


Implementing an evidence-based behavioral weight-loss program in community mental health centers: A randomized pilot study

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Abstract

Background: Obesity is a leading cause of preventable death among individuals with serious mental illness (SMI). A prior randomized controlled trial demonstrated the efficacy of a lifestyle style intervention tailored to this population; however, such interventions need to be adapted and tested for real-world settings.

Aims: This study evaluated implementation interventions to support community mental health program staff to deliver an evidence-based lifestyle intervention to clients with obesity and SMI.

Materials & Methods: In this cluster-randomized pilot trial, the standard arm combined multimodal training with organizational strategy meetings and the enhanced arm included all standard strategies plus performance coaching. Staff-coaches delivered a 6-month group-based lifestyle intervention to clients with SMI. Primary outcomes were changes in staff knowledge, self-efficacy, and fidelity scores for lifestyle intervention delivery. Linear mixed-effects modeling was used to analyze outcomes, addressing within-site clustering and within-participant longitudinal correlation of outcomes.

Results: Three sites were in the standard arm (7 staff-coaches); 5 sites in the enhanced arm (11 staff-coaches). All sites delivered all 26 modules of the lifestyle intervention. Staff-coaches highly rated the training strategy's acceptability, feasibility and appropriateness. Overall, mean knowledge score significantly increased pre-post by 5.5 (95% CI: 3.9, 7.1) and self-efficacy was unchanged; neither significantly differed between arms. Fidelity ratings remained stable over time and did not differ between arms. Clients with SMI achieved a mean 6-month weight loss of 3.8 kg (95% CI: 1.6, 6.1).

Conclusions: Mental health staff delivering a lifestyle intervention was feasible using multicomponent implementation interventions, and preliminary results show weight reduction among clients with SMI. The addition of performance coaching did

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not significantly change outcomes. Future studies are needed to definitively determine the effect on client health outcomes.

KEYWORDS

community mental health services, implementation science, mental disorders, weight reduction programs

1 | INTRODUCTION

Obesity is a leading cause of preventable death among individuals with serious mental illness (SMI)—directly through its effects on cardiovascular disease and indirectly by contributing to its risk factors.^{1–4} Inequities in the prevalence of obesity exist for this population.^{5,6} In general populations, behavioral weight-loss interventions reduce weight and improve cardiometabolic outcomes.⁷ However, these interventions need to be tailored to the particular needs of people with SMI.^{8,9} A systematic review found that effective behavioral weight-loss interventions in this population include: regular contact, tools to support behavior change, and tailored materials.¹⁰ There is a critical need to implement and disseminate effective behavioral weight-loss interventions among persons with SMI to improve cardiovascular health.¹¹ The Achieving Healthy Lifestyles in Psychiatric Rehabilitation (ACHIEVE) randomized controlled trial (RCT) demonstrated that a behavioral weight-loss intervention tailored for individuals with SMI produces clinically and statistically significant weight loss.¹² The 18-month ACHIEVE intervention included group and individual weight-management sessions and group exercise sessions, which were delivered in psychiatric rehabilitation programs (PRPs) by trained interventionists.¹³

The Enhanced Replicating Effective Programs (REP) Framework^{14,15} was used to translate the ACHIEVE evidence-based practice for real-world application through training and supporting mental health center staff to deliver the sessions.¹⁶ This model has four stages: pre-conditions, pre-implementation, implementation, and maintenance. The pre-conditions phase translated the ACHIEVE intervention into the ACHIEVE-Dissemination (ACHIEVE-D) program.^{17,18} In brief, ACHIEVE-D is an adapted 6-month curriculum designed for delivery by mental health center staff, which has weekly, 45-min multi-purpose group sessions structured to include behavioral weight-management lessons and group exercise (26 modules over 6 months) as compared to the 18-month ACHIEVE intervention that included both individual and group sessions delivered by a trained interventionist. A non-randomized proof-of-concept study was previously conducted at a single PRP in Maryland to determine the acceptability of ACHIEVE-D—study staff delivered the adapted curriculum to clients with SMI, which was observed by mental health center staff.¹⁷ Individuals with SMI and program staff were satisfied with the ACHIEVE-D curriculum. In this prior study, no mental health staff facilitated group sessions and no

implementation interventions were tested. The next step in the REP Framework is the pre-implementation phase, where implementation strategies are pilot tested for community mental health center settings.

In this study, a pilot RCT was conducted comparing standard and enhanced implementation interventions to facilitate community mental health program staff serving as coaches delivering the ACHIEVE-D weight management program. The approach leveraged novel training and feedback strategies to address staff logistics and time constraints.¹⁷ Both standard and enhanced implementation interventions included multimodal staff training and organizational strategy meetings. Staff coaches in the enhanced arm also received performance coaching. This study represents the REP pre-implementation stage, and the primary outcomes were weight-management knowledge, self-efficacy, and delivery fidelity to the ACHIEVE-D program among staff-coaches. The rationale for selection of these outcomes is described in the Methods below. Both implementation interventions were hypothesized to increase knowledge, self-efficacy, and fidelity for ACHIEVE-D delivery. Whether performance coaching improved outcomes relative to the standard arm was also examined as a secondary outcome. This pilot RCT was not powered to evaluate both implementation and clinical outcomes—it is not a Type 2 hybrid effectiveness-implementation trial. The study preliminarily explores lifestyle behaviors and weight outcomes among participating clients with SMI. Results from this pilot RCT will determine protocol feasibility and provide parameter estimates for designing a future confirmatory trial.

2 | MATERIALS AND METHODS

2.1 | Study design

A cluster-randomized, parallel-arm pilot RCT was conducted comparing standard and enhanced implementation interventions at 6 months within community mental health programs (NCT03454997; <https://clinicaltrials.gov/ct2/show/NCT03454997>). The sites were adult psychiatric rehabilitation day programs (PRP) within Maryland that provided at least 2 staff to be trained as coaches to deliver the ACHIEVE-D program and could recruit clients with SMI to participate. The Johns Hopkins University School of Medicine Institutional Review Board approved this study (IRB00247344). The full protocol for this study has been published previously.¹⁸

2.2 | Study participants

Site leadership identified potential staff to serve as coaches, and the research team approached these individuals to discuss the study and obtain consent via waiver of documentation. To participate, staff had to be willing to complete all training activities, deliver all components of the ACHIEVE-D program, and complete data collection procedures.

Staff at each site identified potential clients with SMI to participate, and the research team approached these individuals to discuss the study, complete screening, and obtain waiver of documentation of consent. To participate, clients had to be age ≥ 18 years, have BMI ≥ 25 kg/m² (i.e., overweight or greater), as well as be willing to make lifestyle changes to lose weight and participate in the ACHIEVE-D group at least once a week.

2.3 | Randomization & blinding

The following recruitment and baseline data collection, sites were randomized to the standard or enhanced arm. The randomization sequence was generated in a block size of two using a computer software. Due to the nature of the intervention, staff-coaches and some research team members were aware of the assignment. Individuals with SMI were unaware of the assignment, as were study team members who rated the video-recorded sessions for fidelity.

2.4 | Evidence-based practice

The ACHIEVE-D program was an evidence-based intervention. This 6-month program was adapted from the ACHIEVE intervention for delivery by community mental health program staff.^{17,18} Table 1 provides an overview of the ACHIEVE-D program. As this study occurred during the COVID-19 pandemic (March 2021–November 2022), the program was modified for delivery both in-person and remotely by videoconference—sites selected the format (in-person, remote or hybrid) to comply with applicable COVID-19 restrictions. Sites delivering in-person sessions provided exercise counseling rather than group exercise to limit the risk of COVID-19 transmission. Sessions occurred at least once a week and up to three times a week based on site integration and staffing resources. At least two staff were trained at each site—staff-coaches shared responsibility for session delivery at some sites, while other sites designated primary staff-coaches responsible for delivering sessions with trained alternates leading sessions only when primary staff-coaches were absent (e.g., illness, vacation).

2.5 | Interventions

The study team's prior research and experience with ACHIEVE and ACHIEVE-D informed the selection of implementation intervention components for the standard and enhanced arms. Both arms used

multimodal training combined with organizational strategy meetings to support the implementation. In the enhanced arm, staff-coaches also received performance coaching.

Multimodal Coach Training. All staff-coaches had opportunities to practice the skills needed to implement the ACHIEVE-D program—a more effective strategy than didactic education alone.¹⁹ All coaches received real-time initial training via videoconference (~14 h in total) as well as ongoing online training (monthly modules to orient coaches to upcoming content and avatar-assisted motivational interviewing [MI] practice; <30 min/month).^{20,21} After the initial training, staff-coaches received reminders to complete the monthly online modules. Table S1 provides a training overview.

Organizational Strategy Meetings. Monthly meetings were held to support the development, adoption, and sustainment of organizational strategies needed for implementation (e.g., review data on clients and staff-coaches to identify challenges and opportunities for improvement; supervisor reduces staff-coach workload in other areas to increase time dedicated to ACHIEVE-D activities) and provide opportunities to problem-solve barriers encountered (e.g., change class schedule to maximize attendance).²² These meetings were attended by research team members, coaches, and site supervisors/leadership (~30 min/month).

Performance Coaching—Enhanced Arm Only. Performance coaching is an implementation strategy where coaches “learn by doing” and receive feedback on their delivery.^{23,24} At sites randomized to the enhanced intervention arm, staff-coaches received monthly performance coaching from research team members with extensive knowledge of the ACHIEVE-D program, behavioral weight loss, and MI. During these sessions, the performance coach and staff-coach reviewed the staff-coach's monthly video recorded group session identifying areas of strength, opportunities for improvement, and a performance improvement plan (~1.5 h/month). Alternate staff-coaches ($n = 3$), serving only as a back-up to deliver sessions in the primary staff-coaches' absence, did not receive performance coaching.

In this pilot RCT, the role of the study staff was limited to obtaining participant consent, collecting data, providing on-board training to staff-coaches, attending organizational strategy meetings, and delivering performance coaching to staff-coaches (enhanced arm only). Study staff did not deliver any components of the ACHIEVE-D curriculum to SMI clients.

2.6 | Primary outcome measures

The primary outcomes were pre-post changes in staff-coach knowledge, self-efficacy, and delivery fidelity to the ACHIEVE-D program. The Consolidated Framework for Implementation Research (CFIR) informed the selection of these outcomes, as the Individuals Domain includes capability—knowledge, competence, and skill—and these aspects are key for individuals to perform their role.^{25–27} Knowledge and self-efficacy are key when implementing interventions in real-world settings,^{28,29} and fidelity is a crucial assessment of implementation of evidence-based practices.¹⁴ We consider these

TABLE 1 Overview of the ACHIEVE-Dissemination (ACHIEVE-D) program.

Duration	26 modules over 6 months
Facilitator(s)	Trained staff coach ^a
Materials	<ul style="list-style-type: none"> Detailed facilitator guide for each lesson to guide support coach delivery Posters and role model videos to reinforce lessons
Group session structure ^b	<ul style="list-style-type: none"> Held at least once and up to three times per week Delivered either in-person or remotely via videoconference platform
Group session content ^c	<ul style="list-style-type: none"> Weight management (~20 min) <ul style="list-style-type: none"> in-person & remote: Group discussion led by staff coach; assisted with facilitator guide, posters and brief role model videos six core modules: Weight loss success; No sugar drinks; No junk food; eat smart portions; eat more vegetables; putting it all together Weigh-in (~10 min) <ul style="list-style-type: none"> in-person: Staff coach performed weight check and provided brief, individualized feedback to clients remote: Clients provided self-reported weights and staff coach provided brief, individualized feedback to clients Group exercise, when permitted (~15 min) <ul style="list-style-type: none"> in-person: Staff coach promoted moderate intensity exercise outside of class setting remote: Video-assisted moderate intensity exercise
Goal	5-lbs weight loss in 6 months ^d (tailored to individual)

Abbreviation: ACHIEVE, achieving healthy lifestyles in psychiatric rehabilitation trial.

^aSite also had the option of including a peer leader to assist the staff coach. Peer leaders participated in ACHIEVE coach training.

^bDelivery frequency varied between sites based on psychiatric rehabilitation program structure and staffing; delivery modality varied based on state and local restrictions due to the COVID-19 pandemic and psychiatric rehabilitation program structure.

^cAbility to offer group exercise varied based on state and local restrictions due to the COVID-19 pandemic.

^dGoal of a 5-lbs weight loss at 6 months was based on results from the ACHIEVE trial¹² and adult obesity guidelines.⁷

outcomes to be implementation outcomes as defined by Proctor and colleagues,³⁰ as they indicate implementation success and are key intermediate outcomes relative to clinical outcomes among clients.

For knowledge, staff-coaches completed a 22-item *Weight Management Knowledge* measure at baseline and 6 months (max possible score 22).¹⁸ For self-efficacy, staff-coaches completed an *ACHIEVE-D Program Self-Efficacy* measure at baseline and 6 months, where they ranked their confidence (0—not confident to 10—very confident) to perform certain skills (i.e., leading behavioral weight-loss group, completing group weigh-in, and managing a group session in general).¹⁸ Changes in knowledge and self-efficacy scores were calculated between baseline and 6 months.

For fidelity, each coach had their delivery of an ACHIEVE-D group session video-recorded once a month, and the masked research team rated their performance using the *ACHIEVE-D Program Fidelity* tool.¹⁸ Staff-coaches were recorded delivering either the second or third lesson for each 4-week module. Of note, recordings occurred for whichever staff-coach was routinely scheduled to deliver the module—the study team did not require unscheduled staff-coaches (e.g., alternate/back-up staff-coaches) to deliver sessions for the sole purpose of data collection. Study team members rating the videos were blinded to randomization assignment and were not involved in performance coaching. For each video, a total score was calculated by summing items from all segments except group exercise, given the variability in the ability to complete this component due to COVID-19 (max score 34). Fidelity was compared at months 1 and 6.

2.7 | Secondary outcomes

The secondary outcomes included pre-post changes in lifestyle behaviors and weight among clients with SMI. For nutrition, clients completed the National Health Interview Survey Five Factor Dietary Screener,³¹ which was used to estimate daily intakes of added sugar and fruit/vegetables per standard methods. For sedentary behavior, clients completed the CARDIA-EARLY Sedentary Behavior questionnaire.³² Changes in these measures were calculated between baseline and 6 months. For weight, study staff measured weight at baseline and 6 months to the nearest 0.1 lb using a high-quality digital scale with clients wearing light indoor clothes without shoes. Mean weight change was calculated between baseline and 6 months.

Several implementation measures from staff-coaches and process measures from clients with SMI were examined. The acceptability, feasibility and appropriateness of the ACHIEVE-D program and implementation interventions were reported by staff-coaches post-program using questionnaires adapted from previously validated measures—Acceptability of Intervention Measure (AIM), Intervention Appropriateness Measure (IAM), and Feasibility of Intervention Measure.³³ Client attendance was tracked, and the number of weeks where a client attended at least one group was calculated. Post program, clients completed questionnaires on the helpfulness of each program component³⁴ and their satisfaction with the ACHIEVE-D program and staff-coaches.³⁵

2.8 | Statistical analysis

Generalized linear mixed-effects models under the intent-to-treat principle were used to determine the effects of the implementation interventions on the primary outcomes among staff coaches as well as secondary lifestyle behavior and weight outcomes among clients. Mean models included a binary intervention group indicator, a time variable (pre-post binary indicator for non-fidelity analyses; number of days since first video recording for fidelity analyses), and an

intervention by time interaction term. The coefficient of time variables estimated time-specific mean outcome changes in the standard arm and the interaction coefficient estimated the between-arm differences in time-specific outcome changes from baseline. The linear combination of these time-specific coefficients captured the time-specific mean outcome changes in the enhanced arm. Site differences were assumed to follow a normally distributed random effect. An unstructured variance covariance matrix was used for the longitudinal repeated outcomes within individuals in non-fidelity analyses; an autoregressive variance covariance matrix was used for the monthly outcomes over time in fidelity analyses. Descriptive statistics were used for the process and implementation outcomes. Adjustments of the distributions were made for descriptive characteristics and outcome variables through the estimated design effects to account for the cluster-randomized study design.

3 | RESULTS

Overall, 12 sites were screened, of which 9 were randomized and had staff-coaches complete onboard training. Figure 1 displays the CONSORT diagram. One site randomized within the standard arm did not wish to continue in the study at 4 weeks; therefore, this site, its staff-coaches ($n = 2$) and clients ($n = 12$) withdrew. Overall, 8 sites completed the study—the standard arm had 3 sites with 7 staff-coaches; the enhanced arm had 5 sites with 11 staff-coaches. Staff coaches were predominantly women (89%) and had a bachelor's degree or higher (94%) (Table 2). While most staff-coaches reported previously delivering lifestyle classes (72%), few reported prior high-quality training in nutrition, physical activity, or behavioral weight-loss strategies (11%, 17%, and 6%, respectively).

3.1 | Staff-coach engagement with and perceptions of the implementation interventions

All staff-coaches completed onboard training (Table 2), and 28% served in an alternate staff-coach role as a back-up to deliver sessions in the primary staff-coaches' absence. Overall, completion of the ongoing online training modules was low—50% completed less than a third of the assigned modules and only 33% completed more than two-thirds. Module completion differed by group (Table 2). Completion of the online avatar-assisted MI practice was high (83%). Overall, coaches highly rated the acceptability, feasibility and appropriateness of the training strategy post with mean scores of 4.1 (SD 0.4), 4.3 (SD 0.6) and 4.2 (SD 0.5), respectively (max score of 5). There were no statistically significant between-group differences in these outcomes (Table S2). All sites had a representative participate in all monthly organization strategy meetings (100%), and most staff-coaches (83%) attended all organizational strategy meetings. Within the enhanced arm, 88% of staff-coaches completed all performance coaching sessions. Enhanced-arm staff-coaches highly rated the acceptability, feasibility and appropriateness of performance

coaching post with mean scores of 4.1 (SD 0.6), 4.2 (SD 0.9) and 4.2 (SD 0.5), respectively (max score of 5).

3.2 | Knowledge, self-efficacy and fidelity among staff-coaches

Overall, staff-coaches' knowledge score significantly increased from 15.0 at baseline to 20.1 at 6 months (max score 22) (mean change pre-post 5.5, 95% CI: 3.9, 7.1). Staff-coaches in both arms had significant within-group changes in knowledge pre-post (Table 3); however, there was no significant between-group difference in knowledge.

There was little change in self-efficacy pre-post among all staff-coaches (max score 10). At baseline, the mean self-efficacy score for leading a behavioral weight-loss group was 9.0 (SD 0.9), which decreased to 8.5 (SD 1.3) at 6 months (mean change pre-post -0.5 , 95% CI: -1.4 , 0.4). The mean self-efficacy score for completing weigh-ins during the group was 9.2 (SD 1.0) at baseline and 8.4 (SD 1.5) at 6 months (mean change pre-post -0.6 , 95% CI: -1.4 , 0.2). The mean self-efficacy score for managing a group session in general was 9.3 (SD 1.0) at baseline and 8.7 (SD 1.3) at 6 months (mean change pre-post -0.5 , 95% CI: -1.2 , 0.3). Standard-arm staff-coaches had no significant within-group changes in self-efficacy (Table 3); enhanced-arm staff-coaches had a statistically significant decrease in self-efficacy for completing weigh-ins during the group (mean change pre-post -1.4 , 95% CI: -2.4 , -0.3). There were no significant between-group differences in self-efficacy.

Overall, 5 standard-arm staff-coaches (71%) and 8 enhanced-arm staff-coaches (72%) had complete fidelity data. Mean fidelity score at month 1 was 28.2 (SD 3.7) and month 6 was 30.1 (SD 5.0) (max score 34); model-based mean change pre-post of 0.5 (95% CI: -2.0 , 2.9). Staff-coaches in both arms had no significant within-group changes in fidelity (Table 3), and no significant between-group differences were found (Table 3).

3.3 | Delivery of evidence-based practice

All sites delivered all 26 ACHIEVE-D modules. Sites varied in the number of groups offered per week and delivery modality. Two sites offered groups once a week (1 standard arm; 1 enhanced arm), four sites offered groups twice a week (1 standard arm; 3 enhanced arm), and two sites offered groups three times a week (1 standard arm; 1 enhanced arm). Five sites delivered groups in-person (2 standard arm; 3 enhanced arm), while two sites delivered groups remotely (1 standard arm; 1 enhanced arm) and one site used a hybrid approach (0 standard arm; 1 enhanced arm). Given COVID-19 restrictions, group exercise could only be offered during remotely delivered groups (1 standard arm; 2 enhanced arm). Overall, coaches highly rated the acceptability, feasibility, and appropriateness of the ACHIEVE-D program post with mean scores of 4.5 (SD 0.6), 4.5 (SD 0.5), and 4.5 (SD 0.6), respectively (max score 5). There were no significant between-group differences (Table S2).

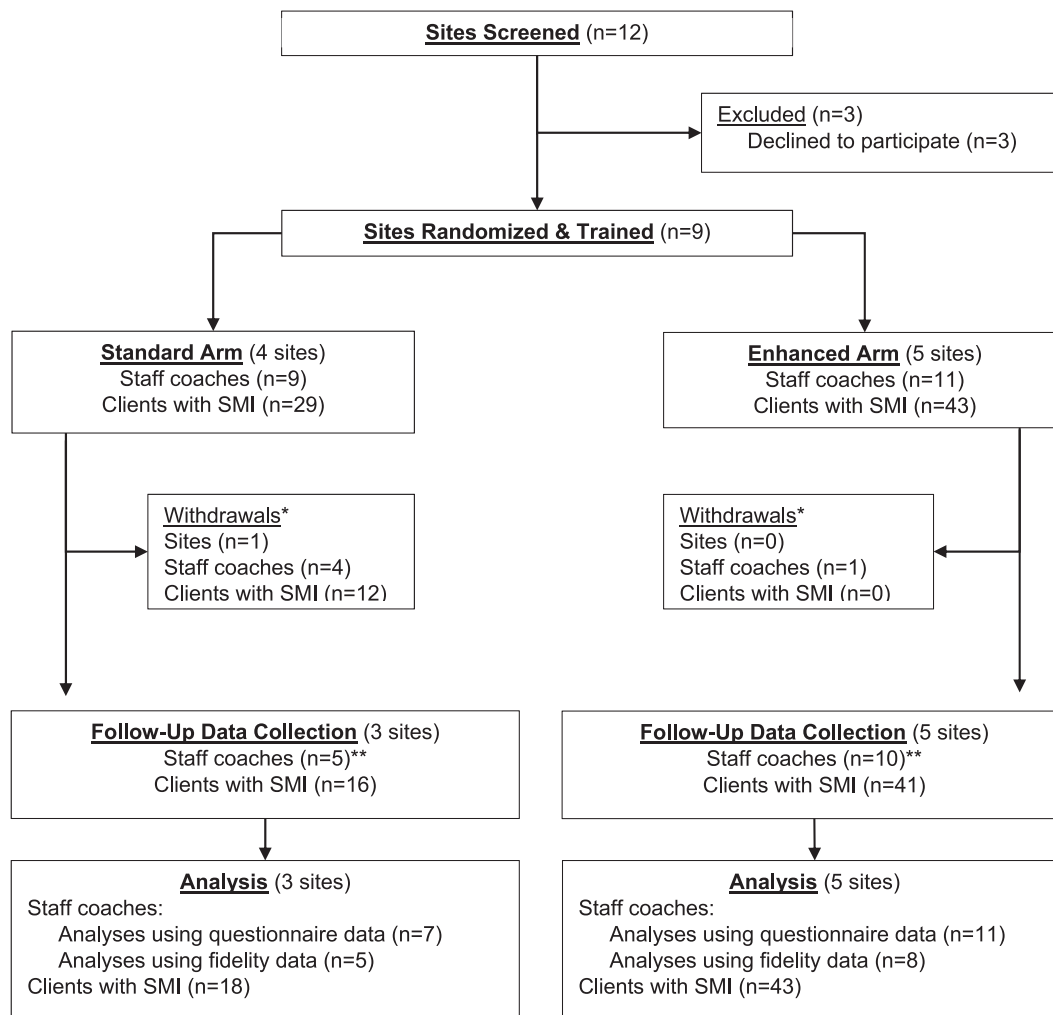


FIGURE 1 CONSORT diagram. *In the standard arm, one site withdrew from the trial (they did not wish to continue), and as a result, the 2 staff coaches and 12 clients with serious mental illness (SMI) from this site were withdrawn. Two additional coaches withdrew from this arm (one left the organization and one did not wish to continue) and 1 additional client with SMI withdrew (left organization). In the enhanced arm, one staff coach withdrew (left organization). **Within the standard arm, 4 staff coaches completed follow-up surveys and 5 staff coaches had at least some fidelity data available. Within the enhanced arm, 10 staff coaches completed follow-up surveys and 8 staff coaches had at least some fidelity data available.

3.4 | Outcomes among clients with SMI

The standard arm had 18 clients with SMI across 3 sites and the enhanced arm had 43 clients with SMI across 5 sites. Table 2 displays the clients' baseline characteristics. Mean age was 46.3 years (SD 15.3), 57% were women, and mean BMI was 39.3 kg/m² (SD 7.0). Clients attended group sessions 85% of the weeks (Table 2), which did not differ substantially between arms. Clients reported being highly satisfied with both the ACHIEVE-D program and their staff-coach, which was similar in both arms (Table S3). For example, 93% of clients agreed/strongly agreed that they would recommend the ACHIEVE-D program to others and 98% agreed/strongly agreed that they had an extraordinary amount of confidence in their ACHIEVE-D staff-coach.

Overall, clients reduced their added sugar intake (mean change -3.3 teaspoons/day, 95% CI: $-6.9, 0.3$) and sedentary time (mean

change -1.6 h/day, 95% CI: $-3.1, -0.2$). Clients achieved a statistically significant weight loss—mean 6-month weight change was -3.8 kg (95% CI: $-6.1, -1.6$) with 36% achieving the program goal of ≥ 5 -lb loss. While there were no significant between-group differences in any outcome (Table 3), enhanced-arm clients achieved a clinically meaningful reduction in added sugar intake (5.8 teaspoon/day) and weight (8.6 kg) relative to standard-arm clients (one teaspoon/day and 2.0 kg).

4 | DISCUSSION

Given that obesity is a leading cause of preventable death among individuals with SMI,¹⁻⁴ there is a critical need to implement and disseminate effective behavioral weight-loss interventions for this population.¹¹ The prior ACHIEVE trial showed that a behavioral

TABLE 2 Baseline characteristics and engagement outcomes of staff coach participants and client participants with serious mental illness.

	Overall	Standard arm	Enhanced arm
Baseline characteristics of Staff Coaches			
N	18	7	11
Mean age in years (SD)	32.7 (8.9)	34.6 (8.8)	31.6 (9.1)
Male gender, %	11%	14%	9%
Race			
White/Caucasian, %	78%	57%	91%
Black/African American, %	11%	29%	0
Other, %	11%	14%	9%
Hispanic/Latino, %	17%	0	27%
Education			
Associate's degree or some college, %	6%	0	9%
Bachelor's degree, %	72%	86%	64%
Master's degree or higher, %	22%	14%	27%
Prior high-quality training in... ^a			
Nutrition, %	11%	14%	9%
Physical activity, %	17%	14%	18%
Behavior change for weight loss, %	6%	0	9%
Leading groups, %	17%	14%	18%
Prior experience leading lifestyle classes, % ^b	72%	86%	64%
Mean years worked in mental health field (SD)	6.9 (8.2)	7.7 (11.0)	6.4 (6.3)
Mean years worked at organization (SD)	3.8 (5.7)	2.4 (3.7)	4.7 (6.5)
Mean confidence to complete computer-based interactive training modules (SD) ^c	9.9 (0.3)	9.9 (0.4)	9.9 (0.3)
Staff Coach Engagement with Implementation Interventions			
Completion of initial onboard training, % ^d	100%	100%	100%
Ongoing online training			
Less than a third of modules completed, %	50%	72%	36%
One- to two-thirds of modules completed, %	17%	14%	18%
More than two-thirds of modules completed, %	33%	14%	45%
Completion of online avatar-assisted MI practice, %	83%	86%	82%
Attendance at all organizational strategy meetings, %	83%	86%	82%
Completion of all performance coaching sessions, %	--	--	88%
Alternate/back-up staff-coach role, %	28%	29%	27%
Baseline Characteristics of Clients with SMI			
N	61	18	43
Mean age in years (SD)	46.3 (15.3)	47.2 (14.1)	45.8 (15.9)
Male gender, %	43%	39%	44%
Race			
White/Caucasian, %	44%	39%	47%
Black/African American, %	52%	61%	49%
Other, %	3%	0	5%
Hispanic/Latino, %	2%	0	2%

(Continues)

TABLE 2 (Continued)

	Overall	Standard arm	Enhanced arm
Primary psychiatric diagnosis ^e			
Schizophrenia, %	23%	22%	23%
Schizoaffective disorder, %	31%	22%	35%
Bipolar disorder, %	21%	33%	16%
Major depressive disorder, %	25%	22%	26%
Mean weight in kg (SD)	112.2 (25.7)	114.8 (27.6)	111.1 (25.1)
Mean body mass index in kg/m ² (SD) ^f	39.3 (7.0)	40.4 (7.4)	38.9 (6.9)
Medical conditions ^e			
Hypertension, %	38%	39%	37%
Diabetes mellitus, %	30%	44%	23%
Dyslipidemia, %	41%	17%	51%
Engagement with Evidence-Based Practice by Clients with SMI			
Median % weeks attended [IQR]	85% [58, 96]	87% [66, 96]	85% [57, 96]
Median # of sessions offered [IQR]	42 [26, 60]	42 [26,60]	51 [26, 76]
Median # of sessions attended [IQR]	26 [19, 48]	31 [17, 49]	26 [20, 48]

Abbreviations: IQR, interquartile range; MI, motivational interviewing; SMI, serious mental illness.

^aParticipants who rated quality of prior trainings as good or better.

^bLifestyle classes defined as classes on nutrition, exercise or wellness.

^cConfidence was rated on a scale of 1–10, where 1 was low and 10 was high.

^dMajority completed all onboard training activities live (72%)—some did complete these activities asynchronously (43% in standard arm; 18% in enhanced arm).

^eExtracted from client medical records. Of note, bipolar disorder label includes any type of bipolar disorder.

^fCalculated from measured height and weight.

weight-loss intervention can produce clinically and statistically significant weight loss among persons with SMI.¹² The current study hypothesized that training mental health center staff as coaches to deliver this intervention would be feasible and help clients with SMI lose weight, thus translating this evidence-based practice into a scalable program for real-world dissemination.¹⁶ An implementation science-informed approach was applied to guide this multi-step process.^{14,15} First, the intervention was modified to an evidence-based behavioral weight management program appropriate for delivery by staff-coaches.¹⁷ This pilot RCT demonstrated that it is feasible for staff-coaches to deliver this program when implemented with multimodal training combined with organizational strategy meetings. All sites delivered all 26 ACHIEVE-D program modules, and on average, staff-coaches delivered the modules with high fidelity over the 6-month program (mean score 28.2 out of 34 at month one; mean score 30.1 out of 34 at month six). Staff-coaches highly rated the acceptability, feasibility and appropriateness of the training strategy as well as the ACHIEVE-D program for their clients.

This study examined changes in staff-coaches' weight management knowledge. According to Bloom's Taxonomy, knowledge involves the recall of information and is the foundation upon which learning occurs.^{36,37} Knowledge is an important outcome when

considering the implementation of evidence-based practices in real-world settings.²⁸ Training on weight management may be particularly key when translating such interventions in the community, as few staff reported prior high-quality training at baseline in nutrition, physical activity, or behavioral weight-loss (11%, 17% and 6%, respectively). Overall, the implementation interventions led to a statistically significant increase in staff-coaches' knowledge (mean change pre-post 5.5, 95% CI: 3.9, 7.1). Participation in onboard training, use of online avatar-assisted MI practice, and attendance at organizational strategy meetings was high among staff coaches—therefore, these activities may have supported improvements in knowledge. Of note, no significant between-group differences in knowledge were found, which suggests that the addition of performance coaching did not impact this outcome. A meta-analysis of workplace coaching found benefits for improving skills, attitudes, and motivations; however, no studies examined coaching's impact on cognitive outcomes such as knowledge.³⁸ Additional research is needed to understand whether performance coaching impacts cognitive outcomes.

This study also evaluated changes in staff-coaches' self-efficacy to deliver key components of the ACHIEVE-D program—particularly, leading a behavioral weight-loss group and completing weigh-ins during the group. According to CFIR,^{25–27} factors at

TABLE 3 Comparison of outcomes of staff coach participants and client participants with serious mental illness by study arm.

	Standard arm ^a			Enhanced arm ^a			
	Baseline	6 M	Mean Δ (95% CI) ^b	Baseline	6 M	Mean Δ (95% CI) ^b	Mean between group Δ (95% CI) ^b
Staff Coach Outcomes^c							
Knowledge (mean score)	13.3 (SD 3.5)	20.5 (SD 1.4)	7.2 (4.6, 9.8)	16.1 (SD 2.8)	19.9 (SD 1.7)	6.6 (4.3, 8.9)	-0.6 (-2.3, 1.1)
Self-efficacy (mean score)							
Leading behavioral weight-loss group	9.3 (SD 1.1)	8.9 (SD 0.7)	-0.4 (-1.8, 1.0)	8.9 (SD 0.7)	8.4 (SD 1.4)	-0.9 (-2.0, 0.2)	-0.5 (-2.0, 1.0)
Completing weigh-ins during group	9.5 (SD 1.0)	9.1 (SD 0.6)	-0.3 (-1.7, 1.1)	9.0 (SD 1.0)	8.1 (SD 1.6)	-1.4 (-2.4, -0.3)	-1.0 (-2.5, 0.5)
Managing a group session in general	9.3 (SD 1.1)	8.9 (SD 0.9)	-0.2 (-1.5, 1.1)	9.3 (SD 0.9)	8.6 (SD 1.4)	-0.7 (-2.0, 0.5)	-0.5 (-2.0, 1.1)
Fidelity (mean score)	25.5 (SD 3.8)	30.7 (SD 2.6)	3.1 (-0.9, 7.1)	29.5 (SD 2.9)	29.9 (SD 5.9)	-1.0 (-4.0, 2.0)	-4.1 (-9.1, 0.8)
Outcomes for Clients with SMI^d							
Added sugar (mean tsp/day)	20.9 (SD 21.0)	20.0 (SD 21.0)	-1.0 (-7.1, 5.1)	20.7 (SD 15.5)	15.0 (SD 10.2)	-5.8 (-13.2, 1.6)	-4.8 (-11.4, 1.8)
Fruit & vegetables (mean servings/day)	4.5 (SD 4.1)	4.7 (SD 3.0)	0.2 (-1.0, 1.4)	3.4 (SD 1.7)	3.8 (SD 2.1)	-0.7 (-1.8, 0.5)	-0.9 (-2.0, 0.2)
Sedentary time (mean hours/day)	11.0 (SD 7.4)	8.5 (SD 5.3)	-2.3 (-4.7, 0.2)	8.9 (SD 5.9)	7.9 (SD 6.6)	-2.9 (-6.7, 1.0)	-0.6 (-4.5, 3.3)
Weight (mean kg)	114.8 (SD 28.2)	112.7 (SD 30.5)	-2.0 (-5.8, 1.8)	111.9 (SD 27.2)	106.5 (SD 27.3)	-8.6 (-22.1, 4.8)	-6.6 (-20.2, 6.9)

Abbreviations: 6M, 6-month follow-up; CARDIA, coronary artery risk development in young adults study; NHIS, national health interview survey; SMI, serious mental illness.

^aStandard arm included data from 7 staff coaches at baseline and 4 at 6-month follow-up. Standard arm included data from 18 clients at baseline and 16 at 6-month follow-up. Enhanced arm included data from 11 staff coaches at baseline and 10 at 6-month follow-up. Enhanced arm included data from 43 clients at baseline and 41 at 6-month follow-up.

^bEstimates derived from outcome specific mixed-effects regression models utilizing all available data, adjusting for study site.

^cKnowledge score calculated by summing number of weight management knowledge questions answered correctly (total possible score is 22).

Participants rated their self-efficacy or confidence to perform a task from 0 (not confident) to 10 (very confident). Video-recorded sessions at month 1 (baseline) and month 6 were graded for fidelity (total possible score 34).

^dDaily intakes of added sugar and fruit & vegetables estimated using standard methods for the NHIS 5-Factor Dietary Screener.³¹ Daily hours of sedentary time estimated using standard methods for the CARDIA sedentary behavior questionnaire.³² Weight was measured using standard procedures.

the mental health provider-level influence evidence-based practice implementation. Prior research has found that provider self-efficacy affects implementation of evidence-based mental health interventions in real-world settings.^{29,39,40} Self-efficacy is typically defined as confidence to deliver a specific intervention or practice,⁴¹ which was similarly applied in this study. Overall, no significant pre-post changes in any self-efficacy component were found, and there were no significant between-group differences. Of note, self-efficacy scores generally decreased at 6-month follow-up from baseline, and a statistically significant decrease in self-efficacy was found for completing weigh-ins during group among enhanced-

arm staff-coaches. This result may have occurred if coaches receiving performance coaching in the enhanced arm had greater awareness of their skill gaps than coaches in the standard arm, which may help explain our self-efficacy results. The ability to detect differences in the self-efficacy outcomes was limited, as baseline ratings were high (typical mean score of 9 out of 10). Prior research has demonstrated that self-efficacy ratings are subject to overconfidence at baseline and result in response-shift bias.^{41,42} Given that 72% of staff-coaches reported prior experience leading lifestyle classes, this experience may have contributed to baseline overconfidence. Future implementation studies that plan to

evaluate self-efficacy as an outcome should be aware of this bias. Strategies to evaluate for this bias may be needed, such as asking participants at follow-up to reflect upon and re-rank their baseline self-efficacy.⁴³

Fidelity was another primary outcome, as fidelity assessments are crucial to implementing evidence-based practices in healthcare settings.¹⁴ Fidelity was high at both months 1 and 6, which may be attributed to all staff-coaches completing onboard training as well as having available a detailed facilitator guide to use to deliver every group session. Having a facilitator guide was a novel and desirable component for mental health center staff during ACHIEVE intervention adaptation to ACHIEVE-D.¹⁷ Given the low use of the ongoing online monthly trainings, this component may not be required when implementing this program. Of note, no significant between-group differences in fidelity were found, which suggests that performance coaching did not impact this outcome.

While this pilot study's primary goal was not to determine the effect on clients with SMI, information was collected on lifestyle habits and weight to preliminarily assess the impact on these outcomes. Weight change is an important outcome, given the burden of obesity in population.¹⁻⁴ Clients with SMI achieved a statistically significant 6-month weight loss (3.8 kg, 95% CI: 1.6, 6.1)—it is notable that this magnitude of reduction is larger than 6-month weight loss in the ACHIEVE trial (1.8 kg, 95% CI: 1.0, 2.5).¹² A statistically significant reduction in clients' behavioral sedentary time was found as well as a clinically meaningful reduction in added sugar intake, although this change was not statistically significant. These results provide preliminary evidence of meaningful weight loss and lifestyle behavioral changes with the ACHIEVE-D program. No significant between-group differences were found in client outcomes, although the study was not powered to detect such differences. Clients also had high levels of engagement and reported satisfaction with the ACHIEVE-D program delivered by their staff-coach.

For the next step in the implementation science-informed process,^{14,15} a large-scale RCT should be conducted to evaluate strategies for dissemination and sustainment of our intervention package—ACHIEVE-D program, multimodal training for staff-coaches, and organizational strategy meetings. Given that no significant between-group differences in the key outcomes were found, it may be concluded that performance coaching is unnecessary in the intervention package, particularly for a prescriptive program like ACHIEVE-D. Performance coaching required additional time from enhanced-arm staff-coaches—approximately, 1.5 additional hours/month—plus time and effort from the performance coach (i.e., person with extensive knowledge of the ACHIEVE-D program, behavioral weight loss, and MI). Some staff-coaches found the online platform hosting the ongoing modules to be challenging to use, which may have contributed to their low use despite staff-coaches rating the feasibility and appropriateness of training fairly highly. As their low use did not appear to impact outcomes, future research may consider whether this content should be an optional component of the intervention package to provide additional support to those staff-coaches who want it or struggling staff-coaches who may need it.

During a prior step in the REP process, mental health center staff identified time constraints as a major challenge to implementing ACHIEVE-D,¹⁷ so future incorporation of performance coaching and ongoing modules will need to carefully balance potential benefits with known challenges. Finding an easy-to-use online platform would also be key for the ongoing modules. Finally, it is anticipated that the next study will report outcomes among clients, including weight loss, among a larger sample than this study, which may therefore be adequately powered to detect differences.

This study has limitations. This pilot trial has a small sample size; however, the results represent a critical step in translating an effective behavioral weight-loss intervention for individuals with SMI to a real-world setting. The study sites were limited to Maryland-based PRPs, which limits generalizability to other states and settings. Staff-coaches were unable to be blinded to study arm allocation due to the nature of the intervention; however, research team members grading fidelity were masked to study assignment. The study was not powered to detect between-group differences in client outcomes. In addition, this trial took place throughout the COVID-19 pandemic, which presented several challenges. First, staff turnover occurred at the community mental health centers, which required onboard training of new staff-coaches at some sites. Staff-coaches' ability to engage in the ongoing monthly online training may have been negatively impacted by increased responsibilities outside the study due to staffing shortages. Second, the format (in-person vs. remote), components of the behavioral weight management program (group exercise vs. exercise counseling), and intervention continuity (e.g., program gaps due to temporary site closures) differed by site due to COVID-19 restrictions, which may have impacted outcomes for clients with SMI. Despite this challenge, this pilot RCT was successfully conducted and demonstrated the effectiveness of our intervention package. Third, fidelity data completion may appear lower than expected, as this data was unavailable for alternate staff-coaches at sites using this model, as they did not deliver any sessions that were video-recorded. Fourth, fewer clients were recruited at sites within the standard arm ($n = 18$) as compared to the enhanced arm ($n = 43$), although the average number of clients per site was similar (~6 clients per site in each arm). The small number of clients in the standard arm may impact client outcomes. Finally, research staff were involved in some aspects of the implementation intervention, specifically providing on-board training to staff-coaches, attending organizational strategy meetings, and delivering performance coaching to staff-coaches. Future research determining the scalability of the ACHIEVE-D intervention package will likely need to transition these roles to non-research staff.

In conclusion, this study demonstrated the feasibility of mental health staff delivering an evidence-based weight management program when implemented with multimodal training for staff-coaches and organizational strategy meetings. The implementation interventions significantly increased staff-coach knowledge on weight management. High fidelity to the ACHIEVE-D program was maintained across the 6-month study. The training was acceptable to the

staff coaches and the clients with SMI were highly satisfied with their experience. Overall, the intervention package—ACHIEVE-D program, multimodal training for staff-coaches, and organizational strategy meetings—holds promise as a scalable strategy to address obesity in this high-risk population.

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CONFLICT OF INTEREST STATEMENT

KAG serves as the medical director for the American Board of Obesity Medicine, has a research grant from Novo Nordisk, is a paid consultant to Novo Nordisk and Eli Lilly, and receives royalties from the Johns Hopkins ACG System. All other authors declare that they have no competing interests.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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