A Randomized, Controlled Multisite Study of Behavioral Interventions for Veterans with Mental Illness and Antipsychotic Medication-Associated Obesity

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BACKGROUND: Weight gain and other metabolic sequelae of antipsychotic medications can lead to medication non-adherence, reduced quality of life, increased costs, and premature mortality. Of the approaches to address this, behavioral interventions are less invasive, cost less, and can result in sustained long-term benefits.

OBJECTIVE: We investigated behavioral weight management interventions for veterans with mental illness across four medical centers within the Veterans Affairs (VA) Healthcare System.

DESIGN: We conducted a 12-month, multi-site extension of our previous randomized, controlled study, comparing treatment and control groups.

PARTICIPANTS: Veterans (and some non-veteran women) diagnosed with mental illness, overweight (defined as having a BMI over 25), and required ongoing antipsychotic therapy.

INTERVENTIONS: One group received "Lifestyle Balance" (LB; modified from the Diabetes Prevention Program) consisting of classes and individual nutritional counseling with a dietitian. A second group received less intensive "Usual Care" (UC) consisting of weight monitoring and provision of self-help.

MAIN MEASURES: Participants completed anthropometric and nutrition assessments weekly for 8 weeks, then monthly. Psychiatric, behavioral, and physical assessments were conducted at baseline and months 2, 6, and 12. Metabolic and lipid laboratory tests were performed quarterly.

KEY RESULTS: Participants in both groups lost weight. LB participants had a greater decrease in average waist circumference [$F(1,1244) = 11.9$, $p < 0.001$] and percent body fat [$F(1,1121) = 4.3$, $p = 0.038$]. Controlling for gender yielded statistically significant changes between groups in BMI [$F(1,1246) = 13.9$, $p < 0.001$]. Waist circumference and percent body fat decreased for LB women [$F(1,1243) = 22.5$, $p < 0.001$ and $F(1,1221) = 4.8$, $p = 0.029$, respectively]. The majority of LB participants kept food and activity journals (92%), and average daily calorie intake decreased from 2055 to 1650 during the study ($p < 0.001$).

CONCLUSIONS: Behavioral interventions specifically designed for individuals with mental illness can be effective for weight loss and improve dietary behaviors. "Lifestyle Balance" integrates well with VA healthcare's patient-centered "Whole Health" approach.

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KEY WORDS: antipsychotic; weight management; obesity; behavioral intervention; mental health.
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INTRODUCTION

Patients taking antipsychotic drugs (APDs) may experience side effects such as obesity, diabetes, dyslipidemia, and cardiovascular disease.[1–5] Weight gain can lead to medication non-adherence and subsequent psychiatric relapse.[6, 7] The total US cost of treatment for people with psychotic disorders in 2013 was estimated at $11.5 billion.[8] Comorbid drug addiction, tobacco dependence, and obesity may all contribute to increased costs and shortened lifespans by 10–25 years[9] and a 3.5-fold increased mortality risk.[10]

Approaches to address weight gain include pharmacotherapy,[5] bariatric surgery,[11, 12] and behavioral interventions.[13, 14] Pharmacotherapy, while shown to have a short-term effect, is often ineffective in the long term.[5] Bariatric surgery also provides short-term results for people with psychiatric

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symptoms, but results 1 year post-surgery are significantly less than in those without psychiatric illness.[11] Cognitive barriers and amotivation may accompany mental illness, affecting adherence to lifestyle changes. The weight gain liabilities of some APDs can also make it more difficult to maintain weight loss. Therefore, patients taking APDs may require additional pre- and postoperative care to improve long-term weight loss.[11, 12]

In contrast, a behavioral approach is the least medically invasive and unlikely to have side effects associated with pharmacotherapy and surgery. The United States Preventative Services Task Force (USPSTF) found behavioral interventions can result in weight loss and improved metabolic parameters in the general population. They recommend intensive, multicomponent programs utilizing groups, individual sessions, dietary modification, exercise, self-monitoring, goal setting, addressing barriers, and maintenance planning.[15]

Awareness of APD-associated weight gain prompted development of behavioral interventions for patients with mental illness. Intervention studies demonstrate weight loss and improved metabolic profiles compared to control groups.[5, 9, 13, 14, 16–21] While durations of interventions vary, these studies highlight the importance of nutrition and exercise modification. Weight loss interventions can reduce concomitant medication use and overall cost.[22–24] This study replicated and expanded our original behavioral intervention research,[25] which added to the literature with a longer 12-month intervention and focus on veterans with APD-associated obesity.

We developed a behavioral weight management program for persons taking APDs based on the Diabetes Prevention Program (DPP), a diet and exercise program that has demonstrated reduced risk of diabetes.[26] Our program, tested at the VA West Los Angeles Medical Center,[25] also met USPSTF recommendations for higher-intensity behavioral interventions.[15] Results of the randomized, controlled study's intention-to-treat analysis indicated that intervention participants were predicted to lose an average 4.6 kg compared to control participants predicted to gain an average 0.6 kg over 12 months.

Building on the single-site trial's successes, we tested this research program at the original and three additional locations. The 12-month controlled, parallel, superiority design was retained; the intervention group was hypothesized to gain more health knowledge, make more healthy lifestyle changes, and achieve better cardiovascular and mental health outcomes. Secondary hypotheses involved weight loss negatively correlating with psychiatric symptoms while positively correlating with motivation and better treatment adherence by the intervention group. This article describes the program's efficacy at these four sites.

METHODS

This study was registered with ClinicalTrials.gov (identifier NCT01052714) and approved by Institutional Review Boards at the VA Greater Los Angeles and VA Long Beach Healthcare Systems. Participants signed informed consent after receiving detailed study information, viewing a video presentation about informed consent,[27] and passing a study participation comprehension assessment. Conserved participants' guardians were required to co-sign consent.

Study Population and Setting

Research activities took place in research offices near mental health clinics at four southern California VA locations. Recruitment occurred September 2010 through March 2014 using flyers and presentations. Inclusion criteria were: age 18–70 years old; diagnosis of mental illness per DSM-IV; APD treatment; BMI over 25 or weight gain over 7% on APDs; and medical and psychiatric stability, confirmed by chart reviews and primary care provider approval. Exclusion criteria were hospitalizations within 30 days, substance abuse history without sobriety over the previous 90 days, and homelessness. Follow-up with the final participant concluded by June 2015.

Study Design

We assumed a conventional medium effect size, with desired power of 80% and two-tailed α set at 0.05, and determined a sample size of n = 60 (per treatment group). A computer pre-generated random number list randomized participants to parallel groups with a balanced allocation ratio (1:1), with clinical raters masked to randomization. Participants were stratified by APD-associated weight-gain risk (high: clozapine/olanzapine; medium: quetiapine/risperidone; low: aripiprazole/ziprasidone; negligible: haloperidol/other), with those on multiple medications assigned based on the highest-risk medication. Participants (n = 121) were randomized into the more intensive "Lifestyle Balance" intervention group (LB, n = 62) or the less intensive "Usual Care" intervention group (UC, n = 59).

Assessments conducted throughout the study are in Table 1.[28–37] Psychiatric diagnosis was confirmed by study psychiatrists or PhD-level psychologists using the Structured Clinical Interview for DSM-IV checklist.[38] Physical stability was determined by physical examination, medical records, Framingham risk assessment,[39] electrocardiogram, Health/Fitness Pre-Participation Screening Questionnaire,[40] and, if necessary after an investigator reviewed all of the above, an exercise tolerance test (ETT). Of 33 participants who underwent the ETT, clinicians admitted 30 to the study.

All study participants met with a research coordinator weekly for the first 8 weeks and monthly through month 12. At every visit, vital signs, weight, waist circumference, BMI, and body fat percentage were recorded. Participants completed a Treatment Adherence Questionnaire and Lifestyle Habits Questionnaire about food, beverage, and exercise habits. If participation ended early, month 12 assessments were completed at the final visit.

Table 1 Schedule of Assessments

Assessment name	Study visit week				
	0	8	26	38	52
Physical exam	X				X
Framingham Hard Coronary Heart Disease	X				X
American Heart Association/American College of Sports Medicine Health/Fitness Pre-Participation Screening Questionnaire	X				
Exercise tolerance test	X				X
Electrocardiogram	X				
Structured clinical interview for DSM-IV checklist	X				
Brief psychiatric rating scale	X	X	X		X
Clinical global inventory	X	X	X		X
Hamilton Depression Scale	X	X	X		X
Beck Anxiety Scale	X	X	X		X
Biopsychosocial/spiritual wellness self-appraisal	X	X	X		X
Antipsychotic side-effects checklist	X	X	X		X
Motivational interview to assess stage of change	X	X	X		X
University of Rhode Island Change Assessment	X		X		X
Self-Appraisal of Illness Questionnaire	X	X	X		X
World Health Organization Quality of Life-BREF	X				X
Assessment of Patient Food Preparation Activity	X	X	X		X
Healthy Lifestyle Balance Knowledge Quiz	X	X	X		X
Laboratory tests	X	X	X	X	X
Vitals and anthropometric measurements	X	X	X	X	X
Lifestyle habits questionnaire	X	X	X	X	X
Treatment adherence log	X	X	X	X	X

Fidelity

Registered dietitians (RD) were trained to administer the LB intervention by the PI; they also worked together for 6 months during the second dietitian's training period. As part of their VA dietetic training, they learned cognitive-behavioral and motivational interviewing techniques, reinforced further by the PI. To facilitate fidelity across all sites, weekly team meetings were held to ensure a standardized intervention was being provided. The PI periodically observed and assessed fidelity of the two dietitians qualitatively using a specially designed fidelity checklist to assess quality of care during class and individual coaching sessions.

Behavioral Intervention: Lifestyle Balance

Educational Materials and Group Classes. LB participants received RD-led classes and individual nutrition counseling. The LB curriculum included 16 topics (Table 2). The first 8 weeks, 60-min classes covered two topics per session. Monthly booster classes reinforced healthy behaviors for the remaining 10 months. Class size typically ranged from 1–4 people. Classes utilized multi-modal techniques including colored handouts, written materials, food models, poster images, and group discussions to accommodate visual, auditory, and kinesthetic learning styles. Concepts were reviewed with repetition to address potential cognitive barriers associated with mental illness.[41]

Table 2 Lifestyle Balance Program Topics

1. Welcome to the Lifestyle Balance Program
2. Effects of Antipsychotic Medications on Weight, Blood Sugar, and Cholesterol
3. Mindful Eating
4. Portion Sizes
5. Becoming Active: A Way of Life
6. Moving Those Muscles
7. Weighing the Risks
8. Tip the Calorie Balance
9. Carbs—Simply Complex
10. Fat Facts
11. Ways to Decrease Stress
12. Take Charge of What's Around You
13. Your Food Away From Home
14. Delicious Decisions
15. Variety on Your Plate
16. Ways to Stay Motivated

Individual Nutrition Counseling. Following each class, participants met RDs for 15 to 60 min of individualized nutrition counseling, depending on participants' needs and time availability. RDs addressed each participant's specific nutrition-related concerns and helped participants set and accomplish both short- and long-term goals.

RDs provided a comprehensive nutrition assessment at the first session, including a 24-h food recall[42] assessing participants' dietary intake. RDs also reviewed medical records and physical activity, stage of change,[43] and cognitive ability. A discussion followed about specific food and activity goals to initiate behavior change. RDs used cognitive behavioral therapy techniques,[44] motivational interviewing[45, 46] and accountability tools, including food and activity journals. RDs reviewed these journals during participants' appointments. For data analysis, 24-h food recalls[42] were used with journals to quantify food and beverage intake changes. These data were input into the USDA "Supertracker" database[47] and analyzed to assess behavioral changes.

During groups and individual sessions, RDs encouraged change using positive affirmations and praise.[41] To enhance motivation and adherence to the program, participants received rewards for meeting goals such as gift certificates, tote bags, and "Healthy Plates." Following the DPP's protocol "Toolbox" and the in-vivo approach to social skills training,[48] RDs met with caregivers at 12 participants' residences to discuss dietary changes; they also taught healthy cooking classes and promoted walking groups. During semi-annual class field trips, RDs provided on-site education at restaurants and grocery stores.[41] Once-daily meal replacement shakes were offered when basic food and exercise changes were less effective in meeting weight loss goals; only 13 participants chose this option.[49]

Usual Care

UC participants met with research coordinators with a frequency and duration equivalent to individual LB counseling

sessions. Anthropometric measures and vitals were recorded. Participants answered questionnaires about diet, exercise, and health. VA-approved self-help educational handouts on health issues were provided. Due to ethical concerns and participant request, 17 UC participants were allowed to begin the active treatment at month 6, and these 17 crossover (CO) participants were not included in any analysis after month 6.

Statistical Analysis

Research staff collected and transcribed data into an electronic database, utilizing double-entry for error checking. Intent-to-treat analyses of primary and secondary hypotheses were performed using a general linear mixed model in SPSS on the 121 randomized participants' data.

RESULTS

Of 121 participants, 62 were randomized to LB and 59 to UC groups. The initial 8-week intervention period was completed by 53 (86%) LB and 50 (85%) UC participants, and the full 12-month follow-up period was completed by 33 (53%) LB, 17 (29%) UC, and 15 CO participants (88%, data excluded after month 6). Among the 56 non-completing participants, 20 voluntarily withdrew. Investigators terminated 19 for nonadherence to study procedures and 12 for adverse medical or psychiatric changes (none study related). Five were lost to follow-up (unresponsive to three telephone calls and a letter). Analysis of baseline demographic and clinical data (Table 3) revealed no statistically significant differences between groups [$\chi^2(4,N = 104) = 4.4$, $p = 0.35$].

Table 3 Participant Demographic Characteristics

Group	UC* (n = 42)	LB† (n = 62)
Sex	N (%)	N (%)
Female	10 (24)	10 (16)
Ethnicity		
African American or Black	13 (31)	19 (31)
Asian or Pacific Islander	3 (7)	2 (3)
Caucasian, White	15 (36)	31 (50)
Hispanic, Latino, or Spanish origin	8 (19)	8 (13)
Native American or Alaska Native	1 (2)	1 (2)
Mixed heritage or other	2 (5)	1 (2)
Living situation‡		
Own home	2 (5)	11 (18)
Rental home/apt	18 (43)	23 (37)
With relatives	8 (19)	11 (18)
Board and care	11 (26)	16 (26)
Transitional	2 (5)	1 (2)
Education‡		
No diploma	2 (5)	3 (5)
HS diploma/GED	33 (79)	47 (76)
Bachelor's or equivalent degree	5 (12)	10 (16)
Higher prof. degree	1 (2)	2 (3)
Marital status		
Married	4 (10)	12 (19)
Single/cohabiting	19 (45)	33 (53)
Divorced/widower	19 (45)	17 (27)
Job status§‡		
Paid work	3 (7)	9 (15)
Unpaid work	5 (12)	8 (13)
None	34 (81)	44 (71)
Diagnosis		
Schizophrenia	19 (31)	12 (29)
Schizoaffective	22 (36)	10 (24)
Bipolar	5 (8)	9 (21)
Multiple	10 (16)	7 (17)
Other	6 (10)	4 (9)
Antipsychotic (weight gain risk)		
Olanzapine/clozapine (high)	5 (12)	8 (13)
Risperidone/quetiapine (med)	20 (48)	30 (48)
Aripiprazole/ziprasidone (low)	18 (43)	24 (39)
Other	3 (7)	7 (11)
Multiple	4 (10)	7 (11)
	Mean (SD¶)	Mean (SD¶)
Age (years)	50.4 (9.0)	51.9 (9.3)
Length of illness (years)	20.6 (13.1)	21.5 (14.0)
Age at onset (years)	29.8 (11.3)	30.1 (12.8)

*UC = Usual care
†LB = Lifestyle balance
‡Some subjects declined to respond
§Unpaid = homemaker, student, volunteer; none = retired, disabled
Based on DSM-IV criteria
¶SD = Standard deviation

Knowledge of Healthy Lifestyles

On a self-developed knowledge quiz (Online Appendix 1), no statistically significant change was found between groups. No association was found between symptoms of cognitive impairment and health knowledge.

Lifestyle Behavioral Changes

Exercise. There was no significant change over time in the number of hours participants exercised per week [$F(1, 1225) = 1.62$, $p = 0.20$]. There was no significant difference in the rate of change between groups [$F(1,1225) = 0.67$, $p = 0.41$], but LB reported an increase of an estimated 33 min per week, while UC increased by an estimated 9 min per week.

Caloric Intake. Overall, average daily calorie intake was 2055 initially for LB participants, which declined to 1650 at week 52 ($p < 0.001$). Total empty calories decreased, for an average reduction from 558 to 365 empty calories (i.e., solid fats, added sugars) per day ($p = 0.04$).

Anthropometric and Laboratory Measures

Participants demonstrated statistically significant differences in percent body fat change, which decreased for LB by an average of 0.4 over 12 months, while the UC group decreased by 0.2 [$F(1,1121) = 4.3$, $p = 0.038$]. Additionally, LB group waist circumference decreased on average by 1.04 cm, while the UC group increased by 0.25 cm [$F(1,1244) = 11.9$, $p < 0.001$]. Both groups lost weight compared to baseline, though differences between groups at 1 year were not statistically significant.

Age group stratification yielded no statistically significant differences, but BMI level stratification revealed significant differences in effect on weight [Table 4; $F(3,1247) = 24.27$, $p < 0.01$]. Participants with BMIs under 25 or over 40 responded

Table 4 Average Weight per Condition over Time and Stratified by BMI* Levels

		Week 0(kg)	Week 52 (kg)	Change (kg)
BMI*: 0–24.9	LB†	70.5	67.5	−2.0
N = 2	UC‡	74.8	74.9	+0.1
		Week 0 (kg)	Week 52 (kg)	Change (kg)
BMI: 25–29.9	LB	87.9	88.3	+0.4
N = 22	UC	80.7	80.1	−0.6
		Week 0 (kg)	Week 52 (kg)	Change (kg)
BMI: 30–39.9	LB	101.0	99.7	−1.3
N = 63	UC	103.1	100.3	−2.8
		Week 0 (kg)	Week 52 (kg)	Change (kg)
BMI: 40+	LB	137.9	131.4	−6.5
N = 17	UC	132.2	137.8	+5.6

*BMI = Body mass index
†LB = Lifestyle balance
‡UC = Usual care

Table 5 Simple Slope Analyses of Predicted Weight Change from Weeks 0 to 52 with Continuous Moderators (Based on Estimated Marginal Means)

Beck simple slope‡	UC*	LB†
	Kg (SD§)	Kg (SD§)
Low anxiety (Beck = 0)	−2.39 (4.94)	−1.27 (4.08)
Average anxiety (Beck = 12)	−0.42 (4.84)	−2.57 (3.97)
High anxiety (Beck = 24)	1.54 (5.22)	−3.86 (4.06)
SAIQ Simple slope‡		
Low SAIQ (SAIQ = 2)	−3.26 (4.85)	−1.14 (4.04)
Average SAIQ (SAIQ = 2.5)	0.09 (4.74)	−3.07 (3.94)
High SAIQ (SAIQ = 3)	3.42 (5.24)	−5.00 (4.23)

*UC = Usual care
†LB = Lifestyle balance
‡Low, average, and high are defined as mean -SD, mean, and mean + SD, respectively
§SD = Standard deviation
SAIQ = Self-Assessment of Illness Questionnaire

better to LB. Those with BMIs between 25 to 40 responded better to UC. Using gender as a moderator, a significant three-way interaction was found among treatment effect, gender, and weight. The treatment effect was larger for LB women, who by 26 weeks lost on average 2.18 kg [$F(1,1265) = 19.6$, $p < 0.001$] compared to between 0.5–1 kg for UC women and men in both groups. BMI followed: LB women decreased 0.9 points [$F(1,1246) = 13.9$, $p < 0.001$]. Waist circumference and body fat percentage also decreased, 2.92 cm [$F(1,1243) = 22.5$, $p < 0.001$] and 0.9% [$F(1,1221) = 4.76$, $p = 0.029$], respectively.

No significant differences were found between groups for hemoglobin A1c. Lipid profiles were either non-significant (HDL-cholesterol, triglycerides) or significant in the reverse direction than hypothesized (cholesterol, LDL-cholesterol).

Correlation with Psychiatric Symptoms

While weight loss was correlated with improvement in quality of life, no significant differences in quality of life scores were seen between groups. For psychiatric symptoms measured by validated scales for depression, psychosis, and anxiety,[28–31] all clinical scores decreased over time (ps < 0.001), but there were no differences between groups. There was evidence of an interaction effect of Beck Anxiety Inventory scores with the treatment on change in weight over time: [$F(1,165) = 3.7$, $p = 0.05$]. Analysts performed a simple slope analysis to explore this three-way interaction (Table 5). Higher anxiety scores were associated with increased treatment effect; LB participants with higher scores had more weight loss while UC participants with higher scores showed reduced weight loss or even weight gain.

Insight into psychiatric illness on the Self-Appraisal of Illness Questionnaire (SAIQ)[36] showed a significant association with treatment effect on weight change [$F(1,192) = 6.1$, $p = 0.01$] with higher scores associated with larger weight loss for LB, while for UC higher scores were associated with less weight loss or even weight gain (see Table 5). When controlling for SAIQ, LB showed significantly greater weight loss than UC [$F(1,192 = 5.2$, $p = 0.02$]. When asked questions about insight regarding weight-related illness, responses also showed higher weight-related SAIQ insight scores associated with larger efficacy of LB [$F(1,192) = 6.6$, $p = 0.01$] and significantly larger weight loss in LB compared to UC when controlling for SAIQ [$F(1,198) = 5.9$, $p = 0.02$].

Treatment Adherence

Based on participants' self-report, no significant difference was found in medication adherence or attendance at psychiatric or study appointments between groups (97–99%; Online Appendix 2). Ninety-two percent of LB participants completed food and activity journals on a regular basis (n = 55).

DISCUSSION

Participants in both LB and UC lost weight. UC was designed to be minimal, but regular research meetings to discuss diet and exercise may have been enough to motivate healthy lifestyle improvement, translating to weight loss. Even provided only self-help materials, participants may have been responsive to the accountability of frequent study appointments.

LB participants demonstrated important changes in nutritional behaviors; they reduced overall caloric intake and improved caloric quality by decreasing empty calories. They experienced additional benefits, decreasing waist circumference and adiposity, reflecting changes in body composition from exercise and weight loss. Food and activity journals also assisted participants in staying accountable to their goals.

Women seemed to be most responsive to LB, consistent with other findings.[50] Although the groups' weight loss was modest, the FDA considers 5% loss clinically important,[15] and

national guidelines recommend counseling obese adults to achieve clinical benefits from a modest 3%–5% loss.[51] Among participants completing at least 6 months, 28% lost 5% bodyweight in LB (N = 42), while 17% lost 5% in UC (N = 43) at last observation. The differences were not statistically significant using chi-square analyses.

Participants with BMIs under 25 or over 40 benefitted most from LB, suggesting the more intensive treatment could be targeted to these groups. Participants under 25 BMI likely passed screening because of recent rapid weight gain. Such patients may benefit from LB as a preventative approach to decrease their obesity risk. LB may also be a low-risk approach for those with BMIs over 40, who have a high chronic disease risk. For the majority of individuals taking APDs with BMIs between 25–40, one can consider UC's less intensive approach for weight loss.

LB participants with more insight into both their psychiatric illness and weight problem experienced the greatest weight loss. This implies LB was more effective for this subgroup of patients, because even with adequate insight UC participants did not lose as much weight, perhaps lacking motivational LB counseling. The association between higher anxiety scores and greater weight loss was unexpected, yet interesting, and merits future investigation.

LB participants were encouraged to reduce sugary beverage intake and portion sizes. These strategies were also found most helpful in the ACHIEVE study,[52] reinforcing the idea that simple strategies are effective for those with mental illness. According to the authors, ACHIEVE participants were provided two reduced-calorie meals as part of their outpatient psychiatric rehabilitation programs,[13] similar to participants in the RENEW program[14, 19] who received two meal replacements per day. In contrast, the primary nutrition intervention in this study involved classes and counseling to help participants independently make healthier decisions. Based on the DPP "Toolbox," one meal replacement per day was used for 13 interested individuals who struggled losing weight.[49]

Limitations

Study limitations included the selection of only patients with sufficient motivation to seek enrollment and competency to give informed consent because of research and HIPAA regulations. Inclusion criteria favored more stable patients, which may have yielded the extremely high treatment adherence we observed. Their health was also monitored more closely during participation, with direct access to RDs. However, some case managers within high-intensity mental health programs make scheduled home visits and may go to grocery stores with veterans, so such attention can be provided without RDs. Similarly, high levels of adherence to food and activity journaling within LB may be a result of constant reinforcement by RDs. In a real-world setting, clinician visits may be shorter because of higher patient volume. However, our results suggest simply asking patients to keep food journals may be enough to increase awareness of healthy choices. This part of LB may generalize to non-research settings as journals themselves may be effective tools for behavioral change. Simple changes can be made by reviewing journals and setting goals at each visit. Results may be less generalizable to the overall population because veterans were the primary participants, though we accepted some non-veteran women to increase their representation beyond current VA levels. Excluding UC participants who switched to LB and a drop-out rate similar to other weight management studies[53–55] limited statistical power.

CONCLUSION

Like our initial LB study, this multi-site replication and extension indicate that individuals with mental illness taking APDs are capable of making lifestyle changes and improving health. Changes in nutritional behaviors, waist circumference, and adiposity point toward long-term outcomes that may lead to reduction in risk from cardiovascular and metabolic diseases. In light of moving toward personalized healthcare, hospital administrators and clinicians can adopt LB and UC into existing outpatient mental health programs, targeted to offer relatively low-cost and noninvasive means to assist veterans taking APDs. Participants with more insight into their illness benefitted most from LB. Positive outcomes for UC participants suggest less intensive treatments can also help, with monitoring and accountability the likely key elements of success. We believe these interventions can be easily adopted in mental health programs, and we hope to disseminate the program further.

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Compliance with Ethical Standards:

Conflict of Interest: *Dr. Charles Nguyen owns stock in Orexigen Therapeutics, Inc., has received research grants from Forest Laboratory, Inc., and is a consultant and part of the Speakers Bureaus for Eisai Co., Ltd., and Otsuka America Pharmaceutical, Inc. All other authors declare no conflicts of interest.*

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