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METABOLIC MANAGEMENT MODEL IN PSYCHIATRIC OUTPATIENTS: A REAL-WORLD EXPERIENCE

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SUMMARY

Obesity and weight gain represent a challenging issue in people suffering from schizophrenia and other severe mental illnesses (SMI). Most of clinical guidelines for the management of overweight and obesity in people with SMI share a stepwise approach starting with more conservative interventions, with diet, physical activity, lifestyle coaching and behavioral modifications. The aim of this study was to evaluate the effectiveness of a group weight management program in a real-world outpatient Italian setting. Data from 100 patients diagnosed with schizophrenia or bipolar disorder, undergone to a group metabolic management program, were analyzed through a 12 months follow-up. The main body weight (kgs) decreased from 98.01±18.30 at baseline to 93.29±17.36 (p>0.001) at 6 months to 90.35±17.90 at 12 months. Parallel statistically significant decreases were found for BMI, waist circumference, glycaemia and systolic blood pressure. After patients' segmentation into normal-weight, overweight and obese at baseline, the significant of the decrease emerged only between baseline and the 6-month endpoint, thus suggesting that the program was successful in the short-term. Notwithstanding the limitations of the study, the 12-month intervention evaluated demonstrated feasibility and a high retention rate. This allowed a relevant weight reduction during the first six months, followed by durable maintenance until the end of the study. Current NICE recommendation guidance indicates that people with SMI, particularly those on antipsychotic treatment, should be provided with integrated nutrition and exercise programmes by their healthcare professional. Future research should focus on the effectiveness and cost-effectiveness of this kind of interventions and their reliability in the different real-world healthcare settings.

Abbreviations: *SMI – Severe Mental Illnesses; WHO – World Health Organization; CVD – Cardiovascular diseases; DSM 5 TR - Diagnostic and Statistical Manual of Mental Disorders 5th Edition Text Revised; BMI – Body Mass Index*

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INTRODUCTION

Antipsychotic drugs are the core pharmacological treatment of schizophrenia and bipolar disorder but they are often associated with an increased risk of weight gain and other cardiometabolic adverse events (Cooper et al. 2016, Huhn et al. 2019). On the other hand, people suffering from schizophrenia are more likely to be obese or overweight, with 25.9% being obese and 60.1% overweight, respectively compared to 13% and 39% in the general population (Afzalet al. 2021, WHO 2021). The World Health Organization (WHO) reports that obesity is the fifth major cause of death worldwide and it may contribute to a broad range of serious health complications, such as type 2 diabetes, cardiovascular diseases (CVD), arthritis and many different cancer types (WHO 2021). However, recent literature has shown that antipsychotic treatment is directly correlated with a significantly decreased risk of all-cause, cardiovascular, and suicide mortality (Vermeulen et al. 2017, Taipale et al. 2020). Such findings on long-term mortality risk may appear in conflict with antipsychotic metabolic potential side effects. This discrepancy is likely due to the improvement in psychopathology linked to continuous antipsychotic therapy. This may facilitate healthier lifestyle behaviors and the proper utilization of health care resources to manage organic diseases (Correll et al. 2018, Taipale et al. 2020). Obesity and weight gain remain a crucial issue that needs to be addressed in people suffering from schizophrenia and other severe mental illnesses (SMI). A broad variety of guidelines dealing with obesity management both for the general population and for SMI have been published in the last decade (NICE 2014, Apovian et al. 2015, Pasquali et al. 2020). Most of them share a stepwise approach starting with more conservative interventions, with diet, exercise, lifestyle coaching and behavioral modifications. Second line approaches include pharmacological interventions (comprising interventions on psychotropic treatments; i.e. switching or reducing medications at higher risk of increasing weight and/or adding weight-loss or appetite regulating drugs). Third-line approaches, when previous lines fail, include bariatric surgery but it is usually considered a last resort and should only be pursued after careful consideration of the risks. The aim of this study was to evaluate the effect on body weight and other anthropometric parameters of a group weight and metabolic management program in a real-world outpatient Italian setting.

SUBJECTS AND METHODS

The objective of this retrospective clinical study was to assess the effectiveness of a weight and metabolic management program in patients with SMI. Specifically, clinical records of outpatients diagnosed with schizophrenia or bipolar disorder according to the Diagnostic and Statistical Manual of Mental Disorders 5th Edition Text Revised (DSM-5-TR) criteria, treated in the Department of Mental Health of ASL Biella (Biella, Italy) from January 2022 and December 2023 and previously included in the weight management program, were analyzed. Inclusion criteria were: patients diagnosed with schizophrenia or bipolar disorder according to DSM-5-TR criteria; aged ≥ 18 years; participation in the weight and metabolic management program. Exclusion criteria were history of traumatic brain injury and mental retardation. Each subject was informed of the purpose, procedures and potential risk of participation and signed an informed consent form authorizing potential use of their anonymously collected data for teaching or research purposes. The weight and metabolic management protocol comprised a 12 months group training of lifestyle coaching along with three visits during which analytical, anthropometrical and clinical parameters were collected. The timeline of the three visits was at baseline, at six months and at 12 months after the baseline. Patients received nutritional and physical lifestyle coaching sessions related to: unhealthy lifestyle and its metabolic consequence; diet education; physical exercise promotion; diet planification and problem solving. Intervention was conducted in a group setting with 10 subjects in each group and lasted 8 weeks. The baseline visit involved gathering of demographic and clinical data, psychotropic treatment and tobacco use collected by means of questionnaire specifically designed for this program and administered by trained healthcare staff. Anthropometric parameters, glycaemia and blood pressure were collected at each of the three visits. Weight was measured in kilograms (kgs), while participants wore their underwear, stood barefoot, with their arms by their sides, and their weight evenly distributed on both feet in the center of the scale. Height was measured in centimeters, with patients standing barefoot and keeping feet together. Waist circumference was measured in centimeters and it was considered the maximum value achieved by surrounding the hip horizontally with the tape. Body mass index (BMI) was calculated by dividing the weight in kilograms by the square of the height in meters (BMI = weight[kg] / Height^2[m^2]). BMI status was determined according to WHO values: BMI 18.5 to 24.9 kg/m^2 normal weight; BMI 25 to 29.9 kg/m^2 overweight; BMI 30 kg/m^2 obese. Anthropometric parameters and glycaemia at baseline, 6 months, 12 months were compared using General Linear Model for repeated measures for continuous variables. Categorial variables were compared using Friedman non-parametric test with Wilcoxon Signed Ranks post-hoc analysis. Statistical analyses were performed by means of the SPSS® software, version 19. Significance cut-off level was set at $p<0.05$.

Table 1. Socio-demographic and clinical characteristics of the sample

Parameters	N=100
Age, years (mean ± SD)	53.1 ± 12.4
Sex, n (%)	
Male	53 (53)
Female	47 (47)
Marital status, n (%)	
Single	24 (24)
Married	58 (58)
Divorced	18 (18)
Educational level, years (mean ± SD)	9.2 ± 4.2
Working for pay, n (%)	
Yes	36 (36)
No	64 (64)
Main psychiatric diagnosis, n (%)	
Schizophrenia	77 (77)
Bipolar disorder	23 (23)
Psychiatirc comorbidities, n (%)	
Yes	62 (62)
No	38 (38)
Type of psychiatric comorbities, n (%)	
Major Depression	13 (38.2)
Substance Use Disorder	2 (5.8)
Panic Disorder	4 (11.7)
Generalized Anxiety Disorder	1 (2.9)
Personality Disorders	1 (2.9)
Borderline	2 (5.8)
Schizoid	1 (2.9)
Schizotypic	1 (2.9)
Pharmacotherapy, n (%)	
Antipsychotics	88
Antidepressants	13
Mood Stabilizers	12
Benzodiazepines	36
No treatment	2
Long – Acting Injectables	10
Polypharmacy	54

RESULTS

100 patients, of which 77 with a diagnosis of schizophrenia and 23 with a diagnosis of bipolar disorder, completed the follow-up period of 12 months. Table 1 shows the socio-demographic and clinical characteristics of the patients included and the relative available data. In terms of pharmacological treatment, 88% of subjects took an antipsychotic (10% of them took a long-acting antipsychotic), and 54% were taking multiple psychotropic medications. The main number

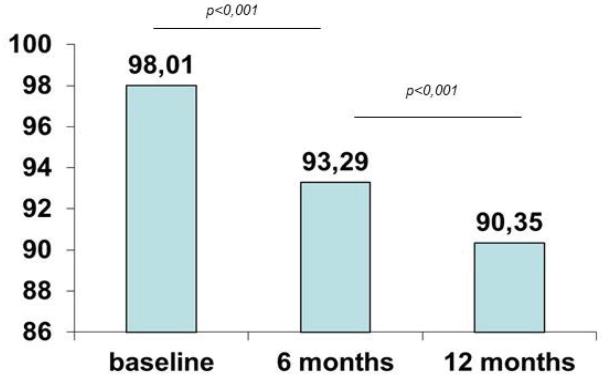

Figure 1. Weight change (kg) in the sample

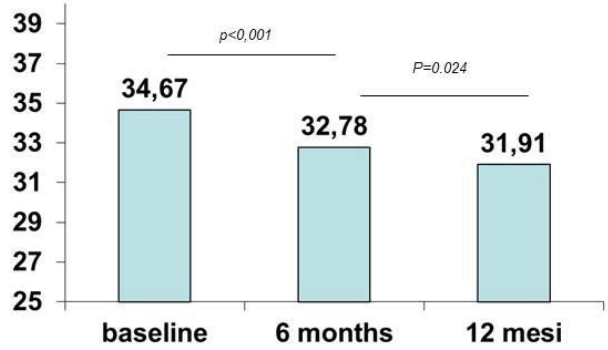

Figure 2. BMI change in the sample

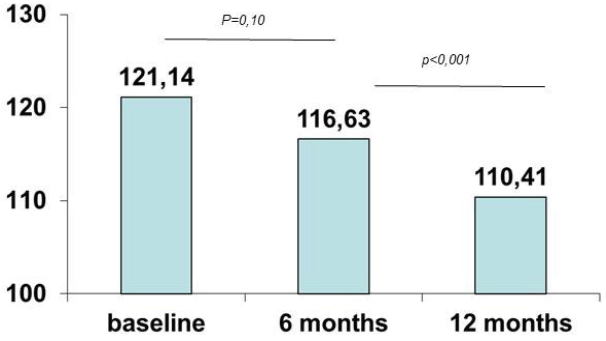

Figure 3. Waist circumference (cm) change in the sample

of psychotropic drugs prescribed was 1.7±0.8. The main weight reduction (kgs) through follow-up was from 98.01±18.30 at baseline to 93.29±17.36 (p>0.001) at 6 months to 90.35±17.90 at 12 months (p>0.001) (Figure 1). In parallel, the mean BMI lowered from 34.67±5.91 at baseline to 32.78±5.99 at 6 months (p>0.001) to 31.91±5.66 (p=0.024) at the end of follow-up (Figure 2). Mean waist circumference (cms) decreased from 114.22±14.55 at baseline to 109.43±12.98 at 6 months (p<0.00) to 106.16±13.68 (p<0.00) at the end of the study (Figure 3). Figure 4 illustrates variation in blood pressure: only systolic pressure was characterized by

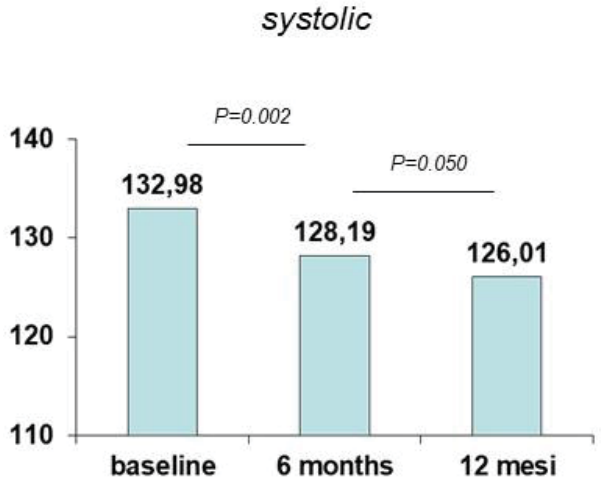

Figure 4. Blood pressure (mmHg) change in the sample

a statistically significant decrease while diastolic values showed only a non-significant decreasing trend. Glycaemia mean values (mg/dL) dropped from 121.14±31.23 to 116.63±26.39 at 6 months (p=0.10) to 110.41±24.00 at 12 months (p<0.00) (Figure 5). After categorizing patients at baseline into normal-weight, overweight and obese the Friedman test and Wilcoxon test reported significant reduction only from baseline to 6 months (p<0.001) while from month 6 to month 12 there was no statistical difference in body weight variation (Figure 6).

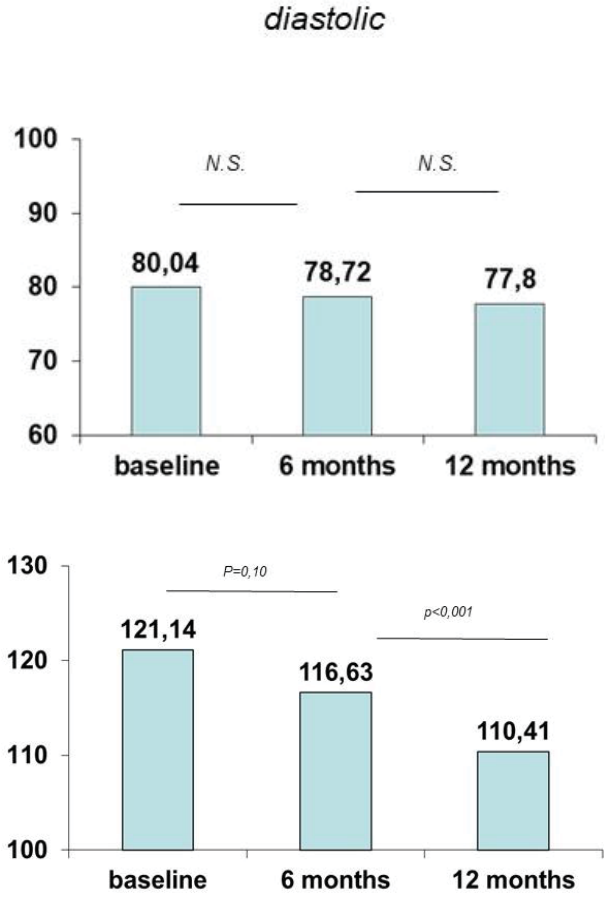

Figure 5. Glycaemia (mg/dL) change in the sample

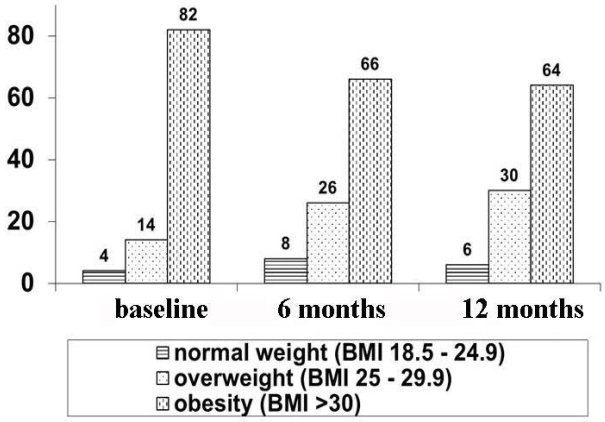

Figure 6. Weight change distribution (N) change according to BMI classes

DISCUSSION

The objective of our study was to investigate the body weight, anthropometric and metabolic variations in patients suffering from SMI who underwent a 12-month weight and metabolic management group program in an Italian mental health outpatient service. Our results showed a progressive reduction in almost all parameters evaluated including body weight, BMI, glycemia, waist circumference, and systolic blood pressure from baseline to the 12-months endpoint. Diastolic blood pressure showed only a non-significant reduction trend. To gain a deeper understanding of the effect of the program on body weight, we categorized patients at baseline into normal-weight, overweight and obese. After this segmentation, a significant decrease emerged only between baseline and the 6-month endpoint. From 6-month to the end of the study there was simply maintenance of the already observed body weight decline. This suggested that the program was successful in reducing body weight in the short-term, but maintenance of the body weight decline was not sustainable in the long-term. Many trials indicate that SMI participants are unlikely to be engaged in weight reduction protocols, possibly because of unaddressed access barriers. Unexpectedly, in our observation, all patients completed the 12 month evaluation period with virtually no drop-outs, thus demonstrating the high acceptability of the program. A behavioral intervention to support weight management in SMI people with a shorter observation period (12 weeks) was recently proposed (Lee et al. 2023) showing a retention rate of 94%. The high difference in study duration makes it impossible to directly compare those results. Recently published meta-analytic findings emphasized significant body weight reduction only in two studies of the six examined with intervention duration longer than 12 months (Naslund et al. 2017). The STEPWISE study, a recent RCT on a weight management group intervention reported that 54% of the 414 included participants had 'good' compliance with the group-tailored program and an 84% completion rate (Holt et al 2019) showing that this type of group intervention may have a high retention rate, though not reaching statistical significance in terms of weight loss compared to the treatment as usual arm. Our results are consistent with two large previous U.S. studies. During the ACHIEVE study (Daumit et al. 2013), participants enrolled in the experimental group lost an average of 3.2 kilograms throughout the 18-month observation; conversely, in the STRIDE study (Green et al. 2015), participants lost 4.4 kg more than controls from baseline to 26 weeks before reducing this difference to 2.6 kilograms after 52 weeks. The ACHIEVE and the STRIDE programs were similarly intensive in nature. In the ACHIEVE protocol, weight supervision consultations were conducted weekly for the first six months, then monthly. These consultations were accompanied by monthly individual visits and three weekly group classes. The STRIDE protocol included the first 26 weeks of weekly group intervention followed by six monthly group sessions for maintenance. The STEPWISE study enrolled patients suffering from schizophrenia; on the other hand, 41.9% of ACHIEVE study subjects and 71% of STRIDE ones were diagnosed with diseases other than the schizophrenia spectrum, likely to be more receptive to behavioral modifications. In our study the percentage of people suffering from schizophrenia was 77% versus 23% of patients with bipolar disorder. The overall low rate of comorbidities in our sample may have contributed to the successful results in the first 6 months of observation and maintenance afterwards. Unfortunately, as a limitation, our study lacks a control group. However, our encouraging results in a sufficiently large population will stimulate further investigations into this kind of intervention. Other limitations of our study may be the single center recruitment and the retrospective nature of data collected that might have affected the generalizability of the findings. The challenge of managing obesity and weight gain in patients with schizophrenia still remains an issue and other approaches are needed. Most of these studies, including ours, focused on lifestyle modification rather than weight gain and obesity contributing factors such as pharmacotherapies. Antipsychotics (mostly some atypicals) are known to be associated with potential excessive weight increase, while schizophrenia itself together with personal psychological factors can interfere with improvements in life habits and healthy behavior. Individual or small group tailored lifestyle modifications supported by psychological assistance, antipsychotic therapy adaptations, or co-prescription of drugs, such as metformin (Cooper et al. 2016), semaglutide (De et al. 2023) or liraglutide (Lee et al. 2022) may be useful and require further investigation.

CONCLUSIONS

Notwithstanding the limitations of the study, our 12-month intervention demonstrated significant feasibility and a high retention rate. This allowed a significant weight reduction during the first six months, followed by durable maintenance until the end of the study. Current NICE recommendation guidance indicates that people with SMI, particularly those on antipsychotic treatment, should be provided with an integrated nutrition and exercise program by their healthcare professional (NICE 2014). Future research directions should address the effectiveness and cost-effectiveness of this kind of interventions and their feasibility in the different real-world healthcare settings.

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Conflict of interest: *None to declare.*

Contribution of individual authors:

Vassilis Martiadis: study design, interpretation of data and manuscript writing.

Enrico Pessina & Azzurra Martini: study design and literature search.

Paola Matera: data collection and study design.

Fabiola Raffone, Francesco Monaco, Annarita Vignapiano: literature search and manuscript review.

Carlo Ignazio Cattaneo: data collection, literature search and manuscript review.

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