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Tailored Weight Loss Programs for Adults With Serious Mental Illness
A Randomized Clinical Trial

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IMPORTANCE Veterans with serious mental illness (SMI) experience a higher prevalence of obesity than the general veteran population; weight loss programs are needed that are tailored to this population.

OBJECTIVE To evaluate a weight loss program, CoachToFit (CTF), which includes weekly calls from a Veteran Health Administration peer specialist, a Bluetooth-enabled scale and fitness tracker, and a smartphone application that provides health education and tracks steps, goals, and weight.

DESIGN, SETTING, AND PARTICIPANTS This randomized clinical trial was conducted within the Pittsburgh Veteran Affairs health care system and presents pre-post (6 months) analysis comparing CTF and usual care. Veterans with body mass index (BMI, calculated as weight in kilograms divided by height in meters squared) of 30 or higher and diagnosis of major depressive disorder, bipolar disorder, or schizophrenia were eligible for inclusion. Exclusion criteria included history of bariatric surgery or recent psychiatric hospitalization. The study was conducted from October 1, 2020, to September 30, 2025, and data analysis was conducted from January to October 2025.

EXPOSURE Random assignment to CTF.

MAIN OUTCOMES AND MEASURES The primary outcomes were weight (in kg), BMI, and cardiorespiratory fitness (meters walked in 6 minutes).

RESULTS Among the sample (n = 256), mean (SD) age was 53.5 (13.1) years, 80 participants (31.3%) were female, and 199 (77.7%) were diagnosed with major depressive disorder. Mean (SD) weight loss at 6 months was −3.2 (6.2) kg in the CTF group (n = 128) compared to −1.6 (4.9) kg in the usual care group (P = .05). After adjustment, participants in CTF experienced greater, nonsignificant weight loss compared to usual care, with an adjusted mean difference (AMD) of −1.62 kg (95% CI, −3.38 to 0.14; P = .07). For BMI, the AMD in change between groups at 6 months was −0.56 (95% CI, −1.15 to 0.03; P = .06). Change in meters walked was not statistically significant between groups, with an AMD of 3.53 m (95% CI, −12.87 to 19.92; P = .67). At 6 months, 34 participants (36.6%) from the CTF group lost 5% or more of their body weight compared to 19 (22.4%) in usual care, representing a 1.93-fold greater likelihood in adjusted analyses (95% CI, 0.96-3.91; P = .07). More participants in CTF (n = 21 [22.6%]) lost 7% or more of their body weight compared to usual care (n = 7 [8.2%]), representing a 3.9-fold greater likelihood in adjusted analyses (95% CI, 1.45-10.36; P = .007).

CONCLUSIONS AND RELEVANCE In this randomized clinical trial, a weight loss program tailored to veterans with SMI using remote technologies and paraprofessionals demonstrated the potential to help this population lose weight.

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Visual Abstract

Multimedia

Supplemental content

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Adults with serious mental illness (SMI) (eg, schizophrenia, schizoaffective disorder, bipolar disorder, and major depressive disorder) show higher rates of overweight and obesity than the general population.[1-7] A recent meta-analysis of 120 studies from 43 countries reported that 25% of such individuals are obese and nearly 60% are either overweight or obese.[8] There are multiple contributing factors, including psychiatric medications[9,10]; sedentary behavior, poor diet, and smoking[3,11-13]; poverty and limited health care access; and cognitive impairment and social isolation.[11,14,15] People with SMI have elevated rates of medically related morbidity and mortality and reduced life expectancy by 15 to 25 years, predominately due to cardiovascular disease, which is associated with obesity.[7,16,17] While SMI contributes to poor health, obesity-related illnesses can worsen psychiatric symptoms, reduce treatment adherence, and cause poorer outcomes.[18,19]

Key Points

Question What is the impact on weight, body mass index (BMI, calculated as weight in kilograms divided by height in meters squared), and fitness of a 6-month weight loss program tailored for obese veterans with serious mental illness (SMI)?

Findings In this randomized clinical trial involving 256 veterans, compared to usual care, program participants reduced their weight and BMI, but not cardiorespiratory fitness, at 6 months. Weight loss of 7% of body weight or greater (22.6% vs 8.2%) was significant; mean weight loss (7.1 vs 3.5 lb), BMI (1.1 vs 0.5), and 5% or greater weight loss (36.6% vs 22.4%) were nonsignificant but clinically meaningful.

Meaning Weight loss programs tailored to those with SMI could reduce obesity common to this population.

Several lifestyle interventions for this population have been evaluated. These interventions typically span 6 to 12 months and often involve weekly sessions led by highly trained staff. Key components include self-monitoring, setting goals, nutritional education (eg, reducing portions, eliminating calorie-rich foods and beverages), and promoting physical activity (eg, intervention-sponsored exercise sessions). To meet cognitive needs, programs use simplified messages, repeated instruction, peer support, skills training, and environmental modifications.[20-22] One example is Steps To Reach Individual Diet and Exercise Solutions (STRIDE), in which mental health counselors and nutritional interventionists offered weekly, 2-hour group meetings over 6 months, with 20 minutes of daily physical activity. Participants set goals, reviewed materials, and kept food diaries. At 6 months, STRIDE participants lost about 10 pounds more than control participants and 6 pounds more at 12 months.[23] Another similar intervention documented a 7-pound-greater weight loss at 18 months.[20] Multiple meta-analyses on these types of interventions have documented small improvements in weight loss.[24-26]

Among US veterans, the Veterans Health Administration (VHA) offers the MOVE! program, which primarily involves hospital attendance at groups taught by health professionals (some individual sessions are available), food diaries, regular weighing, and pedometers for exercise tracking. Although MOVE! helps users,[27] few overweight veterans with or without SMI participate.[28] Individuals with SMI are often reluctant to join groups and experience transportation issues[29,30] and can have cognitive impairments that make MOVE!'s components—eg, calorie tracking, extensive handouts, and meal diaries—difficult to manage. MOVE! recently released a smartphone application (app); however, it is untested and does not capture data for use in coaching.

A feasibility and dissemination limitation with traditional lifestyle interventions for individuals with SMI is that they are staff intensive and require sustained participation in multiple group sessions. One promising solution is using paraprofessionals and remote technologies (ie, wrist-worn fitness trackers). Evidence suggests that interventions using such technology are more effective and better followed when combined with human support, particularly from peers.[31,32] One such paraprofessional is the peer specialist, those with SMI who are trained to use their experience to help others with SMI.[33] VHA employs 1350 peer specialists across multiple settings, including mental health, homelessness, substance abuse, and primary care. Two VHA randomized clinical trials have evaluated their use for weight loss among those with SMI. One 12-month group intervention (but with no remote technology use) found no significant differences in weight loss or cardiovascular fitness.[34] Another compared an online weight management program with peer coaching (WebMOVE) to in-person clinician-led services and usual care within VHA. A subsample who completed at least 1 WebMOVE module saw significant body mass index (BMI) and weight reductions at 6 months; other groups did not.[35]

This article reports on a randomized clinical trial of Coach-ToFit (CTF), a 6-month intervention for veterans with SMI and obesity that includes weekly calls from a VHA peer specialist, a Bluetooth-enabled scale and fitness tracker, and a smartphone app that provides health education and tracks steps, goals, and weight. To our knowledge, it is the first trial to test the use of peer specialists and remote technologies for weight loss among those with SMI. While somewhat similar to WebMOVE in duration, content, and use of peer specialist coaches, CTF has the following features that WebMOVE does not: (1) the intervention is delivered via the app, not a website, which, because users carry their phones with them, makes it much easier to read the educational modules and track their steps and weight; (2) data collected about weight, steps, modules completed, and goals achieved are sent to a dashboard monitored by peer specialists to use in coaching; and (3) the CTF dashboard has a call survey to guide discussions.

Methods

Study Design

CTF was a single-site, parallel 2-arm (balanced 1:1) randomized clinical trial implemented at the Pittsburgh Veterans Affairs hospital. The study was conducted from October 1, 2020, to September 30, 2025, and data analysis was conducted from January to October 2025. We included adult veterans (aged ≥18

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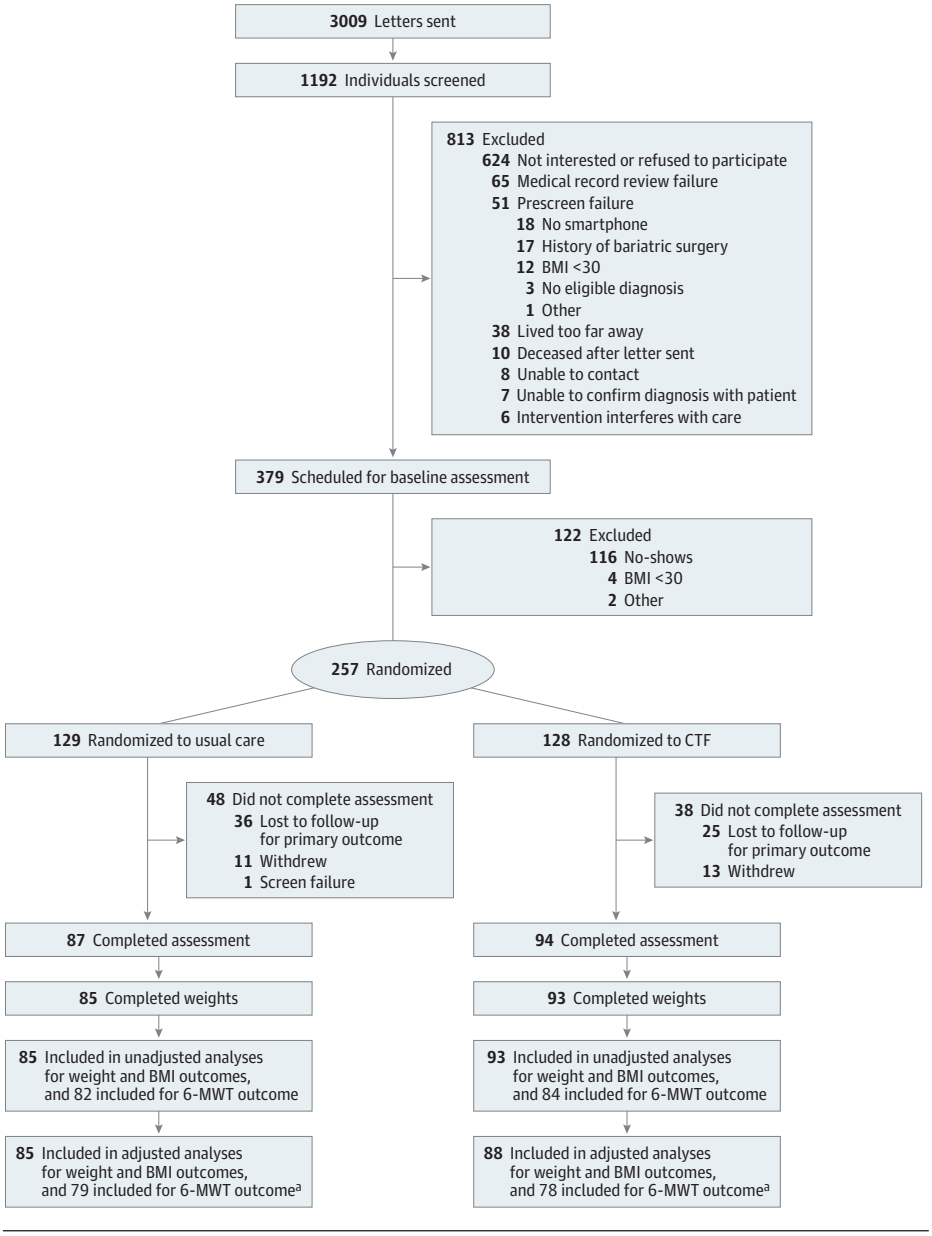
Figure 1. CONSORT Diagram



6-MWT indicates 6-minute walk test; BMI, body mass index (calculated as weight in kilograms divided by height in meters squared); CTF, CoachToFit.

[a]Adjusted analyses included measurements at baseline, age at baseline, birth sex, race, weight-gaining medications, physical activity, and psychosis.

years) with an electronic medical record diagnosis of schizophrenia, schizoaffective disorder, bipolar disorder, or major depressive disorder with or without psychosis (see eTable 1 in Supplement 2 for the *International Statistical Classification of Diseases and Related Health Problems, Tenth Revision* [*ICD-10*] codes used) and with a BMI (calculated as weight in kilograms divided by height in meters squared) of 30.0 or higher (obese) who owned a phone running Android OS or iOS (iPhone). Study exclusion criteria included being pregnant or nursing, inpatient psychiatric hospitalization within the past 30 days, history of bariatric surgery, medical record diagnosis of dementia, or having a conservator or legally authorized representative make their medical decisions. All procedures were reviewed, approved, and monitored by the institutional review board at the Pittsburgh VA. The study protocol is available in Supplement 1. This study followed the Consolidated Standards of Reporting Trials (CONSORT) reporting guideline; the CONSORT flow diagram is provided in **Figure 1**.

Setting, Recruitment, Screening, and Randomization

The VA Pittsburgh health care system provides a full range of medical and mental health services. Data collection started on December 21, 2021, and ended on January 16, 2025. The trial is currently finishing the 12-month data collection and will report on those findings in a separate article. Using the VHA electronic medical record and the VHA Corporate Data Warehouse (CDW), we identified potential participants based on inclusion criteria. Staff mailed recruitment letters and tele-

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phoned potential participants to answer questions and conducted a brief eligibility screening. Potential participants were scheduled for an in-person session where eligibility criteria were reviewed, including participant height and weight.

Written consent was obtained before study procedures were conducted. After research assistants collected baseline measures, participants were randomly assigned to either CTF or usual care using DACIMA software (Dacima Software Inc), a web-based interface for clinical trial data collection and reporting. Randomization was allocated by block (n = 4, 2 usual care and 2 CTF). After randomization, an automatic email was sent to the peer specialists to notify the veteran about their group assignment. Participants received a small stipend for each assessment completed.

Intervention

In CTF, participants had weekly calls with a VHA peer specialist. Each week, veterans were asked to set a health goal, review educational materials, eat healthy foods, and engage in increasing amounts of physical activity (ie, walking). Veterans were given a Bluetooth-enabled fitness tracker and scale, and the CTF app was put on their smartphone. Available for Android and iPhone, the app was developed based on evidence regarding the following e-health design elements that accommodate the cognitive deficits in this population: a shallow hierarchy (only 1 or 2 levels past the initial screen); plain colors, icons, and graphics; explicit navigational aids; simple presentation of choices (1 column of buttons per page); and limited text.[36-40] The app (eFigure 1 in Supplement 2) was developed with extensive user input and testing to meet these design elements. The CTF app has 22 modules providing education on nutrition (n = 12) and exercise (n = 10) that veterans are asked to view on their phone over 6 months, plus 8 review modules (see eTable 2 in Supplement 2). Modules take about 15 minutes to complete, have embedded knowledge quizzes, and end with a choice of 3 goals to practice the following week. After randomization to CTF, research staff held an in-person session with veterans to help them download the app and orient them to its use. Both the peer specialists and the research staff were available in person and by phone to troubleshoot problems during veterans' participation.

The Bluetooth-enabled fitness tracker and scale collected data on weight, steps, goal completion, and modules read, and these data were automatically time stamped and uploaded to a secure server. These data were visualized in real time on the app for participants and on the CTF dashboard for peer coaching (**Figure 2**). Each week, the dashboard guided the peer specialist coach through a structured call survey to ensure consistent topic coverage. During these calls, peer specialists reinforced the module lessons, used motivational strategies to support diet and activity changes, and helped veterans overcome barriers to goals. The dashboard also allows for panel management (eFigure 2 in Supplement 2), identifying upcoming calls and veteran learning progress and last activity. After 6 months, participants could keep using the tracker, scale, and app but no longer received peer specialist calls. Those assigned to usual care were free to pursue weight loss services as they saw fit.[41]

Two peer specialists delivered the intervention, each serving a maximum caseload of 21 veterans at any one time. Prior to the intervention start, the peer specialists progressed through the intervention themselves (watched all the modules, set goals, tracked their weight and steps) and received weekly supervision from a clinical psychologist during the entire intervention period. Additionally, the peer specialists received the CTF Peer Coach Manual, which explains all aspects of the intervention, including using the dashboard, the weekly coaching calls, assisting veterans to set goals, use of motivational interviewing techniques, and how to use the scale and fitness tracker.

Assessment, Data Collection, and Measurement

Outcome Measures

Staff collected assessment data at baseline and then 6 (post-) and 12 months after the baseline appointment. Measurements of weight and height were obtained for all participants. Both 5%[42,43] and 7%[44,45] weight loss are associated with measurable health benefits. Cardiorespiratory fitness was assessed using the 6-minute walk test (6-MWT),[46] which measures the distance in meters an individual can walk in 6 minutes. In adults with obesity, the 6-MWT is a reliable and valid measure of fitness, with favorable test-retest and discriminant validity,[47] and has been used in adults with a variety of chronic health conditions. An increase in distance of more than 50 m is associated with clinically significant reduction in risk for cardiovascular disease.[48,49] It was hypothesized that by 6 months, those in CTF would improve their weight, BMI, and distance walked more than usual care participants and a greater proportion of those in CTF would lose 5% or more and 7% or more body weight than those in usual care.

Covariates and Intervention Participation

Covariates included factors based on prior literature indicating their potential association with the outcomes of interest, including baseline measures of the outcomes,[50-52] age,[50,51,53] sex,[53] race (White vs non-White),[50] use of weight gain–related medications,[54-57] and self-reported physical activity level.[50,53] We used the binary (White vs non-White) version of race to improve model precision because the subgroup sizes for the other racial categories were too small for reliable estimation, especially since the inclusion of this covariate aims to address general demographic imbalance rather than make detailed comparisons among racial groups. At all time points, participants were asked questions on a self-report survey developed by VHA for weight loss classes about sex, race, ethnicity, presence of 12 possible behavioral health diagnoses (eg, schizophrenia, bipolar disorder, substance abuse or dependence), and the number of minutes of moderate physical activity performed in the past week.[58] Age at baseline was calculated from the CDW using date of birth. Prescribed medications known to cause clinically important weight gain[59,60] were obtained from the medical record using both the generic and brand names, and this was treated as a dichotomous variable (eg, prescribed and adherent to weight gain–promoting medication vs not prescribed or prescribed but not adherent). Using stan-

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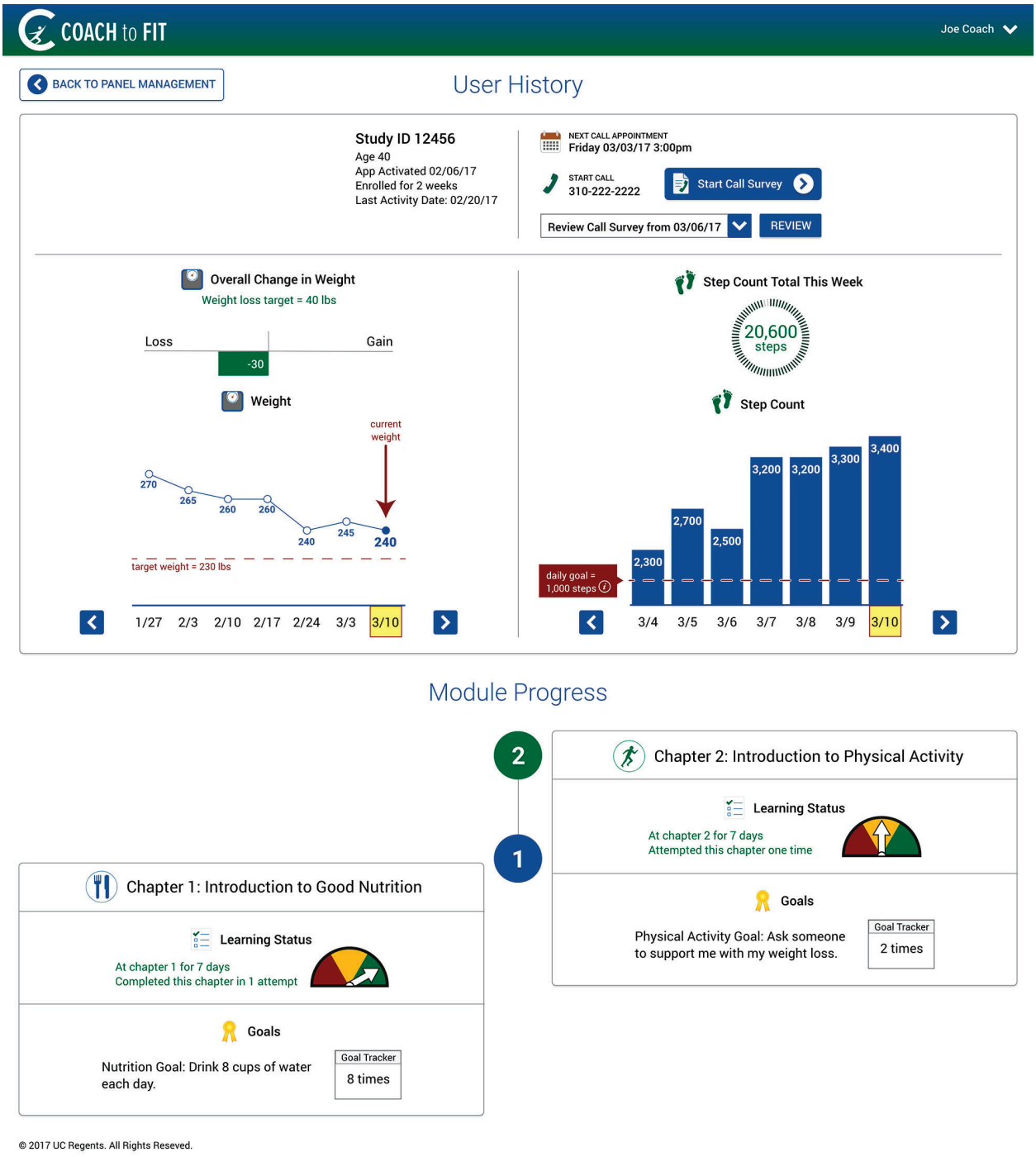
Figure 2. CoachToFit Dashboard



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dardized procedures, medication adherence was calculated by dividing the number of days' supply on hand from a released medication by the number of days' supply that were available from filled medications.[61] If a medication was on hand 80% or more out of the total number of days that the medication was filled, the adherence criteria were met. If patients were taking multiple weight-gaining medications, they were classified as adherent if adherence was met on any of the weight gain medications. Presence of a psychotic disorder (ie, documentation of any disorder with psychosis as a symptom 3 years prior to baseline) was also adjusted for due to unpublished analyses conducted by our group and others[14,62] indicating that those with psychosis face greater weight loss barriers. In the CTF group, data were collected on the number of educational modules completed, times a weight was recorded, and the number of calls with peer specialists.

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Sample Size

Based on a planned sample size of 256 and anticipating a 21% attrition rate (n = 202, 101 per group), the study originally estimated power at 0.77 to detect an effect size of Cohen *d* = 0.38 at 6 months (2-sided type I error rate, α = .05). However, the actual attrition rate was higher than expected (29%). At 6 months, 181 participants completed at least 1 outcome, including 178 with weight data. Adjusted models included 173 participants (88 CTF, 85 usual care), as 5 were missing baseline physical activity. Conservatively, power was recalculated using the smaller group with weight data (n = 85 per group, total n = 170), yielding an estimated power of 0.69.

Statistical Analysis

The intent-to-treat primary analyses evaluating the intervention effect at 6 months were analysis of covariance (ANCOVA) models applied to weight, 6-MWT, and BMI at 6 months, adjusting for baseline measures of the outcomes and covariates mentioned previously. Given that baseline values were balanced and highly correlated with follow-up measures, the adjusted group difference can be interpreted as the estimated difference in change from baseline.[63] Results from ANCOVA and change score analyses, each adjusting for the same covariates, were compared and yielded nearly identical estimates of the intervention effect. For the dichotomized 5% or more and 7% or more weight loss outcomes and the 50-m increase in 6-MWT, Pearson χ^2 tests were used to compare the proportions between groups, and logistic regression models were applied, adjusting for the same baseline covariates as mentioned previously.

As the analysis included only 2 time points, complete case ANCOVA models were applied for continuous outcomes, and logistic regression models for dichotomized outcomes. Baseline characteristics were compared between completers and noncompleters. Statistical significance was defined as $P < .05$, and analyses were conducted using SAS version 9.4 (SAS Institute).

Results

Participants

Study Retention, Baseline Characteristics, and Intervention Attendance

The study recruited 256 participants (Figure 1), 181 (71%) of whom completed data collection at 6 months. Among 256 participants, mean (SD) age was 53.5 (13.1) years, 80 participants (31.3%) were female, and 199 (77.7%) were diagnosed with major depressive disorder. One additional participant was randomized but was deemed ineligible postrandomization and excluded from the analysis. There was no differential attrition between study groups (CTF, 93 of 128 [73%] vs usual care, 85 of 128 [66%]; $\chi^2 = 0.92$; $P = .34$). The sample was mostly older (mean [SD] age, 53.5 [13] years), male (176 [68.8%]), had a diagnosis of major depressive disorder (199 [77.7%]), and was taking a medication that promotes weight gain (162 [63.3%]). Most participants (178 [69.5%]) were White, with 1 (0.4%) Asian participant, 60 Black or African American participants (23.4%), 11 participants (4.3%) with multiple race, and 6 participants (2.3%) of unknown race or who did not wish to provide this information. Six months prior to baseline, use of glucagon-like peptide-1 (GLP-1) receptor agonist medication was low overall and the same in each group (13%), as was use of MOVE! (CTF, 16%; usual care, 11%) (**Table 1**). Among participants randomized to CTF who completed 6-month follow-up with recorded weights (n = 93), the mean (SD) and median (IQR) number of chapters completed were 24.8 (9.55) and 30 (29-30) chapters, respectively. More than half (58%) completed all 30 modules; 78% completed three-quarters of the modules; 84% completed half or more of the modules; and 5% completed none of the modules. The median (IQR) number of calls with the peer specialists was 25 (24-27). CTF participants stepped on their scale a mean (SD) of 45.8 (40.4) times over 6 months. All participants were monitored for study-related adverse events; none were documented.

Primary Outcomes

Table 2 presents the means and SDs of weight, 6-MWT distance, and BMI at baseline, 6 months, and the change from baseline by study group. Analytic sample sizes varied by outcome and model. For weight and BMI, unadjusted analyses included 178 participants (93 CTF, 85 usual care), while adjusted models included 173 participants (88 CTF, 85 usual care) due to 5 participants missing baseline physical activity values. For the 6-MWT, unadjusted analyses included 166 participants (84 CTF, 82 usual care), and adjusted models included 157 participants (78 CTF, 79 usual care). At 6 months, mean (SD) weight loss was −3.2 (6.2) kg in the CTF group compared to −1.6 (4.9) kg in the usual care group ($P = .05$). In the adjusted model, participants in the CTF group experienced greater weight loss compared to the usual care group, with an adjusted mean difference of −1.62 kg (95% CI, −3.38 to 0.14; $P = .07$). Although not statistically significant, the CTF group also showed a greater improvement in 6-MWT, with an adjusted mean difference of 3.53 m (95% CI, −12.87 to 19.92; $P = .67$). For BMI, the adjusted mean difference in change between groups at 6 months was −0.56 (95% CI, −1.15 to 0.03; $P = .06$).

Table 3 presents the results of dichotomized outcomes at 6 months (5% or 7% weight loss, 50-m increase in distance walked) overall and by study group. In unadjusted analyses, the proportion of participants who achieved 5% or more weight loss at 6 months was significantly higher in the CTF group (36.6%) compared to the usual care group (22.4%) ($P = .04$). Also, a significantly greater proportion of the CTF group (22.6%) lost 7% or more of their baseline weight than the usual care group (8.2%) ($P = .009$). Regarding distance walked, 37 participants (22.8%) improved their 6-MWT distance by 50 m or greater, although the difference between groups was not statistically significant ($P = .25$). In adjusted logistic regression models, participants in the CTF group were 1.93-fold more likely to achieve 5% or greater weight loss than those in the usual care group (odds ratio [OR], 1.93; 95% CI, 0.96-3.91; $P = .07$) and 3.9-fold more likely to achieve 7% or greater weight loss (OR, 3.87; 95% CI, 1.45-10.36; $P = .007$). For improvement in 6-MWT by 50 m or more, participants in the CTF group were 1.35-fold more likely to improve compared to those in the usual care group, although this was not statistically significant (OR, 1.35; 95% CI, 0.59-3.11; $P = .48$).

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Table 1. Baseline Demographics and Characteristics for the Full Trial Population

Variable	No. (%)		
	Full sample (N = 256)	CoachToFit (n = 128)	Usual care (n = 128)
Age, mean (SD), y	53.5 (13.0)	53.2 (13.2)	53.8 (12.9)
Birth sex			
Female	80 (31.3)	42 (32.8)	38 (29.7)
Male	176 (68.8)	86 (67.2)	90 (70.3)
Race[a]			
Asian	1 (0.4)	1 (0.8)	0
Black or African American	60 (23.4)	33 (25.8)	27 (21.1)
White	178 (69.5)	83 (64.8)	95 (74.2)
Multiple	11 (4.3)	8 (6.3)	3 (2.3)
Unknown or did not wish to provide	6 (2.3)	3 (2.3)	3 (2.3)
Ethnicity[a]			
Hispanic	6 (2.3)	2 (1.6)	4 (3.1)
Non-Hispanic	244 (95.3)	123 (96.1)	121 (94.5)
Unknown	6 (2.3)	3 (2.3)	3 (2.3)
Diagnosis[b]			
Schizophrenia disorder, any type	6 (2.3)	2 (1.6)	4 (3.1)
Schizoaffective disorder, any type	6 (2.3)	1 (0.8)	5 (3.9)
Bipolar disorder, any type	45 (17.6)	24 (18.8)	21 (16.4)
Major depressive disorder without psychosis	199 (77.7)	101 (78.9)	98 (76.6)
Psychosis[c]	25 (9.8)	8 (6.3)	17 (13.3)
Self-reported substance abuse or dependence	17 (6.6)	7 (5.4)	10 (7.8)
Taking weight gain-associated medication	162 (63.3)	78 (60.9)	84 (65.6)
Physical activity			
None (0 min)	40 (16.1)	15 (12.4)	25 (19.5)
Low (10, 20, or 30 min)	124 (49.8)	66 (54.6)	58 (45.3)
Medium (40, 50, or 60 min)	60 (24.1)	28 (23.1)	32 (25)
High (90, 120, or ≥150 min)	25 (10)	12 (9.9)	13 (10.2)
Physical activity, dichotomized			
None or low (0, 10, 20, or 30 min)	164 (65.9)	81 (66.9)	83 (64.8)
Medium or high (40, 50, 60, 90, 120, or ≥150 min)	85 (34.1)	40 (33.1)	45 (35.2)
Use of weight loss treatment in the prior 6 mo			
GLP-1 medication	33 (12.9)	16 (12.5)	17 (13.3)
MOVE! weight management program	34 (13.3)	20 (15.6)	14 (10.9)

Abbreviation: GLP-1, glucagon-like peptide-1 receptor agonist.

[a] Self-reported.

[b] Diagnosis was documented in the VA medical record or an eligible diagnosis on their active health conditions list at 2 separate visits (including inpatient, outpatient, and emergency department) within 2 years of the period of recruitment.

[c] Psychosis was determined by the presence of any eligible diagnosis associated with psychosis at any of their appointments within 3 years from baseline assessment (see eTable 1 in Supplement 2 for a list of *International Statistical Classification of Diseases and Related Health Problems, Tenth Revision [ICD-10]* codes used to identify a participant as having a history of psychosis).

Discussion

Individuals with SMI are more likely to be sedentary, overweight, and face challenges reversing these trends. Multiple trials show in-person weight management interventions adapted for cognitive deficits have reduced weight[20,64-66]; however, like MOVE!, their impact is limited by low engagement, poor retention, and significant time requirements of highly trained staff, making scaling difficult. CTF addresses these challenges as the first weight loss program tailored to cognitive deficits in SMI, using remote technology (fitness tracker, Bluetooth scale, phone app, coach dashboard, and phone calls) and paraprofessionals (ie, VHA peer specialists) as coaches, thus improving participation and scalability. Over the 6-month intervention, veterans assigned to CTF lost, on average, double the weight as those in usual care (3.2 vs 1.6 kg). Over one-third of CTF-assigned veterans lost 5% of their body weight, and nearly one-quarter lost 7% body weight, compared to 22% and 8% in the usual care group, respectively. Meters walked in 6 minutes did not significantly improve, likely because more intensive exercise, beyond the scope of CTF, is needed to do so. However, multiple guidelines and studies show that engaging in even moderate exercise after being sedentary—the focus of CTF—conveys multiple health benefits.[67-70] Given there are 1350 peer specialists employed by VHA, that CTF is fully remote, and that CTF also works on VHA-issued iPads, this intervention could be a good option.

Compared to WebMOVE's subsample of confirmed intervention participators,[35] the intent-to-treat CTF group had slightly greater average weight loss at 6 months (3.2 vs 2.8 kg) and the same percentage achieving 5% weight loss (36.6%). Mean (SD) modules completed (out of 30) was greater for CTF (24.8 [9.55]) than WebMOVE (14.7 [12.2]). The STRIDE trial, which involved significantly more staff expertise and time and required greater time from participants, demonstrated some-

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Table 2. Mean and Adjusted Mean Outcome Measures by Study Group at Baseline and 6 Months[a]

Outcome	Mean (SD)		Adjusted mean difference (95% CI)[b]	*P* value		Effect size (Cohen *d*)
	CoachToFit	Usual care		Unadjusted[c]	Adjusted[d]	
Weight, kg						
Baseline	110.8 (21.2)	114.4 (20.8)	NA	.17	NA	0.28
6 mo	107.6 (21.1)	111.9 (19.7)		.15		
Change from baseline	−3.2 (6.2)	−1.6 (4.9)	−1.62 (−3.38 to 0.14)	.05	.07	
6-MWT, m						
Baseline	401.5 (96.7)	391.7 (96.2)	NA	.42	NA	0.07
6 mo	415.2 (103)	401.2 (104.6)		.39		
Change from baseline[e]	18.3 (45.9)	13.1 (53.5)	3.53 (−12.87 to 19.92)	.51	.67	
BMI						
Baseline	36.4 (5.4)	37.0 (5.4)	NA	.25	NA	0.28
6 mo	35.3 (5.5)	36.5 (5.2)		.15		
Change from baseline	−1.1 (2.1)	−0.5 (1.6)	−0.56 (−1.15 to 0.03)	.04	.06	

Abbreviations: 6-MWT, 6-minute walk test; BMI, body mass index (calculated as weight in kilograms divided by height in meters squared); NA, not applicable.

[a] Analytic sample sizes varied by outcome and model. For weight and BMI, unadjusted analyses included 178 participants (93 CoachToFit, 85 usual care), while adjusted models included 173 participants (88 CoachToFit, 85 usual care) due to 5 participants missing baseline physical activity values. For the 6-MWT, unadjusted analyses included 166 participants (84 CoachToFit, 82 usual care), and adjusted models included 157 participants (78 CoachToFit, 79 usual care).

[b] Adjusted for baseline outcome measures, age, sex, race, use of weight gain–related medications, presence of psychosis disorder, and physical activity level.

[c] Obtained from 2-sided 2-sample *t* tests.

[d] Obtained from the adjusted models.

[e] In the adjusted model, younger age and lower baseline 6-MWT performance were significantly associated with greater improvement at 6 months.

Table 3. Baseline to 6 Months Change in Binary Outcome by Study Group

Outcome variable	No. (%)			Odds ratio (95% CI)[a]	*P* value	
	Full study cohort	CoachToFit	Usual care		Unadjusted[b]	Adjusted[c]
Weight loss (n = 173)						
≥5%[d]	53 (29.8)	34 (36.6)	19 (22.4)	1.93 (0.96-3.91)	.04	.07
≥7%	28 (15.7)	21 (22.6)	7 (8.2)	3.87 (1.45-10.36)	.009	.007
Increase in 6-MWT (n = 157)						
≥50 m[e]	37 (22.8)	22 (26.5)	15 (19.0)	1.35 (0.59-3.11)	.25	.48

Abbreviation: 6-MWT, 6-minute walk test.

[a] Logistic regression models adjusting for continuous baseline outcome measures, age, sex, race, use of weight gain–related medications, presence of psychosis disorder, and physical activity level.

[b] Obtained from Pearson χ^2 tests.

[c] Obtained from the logistic regression models.

[d] Baseline weight was significantly associated with weight reduction.

[e] Younger age was significantly associated with increase in 6-MWT.

what greater weight loss (4.4 kg), yet a similar percentage of participants achieving 5% weight loss (40%). The mean (SD) number of STRIDE sessions attended was 14.5 (7.2) of 24.[23]

Limitations

There are limitations that should be noted. The study was conducted at 1 VHA site and most participants had major depression; thus, future research should assess the generalizability to other populations beyond veterans (ie, older, male) with depression. Although somewhat underpowered (0.69 based on the final sample size), CTF still demonstrated a statistically borderline but clinically meaningful reduction in weight at 6 months, and significantly more veterans assigned to CTF lost 7% of their body weight at 6 months, a key marker of measurable health benefits. The relatively wide 95% confidence intervals reflect greater than expected variability in the effect estimate. The observed effect size of approximately 0.28, while smaller than the originally planned effect size of 0.38, nonetheless indicates a meaningful benefit, particularly in the context of behavioral weight loss interventions. Completion at 6 months was comparable across groups (73% CTF, 66% usual care), yielding an overall attrition rate of 29%, consistent with prior psychosocial interventions for this population.[71,72] The only difference observed was age, with noncompleters being modestly younger. Age was adjusted for in all primary analyses and was not associated with weight or BMI change. The intervention effect on 6-MWT was nonsignificant, suggesting attrition is unlikely to have biased results. Nonetheless, residual confounding due to unmeasured factors cannot be entirely ruled out as a study limitation. Study data collectors were not able to be blinded; however, all the data collection was through fixed-choice survey and objective measures, minimizing this limitation. Finally, the study did not report on the durability of these outcomes, which is planned in a future report.

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Conclusions

Overall, according to the results of this randomized clinical trial, the CTF program offers a scalable, remote, and cognitively accessible weight loss intervention for veterans with SMI. Despite limitations in sample size and generalizability, the initial outcomes are promising and warrant further study in broader populations and over longer durations.

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