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Long-term psychoeducation in limiting body mass gain in patients treated with atypical antipsychotics

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Summary

Aim. The aim of the study was to assess efficacy of psychoeducation in limiting body mass gain in patients with schizophrenia undergoing atypical antipsychotics monotherapy treatment.

Material and method. Education program *Caring for Health and Silhouette*, commissioned by Moneo Pharma Group, was implemented for patients with schizophrenia. The aim of the program was providing patients with information regarding lifestyle and nutrition.

Results. The one-year follow-up was completed by 7,541 patients. The mean BMI (body mass index) gain in one-year follow-up was 0.56 and the difference between men (0.52) and women (0.60) was statistically significant ($p < 0.001$). The mean one-year body mass gain was 1.63 kg, whilst the mean one-year increase in waist circumference was 1.25 cm. There were no statistically significant differences between sexes. The subjective evaluation of patient compliance increased systematically with every visit, both for men and women. High-compliance patients less frequently experienced body mass gain ($p < 0.001$), while obese patients experienced the greatest decrease in BMI.

Conclusions. Education program resulted in a decrease of body mass gain in obese patients treated with atypical antipsychotics. Patients with BMI ≥30 more often than other patients experienced the reduction of body mass during education program. The quality of cooperation during the first and second visit has a predictive value for the estimation of body mass changes during education program. This method of education is easy to implement in clinical practice.

Key words: schizophrenia, atypical antipsychotics, psychoeducation, body mass

Introduction

Body mass gain in patients treated with antipsychotics is a significant problem, noticeable already in primary care [1, 2]. It may lead to the metabolic syndrome and increase the risk of circulatory system diseases, impaired glucose tolerance and premature death [3–6]. Most sources show that body mass gain is greater after treatment with atypical antipsychotics [7, 8], among which olanzapine and clozapine cause the greatest body mass gain, dependent on the blood drug level [9, 10]. At the same time, the high efficacy of these drugs in combating positive and negative symptoms of schizophrenia make drug discontinuation difficult [11], although the metabolic side effects may be considered an important element in drug selection [12].

Since 2000, there has been a real explosion of research into the metabolic side effects of antipsychotics and attempts to limit such effects both by means of pharmacological [13] and non-pharmacological methods [14]. Recent studies suggest that some drugs are free of metabolic effects [15] or that their metabolic harmfulness is lesser than that of other drugs/ active substances [16].

Psychoeducation is recommended in patients with psychoses. Its skilled and systematic application results in improved compliance and social functioning, earlier treatment of relapse and its overall reduction [17, 18]. However, psychoeducation is time-consuming and increases the risk of suicide [19]. Monitoring body mass gain is considered a significant element in the evaluation of drug tolerance and is often combined with psychoeducation [20]. Single studies report attempts to improve the lifestyle of mentally ill patients [21, 22].

Aim of the study

The aim of the study was to assess long-term efficacy of psychoeducation in limiting body mass gain in patients diagnosed with schizophrenia and undergoing atypical antipsychotics monotherapy treatment. The study was one-year open naturalistic follow-up aimed at creating an easy-to-use tool for use in everyday psychiatric practice.

Method

The creation and implementation of an education program for patients with schizophrenia was commissioned by Moneo Pharma Group. The aim of the program was providing patients with information regarding lifestyle and eating habits directly by their attending physicians during a visit. The name of the program was *Caring for Health and Silhouette* and was supposed to lack stigmatizing features. The educators received informational brochures for patients and additional information to be transmitted orally during individual visits. Key information was reviewed at every visit before moving on to a new issue.

The program objectives were as follows:

(1) to increase the patients' knowledge regarding the rules of healthy eating;
(2) to increase their knowledge regarding the importance of physical activity in maintaining appropriate body mass;
(3) to create in the patients the habit of checking their weight and waist circumference as well as monitoring the number of meals and their energy value;
(4) to raise awareness of lifestyle factors increasing the quantity and energy value of meals (boredom, lack of sleep, lack of physical exercise);
(5) to perform weekly verification of weight and waist circumference by the patient and bimonthly by the doctor.

No specific diet was proposed. The aim of the education program was to improve both health, as a result of limiting body mass gain, and compliance.

The inclusion criteria were as follows: age over 18 years, treatment with atypical antipsychotic at least two weeks before psychoeducation, informed patient consent to participate in the study and the doctor's belief that the patient is able to understand the information they receive. The study was fully naturalistic and was intended to cover the maximum number of patients actually using outpatient psychiatric treatment. The exclusion criteria were as follows: consent withdrawal and the doctor's belief that the patient does not comply with or misunderstands the recommendations. Concomitant diseases like cardiovascular diseases (CVD) or metabolic problems were not considered in the exclusion criteria. 8,000 patients were invited to the program and 7,700 patients were included.

Patient education was divided into six short visits with a formalized structure (Table 1). Each meeting consisted of transmitting brief information and suggestions regarding eating and lifestyle. Three visits were directly devoted to eating-related questions, whilst the remaining meetings involved issues affecting the metabolism and hunger (physical activity, sleep and hobbies). Each visit included a subjective assessment of patient compliance on a scale from 1 to 5. Visits 2–6 also involved a short summary of patient achievements and shortcomings.

Table 1. **Components of visits**

Specification	Components of visits	
	For the doctor	For the patient
Every visit	– Each visit is preceded by a check of mental health and the planning of the continuation of treatment – During each visit the patient is weighed, measure of the abdominal circumference is taken, the BMI is calculated and the results are recorded and interpreted – Any possible weight loss or expression of concern with eventual lack of effects is praised – Control of the correctness of food intake – A reminder to a patient of weekly weight measurement in standard conditions, weekly abdominal circumference measurement and recording the results – Conducting conversations and briefing on topics covered on specific visits – Patient support in perseverance, motivation – Since the second visit the patient is asked how he/she followed recommendations from the last visit, which came easily to him/her and what was difficult	– Getting practical information on the prevention of metabolic diseases – Analysis of previous successes and failures in the field of prophylaxis of metabolic diseases discussed at the previous meeting
First visit	– Oral explanation of information on the potential adverse effects of atypical neuroleptics on body weight, bearing in mind the need to maintain continuity of treatment and the importance of diet and physical activity – Analysis and organization of the daily rhythm of meals (i.e., the number of meals, meal times, eating conditions) – Determining factors which, according to the patient, worsen the maintenance of normal body weight	– Obtaining basic information about atypical neuroleptics and the benefits of using them – Obtaining information on maintaining a healthy body weight as a very important factor for general health – Obtaining information about the principles of proper nutrition
Second visit	– Reminding about the importance of physical activity to maintain the appropriate weight and conducting a brief analysis of the current activity – A conversation about physical activity	– Determining the successes and failures of the last two months in terms of proper nutrition – Obtaining recommendations regarding physical activity

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Third visit	– Reminding about the importance of food diversity for proper metabolism and the desirability of providing sufficient amount of vitamins with food	– Determining the successes and failures of the last two months in terms of physical activity – Obtaining information on the benefits of changing eating habits
Fourth visit	– Informing the patient about the importance of sleep quantity and quality for the proper structure of appetite	– Determining the successes and failures of the last two months in terms of physical activity – Receiving information on the benefits of maintaining good sleep hygiene
Fifth visit	– Recollecting the role of caloric value of drinks in the daily energy balance	– Determining the successes and failures of the last two months in maintaining sleep hygiene – Obtaining information on the benefits of controlling the caloric value of consumed drinks
Sixth visit	– Informing of the role of interests in general well-being beyond nutritional functions of eating, among others, as a method of reducing anxiety or boredom – Summary of the last six visits	– Establishing the successes and failures of the last two months in the field of controlling the caloric value of beverages in the daily energy balance – Getting a broader view on personal hobbies – Summarizing participation in the program

Statistics

Data on body mass, waist circumference and BMI obtained after each visit were compared and the statistical significance of differences was calculated. The results were compared for the entire group and separately for men and women. The correlation between body mass change, patient compliance, baseline body mass and baseline BMI was assessed using Spearman's rank and ANOVA tests. The data was processed using Statistica 10.0 software. The level of statistical significance was $p < 0.05$.

Results

A total of 7,700 patients were included by 105 doctors-educators. The one-year follow-up was completed by 7,541 patients (52.8% women and 46.5% men; sex was not stated in 0.7% patients).

The mean BMI gain in one-year follow-up was 0.56 and the difference between men (0.52) and women (0.60) was statistically significant. The mean one-year body

mass gain was 1.63 kg (1.63 kg in women, 1.64 kg in men), whilst the mean one-year increase in waist circumference was 1.25 cm (1.38 cm in women and 1.16 cm in men). There were no statistically significant differences between men and women in these parameters (Table 2).

Table 2. **Body mass gain, BMI and waist circumference in one-year follow-up (N = 7,541)**

Parameters		Weight (kg)		BMI (kg/m^2)		Waist circumference (cm)	
Sex		mean	standard deviation	mean	standard deviation	mean	standard deviation
Men	visit 1	84.98	13.21	27.19	3.82	95.43	13.20
	visit 2	85.53	13.24	27.36	3.81	95.86	13.19
	visit 3	86.06	13.37	27.53	3.84	96.39	13.25
	visit 4	86.38	13.45	27.63	3.85	96.60	13.24
	visit 5	86.49	13.57	27.67	3.88	96.78	13.25
	visit 6	86.57	13.58	27.70	3.90	96.76	13.39
	difference between v1 & v6	1.639	4.508	0.518	1.437	1.378	4.606
Women	visit 1	70.96	12.79	26.31	4.62	85.46	14.39
	visit 2	71.44	12.73	26.49	4.59	85.81	14.28
	visit 3	71.91	12.77	26.68	4.61	86.11	14.22
	visit 4	72.21	12.82	26.78	4.62	86.38	14.22
	visit 5	72.38	12.71	26.85	4.59	86.49	14.18
	visit 6	72.58	12.82	26.92	4.63	86.61	14.22
	difference between v1 & v6	1.632	4.008	0.608	1.498	1.160	4.007
Total	difference between v1 & v6	1.630	4.252	0.564	1.471	1.252	4.295

Baseline body mass

We attempted to identify features that are noticeable during the first visit and which could facilitate the prediction of the efficacy of the education program. The entire study population was divided according to their baseline BMI. The group with baseline BMI ≥30 was overrepresented by individuals with a BMI drop during the program ($p < 0.01$) (Table 3).

Table 3. **The study group by BMI (N = 7,541)**

BMI change	Number	underweight (<18.50)	Normal weight (18.50–24.99)	Overweight (25.00–29.99)	1st degree obesity (30.00–34.99)	2nd degree obesity (35.00–39.99)	3rd degree obesity (>40.00)	Total
Decrease	empirical	11	395	717	309	102	23	1,557
	expected	17.5	524.8	726.7	223.9	49	15.1	1,557
No change	empirical	19	629	726	210	24	15	1,623
	expected	18.2	547.1	757.5	233.4	51.1	15.8	1,623
Increase	empirical	53	1,472	2,013	546	107	34	4,225
	expected	47.4	1,424.1	1,971.9	607.6	132.9	41.1	4,225
Total	empirical	83	2,496	3,456	1,065	233	72	7,405
	expected	83	2,496	3,456	1,065	233	72	7,405

The analysis of the empirical and expected values demonstrated that patients with a BMI drop during the program were those who at the first visit, more frequently than the remaining groups, suffered from 1st,2nd and 3rd degree obesity.

Subjective evaluation of compliance

The subjective evaluation of patient compliance increased systematically with every visit, both for men and women. The correlation between patient compliance and BMI increase assessed using Spearman's rho was 0.184 (Table 4).

Table 3. **Subjective evaluation of patient compliance (N = 7,541)**

Parameters		N	Mean	Standard deviation	Minimum	Maximum
Visit 1 – BMI	BMI decrease	1,557	27.89	4.71	15.90	50.78
	no change in BMI	1,632	26.26	4.01	14.58	50.15
	BMI increase	4,230	26.48	4.14	13.17	46.37
	total	7,419	26.73	4.28	13.17	50.78
Visit 1 – weight	BMI decrease	1,557	80.81	15.99	44.00	150.00
	no change in BMI	1,632	76.23	13.86	41.00	130.00
	BMI increase	4,230	76.86	14.36	35.00	145.00
	total	7,419	77.55	14.71	35.00	150.00

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Visit 1 – compliance	BMI decrease	1,475	3.41	1.01	1.00	5.00
	no change in BMI	1,568	3.50	0.97	1.00	5.00
	BMI increase	4,111	3.22	0.98	1.00	5.00
	total	7,154	3.32	0.99	1.00	5.00
Visit 2 – compliance	BMI decrease	1,442	3.46	1.01	1.00	5.00
	no change in BMI	1,530	3.52	0.93	1.00	5.00
	BMI increase	4,045	3.26	0.92	1.00	5.00
	total	7,017	3.36	0.95	1.00	5.00
Total compliance	BMI decrease	1,482	3.67	0.87	1.00	5.00
	no change in BMI	1,570	3.62	0.89	1.00	5.00
	BMI increase	4,119	3.41	0.83	1.00	5.00
	total	7,171	3.51	0.86	1.00	5.00

The comparison of subgroups with good and poor compliance assessed at first and sixth visit showed that the doctor's subjective evaluation of patient compliance has a predictive value for BMI change during the program. High-compliance patients less frequently experienced body mass gain (Table 5).

Table 5. **Factors influencing the effects of education (N = 7,541)**

Parameters		df	F	Level of significance
Visit 1 – BMI	comparison between groups	2	75.58	.000
Visit 1 – weight	comparison between groups	2	50.18	.000
Visit 1 – compliance	comparison between groups	2	55.68	.000
Visit 2 – compliance	comparison between groups	2	50.65	.000
Total compliance	comparison between groups	2	70.46	.000

Discussion

Pharmacological interventions are the most frequent method of limiting body mass gain during treatment with antipsychotics. According to the meta-analysis conducted by Fiedorowicz et al. [13], metformin is the most efficacious drug limiting body mass gain, followed by: H(2) antagonists, topiramate and norepinephrine reuptake inhibitors. Similar results were reported by Ellinger et al. [23]. However, as yet there is no precise method of limiting post-neuroleptic obesity [8].

Attempts have been made to raise primary care doctors' awareness of post-neuroleptic obesity and the reduction of its harmful effects on health [2]. However, also patients themselves should be informed as to the possible ways of optimizing their lifestyle [21]. The literature review presented by Loh et al. [24] reveals numerous shortcomings in the

methodology of studies presenting behavioral interventions aimed at preventing body mass gain in schizophrenia patients. Similar conclusions are formed by Papanastasiou [25] who claims that only few studies focused on mixed behavioral and pharmacological interventions. The results appear inconsistent and limited. However, the authors of the review article from 2018 [26] adopted a completely different approach. They emphasize the importance of psychoeducation, diet and physical activity as factors helpful in controlling the growth of neuroleptic-induced weight, while defining them as safe, cheap and quality-enhancing methods of interaction.

The advantage of our study is its fully naturalistic character. One of the objectives of the program was to examine the suitability of daily unstructured medical observation for the assessment of compliance. The term 'subjective evaluation of patient compliance' used in Table 4 is a subjective clinical impression of the treating physician. The results of our research indicate that this kind of doctor's impression should not be underestimated. Educators were specialists in psychiatry employed in outpatient care and doctors specializing in psychiatry after at least two years of specialization. All physicians participating in the program were trained on the objectives of the project and the rules of intervention. This modality not only facilitated the participation in the psychoeducation program of a considerable number of patients but also demonstrated that the method is easy to use. Despite its simplicity, our method of education, combined with body mass checks performed by the doctor and the patient, significantly limited body mass gain over a relatively long follow-up period. A similar project (*Wellness Program*) was created by researchers from Canada to evaluate the efficacy of non-pharmacological interactions in patients with psychosis and mood disorders in dealing with weight maintenance during treatment with psychotropic drugs. Patients were divided into 2 groups depending on the speed of intervention which consisted of: improvement of physical condition, information about proper nutrition and meals preparation, psychoeducation, work on motivation, relaxation training, walking. Participants met 2–3 times a week for a period of 12 weeks. Measurements of body mass, BMI, abdominal circumference as well as psychiatric assessment, cooperation in treatment and quality of life – as determinants of program effectiveness – were made at the end of the 3-month period and after the next 3 months. After 3 months, there were no significant differences between the groups, but the next measurement revealed a clear difference in weight loss, reduction of BMI and abdominal circumference as well as improvement in some determinants of quality of life in favor of the group in which the intervention was taken earlier. Researchers emphasized that despite the small number of people participating in the project (31 and 16), it fulfilled its purpose by proving the beneficial effect of a healthy lifestyle on weight control in mentally ill patients [22].

Another strength of our study is the identification of parameters that differentiate good from poor responders to education. Both baseline BMI and subjective evaluation

of compliance at the start of the program are easily identifiable. The awareness of the two simple features enables the doctor to identify patients in whom education alone may be sufficient. An additional advantage of the conducted education program is improved patient-doctor cooperation. By implementing educational activities beyond the standard procedures, the doctor strengthens the therapeutic relationship. Improved cooperation may lead to improved compliance.

An obvious limitation of the presented methodology is its subjective character. The fact that patients were invited to participate in the program based on the doctor's subjective beliefs about the chances of the effectiveness of specific interactions in individual patients may also be considered a limitation. Nevertheless, this methodology clearly suggests that doctors' subjective beliefs cannot be underestimated, on the contrary – they should be used for the benefit of the ill. The participation in the proposed program requires discipline and regularity both from patient and doctor.

Despite these limitations, there is no doubt that the implementation of the education program resulted in decrease of body mass gain in obese patients treated with atypical antipsychotics. Moreover, the proposed model of education significantly increases the chances of reducing body mass in the subgroup of obese people. Individuals with BMI ≥30 more frequently achieved body mass reduction than individuals with BMI <30. The quality of doctor-patient cooperation at first and sixth visit had a predictive value for the assessment of body mass change during the program. The method is easy to implement in clinical practice.

Conclusions

1. Reduction in body weight was achieved in 20.6% of patients, despite continuous use of second-generation antipsychotics
2. Individuals with BMI ≥30 more frequently achieved body mass reduction during the education program.
3. The quality of cooperation during the first and second visit has a predictive value for the evaluation of body mass changes during the time of education program.
4. The method is adapted for an easy use in clinical practice allowing not only for the body mass control but also for the improvement of compliance.

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