Outcome Evaluation of a Structured Educational Wellness Program in Patients With Severe Mental Illness

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Objective: Obesity is increasing at an alarming rate in the United States, as is the obesity rate in patients with schizophrenia. Our study retrospectively evaluated the effectiveness of the Solutions for Wellness and Team Solutions programs, 2 structured educational patient programs, and evaluated the effects on obesity and other metabolic markers in a large, naturalistic inpatient sample.

Method: Between September 18, 2006, and September 15, 2007, 275 inpatients with *DSM-IV-TR*–diagnosed chronic mental illness admitted to a tertiary care psychiatric facility were included in the 36-week comprehensive and manualized educational program for healthy lifestyles for patients with chronic mental illness incorporating psychoeducational small-group curricula. Patients were tested before and after each of three 12-week group periods by 30 knowledge-assessment questions, and metabolic markers were recorded at baseline, midpoint, and endpoint.

Results: Of the 275 included inpatients, 50.5% completed more than 5 modules, 20.4% completed less than or equal to 2 or fewer modules, and 5.1% completed all 11 modules. Significant increases in scores were observed for 7 of the 11 modules in the knowledge assessments ($P < .001$). Eighty-seven patients (43.72%) had a body mass index (BMI) ≥ 30 (indicating obesity) at the start of the program. There was a significant mean weight loss of 4.88 lb ($P = .035$) together with a significant decrease in mean BMI ($P = .045$). Patients with diabetes showed a reduction in mean weight of 5.98 lb. Significant reductions were observed in glucose and triglyceride levels (both $P < .05$). Patients with impaired glucose tolerance showed a significantly greater decrease in glucose level ($P = .000$). Sixty-nine patients (25.46%) met criteria for metabolic syndrome at baseline, and this number was reduced to 53 patients (19.56%) at endpoint; this decrease was significant ($P = .027$). Regarding relationship of change in knowledge after completion of the modules and metabolic changes, we found a significant correlation between reduction in weight and change in Fitness and Exercise score ($r = 0.62$, $P = .001$) and a significant correlation between the change score on Nutrition/Healthy Lifestyles and change in glucose values ($r = 0.56$, $P = .001$).

Conclusions: We found that a structured wellness program using a psychoeducational curriculum can be successfully implemented in a large, naturalistic psychiatric setting with unselected, chronically mentally ill inpatients. Results may help both clinicians and hospital managers to implement similar programs or to include successful components in existing programs for psychiatric patients.

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Obesity is increasing at an alarming rate in the United States, as is the obesity rate in patients with schizophrenia, in part due to the increased use of atypical antipsychotics.[1,2] Obesity can cause both short-term and long-term complications, which will further increase the burden of illness in patients with persistent mental illness. Complications include the development of diabetes, metabolic syndrome, hypertension, and other risk factors for cardiovascular disease, which occur in persons with schizophrenia at rates twice those of the general population.[3] Epidemiologic studies also reveal that persons with schizophrenia are likely to have their lives shortened by as much as 20%. Since obesity is a modifiable risk factor for heart disease, dyslipidemia, and diabetes, interventions that decrease the rates and severity of obesity have the potential for reducing both morbidity and mortality in persons with schizophrenia.

A range of factors contributes to obesity in people with serious and persistent mental illness, including lifestyle factors, such as poor diet, lack of exercise, and use of psychotropic medications.[4] Weight gain associated with the use of many psychotropic medications and particularly with the use of atypical antipsychotic medications[5] may lead directly or indirectly to insulin resistance over time. Although the second-generation antipsychotics have received wide acceptance in replacement of typical antipsychotics due to their reduced incidence of extrapyramidal symptoms, patients receiving atypical antipsychotics may experience a variety of other adverse effects, including weight gain and metabolic syndrome.[6] Atypical antipsychotics appear to have

a differential effect on weight gain, with olanzapine and clozapine causing most weight gain, risperidone and quetiapine causing intermediate weight gain, and ziprasidone and aripiprazole causing least weight gain.[7] In addition, higher triglyceride and cholesterol values have been reported in association with the use of atypical antipsychotics, suggesting that regular monitoring of weight, glucose values, and lipid levels in patients treated with these medications is extremely important.[8,9]

In response to these weight and metabolic morbidities in patients with persistent mental illness, there has been an effort to develop both preventive and therapeutic measures to address some of the metabolic complications. Interventions that decrease the rates and severity of obesity have the potential for reducing both morbidity and mortality in persons with schizophrenia. These interventions have ranged from pharmacologic treatments to dietary programs and more comprehensive educational interventions targeting change in lifestyles, dietary habits, and exercise.[10] Several lifestyle interventions have been used to specifically reduce obesity or to prevent weight gain induced by atypical antipsychotic medications.[11–15] Two recent studies have shown that obese adults treated with atypical antipsychotic medications for their severe mental illness were able to significantly decrease their weight, body mass index (BMI), glycosylated hemoglobin (HbA_{1c}) levels, and other metabolic measures after participating in a structured weight loss and educational program.[4,16] In contrast, patients who did not receive the weight control intervention continued to gain weight. While short-term weight loss can be achieved, there are few published long-term, randomized, controlled clinical trials to determine whether weight loss achieved in short-term studies is maintained. Two studies[4,16] were the first to provide long-term data (12 weeks and 24 weeks) showing that patients treated for schizophrenia or schizoaffective disorder with atypical antipsychotics can benefit from a weight control program. Another study has demonstrated successful weight loss with a 14-week behavioral program.[11] Two-thirds of patients lost at least 3% of body weight, and around 40% lost 5% of body weight or more.[11]

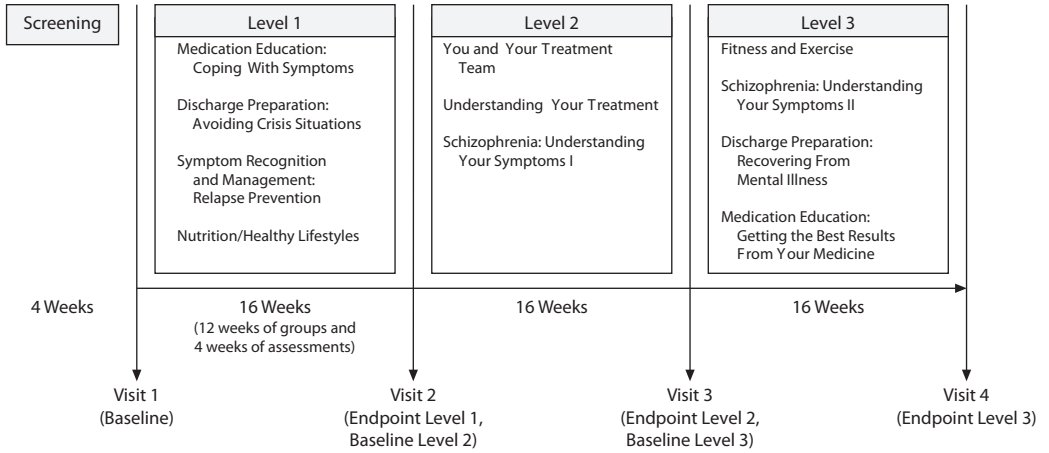
Lifestyle interventions have demonstrated efficacy for weight loss in obese persons without mental illness and have been shown to prevent or delay the development of type II diabetes in 40%–60% in different populations in controlled studies.[17,18] While behavioral interventions appear to be effective in weight gain control for patients who had weight gain induced by antipsychotics, the effectiveness of these interventions ranges from modest to good.[10] In addition, few programs have been developed in a manualized, comprehensive fashion and accompanied by teaching materials for such interventions to assist mental health professionals in treating metabolic disturbances in these patients.

The Solutions for Wellness[13] and Team Solutions[19] programs were disseminated by Eli Lilly and Company and the now defunct Partners for Excellence in Psychiatry at the University of Dentistry and Medicine of New Jersey. Eli Lilly and Company remains committed to the Team Solutions and Solutions for Wellness programs and continues to make them available for free on their Web site at www.treatmentteam.com. These comprehensive, modularized, psychoeducational programs were designed by psychiatric researchers, advocates, and clinicians with support from Eli Lilly and Company in an attempt to create a free and easily accessible psychoeducational approach to illness. The programs teach healthy lifestyles for people with chronic mental illness, incorporating psychoeducational small-group curricula on living healthy lifestyles, dietary information, exercise, illness knowledge, and relapse prevention. Some initial data on their implementation and effectiveness in patients with persistent mental illness have been reported.[13,20,21] However, there are few systematic outcome data on the effectiveness of this comprehensive wellness management program for larger samples of chronic schizophrenia patients and even fewer data on the effectiveness of the Solutions for Wellness and Team Solutions programs in hospitalized patients with persistent mental illness.

The present study was designed to evaluate the effectiveness of the Solutions for Wellness and Team Solutions programs in a large inpatient hospital setting for patients with schizophrenia or bipolar disorder. Our study aimed at expanding results of a recent smaller outpatient efficacy study performed by the authors of the Team Solutions program.[20] This randomized, single-blind study examined the effectiveness of the Team Solutions program during a 36-week period and found statistically significant improvement in the experimental group, in comparison to the control group, in knowledge about schizophrenia and found trends toward improved medication adherence and awareness of mental illness, suggesting that the Team Solutions psychoeducational program had empirical validity.[20] Utilizing Nutritional Knowledge modules and the structured exercise programs, these authors also found significant improvement in fasting glucose, diastolic blood pressure, hunger level, hip circumference, nutrition knowledge, and exercise level as compared to a nonintervention group.[20] However, these previous studies are limited due to small sample sizes and prescreened patient populations.

This was a retrospective, uncontrolled study including all patients who had been admitted to a tertiary care psychiatric facility and who participated in the program, which was integrated into the mandatory treatment mall hours (see Method, Intervention and Outcome Measures section), between September 1, 2006, and September 30, 2007. Inpatients were diagnosed as having *Diagnostic and Statistical Manual of Mental Disorders*, Fourth Edition, Text Revision (*DSM-IV-TR)* schizophrenia, schizoaffective disorder, or bipolar disorder. It was hypothesized that subjects participating in the 36-week Solutions for Wellness and Team Solutions programs would show improvements

Figure 1. Study Design of the Structured Educational Program for the Treatment of Obesity in Patients With Severe Mental Illness



from baseline (day 1) to endpoint (week 36) in the following: (1) knowledge about their mental illness as evidenced by a significant increase in scores on knowledge assessment scales and (2) improvement in metabolic markers (fasting glucose, HbA_{1c}, cholesterol, high-density lipoprotein [HDL] cholesterol, low-density lipoprotein [LDL] cholesterol, and triglycerides) and decrease in weight for patients who were overweight (defined as a BMI of 25.0–30.0) or obese (defined as BMI > 30) at baseline.

METHOD

Intervention and Outcome Measures

The Solutions for Wellness program (2nd ed, 2005;)[19] and Team Solutions program (2005 ed) [19] (current editions of both programs are available at www.treatmentteam.com) were implemented in a 340-bed tertiary state psychiatric inpatient setting, imbedded within a well-functioning rehabilitative treatment mall program with 4 hours of daily structured therapy and mandatory class times for all inpatients from Monday through Friday. The 2 programs are implemented together in 3 detailed segments that provide a manualized lesson-by-lesson curriculum for implementation on the treatment mall. The combined programs are comprised of detailed instructor and patient manuals, specific curricula, and pretests and posttests to determine the degree of acquisition of the learned materials. In the modules of Team Solutions, people with mental illness learn about symptoms of mental illness and what they can do to promote recovery and prevent relapse; in Solutions for Wellness, patients learn information and tips on nutrition, fitness, and practice exercise.

Group leaders for the programs were recruited from all mental health disciplines (psychiatry, psychology, social work, nursing, and rehabilitation). Preceding the inception of the program, group leaders were trained extensively on how to facilitate the successful implementation of the educational curriculum on the basis of the instructor and patient manuals. Care was taken to customize the program at the facility level. Instructions were given to staff on utilizing Web resources and on-site help. Once the curriculum material was integrated, staff was asked to practice the educational curriculum in simulated group sessions under supervision. In order to maintain fidelity of the program, discipline supervisors would regularly review the group sessions of their respective group leaders and give feedback.

This was a retrospective inpatient study using medical records data, laboratory records, and data generated by the Solutions for Wellness and Team Solutions programs. There were three 12-week group periods in which patients progressed from Level 1 to Level 3. Workbooks for each of 11 modules were provided to instructors and patients. Materials from the workbooks were discussed in daily morning and afternoon group sessions that were 50 minutes long. The 12 weeks of group work were complemented by two 2-week periods, one before and one after completion of the modules for pretest and posttest administration and scoring. Each group had 2 trained instructors with ≤ 15 patients per group. Sessions were interspersed within the patient's regular Treatment Mall classes (see Figure 1). The Treatment Mall is a physically distinct area from the inpatient wards, consisting of classrooms, group rooms, a library, a gymnasium, and computer rooms. Patients were required to leave their wards to attend the Treatment Mall from Monday to Friday.

Outcome Measures

The primary outcome measures for the Solutions for Wellness and Team Solutions programs were (1) change in pretest and posttest knowledge assessment scores attained for each module and (2) change in weight/BMI, blood

pressure, and metabolic markers (fasting glucose, HbA_{1c}, total cholesterol, total triglycerides, HDL, and LDL).

Knowledge assessment scores. Patients' knowledge of material from each particular 12-week group period was tested before and after the completion of the period. These self-assessments consisted of 30 questions presented in a questionnaire in a yes/no format. Questions were formulated in simple English, and patients were asked to complete each question with a yes or no under supervision of the group instructors. Difficult questions were read to the group by the instructors, and monolingual Hispanic patients had the questions translated into Spanish. When patients were assisted in comprehending the questions, instructors were asked not to suggest any answers. Each knowledge assessment resulted in 30 scores that were summed. Only patients who completed at least 1 pretest and posttest were included in the analyses.

Weight/BMI and metabolic markers. Weight was measured by nursing staff monthly in a standardized fashion; height was measured at admission. Fasting blood samples for biochemistry and hematology were taken at baseline for complete blood cell count, and comprehensive metabolic panel (drawn fasting between 6:00 and 8:00 am), including glucose, HbA_{1c}, total cholesterol, total triglycerides, HDL, and LDL. Although smoking is not permitted at the inpatient facility, data on smoking history of participants were obtained from medical records and from medical order forms for patients who were prescribed nicotine patches, and from staff observations for patients who, despite hospital rules, were observed smoking. These assessments were repeated at midpoint and at endpoint. All patients participating in the program also enrolled in a physical exercise program that included warm-ups, stretching, and mild to moderate aerobic exercise; all patients were required to participate in at least 10 minutes of exercise 5 days a week. Metabolic syndrome was defined according to World Health Organization (WHO) criteria (Appendix 1).[22]

Participants

All inpatients with *DSM-IV-TR* Axis I psychiatric diagnoses were included with the exception of patients on 3 units, who did not participate in the mall program. These 3 units (Admissions, Intensive Care, and Geriatric Unit) were not included either because of their high volume of short-term patients, enrollment in other specialized programs which did not permit them exposure to all modules, or because of patients' age. Also, patients from a specialized cognitive-behavioral program for patients with sociopathy (Service for Treatment and Abatement of Interpersonal Risk [STAIR]) were not included in the present analysis as these patients' curriculum is focused on programs geared toward addressing their sociopathy and as a result, they do not participate in all Solutions for Wellness and Team Solutions programs. All other male and female psychiatric inpatients were mandated to attend all Treatment Mall activities and were therefore included. Patients were aged at least 18 years and ≤ 65 years. For this program evaluation, as all of the assessments were part of the hospital-mandated Solutions for Wellness and Team Solutions programs, a waiver of informed consent was granted by the facility's institutional review board.

Concomitant Therapy

All patients received their prescribed medication treatment throughout the study period and were permitted to undergo significant medication changes when the clinical situation required it. In addition to the Solutions for Wellness program, patients also participated in additional classes in the following areas in the Treatment Mall: Aggression Management/Sexual Impulsive Behavior, Mental Illness-Chemical Abuse (MICA), Cognitive Rehabilitation, Social Skills, and Community Preparation. The Treatment Mall takes place during 2 consecutive hours in the morning and 2 consecutive hours in the afternoon from Monday to Friday. Each patient has an individualized weekly schedule for all mall activities. The Solutions for Wellness and Team Solutions programs were integrated into the existing mall structure and comprised about 80% of the 20 hours of weekly program time on the patient Treatment Mall.

Data Analysis

Demographic data were tabulated using standard statistical frequencies and descriptive methods. Continuous variables were summarized by sample size, mean, median, standard deviation, minimum and maximum, and range; discrete variables were summarized by frequencies and percentages. Only patients who took both the pretest and a posttest knowledge assessment for at least 1 knowledge assessment measure were included in the analysis. Our analysis used Little and Yau's[23] multiple imputation method for intent-to-treat analysis of repeated measures data for metabolic markers. For change in knowledge assessment scores, general linear mixed model–repeated measures (GLMM-RM) was used, with the knowledge assessments (endpoint – baseline for each level [16 weeks], then for the entire study period [48 weeks]) as the dependent variable. Type III sums of squares were used to test both main effects and interactions. All tests for knowledge assessments were set using a 2-tailed .001 significance level; all other evaluations were set to .05 significance levels.

The change in laboratory measures of metabolic markers (fasting blood samples for biochemistry including glucose, HbA_{1c}, total cholesterol, total triglycerides, HDL, and LDL) and treatment effect on change from baseline were assessed using a GLMM-RM, with baseline laboratory values as independent variables. All patients were compared at each visit and at endpoint via analysis of covariance with adjustment for age for specific knowledge assessments and length of hospitalization. Baseline weight and BMI values served as covariates. Generalized estimating equations

linear regression models, fit to repeated measurements of a particular scale, included effects for time trends, length of hospitalization, age at first hospitalization, baseline medical diagnosis of diabetes, and interactions, as well as other important baseline covariates. Chi-square analyses and the Fisher exact test (if there were fewer than 5 cases per cell) were conducted to assess the number of patients who met each criterion of the WHO definition of metabolic syndrome. If data were not available to adequately assess the presence of the metabolic syndrome, the variable was identified as "unclear evidence of metabolic syndrome" (8 patients). A linear regression model was applied to evaluate the impact of exposure to the program on outcomes (knowledge assessments and metabolic values). All statistical analyses were performed using SPSS 15.0 for Windows (SPSS Inc, Chicago, Illinois).

Table 1. Population Characteristics of Patients With Severe Mental Illness Participating in a Structured Educational Program for the Treatment of Obesity (N = 275)

Characteristic	Mean (SD)	Range
Age, y	44.25 (10.87)	19.99–64.24
Length of stay, mo	4.49 (6.75)	0.00–31.33
No. of previous hospitalizations	9.55 (6.48)	0–32
Axis I diagnosis	n	%
Schizophrenia	170	61.82
Schizoaffective disorder	46	16.73
Bipolar disorder	39	14.18
Other	20	7.27
Ethnicity		
Hispanic	61	22.18
Asian	9	3.27
White	22	8.00
African American	179	65.09
Other	4	1.45
Sex		
Male	229	83.27
Female	46	16.73

RESULTS

Participants and Baseline Data

A total of 402 inpatients (mean [SD] age: 42.94 [10.96] years, range, 18.63–64.41 years) were enrolled in the program at some time between September 18, 2006, and September 15, 2007, and completed at least 1 level of pretests and posttests. Although there were 402 patients who participated in the program, 127 patients who took pretest and posttest assessments were not included in the analysis (15 patients were > 65 years old; the remaining 112 were in the specialized STAIR program and did not participate in all aspects of the Solutions for Wellness and Team Solutions program), resulting in 275 evaluable patients. The *DSM-IV-TR* diagnoses at study entry of enrolled patients are presented in Table 1.

Medications. All enrolled patients continued on treatment with their medications; 31.27% of patients (n = 86) were taking 1 antipsychotic, and 68.73% of patients (n = 189) were taking 2 antipsychotics. Of the patients on monotherapy only, 97.67% (n = 84) were taking atypicals; for polypharmacy patients, 46.56% (n = 88) were taking 2 atypicals. Two patients were listed as being on no antipsychotic treatment.

The change in use of antipsychotic medications for olanzapine, clozapine, quetiapine, and risperidone during the study period was as follows.

Olanzapine. At baseline, n = 24, and at endpoint, n = 28; baseline mean length of time was 960.46 (732.46) days, endpoint = 1029.11 (839.14) days; baseline mean (SD) dose = 13.33 (11.43) mg/d, endpoint = 13.75 (6.18) mg/d.

Clozapine. At baseline, n = 61, and at endpoint, n = 73; baseline average length of time was 1004.34 (715.43) days, endpoint = 971.64 (815.23) days; baseline mean (SD) dose = 613.73 (119.032) mg/d, endpoint = 610.96 (165.04) mg/d.

Quetiapine. At baseline, n = 68, and at endpoint, n = 85; baseline average length of time was 733.98 (549.22) days, endpoint = 620.89 (602.29) days; baseline mean (SD) dose = 280.26 (125.42) mg/d, endpoint = 298.82 (102.36) mg/d.

Risperidone. At baseline, n = 40, and at endpoint, n = 46; baseline average length of time was 598.82 (592.62) days, endpoint = 526.28 (630.28) days; baseline mean (SD) dose = 2.67 (0.99) mg/d, endpoint = 2.46 (1.02) mg/d.

It should be noted that patients were not always exclusively taking 1 antipsychotic, thus statistical comparisons were not computed. Within the entire sample, 14.55% of patients (n = 40) were identified as smokers, 68.00% (n = 187) as nonsmokers, and 17.45% (n = 48) as "suspected/unclear evidence of smoking."

Program exposure. Of the 275 patients who were evaluable, 50.5% (n = 139) completed more than 5 modules, 20.4% completed less than or equal to 2 modules, and 14 (5.1%) completed all 11 modules. A total of 59 patients (21.45%) were discharged prior to the end of the study. The possible effects of the duration of exposure of the programs on knowledge assessment and metabolic outcomes were tested with a linear regression model. The model was applied to all patients exposed to treatment and did not show duration of exposure as a significant determinant of patient outcomes ($P > .05$ for all variables).

Baseline pretest assessments. No statistically significant baseline differences were observed in all pretest knowledge assessment scales with reference to the following parameters: age, sex, diagnosis at entry, and length of stay when these variables were introduced as covariates in the RM ANOVA.

Knowledge Assessment Scales

The numbers of weeks patients were in the program ranged from 12 to 36, and the mean (SD) number of knowledge assessments completed per patient was 6.79 (3.54). Statistically significant increases in scores were observed for 7 of the 11 knowledge assessment modules (Table 2). The greatest improvements in scores were observed for the Discharge Preparation: Avoiding Crisis Situations module,

Table 2. Change in Knowledge Assessments

Knowledge Assessment Module	n	Pretest, Mean (SD)	Posttest, Mean (SD)	Significance ($P<.001$)
Level 1				
Medication Education: Coping With Symptoms	126	18.08 (5.81)	20.30 (6.17)	$F_{1,125}=36.657$, $P<.001$
Discharge Preparation: Avoiding Crisis Situations	136	16.76 (6.25)	20.70 (6.44)	$F_{1,135}=85.550$, $P<.001$
Symptom Recognition and Management: Relapse Prevention	150	16.67 (7.15)	20.07 (6.34)	$F_{1,149}=75.697$, $P<.001$
Nutrition/Healthy Lifestyles	164	17.10 (7.57)	20.82 (6.64)	$F_{1,163}=69.268$, $P<.001$
Level 2				
You and Your Treatment Team	154	18.73 (7.25)	21.49 (6.81)	$F_{1,153}=44.291$, $P<.001$
Understanding Your Treatment	137	21.09 (6.46)	23.23 (6.79)	$F_{1,134}=33.707$, $P=.060$
Schizophrenia: Understanding Your Symptoms I	160	19.81 (7.14)	22.76 (7.06)	$F_{1,159}=57.410$, $P<.001$
Level 3				
Fitness and Exercise	112	16.97 (6.48)	20.27 (5.96)	$F_{1,111}=50.030$, $P<.001$
Schizophrenia: Understanding Your Symptoms II	113	18.47 (6.48)	19.91 (6.66)	$F_{1,112}=2.254$, $P=.085$
Discharge Preparation: Recovering From Mental Illness	129	17.54 (9.36)	18.39 (9.32)	$F_{1,128}=3.785$, $P=.059$
Medication Education: Getting the Best Results From Your Medicine	142	18.98 (6.33)	19.70 (6.31)	$F_{1,141}=4.616$, $P=.058$

Table 3. Distribution of Change in Scores on Knowledge Assessment Scales

	Change in Scores				
Module	Mean	SD	Mode[a]	Median	Range[b]
Overall change in scores (for all Knowledge Assessments)	2.49	4.77	2.00	2.50	−21.00 to 27.00
Discharge Preparation: Avoiding Crisis Situations (n = 136)	3.94	4.97	2.00	4.00	−19.00 to 18.00
Nutrition/Healthy Lifestyles (n = 164)	3.73	5.73	3.00	3.00	−17.00 to 21.00
Symptom Recognition and Management (n = 150)	3.39	4.78	2.00	2.50	−10.00 to 18.00
Fitness and Exercise (n = 112)	3.29	4.93	5.00	3.00	−13.00 to 27.00
Understanding your Symptoms I (n = 160)	2.96	4.94	0.00	3.00	−18.00 to 19.00
You and Your Treatment Team (n = 154)	2.75	5.13	3.00	3.00	−19.00 to 20.00
Medication Education: Coping with Symptoms (n = 126)	2.22	4.12	0.00	2.00	−17.00 to 12.00
Understanding Your Treatment (n = 135)	2.14	4.31	2.00	2.00	−14.00 to 16.00
Understanding your Symptoms II (n = 113)	1.44	4.57	1.00	1.00	−21.00 to 12.00
Discharge Preparation: Recovering from Mental Illness (n = 129)	0.85	4.93	0.00	0.00	−15.00 to 20.00
Medication Education: Getting the best results from your medicine (n = 142)	0.73	4.02	0.00	0.00	−13.00 to 18.00

[a]Scores of 0.00 indicate no change in scores from baseline to endpoint.
[b]Negative scores indicate a decrease in total score from baseline to endpoint.

with a 3.94 point increase in overall scores ($F_{1,135}=85.550$, $P<.001$); the Understanding Your Treatment module, which showed a 3.40 point increase in overall scores ($F_{1,149}=75.697$, $P<.001$); and the Fitness and Exercise module, showing a 3.30 point improvement in overall scores ($F_{1,111}=50.030$; $P<.001$). Table 3 illustrates changes in scores for all knowledge assessments scales. It should be noted, although all patients were required to take both pretests and posttests, that some patients were discharged prior to completion of posttests; therefore, not all of the 275 patients had pretest and posttest data.

We examined the effects of severity of illness on the change in knowledge assessment scores by using the length of stay as a proxy. The median length of stay prior to the start of the program was 12.08 months; therefore patients were grouped into a shorter length of stay group ≤ 11.92 months' length of stay and a longer length of stay group > 11.92 months' length of stay. Results indicated that for the Symptom Recognition and Management: Relapse Prevention module, patients with ≤ 11.92 months' length of stay (n = 108) showed significantly greater increases in posttest scores (pretest mean [SD] = 17.27 [7.95] and posttest = 21.63 [5.88]), compared to patients with > 11.92 months' length of stay (n = 41) (pretest mean [SD] = 19.41 [7.28] and posttest = 21.39 [6.69]; $F_{1,147}=8.198$, $P=.005$, $\eta^2=0.283$). Similarly, a significantly greater improvement was observed for the Understanding Your Symptoms I module for patients with ≤ 11.92 months' length of stay (n = 67; pretest mean [SD] = 22.45 [6.30] and posttest = 25.13 [5.56]) compared to > 11.92 months' length of stay (n = 70; pretest mean [SD] = 19.66 [7.52] and posttest = 20.29 [8.28]; $F_{1,135}=6.403$, $P=.013$, $\eta^2=0.210$).

Assessment of Degree of Improvement on Knowledge Assessments

Increase in knowledge was assessed as the percent of patients who showed 10%, 20%, and 30% improvement from baseline for each knowledge assessment scale. The largest percentage improvement was observed for the Medication Education: Coping with Symptoms module, which showed 56.35% (71/126) of patients experiencing ≥ 30% improvement. Overall, there were scores available for 1521 knowledge assessment tests (for paired pretest and posttest) completed by patients. Of all pairs of pretests and posttests completed, 57.40% (n = 873) were scored with ≥ 10% improvement, 37.80% (n = 575) with ≥ 20% improvement, and 31.03% (n = 472) with ≥ 30% improvement.

The change in scores for all knowledge assessment scales ranged from −21.00 decrease (less knowledge after

Figure 2. Change in Weight During Participation in the Program

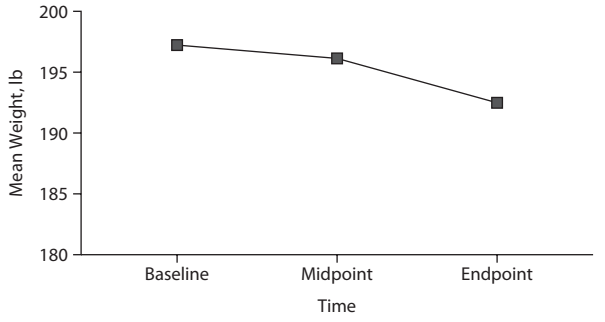
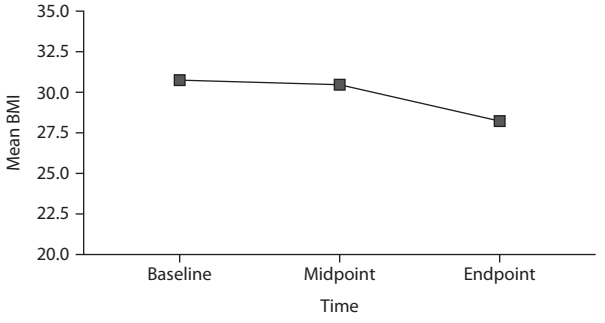


Figure 3. Change in Body Mass Index (BMI) During Participation in the Program

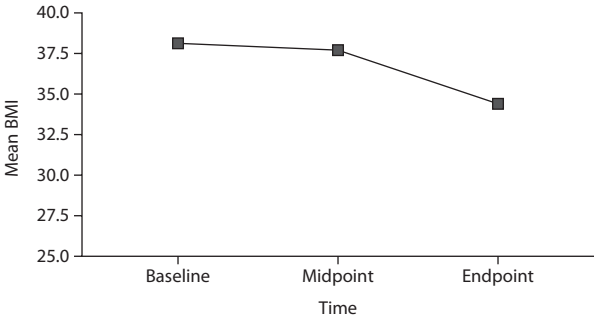


the intervention) from baseline to endpoint (Understanding Your Symptoms II) to a 27.00 point increase (increase in knowledge) from baseline to endpoint (Fitness and Exercise). The overall mean (SD) change in scores on all knowledge assessments was a 2.49 (4.77) point increase. The highest mean (SD) increase in scores from baseline to endpoint was observed for Discharge Preparation: Avoiding Crisis Situations, with a 3.94 (4.97) point increase in scores; Nutrition/Healthy Lifestyles, with a 3.73 (5.73) point increase in scores; and Symptom Recognition and Management, with a 3.39 (4.78) point increase in scores. See Table 3 for a distribution of change in scores on all knowledge assessment scales.

Body Weight and Metabolic Changes

A progressive and significant weight loss was observed for patients whose weight data were available for the 3 time periods (n = 199; $F_{1,198} = .613$, $P = .035$) (Figure 2). Mean baseline weight was 197.27 lb (SD = 40.23), showing a mean weight loss of 4.88 lb at endpoint. A significant difference was also found for change in BMI ($F_{1,198} = 20.976$, $P = .045$) (Figure 3). Eighty-seven patients (43.72%) had a BMI ≥ 30 (indicating obesity) at the start of the program.

Figure 4. Change in Body Mass Index (BMI) for Patients With BMI ≥ 30 During Participation in the Program



Repeated measures ANOVA for these 87 patients showed that there was a statistically significant reduction in BMI from baseline to endpoint ($F_{1,86} = 58.483$, $P = .024$) (Figure 4). Significant reductions were observed in glucose and triglyceride levels (both $P < .05$) but not in cholesterol levels after excluding patients taking cholesterol lowering medications (65 patients) (Table 4). No significant changes were observed for HbA_{1c} ($F_{1,93} = 1.821$, $P = .183$), HDL cholesterol ($F_{1,25} = 2.503$, $P = .064$), or LDL cholesterol ($F_{1,112} = .030$, $P = .864$) levels.

The relation between change in score in the Fitness and Exercise module and change in weight were reviewed. Pearson correlation analysis showed a significant correlation between weight and change in Fitness and Exercise score ($r = 0.62$, $P = .001$). Also, relation between change in score on Nutrition/Healthy Lifestyles and change in glucose, triglyceride, and HDL cholesterol levels were examined. Pearson correlation analysis showed a significant correlation between the change score on Nutrition/Healthy Lifestyles and change in glucose values ($r = 0.56$, $P = .001$). None of the changes in knowledge scores of the other modules resulted in significant correlations.

Concomitant Medical Conditions

Metabolic syndrome. Four distinct patients were identified as having unclear evidence of metabolic syndrome at baseline and endpoint, and these patients were excluded from the final analyses. Therefore, of the 271 patients, 69 (25.46%) at baseline and 53 (19.56%) at endpoint (Table 5) met WHO criteria for the metabolic syndrome; this decrease was significant ($P = .027$). Baseline and endpoint characteristics of the study population according to metabolic syndrome status are shown in Table 5. Categorical comparisons of WHO markers of metabolic syndrome of blood pressure ($\chi^2_1 = 33.783$, $P < .001$) and BMI ($\chi^2_1 = 38.613$, $P < .001$) showed significant differences from baseline to endpoint (Table 5).

Using the WHO definition for metabolic syndrome[22] and the NCEP ATP-III (Third Report of the National

Table 4. Change in Weight, BMI, and Metabolic Markers

Metabolic Marker	n	Baseline, Mean (SD)	Midpoint, Mean (SD)	Endpoint, Mean (SD)	Significance ($P < .05$)
BMI	199	30.71 (5.75)	30.47 (5.60)	27.20 (5.01)	$F_{1,198} = 20.976$, $P = .045$
Weight	199	197.27 (40.23)	196.13 (39.36)	192.39 (40.25)	$F_{1,198} = 6.367$, $P = .012$
Laboratory values					
Glucose	228	99.17 (31.07)	95.20 (27.26)	90.55 (18.49)	$F_{1,227} = 27.186$, $P < .001$
Triglycerides	249	152.48 (83.73)	151.20 (87.71)	143.44 (73.34)	$F_{1,248} = 4.707$ $P = .031$
Cholesterol	101	171.01 (34.46)	170.91 (42.38)	165.99 (35.08)	$F_{1,100} = 2.503$, $P = .117$
HDL cholesterol	251	46.227 (11.92)	45.13 (11.57)	45.12 (12.62)	$F_{1,250} = 2.503$, $P = .064$
LDL cholesterol	251	94.86 (26.08)	94.81 (25.98)	95.34 (30.27)	$F_{1,250} = .030$, $P = .864$
HbA_{1c}	94	5.68 (0.74)	5.77 (0.60)	5.78 (0.65)	$F_{1,93} = 1.821$, $P = .183$

Abbreviations: BMI = body mass index, HbA_{1c} = glycosylated hemoglobin, HDL = high-density lipoprotein, LDL = low-density lipoprotein.

Table 5. Change in Components of Metabolic Syndrome Before and After the Intervention

World Health Organization Criteria	n	Baseline n	%	Endpoint n	%	Categorical Data Analyses
Type II diabetes	275	72	26.18	72	26.18	NA
Blood pressure (≥ 140 mm Hg systolic or ≥ 90 mm Hg diastolic)	275	138	50.18	117	42.55	$\chi^2 = 33.783$, $P < .001$[a]
HDL cholesterol (male < 35 mg/dL, female < 39 mg/dL)	250	87	34.80	76	30.40	$\chi^2 = 2.871$, $P = .900$[a]
Plasma triglycerides (≥ 150 mg/dL)	252	92	36.51	91	36.11	$\chi^2 = 2.611$, $P = .981$[a]
BMI > 30 kg/m^2	174	88	50.57	54	31.03	$\chi^2 = 38.613$, $P < .001$[a]
Urinary albumin excretion rate ≥ 20 µg/min or albumin:creatinine ratio ≥ 30 mg/g	252	19	7.54	20	7.94	$\chi^2 = 2.164$, $P = .911$[a]
Metabolic syndrome present	271	69	25.46	53	19.56	Fisher exact $P = .027$

[a] $df = 1$.
Abbreviations: BMI = body mass index, HDL = high-density lipoprotein, NA = not applicable.

Table 6. Comparison of Diabetic Patients and Nondiabetic Patients Regarding Change in Metabolic Markers

Measure	n	Diabetic Patients, Mean (SD)	n	Nondiabetic Patients, Mean (SD)	Difference Between Groups ($P < .05$)
BMI					
Baseline	46	33.94 (6.33)	128	29.55 (5.06)	$F_{1,172} = 19.220$, $P = .060$
Midpoint		33.34 (6.25)		29.44 (4.97)	
Endpoint		30.55 (5.77)		27.36 (4.44)	
HDL					
Baseline	66	44.59 (13.07)	185	46.88 (11.45)	$F_{1,249} = 2.062$, $P = .152$
Midpoint		42.92 (11.94)		45.92 (11.37)	
Endpoint		43.77 (13.84)		45.61 (12.16)	
Cholesterol					
Baseline	31	168.26 (40.78)	71	172.33 (31.51)	$F_{1,100} = 2.545$, $P = .114$
Midpoint		164.00 (44.70)		173.91 (41.77)	
Endpoint		152.19 (33.50)		172.10 (34.34)	
Triglycerides					
Baseline	64	165.11 (94.07)	185	148.11 (76.66)	$F_{1,247} = 1.431$, $P = .233$
Midpoint		144.33 (97.59)		146.31 (83.75)	
Endpoint		145.39 (77.12)		142.76 (72.20)	
Glucose					
Baseline	63	115.84 (47.49)	145	92.81 (18.34)	$F_{1,206} = 27.729$, $P < .001$
Midpoint		106.60 (44.68)		90.85 (14.32)	
Endpoint		98.05 (27.56)		87.69 (12.50)	
Weight					
Baseline	55	215.96 (41.26)	144	190.13 (37.58)	$F_{1,197} = 16.396$, $P < .001$
Midpoint		212.59 (41.28)		189.84 (36.85)	
Endpoint		209.98 (41.03)		185.67 (37.99)	

Cholesterol Education Program Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults) version of the Framingham risk scoring (FRS)[24] system for calculation of 10-year coronary heart disease (CHD), we found that at baseline, 166 patients (60.36%) of the total sample were classified as having low risk (< 5%), while 41 (14.91%) were classified as having high risk (> 5%) for a CHD event. Among patients with metabolic syndrome at baseline, 33.3% (n = 23) were at significantly greater risk (> 5%) for developing a CHD event as compared to those without metabolic syndrome (21.78%, n = 44) (risk ratio = 1.64). Forty-three patients had metabolic syndrome at baseline, yet were at low risk for CHD, while 44 patients without metabolic syndrome were still at high risk for CHD.

Of the 43 patients with metabolic syndrome and < 5% CHD risk, 21 had < 1% and 22 had 2%–4% CHD risk. Analyses were not conducted on the effects of antipsychotic treatment on CHD risk, as the sample sizes for antipsychotic groups were highly unbalanced.

Diabetic patients. Seventy-two patients (26.18%) presented with type II diabetes, impaired fasting glucose, and/or impaired glucose tolerance at baseline. Patients with and without diabetes were compared on change in metabolic markers and change in knowledge assessments to assess differences. Results indicate a significant difference between groups for change in glucose ($F_{1,226} = 27.729$; $P < .001$), with the diabetic group showing significantly more reduction in glucose levels ($P < .001$). Group differences were also observed for change in weight ($F_{1,197} = 16.396$, $P < .001$), with the diabetic group showing a slightly greater mean reduction in weight of 5.98 lb compared with the nondiabetic group, which had a 4.46 lb decrease in mean weight. Data also indicate a trend in decrease in BMI from baseline to endpoint ($F_{1,172} = 19.220$, $P = .060$). Data on additional metabolic variables are presented in Table 6. Diabetic and nondiabetic patients were also compared on change in scores on 2 knowledge assessment scales: Nutrition/Healthy Lifestyles and Fitness and Exercise. Significant differences were observed between groups for change in the Fitness and Exercise module ($F_{1,110} = 5.330$, $P = .023$), with the diabetic group showing a 5.00 point increase in scores and the nondiabetic group showing only a 2.64 point increase in score. No group differences were observed for scores on the Nutrition/Healthy Lifestyles scale ($F_{1,162} = 0.023$, $P = .880$).

DISCUSSION

This program evaluation study showed that a structured, manualized group program focusing on wellness and psychoeducational targets can be successfully introduced in a large psychiatric inpatient setting with chronically mentally ill inpatients. Results from this naturalistic setting, which included an unselected wide spectrum of inpatients, indicate that there was a significant increase in many areas of patients' knowledge of illness management and healthy lifestyles. Out of 11 modules, 7 showed significant improvement, and 3 showed a trend toward improvement. In particular, participants gained a significantly greater understanding of nutritional issues and healthy lifestyles after the intervention as compared to baseline knowledge scores. Supporting the potentially positive effect on objective markers by gaining greater knowledge in areas of nutrition and healthier lifestyles, we found significant positive correlations between change in scores on the Nutrition/Healthy Lifestyles module and decrease in weight and fasting glucose levels. Patients also improved in areas of medication education, coping with symptoms, relapse prevention, discharge preparation, and crisis prevention, which may also have mediated some of the improvements in objective metabolic markers. Better understanding of key illness parameters, such as one's medications, and better understanding of one's symptoms may support more healthy lifestyles.

Younger age and shorter length of hospital stay prior to program start also significantly increased the response to some of the aspects of the program. Patients under the age of 43 gained greater knowledge in the Understanding Your Symptoms module compared to older patients. Patients with a median length of stay below 11.9 months acquired significantly greater knowledge than patients with longer lengths of stay in the Symptom Recognition and Management: Relapse Prevention module. It may be that younger patients and those with a shorter length of stay show more overall cognitive intactness and are able to retain better the materials taught in these modules. The largest increase in knowledge after completion of the program was seen in the Discharge Preparation module (3.94 point increase), while the least change was seen in the Getting the Best Results From Your Medicine module (0.73 point increase). These results may understandably reflect the greater motivation for discharge in these chronically hospitalized patients. In terms of degree of knowledge increase on modules focused on healthy lifestyles, the module Nutrition and Healthy Lifestyles garnered a 50% increase in knowledge scores seen in 39% of patients, pointing to the fact that this module effectively transmitted important knowledge about healthy nutrition principles and lifestyles. Both of these aspects may have had a beneficial impact on participants' improving some of their metabolic markers.

The metabolic baseline characteristics of this unselected and naturalistic sample of inpatients were significant for the marked presence of obesity and the metabolic syndrome. Eighty-seven patients (43.72%) had a BMI ≥ 30 (indicating obesity) at the start of the program, which is almost identical to the data obtained in the Clinical Antipsychotic Trials of Intervention Effectiveness (CATIE) study (42%).[7] We found that 25% of our patients were classified as having the metabolic syndrome and 26% were showing diabetes and/or glucose tolerance impairments. These latter numbers are comparable to those reported by CATIE, in which 11% of patients were found to be diabetic at baseline and 18.5% showed impaired fasting glucose.[7] In contrast, our rate of metabolic syndrome of 25.46% (at baseline) and of 19.56% (at endpoint) is lower than the one found for the CATIE sample (44%),[7] which may be in part related to our more stringent definition of metabolic syndrome. Overall, these data point to a population of patients with significant metabolic and cardiovascular risk factors in our study. This is also reflected in our calculation of the CHD risk rate, which resulted in 14.91% of patients being at high CHD risk in our sample. The CATIE patients showed a somewhat lower risk with 8% of patients being at high CHD risk. This makes it very urgent that methodologies be developed that achieve a reduction in metabolic risk factors.

In terms of objective markers for change in metabolic indices, we found modest but significant decreases in weight, BMI, fasting blood sugar, and triglyceride levels over the course of the program. There were no changes in HDL cholesterol, LDL cholesterol, and HbA_{1c} levels. In particular, for patients with a BMI ≥ 30 at the start of the program (ie, obese), we found a statistically significant reduction in BMI from baseline to endpoint. There was also a significant decrease in the number of patients who were classified as having the metabolic syndrome at baseline as compared to endpoint. The 2 components that significantly contributed to this decrease were the blood pressure decrease and BMI decrease, further supporting the effect of our intervention. We also found that patients with diabetes and/or impaired glucose tolerance at baseline showed significantly more reduction in blood sugar and weight as compared to patients without impaired glucose tolerance. It appears, then, that the program was able to target patients who were at particular metabolic and cardiovascular risk from impaired glucose tolerance.

Our results need to be placed in the context of results of other published wellness and weight reduction studies. Jean-Baptiste and colleagues[25] have comprehensively reviewed studies that have used a variety of controlled interventions and found decreases in weights, similar to our own results. The average duration of these interventions was 19.5 weeks (range, 12 weeks to 52 weeks) and resulted in a mean loss of weight of only 4.5 lb from baseline to endpoint. Only 6 of a total of 9 studies had significant results in weight reduction. Our own results of a loss of 4.51 lb are therefore comparable to the published literature[25] and are particularly noteworthy, as all our available patients were included in our naturalistic study, in contrast to all published studies, which included only patients who volunteered to enter the various treatment interventions and could be therefore termed as being more motivated. Wu et al[10] included interventions similar to ours, such as psychoeducational, dietary, and exercise programs, in their 12-week study comparing lifestyle changes with and without concomitant metformin. They also found significant changes in weight, BMI, and FBS for the group using lifestyle changes alone.

Our results are also similar to the ones obtained by Vreeland et al,[20] who used the new edition of the Team Solutions program. These authors offered a daily, 60-minute Solutions for Wellness group (n = 34) 5 times per week, for 8 weeks and compared this to another outpatient site where clients received "treatment as usual" (n = 31). They found a reduction of 1.3 lb over the 8-week duration of the intervention as compared to an increase in weight of 2.8 lb in their comparison group. In addition, similar to our results, subjects in the intervention group, compared to subjects in the control group, evidenced statistically significant ($P < .001$) improvements in knowledge and attitudes about wellness, as well as significant reductions in body weight ($P < .05$).

The moderate weight-loss results seen in our as well as in other studies, in spite of a variety of comprehensive interventions directed at lifestyle changes and the use of multiple modalities, reflect the challenge persistently mentally ill patients have to overcome in order to change lifestyles and to maintain helpful dietary behaviors. Part of this difficulty is also related to the weight gain associated with antipsychotic medication treatment. In the CATIE study, Lieberman et al[7] found that over an 18-month period, considerable weight gain (7% of baseline weight) occurred in 30% of olanzapine patients, but in only 7%–16% of patients taking other antipsychotic drugs. In a large schizophrenia first-episode study, patients gained an average of 16 kg on treatment with olanzapine and 7.5 kg with haloperidol, with BMI increases of 4.7 and 2.7 kg/m^2, respectively, over a course of 2 years.[26] Interventions to reduce or neutralize potential weight gain need therefore to be multifaceted. On the behavioral level, such interventions need to include at a minimum a whole array of illness management and healthy lifestyle interventions, such as those used in the Solutions for Wellness and Team Solutions programs, together with exercise programs. In addition, interventions using behavioral reinforcements may have to be added to the program. A recent pilot study by Jean-Baptiste and colleagues[25] used a behavior modification intervention in addition to traditional dietary counseling sessions to address weight gain in obese patients with schizophrenia. This included weekly payments of up to 25 dollars, which was an indirect method of food provision and at the same time served as a financial incentive for group attendance. While the magnitude of weight loss at the end of the 16-week intervention period (mean = 6.41 lb) was comparable to other similar studies, the mean weight loss at 6 months after completion of the intervention of 10.41 lb exceeded most previous studies and was achieved without booster sessions.

There are a number of limitations to our study. Our outcome data are based on patient data from a nonrandomized sample without a parallel control condition. It may be that patients in our study would have improved on our outcome measures just due to the passage of time or due to staff enthusiasm with the program. Another confounding limitation is possible medication changes during the program implementation, which may have contributed to our findings. Since we did not specify the type and dosage of antipsychotics and other psychotropics that clinicians could use during the duration of the program, it is possible that such changes may have confounded our data. In fact, as our medication data show, the use of typically weight-adding medications did slightly increase during the study period, making a change in the use of these medications therefore an unlikely factor in our weight reduction results. In addition, we have been able to exclude the effects of any specific weight-reducing pharmacologic interventions as we did not find any use of methylphenidate-type drugs or topiramate in our medication data from our facility during the time of our study.

On the other hand, the validity of our data is enhanced by the large sample size (N = 275) and the naturalistic and unselected characteristics of our sample. Patients included in this program were not volunteering, and some of them were most likely rather unmotivated to change their lifestyles and reduce weight, unlike in controlled studies, in which it can be assumed that all participating patients are motivated to enter a weight-reduction program. Our open inclusion criteria represent a strength of our study as these patients are usually not part of studies testing the effectiveness of a new intervention.

Another limitation is the design of the study, whereby not all of the patients whose weight and metabolic data we were able to analyze had the full exposure to all the modules of the program for the entire duration of the program. While all patients included in the weight and metabolic data analysis had an exposure of at least 1 group period of 12 weeks' duration with pretest and posttest knowledge assessments, it is possible that our metabolic results might have been even stronger if all patients had the benefit of exposure to all modules of the program. Another limitation is that we do not have at this time data on the maintenance of the effects of our intervention after patients leave the program.

Finally, patients who were tested on the knowledge questions received the same set of questions after completion of a group period of 12 weeks. It is possible that some of the increase in knowledge observed in the posttest scores was related to the fact that patients remembered the answers to the pretest questions. However, we feel that this possibility is less likely to have been a factor, as not all modules showed improvement; 7 of 11 modules of the program showed improvement. In addition, patients with chronic schizophrenia are known to have significant memory impairments, which usually are 1 to 2 standard deviations below values seen in healthy people.[27]

CONCLUSIONS

We found that a structured wellness and psychoeducational program can be successfully implemented in a large naturalistic setting with unselected, chronically mentally ill inpatients. Results indicate that there was a significant increase in many areas of patients' knowledge of illness management and healthy lifestyles. The program contributed to a significant reduction in objective metabolic indices, such as weight, BMI, FBS, and triglyceride levels. Results from this outcome analysis may help both clinicians and hospital managers to implement similar programs or to include successful components in such programs addressing weight and metabolic abnormalities in psychiatric patients.

Drug names: aripiprazole (Abilify), clozapine (Clozaril, FazaClo, and others), haloperidol (Haldol), metformin (Riomet, Fortamet, and others), olanzapine (Zyprexa), quetiapine (Seroquel), risperidone (Risperdal and others), topiramate (Topamax), ziprasidone (Geodon).

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Appendix 1. WHO Criteria for Metabolic Syndrome[a]

Patients classified as having the metabolic syndrome had to show the following criteria:

A. Insulin resistance, identified by 1 of the following:
- Type 2 diabetes
- Impaired fasting glucose
- Impaired glucose tolerance (IGT; 2-hour glucose levels of 140–199 mg/dL [7.8–11.0 mmol/L] on the 75-g oral glucose tolerance test. A patient is said to be under the condition of IGT when he/she has an intermediately raised glucose level after 2 hours, but less than would qualify for type 2 diabetes mellitus. The fasting glucose may be either normal or mildly elevated.)
- or for those with normal fasting glucose levels (< 110 mg/dL), glucose uptake below the lowest quartile for background population under investigation under hyperinsulinemic, euglycemic conditions

B. Plus any 2 of the following:
- Antihypertensive medication and/or high blood pressure (≥ 140 mm Hg systolic or ≥ 90 mm Hg diastolic)
- Plasma triglycerides ≥ 150 mg/dL (≥ 1.7 mmol/L)
- HDL cholesterol < 35 mg/dL (< 0.9 mmol/L) in men or < 39 mg/dL (1.0 mmol/L) in women
- BMI > 30 kg/m^2 and/or waist:hip ratio > 0.9 in men, > 0.85 in women
- Urinary albumin excretion rate ≥ 20 µg/min or albumin:creatinine ratio ≥ 30 mg/g

[a]Reprinted from Alberti and Zimmet.[22]
Abbreviations: BMI = body mass index, HDL = high-density lipoprotein.