and related to the PeerFIT objectives.

Wearable Activity Trackers—Fit Forward participants will be provided with wearable activity trackers for selfmonitoring physical activity. Participants will receive either a Fitbit Zip or Fitbit Flex 2 depending on availability of the device by the manufacturer. Both Fitbit devices are wearable accelerometers designed to motivate users to reach health and fitness goals by tracking activity, exercise, sleep, weight, and water and dietary intake. The Zip clips onto clothing and participants can view their steps on the LCD display, whereas the Flex 2 is worn on the wrist and participants can monitor progress towards their step goal through LED lights that light up as activity occurs. Both the Zip and Flex 2 connect wirelessly to the Fitbit mobile application, which shows progress towards daily goals for steps, distance, calories burned and active minutes, and trends over time. Participants can also compare steps and progress by connecting with each other through the mobile application. The lifestyle coach helps participants set weekly step goals and adjust their

goals according to recent progress and setbacks. In our pilot studies, participants expressed high satisfaction with using wearable activity trackers, found these devices easy to understand, and valued using wearable devices for tracking their steps each day [15].

Text Messages—The text message component of the PeerFIT intervention is intended to increase participants' self-efficacy for health behavior change according to principles of Social Cognitive Theory [23] by providing personalized guidance, coaching support, and reinforcement for desired behavioral changes. Text messages from the lifestyle coach contain content to promote attendance and to increase motivation for small goal changes related to healthy eating and being physically active. The PeerFIT lifestyle coach creates customized text messages using a library matrix with example messages grounded in communication and behavioral change theory and linked to specific desired outcomes. The text messages are generally structured the same way for each participant, with minor customizations according to name, gender, and other personal characteristics. Text messages become increasingly personalized over time as the coach becomes more familiar with participants' lifestyle and preferences for supportive messages. The PeerFIT lifestyle coach sends participants text messages 3-5 times per week over the 12-month intervention period. 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.

Lifestyle Coach Training and Supervision—PeerFIT lifestyle coaches will be hired to deliver the PeerFIT intervention at each site. PeerFIT lifestyle coaches must have the following qualifications: Associate's degree or certified health coach, prior experience with health coaching and motivational interviewing, prior experience coaching or teaching weight management skills, basic knowledge of nutrition and fitness, and familiarity with smartphone technology and social media. PeerFIT lifestyle coach training will include a 4-hour initial training covering group coaching techniques, motivating lifestyle change for young adults with SMI, and the PeerFIT lifestyle session curriculum, a 2-hour initial training with a certified personal fitness trainer covering physical activity, exercise, and sedentary behavior, and a 2-hour initial training in the technology used in the intervention, including wearable activity trackers, text messaging, and social media. After the initial training, PeerFIT lifestyle coaches will meet weekly with the study PI (Aschbrenner) and Co-I (Naslund) for ongoing supervision of participant engagement, implementation of the intervention techniques, and group facilitation skills. The weekly supervision meetings also cover the technology component of PeerFIT, including the content posted in the private Facebook group, participants' use and engagement with technology, and troubleshooting technical challenges that may arise with study smartphones, wearable activity trackers, or use of social media. The PeerFIT lifestyle coaches will also meet once monthly with a certified personal fitness trainer for supervision of the exercise groups.

BEAT Intervention (Control condition)

The BEAT intervention involves one-on-one basic education in fitness and nutrition delivered by a lifestyle coach and supported by mobile health technology. Participants receive once monthly mobile lifestyle coaching for six months in which basic information

on physical activity and healthy eating is used to support participants' goals to achieve 5% weight reduction and to increase physical activity gradually to 150 minutes per week over a 6-month period. The BEAT lifestyle sessions last approximately 30-45 minutes with the first session occurring in person at the mental health center or at a location in the community selected by the participant, and the subsequent five sessions delivered via telephone. During the first session participants are given and taught to use a mobile body weight scale for home use and a wearable activity tracker (i.e., Fitbit) for self-monitoring activity. Participants are taught behavioral self-regulation skills for weight loss, including: a) to weigh themselves daily; b) to track their daily step count; c) detect small changes in weight and physical activity as they occur; d) problem solve barriers to achieving healthy changes; and e) recognize their own success. The BEAT lifestyle coach sends participants 3-5 text messages per week with reminders and encouragement for daily self-weighing, physical activity tracking, and engaging in healthy eating and physical activity.

The BEAT lifestyle intervention sessions end after Month 6; however, participants have continued access to the Fitbit activity tracker and weekly text messaging support from the lifestyle coach through Month 12 of the study. Participants randomized to the BEAT comparison condition receive the same type of wearable activity tracker and weekly text messaging support (3-5 texts per week) as participants randomized to PeerFIT; however, they do not get access to facilitated peer support through group-based lifestyle sessions or the private Facebook group like participants do in PeerFIT.

Lifestyle Coach Training and Supervision—BEAT lifestyle coaches will be hired to deliver the BEAT intervention at each site. The BEAT coaches must have the following qualifications: Associate's degree or certified health coach, prior experience with health coaching and motivational interviewing, prior experience coaching or teaching weight management skills, basic knowledge of nutrition and fitness, and familiarity with smartphone technology. BEAT lifestyle coach training will include a 4-hour initial training covering the BEAT lifestyle session curriculum and the text messaging protocol, and motivating lifestyle change in young adults with SMI. After the initial training, the BEAT lifestyle coaches will meet weekly with the study PI (Aschbrenner) and Co-I (Naslund) for ongoing supervision of coaching strategies, implementation of the intervention, completion of intervention tasks, and to troubleshoot technical challenges that may arise with study smartphones, wearable activity trackers.

Fidelity Monitoring

Fidelity (or adherence) of the coaches to the PeerFit or BEAT program guidelines will be monitored throughout the trial. After each session, the PeerFIT and BEAT lifestyle coaches will be asked to complete a web-based fidelity checklist that covers core components of the intervention. The checklists will assess: (1) core content covered and (2) key activities conducted during the intervention session. In addition, data are collected on attendance at the intervention sessions for both treatment groups. We selected a self-report checklist as a methodology for assessing fidelity in this study because this pragmatic approach is most likely to be used in real world mental health settings in the future. In addition to the fidelity monitoring practices described above, during supervision meetings, the researchers review

attendance logs and use problem-solving strategies to troubleshoot any difficulties with implementing the intervention

Data Collection and Measures

Trained research interviewers who are blind to group assignment will administer research assessments to participants at baseline, and at 6 and 12 months after randomization. Participants will receive $50 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, a separate research interviewer will conduct a brief 30-minute telephone assessment with PeerFIT participants to collect data on perceived peer group support specific to the experimental condition. PeerFIT participants will be paid an additional $15 for participating in the telephone interview. See Table 2 for a schedule of assessments and description of the measures included in this trial.

Procedures for Minimizing Dropouts and Optimizing Retention

A systematic protocol will be followed to minimize dropouts. Participants in the interventions will be called or sent a text message reminder before each session. If a participant has an unexpected absence, they will be contacted and helped to overcome any barriers to attendance. Participants will be encouraged to complete assessment visits regardless of their level of participation in the interventions. At baseline, names and contact information of two friends or family members who can be contacted will be obtained for use if we are unable to contact the participant.

Analysis Plan

The analysis of data will address the hypotheses posed in Specific Aims 1 and 2 described below. 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 explore whether the PeerFIT and BEAT groups differed significantly on any demographic characteristics or baseline psychiatric or physical health variables 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 [24]. We will also perform sensitivity analyses to examine stability of treatment effects 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) [25].

Analyses for Study Aims and Hypotheses:

(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).

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 previously evaluated InSHAPE lifestyle intervention and active control [6, 7], these standardized effect sizes are equivalent to difference between arms of 21.6-36.0 lbs, 3.20-5.40 BMI units, and 126-210 m 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 143-245 m over 12 months. True power/detectable difference likely lies in between that stated above for 144 and 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 [7]. 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 [45] 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 for testing the influence of peer social support on weight and fitness outcomes (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). The product of coefficients (coefficient associated with path between treatment and mediator x coefficient associated with the path between the mediator and outcome) will be estimated along with bias-corrected bootstrap confidence intervals to determine the significance of the effect. Part of the mechanism of PeerFIT is through its hypothesized influence on perceived peer group social support, thus we will examine the relationship between the slope of peer support, and the change in outcomes.

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 (proposed mediator). 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 [46]. 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 [47] (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%. The power for the association between the slope of peer support (within the PeerFit arm) and the slope of the outcomes in the parallel process latent growth curve model is based on an individual-level sample size (one slope for each individual per measure). Given this, with 72 participants in the PeerFit arm, there will be power to detect standardized path coefficients of at least 0.32.

Data and safety monitoring board (DSMB)

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.

3. Discussion

To date, randomized clinical trials of lifestyle interventions targeting individuals with SMI have predominately engaged middle-aged samples with very few young adult participants. The Fit Forward randomized controlled trial is designed to test a novel peer group and technology-enhanced approach to weight loss and fitness among overweight and obese young adults ages 18 to 35 years old with SMI receiving public mental health services. Participants will be recruited from demographically distinct areas in the Northeastern US, with efforts made to ensure gender, race, and ethnic variability within the sample. Two different types of lifestyle interventions will be compared – one approach involving highly flexible one-on-one mobile lifestyle coaching with basic education in fitness and nutrition supported by a wearable activity tracking device (BEAT) and the other a peer group coaching model where a lifestyle coach facilitates peer-to-peer support for behavior change (PeerFIT). Both approaches incorporate popular mobile health technologies to enhance lifestyle coaching and support behavior change. We hypothesize that the PeerFIT group-based model with peer social support will be more effective at achieving clinically significant weight loss and improvements in cardiorespiratory fitness at 6 and 12 months follow-up compared to BEAT. The results of this study will inform early intervention for cardiovascular risk among young people with SMI, an area of mental health services currently lacking evidence-based practices.

Young adult populations have been historically difficult to engage in mental health treatment for a variety of reasons, including poor alliance with providers, mistrust of the mental health system, and poor insight into the need for treatment [48]. To be effective, health promotion programs targeting early intervention of young adults in mental health settings will likely need to include strategies tailored to address the inherent difficulties of engaging this population in treatment. Studies have consistently shown that young adults with SMI want to feel empowered by services that prioritize their life goals, support autonomy, and promote social inclusion as part of mental health treatment [49, 48, 50]. The interventions evaluated in the Fit Forward Study were specifically designed to appeal to a subgroup of the Millennial generation (which includes people born from 1980 to 2000) of mental health service users by incorporating popular technologies and flexible text messaging with providers to make their participation in the interventions easier and more convenient. In addition, recruitment strategies tailored to a young adult population are used in this study. For example, Fit Forward Study advertisements emphasize overall lifestyle coaching, self-improvement and fitness, in addition to weight loss, consistent with motivations and preferences for behavioral weight loss programs expressed by this age group [11].

Both interventions in the Fit Forward Trial are designed to be scalable in public mental health settings with the use of smartphone technology to engage participants and enhance outcomes. A recent survey of technology use among individuals with mental illness in community settings indicated that 67% of young adults owned smartphones [51]. While a

digital divide may still exist between lower and higher income Americans [52], there is evidence that mobile phone ownership among individuals with SMI has been significantly increasing over the past decade [53]. Smartphones are increasingly leveraged to deliver and enhance mental health services for individuals with SMI with text messaging and a broad range of mobile applications [54-57]. The Fit Forward Trial is one of the first randomized clinical trials to evaluate the impact of lifestyle interventions that leverage technology to promote weight loss and improved fitness in young adults with SMI in public mental health settings. The results of this study will inform the development and implementation of next generation mental health services equipped with ubiquitous technologies to improve the health and mental health of a young adult population.

The primary aim of the Fit Forward Trial is to evaluate the effectiveness of a peer group support lifestyle intervention for achieving cardiovascular risk reduction among young adults with SMI. Social Learning Theory posits that behaviors are learned through observation, modeling, and imitating other peoples' behaviors [23]. Young adults with serious mental health challenges have reported having fewer close friends, less diverse social networks, less perceived social support, poorer relationship quality with family and friends, and more loneliness than young adults without mental health problems [58]. The PeerFIT intervention is designed to create a peer network where participants can connect with similar others who seek mutual support for health behavior change. Participants randomized to the BEAT comparison condition receive the same wearable activity tracker and weekly text messaging support as participants randomized to PeerFIT; however, they do not get access to peer group lifestyle and exercise sessions or the private Facebook group like participants in PeerFIT. The PeerFIT lifestyle coach facilitates positive social interactions in a dynamic group setting (either in person or online using social media), which is hypothesized to moderate the behavior change process (e.g., learning from others' success and failure motivates change, receiving emotional support from peers encourages healthy changes). The Fit Forward Trial will provide evidence as to whether this approach works for young adults with SMI.

Conclusion

Individuals with SMI face a higher risk of early death due to cardiovascular disease and other preventable chronic illnesses. Young adulthood is a critical window of development for lifestyle interventions to improve the long-term health and quality of life in this population. Fit Forward is an NIH-funded randomized clinical trial examining the effectiveness of a group lifestyle intervention (PeerFIT) enhanced with mobile technology and social media compared to one-on-one mobile lifestyle coaching with Basic Education in fitness and nutrition supported by a wearable Activity Tracking device (BEAT) in achieving clinically significant weight loss and improved cardiorespiratory fitness in young adults with SMI. The trial will provide important information about whether either or both of these novel interventions are effective in addressing obesity-related cardiovascular risk in this young adult population.

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Table 1.

Eligibility criteria for Fit Forward trial

Inclusion Criteria	
Demographics	Male, female, or transgender, 18 to 35 years of age, any race/ethnicity who are English speakers and are active mental health clients at the agency
Mental health diagnosis	Chart-verified diagnosis of Schizophrenia, Schizoaffective Disorder, Major Depression Disorder, Bipolar Disorder, Anxiety Disorder, PTSD, Mood Disorder-NOS, or Psychotic Disorder-NOS
Body mass index	BMI ≥ 25 (kg/m2)
Informed consent	Able and willing to give written informed consent to participate in the study, able to assent with guardian consent, and willing and able to participate in either of the two programs to which the person is randomized
Medical clearance	If screening indicates a cardiovascular disease risk based on the existence of diabetes, angina, heart condition, or history of anorexia nervosa or bulimia nervosa, or self-report on the Physical Activity Readiness Questionnaire (PAR-Q) indicates contraindications to exercise, the participant must be able and willing to obtain a medical clearance letter from a primary care provider prior to enrollment in the study.
Psychiatric medications	Must not have started within the prior two months either of two antipsychotic medications with the highest risk for weight gain: olanzapine or clozapine (dose changes are allowed)
Randomization	Willing to be randomized to either of the two conditions
Exclusion Criteria	
Substance abuse	Self-report of ≥4 (female) or ≥5 (male) drinks/day ≥3 weeks in the past month, ≥2 days/week on average in the last month of non-prescribed illicit drugs (e.g., opiates/cocaine/hallucinogens), ≥4 days/week in past month of marijuana use
Cognitive impairment	Marked cognitive impairment, as determined by a score of less than 24 on Mini Mental Status Exam (MMSE)[21].
Medication use	Use of anabolic steroids at least “most days of the week for the previous month”
Medical contraindications	Self-report of any of the following medical conditions that are contraindicated to participation in standard weight loss treatment: cancer requiring active treatment or cancer within the past 5 years (except for non-melanoma skin cancers), liver failure, history of stroke, walking limitations preventing participation in exercise, 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, less than 6 months postpartum, breastfeeding or breastfed in past 3 months, or planning a pregnancy during study period
Visual and hearing impairments	Hearing or visual impairment that would preclude ability to participate in the groups or read the program materials.
Concurrent weight loss treatment	Concurrent participation in a weight loss, physical activity, or exercise program
Planned change in mental health services and/or relocation	Plans to leave mental health services at a study site or move out of geographic area within the next 12 months

Table 2.

Fit Forward trial measures and schedule

Measure	Construct	Description	Timeline
Anthropometric	Weight (primary outcome), Waist circumference, Height, Body mass index	Measured in lbs. in light indoor clothing without shoes using a calibrated digital scale. Waist circumference measured to the nearest 0.1 cm with an anthropometric tape on a horizontal plane at the iliac crest landmarks. Height measured without shoes with a medical grade stadiometer to the nearest 0.1 cm at entry into the study. Body mass index: will be calculated from measured height and weight (kg)/ height(m)^2.	B, 6, 12
Physical Health	Lipid profile	Assessed with the CLIA-waived CardioChek Plus analyzer. Non-fasting values include total cholesterol, HDL, LDL, triglycerides, and total cholesterol/HDL ratio.	B, 6, 12
	HgA1c	Assessed with the CLIA-waived A1cNow+ device for an immediate HgA1c percent.	B, 6, 12
	Blood pressure	Blood pressure assessed on the right arm of participants after they rest quietly in a seated position for at least 5 minutes, using a validated automated medical grade sphygmomanometer.	B, 6, 12
	Medication use	Self-reported list of prescribed medications taken at the time of the study.	B, 6, 12
	Cardiorespiratory fitness (primary outcome)	Cardiorespiratory fitness will be assessed using the 6-Minute Walk Test (6-MWT) [26]. The 6-MWT assesses cardiovascular endurance by instructing the individual to complete as many laps as possible in 6 minutes on a flat, hard surface. An increase in distance of more than 50 m on the 6-MWT has been associated with clinically significant reductions in risks for cardiovascular disease [27]. This measure has been used to detect clinically significant changes in fitness in prior health promotion trials with people with SMI [6, 7].	B, 6, 12
Mental Health	Psychiatric Diagnosis	Primary medical record diagnosis, verified from a participant's chart.	B
	Depressive Symptoms	The Center for Epidemiologic Studies Depression (CES-D) Scale will be used to assess depressive symptoms [28]. The CES-D is a 20-item self-report measure that asks participants to rate how often over the past week they experienced symptoms associated with depression, such as restless sleep, poor appetite, and feeling lonely. Response options range from 0 to 3 for each item (0 = Rarely or None of the Time, 1 = Some or Little of the Time, 2 = Moderately or Much of the time, 3 = Most or Almost All the Time). Scores range from 0 to 60, with high scores indicating greater depressive symptoms.	B, 6, 12
Physical Activity	Physical activity	We will use the 9-item International Physical Activity Questionnaire (IPAQ) short form self-report measure to assess the number of days per week and the amount of time per day participants' spent in physical activity during the 7 days prior to the interview [29]. Summary scores will be calculated for vigorous activities obtaining an estimate of weekly metabolic equivalent expenditure (MET) minutes of vigorous physical activity. The reliability and validity of the IPAQ for use among persons with serious mental illness is comparable to that in the general population [30].	B, 6, 12
	Sedentary activity	The Sedentary Behavior Questionnaire (SBQ) assesses the number of hours participants spend engaging in nine sedentary behaviors. Response options range from "15 minutes or less" to "6 hours or more." Higher scores on the SBQ indicate more time performing sedentary behaviors. The SBQ has acceptable measurement properties for use among overweight adults [31].	B, 6, 12
Dietary Behaviors	Daily meal patterns	This measure identifies an individual's typical meal pattern and was adapted from the NIH Early Adult Reduction of weight through LifestYle intervention (EARLY) Trials [32]. It determines the number of times a respondent (a) eats breakfast; (b) eats a mid-morning snack; (c) eats lunch; (d) eats a midafternoon snack; (e) eats dinner; (f) eats an evening snack; and (g) eats within an hour of bedtime in a typical week.	B, 6, 12
	Eating away from home	The Eating Away from Home Questionnaire assesses the frequency with which an individual consumed food outside the home (e.g., fast food, restaurant buffets) in the past 30 days [32]. Respondents also	B, 6, 12

Measure	Construct	Description	Timeline
		report the number of days over the past week that they prepared breakfast, lunch, or dinner at home.	
	Sugar sweetened beverage consumption	The Sugar Sweetened Beverages Survey is a self-report measure adapted from the NCI Diet History Questionnaire [33] that assesses the amount of sugar-sweetened beverages, including soda and sports drinks, consumed in a typical week.	B, 6, 12
Self-Weighing Behaviors	Weight self-monitoring	Four items from the Weight History Questionnaire developed for the National Health and Nutrition Examination Survey (NHANES) will be used to assess participants' perception of their weight (e.g., overweight), what they are trying to do about it (e.g., lose weight), their highest weight, and frequency of self-weighing [34].	B, 6, 12
	Weight control strategies	The Weight Control Strategies Scale (WCSS) is a self-report measure used to assess use of specific strategies for losing weight or maintaining weight loss in the past month. The 30-item WCSS contains 4 subscales: Dietary Choices, Self-monitoring Strategies, Physical Activity, and Psychological Coping. The WCSS subscales and total score have good internal consistency reliability in a weight loss treatment seeking sample of overweight and obese individuals [35].	B, 6, 12
Mediators	Exercise self-efficacy	The Exercise Self-efficacy measure assesses participants' confidence in their ability to persist in exercising in various situations [36]. Five items represent the following areas: negative affect, resisting relapse, and making time for exercise. Respondents rate their confidence on a five-point Likert scale. Higher overall scores indicate higher exercise self-efficacy.	B, 6, 12
	Perceived social support	Perceived social support is assessed with the brief, multidimensional 19-item Social Support Survey that assesses four domains of social support: (1) emotional support/informational support, (2) tangible support, (3) positive social interactions, and (4) affectionate support. Higher subscale and total scores indicate higher levels of perceived social support from friends and family members [37].	B, 6, 12
	Peer Group Support (PeerFIT only)	The Group Climate Questionnaire-Short Form (GCQ) is a self-report measure of the group member's perception of the group atmosphere [38]. Participants rate items on a 7-point Likert scale "not at all" to "extremely." The GCQ has three subscales: Engagement, which is composed of items pertaining to self-disclosure, cognitive understanding, and confrontation; Avoidance, with items measuring the extent that group members avoid responsibility for their change processes; and Conflict, which measures interpersonal conflict and distrust. The Social Provisions Scale consists of 10-items across five subscales that measure the participant's perception of social support availability in the PeerFIT group: emotional support or attachment, social integration, reassurance of worth, tangible help, and orientation [39]. The items are rated on 4-point Likert scales from "strongly disagree" to "strongly agree," and higher scores indicate greater perceived support from group relationships. We will measure group cohesion in the PeerFIT intervention with the 25-item Group Cohesion Scale-Revised [40], which assesses participants' perception of group cohesion across domains including interaction and communication, member retention, decision making, vulnerability among group members, and consistency between group and individual goals. Participants rate the extent to which they experience group cohesion on each of the domains from 1= strongly disagree to 4 = strongly agree across, and items are summed with higher subscale scores and total scores indicating more cohesion.	6, 12
Other*** Questionnaires	Demographic data	Client demographics instrument developed by our research group, includes items such as age, race, ethnicity, marital status, education, employment, living situation, and number of times hospitalized for psychiatric conditions.	B
	Tobacco and alcohol use	A series of questions adapted from the Behavioral Risk Factor Surveillance System (BRFSS) will be used to asses tobacco and alcohol use, including frequency and amount of use [41].	B, 6, 12
	Sleep habits	The Pittsburg Sleep Quality Index is a 19-item measure that assesses an individual's quality of sleep over the past month, including sleep latency, duration of sleep, sleep efficiency, frequency of sleep-related problems, use of pharmacological sleep aids, and impaired daytime functioning [42]. Higher scores indicate poorer sleep quality.	B

Measure	Construct	Description	Timeline
	Parental contact	Frequency of contact with parents will be assessed by asking participants to report the type of contact (in person, telephone phone, and/or text message) and amount of contact in the past year with the parent with whom they have had the most contact.	B
	Built Environment	The 17-item Physical Activity Neighborhood Environment Survey (PANES) will be used to asses environmental factors that influence walking and bicycling in participants' neighborhoods [43]. Respondents rate their level of agreement with statements regarding different aspects of the built environment in which they live on a four-point Likert scale (1=Strongly disagree to 4=Strongly agree). Higher scores on the PANES indicate greater environmental support for physical activity.	B
	Technology use	Developed and piloted tested by our research team [44], the Consumer Technology Use Survey includes 39 items that assess the use of mobile phones, smartphones, personal computers, the Internet, and popular social media among persons with serious mental illness.	B
Adherence	Attendance at lifestyle sessions	The PeerFIT and BEAT lifestyle coaches record attendance electronically at each session.	0-6 mo
	Attendance at exercise sessions	The PeerFIT lifestyle coach records attendance electronically at each exercise session.	0-6 mo
	Wearable activity tracker adherence	Measured as the proportion of days the participant wore the Fitbit device during the 12 months of study participation.	0-12 mo
	Facebook group adherence	Number of participants who used the Facebook group and number of interactions (including posts, comments, or "likes") in the Facebook group.	0-12 mo