HHS Public Access

Author manuscript

Psychiatr Serv. Author manuscript; available in PMC 2022 May 01.

Published in final edited form as:

Psychiatr Serv. 2021 May 01; 72(5): 555–562. doi:10.1176/appi.ps.202000304.

Main Outcomes of the Peer-Led Healthy Lifestyle Intervention for People with Serious Mental Illness in Supportive Housing

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Abstract

Objective: This study tested the effectiveness of the Peer-led Group Lifestyle Balance (PGLB) intervention in a predominantly racial/ethnic minority sample with serious mental illness who was overweight/obese and living in supportive housing.

Methods: The trial was conducted in three supportive housing agencies enrolling 314 participants randomly assigned to PGLB or usual care. PGLB is a 12-month manualized healthy lifestyle intervention delivered by peer-specialists. Assessments were conducted at baseline, 6, 12, and 18 months. Study outcomes examined for the total sample and by study site were clinically significant changes from baseline on: weight loss (≥5% weight loss), cardiorespiratory fitness (CRF, ≥50-meter increase in the 6-minute walking test [6MWT]) and cardiovascular (CVD) risk reduction (clinically significant weight loss or CRF improvement).

Results: Participants were predominantly racial/ethnic minorities (81.7%) with a mean baseline weight of 218.8±54.0 pounds and mean Body Mass Index=33.7±7.2. Although a larger proportion of participants in PGLB than in usual care achieved clinically significant changes in study outcomes at 12 and 18 months, none were statistically significant. Outcomes differed by study site: two sites reported no significant differences between PGLB and usual care and one site

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reported that PGLB significantly outperformed usual care on clinically significant weight loss at 18 months and on CVD risk reductions at 6 and 12 months.

Conclusions: PGLB was not superior to usual care in achieving clinically significant changes in weight loss, CRF, and CVD risk reductions at 12 and 18 months. Questions remain regarding how PGLB works, for whom, and in which settings.

Keywords

healthy lifestyle intervention; peer-delivered; supportive housing; serious mental illness; pragmatic trial

Compared to the general population, people with serious mental illness (e.g., schizophrenia) continue to experience reduced life expectancy due to higher rates of obesity, type-2 diabetes (T2D), and cardiovascular disease (CVD)(1). Racial/ethnic minority status exacerbates these health inequities. Hispanics and blacks with serious mental illness have elevated risk of obesity and T2D compared to non-Hispanic whites with serious mental illness (2, 3). Reducing obesity in people with these mental health conditions, particularly in racial/ethnic minority groups, is important for improving the health of these historically underserved populations.

U.S.-based clinical trials show that lifestyle interventions that increase healthy dietary habits and physical activity can improve the physical health of people with serious mental illness through weight reduction and improved cardiorespiratory fitness (CRF, the circulatory and respiratory systems' ability to supply oxygen to working muscles during physical activity) (4-7). Despite these results, several gaps remain. First, these trials used clinical staff as interventionists, limiting the workforce that can deliver these interventions. The use of peer-specialists, people with lived experience of serious mental illness, to deliver healthy lifestyle interventions is a promising approach to increase the reach of these interventions since they are a growing workforce in the U.S. (8). Rigorous studies are needed to test the effectiveness of peer-led interventions on the health of people with serious mental illness (9). Second, existing trials were conducted in clinical settings (e.g., outpatient clinics), restricting the accessibility of these interventions. Moving interventions closer to the community by delivering them in supportive housing agencies can help address access barriers by bringing interventions to "people's doorsteps"(10). Supportive housing programs are an important setting for people with serious mental illness because they provide physical, mental health, and social services (11). Lastly, racial/ethnic minorities with serious mental illness are underrepresented in existing trials. However, two recent trials have made efforts to recruit racial/ethnic minorities: 46% of participants in the InShape Replication trial (5) were minorities, largely black and Hispanic, and 38% of ACHIEVE trial participants were black (6).

To address these gaps, we conducted a Hybrid Type 1 Trial to pragmatically test the effectiveness and examine the implementation of a 12-month Peer-led Group Lifestyle Balance (PGLB) intervention in a predominantly racial/ethnic minority sample with serious mental illness who was overweight/obese (BMI ≥ 25) and living in supportive housing. This design tests the effectiveness of an intervention while collecting data about the

intervention's potential for community implementation (12). Here, we present results for our main effectiveness outcome, clinically significant weight loss, and our secondary outcomes, clinically significant improvements in CRF and reductions in CVD risk. We hypothesized that, compared to usual care, significantly larger proportions of PGLB participants would achieve clinically significant weight loss, improved CRF, and reduced CVD risk at 12 and 18 months post-randomization, regardless of study site.

Methods

Study Overview.

The study protocol is published elsewhere (30) and registered in clinicaltrials.gov (NCT02175641). This trial was conducted in three supportive housing agencies located in two Northeastern U.S. cities. One site follows a housing-first model (13) and two sites follow a treatment-first model (11). All participants gave written informed consent, and the study was approved by the institutional review boards of Columbia University and the Philadelphia Department of Public Health.

Participants.

Following a pragmatic trial design, study inclusion criteria were minimal (14). Eligible participants were residents of their supportive housing agency, 18 years of age or older, English or Spanish speaking, with a chart diagnosis of serious mental illness, and a Body Mass Index (BMI) ≥25 kg/m^2 assessed by a research assistant (RA). Participants randomized to PGLB obtained medical clearance from their primary care physician. We excluded participants who at time of recruitment required detoxification services, posed a danger to self or others, failed a capacity-to-consent questionnaire (15), self-reported medical conditions that contraindicated participation in a weight loss program (e.g., cancer, stroke), and for participants above age 64, screened positive for cognitive impairment on the Mini-Cog clock test (16).

Study Procedures.

Recruitment occurred between June 2015 and January 2018 via word-of-mouth and staff referrals. Participants were screened for study eligibility by the study team at each agency. Independent assessors employed by the study team not blinded to participants' group assignment conducted face-to-face interviews at the participants' supportive housing agency at baseline, 6, 12, and 18 months post-randomization. Randomization to PGLB or usual care was conducted at the participant level after the baseline interview in blocks of four stratified by site. Participants received $25 for completing assessments but not for attending PGLB sessions. Measurement protocols are described elsewhere (30).

Intervention.

PGLB is a 12-month, manualized, healthy lifestyle intervention adapted from the Group Lifestyle Balance (GLB) intervention to meet the needs of people with serious mental illness living in supportive housing as delivered by peer-specialists. Adaptations were reviewed by GLB developers and remained consistent with the program's core components (17). PGLB consisted of weekly core sessions for 3 months, bi-monthly transition sessions for 3 months,

and monthly maintenance sessions for 6 months, for a total of 22 sessions. Sessions lasted 60 minutes and were delivered to groups of 3-6 participants in their housing agency with the option of receiving individual sessions. PGLB focused on improving dietary habits and physical activity using behavioral techniques (19).

Peer specialists delivering PGLB were employed at their respective housing agencies and trained and supervised by the study team. Training included: 1) a two-day GLB certification program delivered by a GLB master trainer and 2) a three-month session-by-session training that included using intervention elements (e.g., food logs) in their everyday lives and delivering mock sessions to supervisors prior to facilitating the intervention. Throughout the trial, study team monitored fidelity by reviewing session audio recordings and rating the degree to which key PGLB elements were present. Weekly supervision meetings occurred in person or by telephone to avoid intervention drift (18).

Usual Care.

All participants continued to receive usual care for physical health throughout the trial. These services consisted of health promotion groups (e.g., cooking groups) and linkages to medical care and community resources (e.g., gym). Health promotion groups were not manualized interventions and focused on health education. Agency staff (e.g., case managers) at study sites helped clients connect with primary care and specialized health services as needed. The use of usual care services was tracked at each assessment period.

Primary Outcome.

The main outcome was the proportion of participants who achieved clinically significant weight loss, defined as weight loos of ≥ 5% total body weight from baseline at 12 and 18 months. Weight (lbs.) was measured by an RA with a calibrated digital scale with participants wearing indoor clothing without shoes.

Secondary Outcomes.

Secondary outcomes included the proportion of participants who achieved clinically significant improvements in CRF and CVD-risk reduction at 12 and 18 months. CRF was measured with the 6-minute walk test (6MWT), an objective measure of functional exercise capacity that captures the distance (in meters) that participants walk at a normal pace along a flat and straight course for six minutes (19). The 6MWT is a reliable and valid measure among obese adults and was used in previous trials of people with serious mental illness (4). Consistent with past studies, clinically significant improvement in CRF was defined as an increase of 50 meters or more in the 6MWT from baseline (4, 5). This level of improvement is associated with reduction in CVD risk (19, 20). Consistent with previous trials, clinically significant reduction in CVD risk was defined as either weight loss of ≥5% from baseline or an increase of ≥50 meters on the 6MWT from baseline (5).

Data Analysis.

Bivariate analyses examined baseline differences between PGLB and usual care groups in demographics, clinical variables, and primary and secondary outcomes. An intent-to-treat approach was used for all analyses. Logistic regression models tested our main hypothesis

on the three dichotomous outcomes at 6, 12, and 18 months, comparing PGLB vs. usual care using listwise deletion for missing data. Generalized linear mixed-effects models with a logistic link explored within and between-group changes in trends over time for each outcome. All models adjusted for site, baseline weights, 6MWT, or both, accordingly.

Due to imbalances at baseline between PGLB and usual care in BMI, weight, and number of medical conditions (see Table 1), sensitivity analyses using the inverse probability of treatment weighting (IPTW) estimator corrected for selection biases generated by group assignment (21). This method treats the estimated propensity score as a sampling weight incorporating weights in the multivariate analyses (e.g., weighted logistic regression) to estimate the average treatment effect and average treatment effect for treated (see Supplementary Table 1). Since no differences were observed between our primary and sensitivity analyses, we report the results from the primary analyses. Study site was a significant factor in our models.

Therefore, we conducted post-hoc analyses to explore site differences. We conducted the analyses described above for each outcome stratified by site. Two-tailed statistical tests were conducted and $p<0.05$ was used to determine statistical significance.

Results

Sample Characteristics.

Of 448 people screened, 340 were eligible, and 314 were enrolled and randomized to PGLB or usual care (see Figure 1). At baseline, participants were, on average, 48.7±11.6 years old, and 43% were female (see Table 1). Most were racial/ethnic minorities (82%, n=255), particularly non-Hispanic blacks (58%, n=181), and had a high school education or more (62%). Most were unemployed (90%), in the Supplementary Nutritional Assistance Program (91%), on Supplemental Security Income/Social Security Disability Insurance (78%), and on Medicaid (83%). The most common lifetime psychiatric diagnoses at baseline were major depression (80%) and schizophrenia/schizoaffective disorder (57%). Thirty-nine percent reported a lifetime alcohol or substance use disorder. At baseline, participants had a mean BMI of 33.7±7.2 and mean weight of 218.8±54.0 lbs. On average, participants reported 3.7±2.4 medical illnesses, most commonly hypertension (56%), high cholesterol (37%), and diabetes mellitus (33%). Sixty-three percent were current smokers. At baseline, 32% reported using usual care services in the past 6 months. PGLB and usual care groups did not differ significantly on any baseline characteristics except for weight and BMI (higher for PGLB) and number of medical conditions (higher for usual care group). Follow-up data collection was completed by 93% of participants (n=293) at 6 months, 84% (n=265) at 12 months, and 80% (n=252) at 18 months with no differential attrition between groups at each timepoint. Missing data were not conditional on group assignment.

Participation in PGLB and Usual Care.

The median of total PGLB sessions attended was 18 of 22 with 59% attending ≥50% of sessions, and 36% attending all 22 sessions. Most sessions (63%) were delivered in groups. There were no statistically significant differences in the use of usual care services

for physical health between PGLB and usual care participants throughout the study (see Supplementary Table 2).

Primary outcome.

A higher proportion of PGLB participants versus usual care achieved clinically significant weight loss at 12 and 18 months, yet none of these differences were statistically significant (see Table 2). The increases in the proportion of participants achieving clinically significant weight loss from 6 to 18 months were statistically significant for PGLB (Adjusted Odds Ratio [AOR]=2.26, 95% Confidence Intervals [CI]=1.51, 3.39) and usual care (AOR=1.90, 95% CI=1.29, 2.80), indicating that both groups improved over the course of the study.

Secondary outcomes.

No statistically significant differences were reported for mean weight loss and mean increases in 6MWT between the usual care and PGLB groups (see Supplementary Table 3). A higher proportion of PGLB participants compared to usual care achieved clinically significant improvements in CRF at 6, 12, and 18 months, yet none of these comparisons were statistically significant (see Table 2). The increases in the proportion of participants achieving clinically significant CRF over the course of the study for both groups were likewise not statistically significant. A higher proportion of PGLB participants compared to usual care achieved clinically significant reductions in CVD risk at 6 and 12 months, but the comparisons were not statistically significant (see Table 2). The increases in the proportion of participants achieving clinically significant reductions in CVD risk over the course of the study were statistically significant for PGLB (AOR=1.54, 95% CI = 1.12, 2.11) and usual care (AOR=1.73, 95% CI = 1.26, 2.37), indicating both groups improved over the course of the study.

Site Differences.

Study outcomes differed by study site (see Table 3). At sites 1 and 2, usual care tended to do better than PGLB at all time periods, with some minor exceptions, but no comparisons were statistically significant. Site 3 showed a different pattern. At this site, PGLB consistently outperformed usual care at all time periods, particularly for clinically significant weight loss at 18 months (PGLB=42% vs. Usual Care=22%, AOR=2.57, 95% CI=1.02, 6.49) and clinically significant reductions in CVD risk at 6 months (PGLB=48 vs. Usual Care=27, AOR=2.51, 95% CI=1.07, 5.90), and 12 months (PGLB=59% vs. Usual Care=33%, AOR=2.99, 95% CI=1.33, 6.72).

Discussion

Our findings did not support our hypothesis. Although a larger proportion of participants in PGLB than in usual care achieved clinically significant changes in weight loss, increases in CRF, and reductions in CVD risk at 12 and 18 months, these differences were not statistically significant. PGLB's impact compared to usual care differed by study site.

Our null findings do not appear to be due to underperformance of PGLB. Instead, our results indicate that PGLB achieved outcomes comparable to those from other U.S.-based

healthy lifestyle trials of people with serious mental illness (5-7) and a recent meta-analysis (22). The ACHIEVE trial tested the effectiveness of an 18-month behavioral weight loss intervention for people with serious mental illness in psychiatric rehabilitation programs (6). ACHIEVE was associated with clinically significant weight loss for 32.5% of participants at 12 months and 37.8% at 18 months (6), comparable to our results of 28.9% and 32% during the same time periods. The InShape trial tested the effectiveness of a 12-month health promotion program based on individualized sessions with a health coach and free gym memberships (5). InShape was associated with clinically significant reductions in CVD risk for 51% of participants at 12 months and 46% at 18 months (5), resembling our results for the same outcome and time periods of 48% and 49%. Our findings suggest that PGLB delivered in supportive housing can produce clinically significant health improvements in racially/ethnically diverse samples with serious mental illness that are consistent with the outcomes of other non-peer-led healthy lifestyle interventions.

The lack of significant differences between PGLB and usual care in study outcomes indicates that several methodological and contextual factors need to be considered. The imbalance at baseline between our two groups on weight, an average difference of 13.9 lbs. favoring the usual care group, suggests that PGLB participants needed to achieve greater weight loss than usual care to counteract this difference. Although we corrected for this imbalance in our analyses, the PGLB group, on average, still did not achieve greater weight loss than usual care.

The use of usual care services related to physical health at our study sites could have increased over the course of the study, with more use among the usual care group, thus influencing their outcomes. Our data do not support this pattern since there was no differential use of usual care services between groups and the use of usual care decreased throughout the trial for both groups (see Supplemental Table 2).

The usual care group reported improvements on study outcomes over the course of the trial, mimicking improvements in the PGLB group, suggesting that some usual care participants engaged in weight loss strategies. Contamination between groups could account for these improvements in the usual care group since we randomized at the participant level due to the small number of study sites. One potential source of contamination was the PGLB peer-specialists, who were employees of the supportive housing agencies. However, PGLB peer specialists' sole responsibility was to deliver PGLB to participants randomized to the intervention, and they had little contact with usual care participants.

Another source of contamination could have been interactions throughout the trial between PGLB and usual care participants leading to sharing PGLB materials/strategies for weight loss, thereby activating usual care participants to lose weight. We checked for contamination by asking all participants at 6, 12, and 18 months whether they engaged in PGLB strategies using a 6-item self-report measure. On average, PGLB participants reported significantly greater engagement in PGLB strategies throughout the trial than usual care participants (see Supplementary Table 4). However, over 40% of usual care participants reported engaging in PGLB strategies, particularly tracking their eating and exercise, and setting weight and exercise goals. Although this may have influenced our null findings, it suggests that

elements of PGLB resonated with participants to the point of possibly being shared with and used by usual care participants. A social proliferation process may have occurred whereby PGLB participants shared their new knowledge with their social circles within these agencies, helping diffuse PGLB strategies and activating usual care participants to engage in healthy lifestyle changes (23). More research is needed to better understand how this social proliferation process potentially unfolded and its impact on helping participants achieve clinically significant changes in weight and CRF.

Losing weight and improving CRF are major challenges for people with serious mental illness who are overweight or obese (24). Effective interventions utilize intensive manualized programs that combine coached and structured physical activity, support dietary changes with behavioral techniques, and last over 9 months (25). Our null findings suggest that for some participants enrolling in a weight loss study having their weight, CRF, and other health indicators assessed every 6 months and potentially learning about PGLB from other participants may have activated them to lose weight and improve their CRF. A similar finding was reported in a small study of Hispanic patients who attributed their weight loss at 40 weeks after baseline to regular weight checkups by staff, increasing their attention to these issues (26). A one-size-fits-all healthy lifestyle approach may not be the most efficient way for helping people with serious mental illness. Personalized strategies based on individual's characteristics, needs, and preference may be needed for people with serious mental illness, with some requiring intensive and structured behavioral approaches while others may need fewer strategies, such as frequent weight monitoring and goal setting.

PGLB benefits were not uniform across study sites. At site 3, PGLB consistently outperformed usual care. Although this site included 40% of PGLB participants, they accounted for over half of participants who achieved clinically significant weight loss (51%), improved CRF (68%), and reduced CVD risk (55%) at 18 months. We know of no published effectiveness trial of healthy lifestyle interventions for people with serious mental illness that reported or examined site differences. More in-depth analyses of the qualitative and quantitative data collected as part of our Hybrid trial is required to examine the heterogeneity between sites, including whether potential differences in fidelity, staff turnover, participants' experiences with PGLB or other contextual factors could explain these site differences. We are in the process of conducting these analyses and plan to publish these results in the future. This exploration may uncover contextual and implementation factors necessary to identify how and why PGLB works in certain settings and not others and can inform the development of implementation strategies for PGLB (27, 28). More studies are needed since little is known about the type of implementation strategies that can support the adoption of healthy lifestyle interventions for people with serious mental illness in routine practice settings.

Our trial has several limitations. Due to logistical constraints, we did not use blind assessors to measure study outcomes, which could have biased study assessments. We conducted our trial in three supportive housing agencies that can be considered early adopters, since these agencies typically do not include health interventions as part of their services. Studies with larger samples of supportive housing agencies are needed to examine the generalizability of our findings. The baseline imbalance regarding weight that favors the usual care group

suggests that the randomization was not successful due to unobserved factors. Although we adjusted for these imbalances in our analyses, these differences in weight at baseline between study conditions potentially threaten the internal validity of our findings (29). Future studies could use different randomization strategies, like stratifying randomization by BMI ranges (e.g., BMI=25-29, BMI≥30) to reduce the chance for these imbalances. Potential contamination between the study arms may have contributed to our null findings. Future trials could avoid contamination by recruiting a larger sample of supportive housing sites and using a clustered randomized design in which sites rather than individuals are randomized to study conditions. Most of our sample belonged to racial/ethnic minority groups, particularly non-Hispanic blacks, and we did not have the statistical power to examine intervention differences between racial/ethnic groups. More studies are needed to examine intervention effects between different minority groups.

In conclusion, PGLB was not superior than usual care in achieving clinically significant changes in weight loss, increases in CRF, and reductions in CVD risk. Although our findings suggest that some racial/ethnic minority individuals with serious mental illness who are overweight/obese and in supportive housing could benefit from a peer-led healthy lifestyle intervention, multiple questions remain about how this intervention works, for whom, and under which conditions it exerts the biggest impact. More studies are needed to clarify why PGLB works in certain settings and not others. Increasing the life expectancy of people with serious mental illness requires bridging the gap between research and practice and developing evidence on how to best implement health interventions in routine practice settings to increase their reach and benefits.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Disclosures and acknowledgments.

The authors have no conflict of interest to report. The authors would like to thank the participants and community partners who participated in this study. This study is dedicated to Kelli Adams, our beloved colleague, who passed away during this project. Her dedication and passion for improving the physical health of people with serious mental illness inspire us every day to conduct this important work

Grant:

National Institute of Mental Health: R01MH104574

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Highlights:

- Racial and ethnic minorities with serious mental illness who are overweight or obese and living in supportive housing could benefit from a peer-led healthy lifestyle intervention that focuses on improving dietary habits and physical activity
- Results from this pragmatic randomized trial indicate that the Peer-led Group Lifestyle Balance intervention delivered in supportive housing by trained peer-specialists was not superior than usual care at achieving clinically significant changes in weight loss, cardiorespiratory fitness and reductions in cardiovascular risk factors.
- More studies are needed to examine how peer-led healthy lifestyle interventions works, for whom, and why they work in some settings and not others.

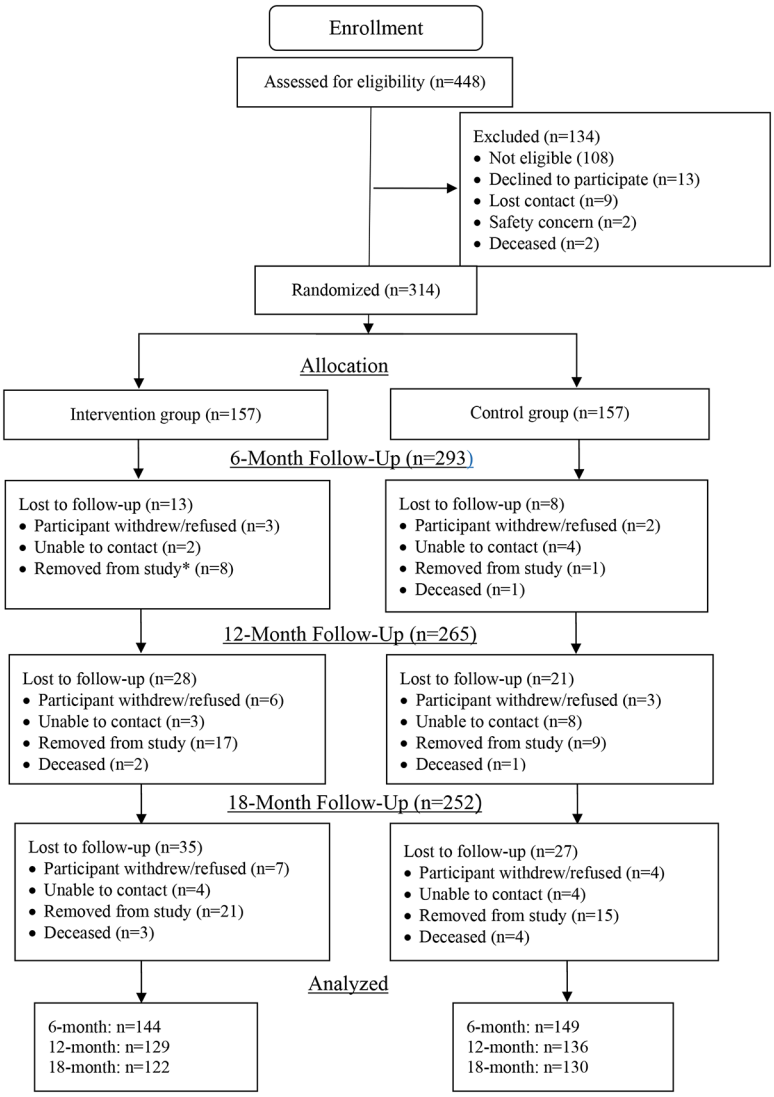

Figure 1. Study Flow Diagram

*The most frequent reason for removal from study was participant no longer being a client of the supportive housing agency. Other reasons included participant developing conditions meeting exclusionary criteria, such as substance abuse that required detoxification, potential for harm to self/others, or medical conditions contraindicated with weight loss, none of which were related to participation in the study.

Table 1.

Baseline characteristics

	Total (N = 314)		Usual Care (N = 157)		PGLB (N = 157)	
	Mean	**SD**	**Mean**	**SD**	**Mean**	**SD**
Age	48.65	11.56	48.81	11.60	48.50	11.56
Weight (pounds) *	218.79	54.01	211.84	48.83	225.75	58.07
BMI[a]*	33.72	7.22	32.87	6.72	34.57	7.61
6-minutes walking test (meters)	318.42	96.87	328.71	100.77	308.07	91.95
Number of medical conditions *	3.66	2.41	4.00	2.55	3.32	2.20
Number of psychiatric medications	1.68	1.16	1.68	1.18	1.67	1.15
	N	%	N	%	N	%
Female	133	43	66	42	67	43
Race/Ethnicity						
Non-Hispanic White	57	18	29	19	28	18
Non-Hispanic Black	181	58	77	50	104	66
Hispanic	39	13	26	17	13	8
Non-Hispanic Other	35	11	23	15	12	8
High School Education or Above	193	62	100	65	93	59
Health Insurance						
Medicaid	258	83	130	84	128	83
Medicare	114	37	55	36	59	38
Receiving SNAP[b]	287	91	142	91	145	92
Receiving SSI/SSDI Benefits[c]	245	78	121	77	124	80
Currently Employed (Part-time or Full-time)	32	10	12	8	20	13
Lifetime Physician Confirmed Psychiatric Diagnosis						
Depression	236	80	115	74	121	78
Schizophrenia/Schizoaffective Disorder	178	57	85	55	93	60
Anxiety disorders	158	51	82	53	76	48
Bipolar Disorder	146	47	72	47	74	47
Alcohol or Substance Use Disorder	121	39	59	38	62	40
Current smoker	197	63	95	61	102	65
Lifetime Physician Confirmed Medical Conditions						
Hypertension	173	56	89	58	84	54
High cholesterol	114	37	60	39	54	35
Diabetes Mellitus	102	33	51	33	51	33
Arthritis	100	32	50	32	50	32
Taking Any Antipsychotic Medications	197	62	97	62	100	64
Taking Second-Generation Antipsychotics[d]	157	80	75	77	82	82
Use of Usual Care Services	98	32	55	36	43	28

Note:

[*] Statistically significant difference ($p < 0.05$) between Usual Care and PGLB groups.

[a] Body Mass Index.

[b] Supplemental Nutrition Assistant Program.

[c] Supplemental Social Security Income and Social security Disability Insurance.

[d] Percentage is calculated based on the sample taking any antipsychotic medications (Total sample n = 197, UC n = 97, and PGLB n = 100). Per journal style all percentages are rounded to whole numbers.

Table 2.

Clinically significant weight loss, improvements in cardiorespiratory fitness and cardiovascular disease (CVD)-risk reduction at 6, 12, and 18 months per study condition

	Usual Care		PGLB			
Main Outcome	**N**	**%**	**N**	**%**	**OR[a]**	**95% CI**
≥ 5% total body weight loss from baseline						
6 months	25	17	22	15	0.93	0.49, 1.76
12 months	33	24	37	29	1.36	0.78, 2.37
18 months	40	31	39	32	1.07	0.62, 1.84
	OR	**95% CI**	**OR**	**95 %CI**		
Within-group changes from 6 to 18-months[b]	**1.9**	**1.29,2.80**	**2.26**	**1.51, 3.39**		
Secondary Outcomes	**N**	**%**	**N**	**%**	**OR[a]**	**95% CI**
≥ 50 meters increase from baseline on 6MWT[c]						
6 months	26	18	36	26	1.35	0.72. 2.51
12 months	34	26	34	29	1.01	0.56, 1.81
18 months	31	25	34	29	1.09	0.56, 2.11
	OR	**95% CI**	**OR**	**95 %CI**		
Within-group changes from 6 to 18-months[b]	1.39	0.93, 2.06	1.20	0.81, 1.77		
Clinically significant reduction in CVD risk[d]	**N**	**%**	**N**	**%**	**OR[a]**	**95% CI**
6 months	46	31	54	38	1.32	0.80, 2.19
12 months	56	41	62	48	1.32	0.80, 2.20
18 months	63	49	60	49	0.97	0.58, 1.65
	OR	**95% CI**	**OR**	**95 %CI**		
Within group changes from 6- to 18-months[b]	**1.73**	**1.26, 2.37**	**1.54**	**1.12, 2.11**		

Note:

[a]Odds Ratios from logistic regression models adjusted for site, baseline weight, and/or baseline 6MWT, respectively; usual care is the reference group for these models.

[b]Generalized linear mixed-effects models with a logistic link to explore within-group 6-month changes from 6 to 12 to 18 months for each outcome measure, adjusting for site, baseline weight, and/or baseline 6MWT, respectively; within-group change at 6 months is the reference group for these models.

[c]6MWT = six-minutes walking test.

[d]Clinically significant reduction in cardiovascular disease risk is defined as either achieving ≥5% weight loss from baseline or ≥ 50 meters increase from baseline on the 6-minute walking test. Per journal style all percentages are rounded to whole numbers.

Table 3.

Site differences on primary and secondary outcomes, by study condition

	Site 1 (N = 78)						Site 2 (N = 112)						Site 3 (N = 124)					
	Usual Care		PGLB				Usual Care		PGLB				Usual Care		PGLB			
Main Outcome	**N**	**%**	**N**	**%**	**OR[a]**	**95% CI**	**N**	**%**	**N**	**%**	**OR[a]**	**95% CI**	**N**	**%**	**N**	**%**	**OR[a]**	**95% CI**
≥ 5% total body weight loss from baseline																		
6 months	10	29	7	21	0.59	0.18, 1.81	9	16	7	14	0.85	0.28, 2.52	6	10	8	14	1.50	0.47, 4.96
12 months	11	37	9	33	0.84	0.28, 2.52	13	26	11	23	1.02	0.39, 2.67	9	16	17	32	2.47	0.97, 6.33
18 months	16	49	9	32	0.50	0.17, 1.44	14	28	10	22	0.73	0.28, 1.85	10	22	20	42	**2.57**	**1.02, 6.49**
Secondary Outcomes																		
≥ 50-meter increase from baseline on 6MWT[b]																		
6 months	6	21	6	19	0.85	0.21, 3.53	8	15	7	15	0.98	0.40, 2.39	12	20	23	39	2.00	0.83, 4.93
12 months	6	23	4	17	0.54	0.12, 2.51	15	29	10	23	0.71	0.30, 1.72	13	24	20	38	1.67	0.70, 3.73
18 months	3	10	4	15	2.43	0.37, 15.3	8	16	7	17	0.69	0.29, 1.64	20	44	23	48	0.97	0.39, 2.40
Clinically significant reduction in CVD risk[c]																		
6 months	15	44	13	38	0.77	0.29, 2.05	15	27	13	26	0.98	0.40, 2.39	16	27	28	48	**2.51**	**1.07, 5.90**
12 months	14	47	12	44	0.75	0.25, 2.29	24	47	18	38	0.71	0.30, 1.72	18	33	32	59	**2.99**	**1.33, 6.72**
18 months	18	55	12	43	0.55	0.18, 1.61	21	41	15	33	0.69	0.29, 1.64	24	52	33	69	1.97	0.80, 4.88

Note:

[a]Logistic regression models adjusted for baseline weight, and/or baseline 6MWT, respectively; usual care is the reference group in all models.

[b]6MWT = six-minute walking test.

[c]Clinically significant reduction in cardiovascular risk is defined as either achieving ≥5% weight loss from baseline or ≥ 50 meters increase from baseline on the 6-minute walking test. Per journal style all percentages are rounded to whole numbers.