Alpha Psychiatry

ORIGINAL ARTICLE
Alpha Psychiatry 2024;25(6):737-745
DOI: 10.5152/alphapsychiatry.2024.241718

Development and Evaluation of the "Eating More Consciously" Module of a Lifestyle Intervention Program to Prevent Medication-Induced Weight Gain in Psychiatric Patients: A One-Arm Pilot Study

ABSTRACT

Objective: Overweight and obesity are health issues that are increasing worldwide. Patients with severe mental illness are particularly vulnerable for various reasons, including the intake of weight gain-associated drugs. In this pilot study, we targeted eating behavior as a predictor for medication-induced weight gain and developed a module of a prevention program ("Eating More Consciously") to be evaluated by psychiatric inpatients.

Methods: Thirty-three patients participated in a behaviorally oriented group therapy program with 2 modules of 120 minutes each and weekly follow-up measurements over 4 weeks. Measures included weight, laboratory parameters, the German versions of the Three-Factor Eating Questionnaire (Fragebogen Essverhalten; FEV) and the Food Craving Inventory (FCI) as well as a questionnaire on the implementation of the strategies in everyday life.

Results: Thirty-three participants completed both modules and felt that they had benefited from the module "Eating More Consciously". Fragebogen Essverhalten domain "cognitive restraint" scores increased significantly throughout the study ($P = .039$), and the FCI sum score decreased significantly ($P = .003$).

Conclusion: We propose that the "Eating More Consciously" module is a promising approach to behavioral intervention in weight management in patients with severe mental illness. Prospective randomized controlled studies with a larger sample and a longer follow-up are needed.

Keywords: Behavioral therapy, drug-induced weight gain, eating behavior, prevention, severe mental illness, weight management

Introduction

Obesity is an increasing health issue worldwide and raises the risk of diabetes and cardiovascular disease.[1] The prevalence of obesity is nearly twice as high in adults with psychiatric disorders relative to those without a psychiatric disorder.[2] Patients with severe mental illness often experience poorer screening by primary care practices,[3] may not implement health-seeking behaviors, and, as a result, may experience obesity and develop obesity-associated comorbidities.[4,5] Both conditions often occur with maladaptive eating behaviors, such as emotional eating, binge eating, and loss of control over eating, and involve the implementation of problematic coping strategies.[6]

Reduced physical activity,[7] poorer dietary habits among psychiatric patients compared with the general population,[8] and the role of psychotropic drugs are factors that might explain the high prevalence of overweight and obesity among psychiatric patients.[9] In the treatment of patients with psychiatric disorders, psychotropic drugs are used in most disease profiles.[10] Some of these substances show weight gain and metabolic changes as an adverse drug reaction.[10,11] The degree of weight gain can vary depending on the type of medication[12] and

Catherine Glocker[1]
Maria S. Simon[1]
Nicole Adler[1,2]
Julia Eder[1]
Barbara B. Barton[1]
Richard Musil[1,3]

[1]*Department of Psychiatry und Psychotherapy, LMU Klinikum, München, Germany*
[2]*IFT Institut für Therapieforschung, Centre for Mental Health and Addiction Research, Munich, Germany*
[3]*Oberberg Fachklinik Bad Tölz, Bad Tölz, Germany*

Corresponding author:
Catherine Glocker
✉ Catherine.Glocker@med.uni-muenchen.de

Received: May 31, 2024
Revision Requested: June 18, 2024
Last Revision Received: July 26, 2024
Accepted: August 5, 2024
Publication Date: December 15, 2024

Cite this article as: Glocker C, Simon MS, Adler N, Eder J, Barton BB, Musil R. Development and evaluation of the "eating more consciously" module of a lifestyle intervention program to prevent medication-induced weight gain in psychiatric patients: A one-arm pilot study. *Alpha Psychiatry.* 2024;25(6):737-745.

individual risk factors include a younger age, low baseline Body Mass Index (BMI), and previous exposure to psychotropic drugs.[13] A lack of cognitive control in the presence of an increased appetite is regarded as an additional predictor of weight gain.[14]

In a previous study, we found that patients who showed a weight gain of ≥5% in the first 4 weeks of drug treatment exhibited conspicuous eating behavior that was reflected in higher disruptibility, lower cognitive control, and a more pronounced feeling of hunger.[15] Munsch et al[16] demonstrated a correlation between weight reduction and alterations in eating behavior, emphasizing the significance of eating behavior in the prevention and management of weight gain.

Studies and meta-analyses to date that address weight management in patients on antipsychotic medication show the effectiveness of psychoeducation, exercise, and dietary interventions,[17,18] although it remains difficult to implement weight management strategies for people with chronic mental illness.[19] A recent lifestyle intervention study included overweight patients with severe mental illness and reported a weight reduction of 3.3 kg after 12 months.[20] These findings implicate the need for preventive strategies to be applied before the weight gain happens.

It has been shown that most of the weight gain occurs in the first weeks after the start of drug therapy.[21-23] Vandenberghe and colleagues[24] also showed that a weight gain of ≥ 5% during the first 4 weeks was a reliable predictor of subsequent weight gain. Consequently, the implementation of interventions at the earliest possible stage of treatment may prove to be the most efficacious approach.[18,25]

To our knowledge, there has not yet been a specific intervention program reported for patients with mental illness who are at risk of gaining weight under psychopharmacological treatment. Since eating behavior is an identified and changeable predictor and risk factor for medication-induced weight gain that can be well addressed in therapy, we developed a module of a prevention program ("Eating More Consciously"). As other studies have already shown the effects of mindfulness on the prevention and treatment of weight gain through changes in eating behavior,[26,27] we chose this method as a key element of our behavioral intervention. The focus of our study was the acceptance and perceived benefit by patients. Additionally, we aimed to examine changes in eating behaviors after intervention. Our hypothesis was that there would be an improvement in eating behaviors following the intervention.

Methods

Study Design

In this prospective interventional study, vital signs, laboratory parameters, and questionnaires were examined over 4 weeks, which is the mean duration of an inpatient stay in our hospital. An overview of the study procedure is shown in Figure 1. The study was conducted at the Psychiatric Clinic of the Ludwig Maximilian University (LMU), Munich and in accordance with the Declaration of Helsinki and its most recent amendments. The local ethics committee approved the study (project number 17-675).

MAIN POINTS

- *A therapy module was developed for the prevention of drug-induced weight gain.*
- *The intervention target was eating behavior as a predictor of drug-induced weight gain.*
- *All participants subjectively benefited from the "Eating More Consciously" module.*
- *Cognitive restraint and food craving can be significantly improved*

Study Participants

The Fragebogen Essverhalten (FEV) questionnaire was given to all new psychiatric inpatients at the LMU Hospital for Psychiatry and Psychotherapy as part of clinical assessment and used for prescreening. Patients were included in our study after informed consent. Inclusion criteria were a psychiatric ICD-10 diagnosis code, age between 18 and 75 years, and an FEV profile with values of <7 in the domain "cognitive restraint" (low cognitive control), or >8 in the domain "disinhibition" (high disruptibility of eating behavior), or >6 in the domain "hunger" (subjectively high sensation of hunger). Exclusion criteria were acute suicidality, acute psychosis, acute mania, severe addiction, or diagnosed anorexia or bulimia nervosa as well as insufficient language skills. Study participants were recruited between January 2018 and November 2019. Group size was set between 3 and 10 participants. The group therapy modules lasted 120 minutes each, with a 15-minute break after 50 minutes.

Group Therapy Module 1

In the first session, patients were asked to fill out questionnaire module 1a, to assess previous experience, interest in the topic, and motivation. The group leaders presented the 10 rules of the German Nutrition Society. Focus was placed on the rule "Eat Mindfully and Enjoy". Subsequently, the group discussed different factors that can influence eating. The developed aspects were then classified into 2 categories: internal and external. The concept of behavioral analysis was explained. Patients identified and analyzed one situation of eating without being hungry every day until the second group session, filling in the behavior analysis forms for self-observation. Finally, the patients filled out the questionnaire for module 1b, which contained information about the personal benefit of the first group therapy session, the motivation to implement the homework, as well as open questions concerning their personal opinions regarding helpful aspects or wishes.

Group Therapy Module 2

Before the second part of the module, 1 week after part 1, patients were again asked to complete a questionnaire module (2a), where the implementation of the homework and the interest in the following session were queried. The patients' experiences during self-observation were discussed in the group. Patients were trained to identify internal and external stimuli for their eating behavior and to identify the emotions and needs associated with them. Mindfulness-based practices were introduced, and the "raisin exercise" by Bays[28] was instructed. The discussion encompassed alternative behaviors that may be employed to fulfill certain needs in lieu of eating. Patients were asked what they had learned in the module and wanted to remember for the future. Finally, the patients filled out the questionnaire for the module (2b), according to the items after module 1.

During the following study weeks, patients were asked to rate the implementation of the strategies in everyday life via another questionnaire.

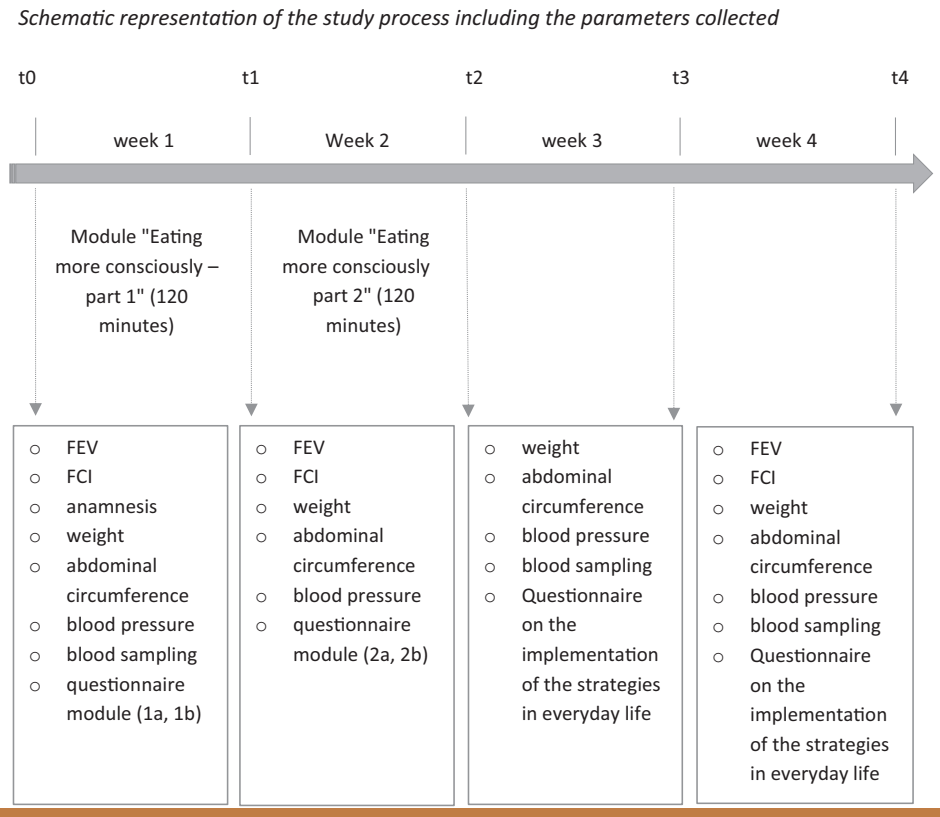

Figure 1. Schematic representation of the study process including the parameters collected. Three-Factor Eating Questionnaire (FEV, Fragebogen Essverhalten; FCI, Food Craving Inventory).

Measuring Instruments

Questionnaires

The FEV is the German version of the Three-Factor-Eating-Questionnaire.[29,30] Fifty-one FEV items are coded with either 0 or 1 point, leading to maximum total scores of 21 points for the domain of "cognitive restraint" (degree of cognitive control in daily food intake), 16 points for "disinhibition" (loss of control in food intake), and 14 points for hunger (susceptibility to internal or external hunger signs). A validation study showed satisfying results for all 3 domains, with Cronbach's alpha ranging from 0.74 to 0.87.[31]

The Food-Craving Inventory[32] (FCI; the German version of "Fragebogen Food Craving" by Dalkner et al, personal communication;[33]) is a self-rating measure of general and specific food cravings. The FCI consists of 28 items and 4 subscales that represent cravings for carbohydrates, sweets, high-fat food, and fast food. Items are rated on a 5-point Likert scale ranging from 1 (never) to 5 (always/almost every day). It has good test-retest reliability for both the total score and subscale scores, and its criterion validity has been demonstrated previously.[34]

Before and after every module, the participants filled out another self-rating questionnaire that was designed for our survey and uses qualitative and quantitative questions to assess satisfaction with the program as well as to record whether and what participants have learned or implemented yet. At week 2 (t2), week 3 (t3), and week 4 (t4), a questionnaire on the implementation of the strategies in everyday life was completed.

Laboratory Assessments and Vital Signs

Metabolic syndrome was determined according to the criteria of the International Diabetes Federation (IDF).[35] Cardiovascular risk profile was determined using the Prospective Cardiovascular Münster Study (PROCAM) system,[36] using Low Density Lipoprotein (LDL) cholesterol, High Density Lipoprotein (HDL) cholesterol, triglyceride level, systolic blood pressure, fasting glucose levels, smoking status, and family history of a heart attack before the age of 60 years.

HbA1c was measured (HbA1c > 6.5% indicates diabetes, HbA1c < 5.7% indicates no diabetes), and in the case of prediabetes (HbA1c between 5.7% and 6.5%), fasting glucose levels were used (>125 mg/dL indicates diabetes). Body mass index was calculated by dividing body weight (kg) by the square of the body height (m^2). According to the World Health Organization,[37] a BMI of < 18.5 indicates underweight, 18.5-24 indicates normal weight, 25-29 indicates overweight, and ≥30 indicates obesity.

Blood sampling was performed after fasting. Blood pressure was assessed following a 3- to 5-minute period of rest in a seated position at heart level. Weight measurement was performed in light clothing without shoes. Waist circumference, an indirect method for determining the amount of visceral fat,[38] was also measured in the morning before breakfast, standing, at the thickest part of the abdomen during light expiration (about 2 cm above the navel).

Data Processing and Statistics

This study used paper survey forms, and data were subsequently entered pseudonymously into an electronic file. All calculations

were done using IBM SPSS Statistics for Windows (Version 25.0). IBM Corp; Armonk, New York, United States of America. Most tests were exploratory in nature, and thus no adjustment for multiple testing was conducted. Only those participants who completed both intervention modules were included in the calculations (n = 33). Missing values were imputed using the median value. Values were analyzed regarding their baseline levels and change over time, which were calculated by subtracting t0 from t4. Thus, a positive score represented an increase, and a negative score represented a reduction. Descriptive statistics are presented as frequency, mean, and SD (standard deviation), or median and interquartile range where applicable. Since deviations from normal distribution were present, we decided to use nonparametric tests. To compare baseline and endpoint values, the paired Wilcoxon test was carried out for continuous variables. For comparison of multiple groups, the Kruskal-Wallis test was used. For correlation coefficients, Spearman rank correlation was used. Multiple linear regression analyses were performed to explore the predictive value of parameters at baseline and their change from baseline to endpoint for the change of body weight over the treatment period. The dependent variable was weight change percentage, and the independent variable was changed on the respective FEV scale. Medication, age, and sex were analyzed as covariates. Due to the small number of cases, a normal distribution cannot be assumed, but regression analysis is nevertheless a robust statistical method allowing for the inclusion of covariates.[39] Tests were conducted 2-sided, and the significance threshold was set at $\alpha = 0.05$.

Results

Demographics

Sixty-three participants were included in our study, 52 started module 1 and thus received some intervention. Thirty-three participants completed both modules (see Figure 2). The dropouts during the course of the intervention and follow-up (36.5%) resulted partly from scheduling conflicts and lack of attendance, and mainly from failing to provide follow-up data without giving further reasons.

Twenty-five participants (75.8% of the 33 participants who completed the study) were female. Most participants were diagnosed with a depressive episode (69.7%). Further sociodemographic and disease-related data of the 32 participants who filled out the medical history questionnaire are listed in Table 1.

Participants had been suffering from their disease for a median of 6 years and were 35 years of age at the beginning of the survey. All participants had been in inpatient treatment at least once before. Only 4 (12.1%) participants reported new symptoms leading to the current admission.

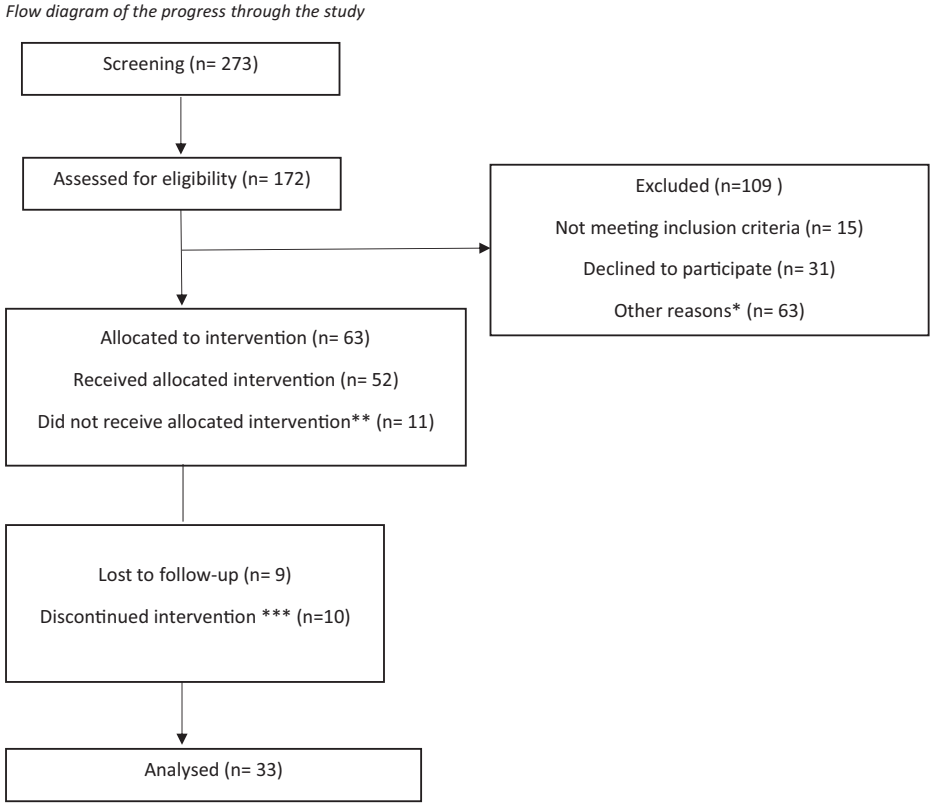

Figure 2. Flow diagram outlining the progress through the study.

Table 1. Sociodemographic and Disease-Related Data

Variable	N	%
Sex		
Male	8	24.2
Female	25	75.8
ICD-10 Diagnosis		
Mental and behavioral disorders caused by psychotropic substances (F10-F19)	4	12.1
Schizophrenic, schizotypal, and delusional disorders (F20-F24.9, F28-F29)	1	3.0
Mania and bipolar disorder (F30-F31.9)	4	12.1
Major depression (F32-F33.9)	23	69.7
Neurotic, stress, and somatoform disorders (F40-F48)	10	30.3
Personality disorders (F60-F69)	8	24.2
Current psychiatric disorder		
First time appearance	4	12.1
Continuation of a long existing condition	8	24.2
Deterioration of a chronic condition	16	48.5
Recurrence of a similar previous condition	4	12.1
Marital status		
Single	20	60.6
Married, cohabitating	9	27.3
Married, living separately	1	3.0
Divorced	1	3.0
Relationship > 3 months, cohabitating	1	3.0
Education		
Qualified secondary school diploma	4	12.1
Secondary school level	11	33.3
A-Levels	17	51.5
Apprenticeship	12	36.4
Master school	3	9.1
University/University of applied sciences	11	33.3
No professional training	6	18.2
Occupational situation		
Full time	9	27.3
Part-time	1	3.0
Housewife/man	3	9.1
Ongoing education	2	6.1
Unemployed	7	21.2
Pension	5	15.6
Other	5	15.6
Current maintenance		
Self-maintenance	11	33.3
External revenue	14	42.4
Part/part	5	15.2
Medication pretreatment		
No medication pretreatment	6	18.2
Antipsychotic drugs, high potency	8	25.0
Antipsychotic drugs, low potency	4	12.5
Second generation antipsychotic drugs	10	31.3
Tricyclic antidepressants	10	31.3
Selective serotonin reuptake inhibitors	15	46.9
Other antidepressant drugs	6	18.8
Lithium	4	12.5
Other mood stabilizer	4	12.5
Benzodiazepines	9	28.1
Additional physical disease/vascular risk factor		
No physical disease	7	21.2
Autoimmune disease	9	27.3
Hypertension	4	12.1
Diabetes mellitus II	1	3.0
Smoking status		
Non-smoker	15	45.5
Ex-smoker	1	3.0
Occasional smoker	5	15.2
Smoker	11	33.3

ICD, International Classification of Diseases, Tenth Revision; WHO. (Several part-answer options possible).

Only 6 participants had no medication prior to our survey, while 23 participants (69.7%) were treated with weight gain-associated medication. Despite unipolar depression being the main diagnosis, 16 participants (48.5%) were receiving antipsychotic drugs at t0.

Median BMI at t0 was 28.8, and median weight change between t0 and t4 was 0.18% (min. −5.09, max. 13.78%). Data on waist circumference were not included in the statistical evaluation due to the high rate (18%) of missing data at t4.

Changes in Scale Scores Between t0 and t4

Changes in FEV scores, FCI scores, and metabolic blood values are listed in Tables 2 and 3. Eating behavior was significantly improved in 2 areas: FEV domain "cognitive restraint" scores increased significantly throughout our study ($P = .039$). Food Craving Inventory total scores decreased significantly between t0 and t4 ($P = .003$). No statistically significant changes in metabolic blood values were found. Triglycerides increased over time with a trend toward significance ($P = .088$), but there was no significant correlation between triglycerides and weight change. Despite this finding, triglycerides increased in all 3 cases with a weight gain of ≥ 5% between t0 and t4. All 3 patients had been treated with weight gain-associated medication before and during the study period. Eight participants fulfilled the criteria for metabolic syndrome at t0. At t4, 1 additional participant developed metabolic syndrome whereas in 2 patients it declined. The PROCAM criteria showed a moderate (10%-19%) 10-year risk for a major cardiovascular event for 1 participant, without a change at t4.

There was no significant correlation between the motivation to change eating behavior at t0 and changes in weight or any FEV subscale score. Patients who rated module eating behavior part 1 as helpful showed a significant decrease in the FEV domain "disinhibition" at t4 ($P = .041$). The decrease in the FEV domain "disinhibition" score was also significant for participants who considered the learned exercises helpful in changing eating behavior ($P = .004$).

The overall model of multiple regression analysis for the predictive value of change in the FEV domain "hunger" score between t0 and t4 and the binary variable psychiatric medication yes or no for weight change was not statistically significant ($R^2 = 0.14$; F (2, 30) = 2.49; $P = .10$), but showed a trend with the biggest influence for the change in the domain "hunger" ($\beta = 0.325$; $T = 1.87$; $P = .071$; CI (Confidence

Table 2. Changes in Fragebogen Essverhalten (FEV) and Food Craving Inventory (FCI) Questionnaire Domain Scores Between t0 and t4

	N	Mean Value	Median	SD	Minimum	Maximum	*Z*	*P*
FEV cognitive restraint t0	33	6.88	7	3.54	1	16		
FEV cognitive restraint t4	33	8.35	8.5	4.21	0	18	−2.061	.039
FEV disinhibition t0	33	8.03	8	3.97	2	15		
FEV disinhibition t4	33	7.42	8	3.56	2	14	−1.217	.223
FEV hunger t0	33	6.88	7	2.96	1	13		
FEV hunger t4	33	6.67	7	3.35	1	14	−0.252	.801
FCI fat t0	33	7.64	8	5.51	0	22		
FCI fat t4	33	6.67	6	6.03	0	22	−1.836	.066
FCI sweets t0	33	13.89	14.5	5.34	0	26		
FCI sweets t4	33	11.82	10	6.27	0	27	−2.473	.013
FCI carbohydrates t0	33	11.23	12.5	6.31	0	22		
FCI carbohydrates t4	33	9.71	9.5	5.79	0	24	−1.907	.056
FCI fast food t0	33	6.73	7	3.59	0	13		
FCI fast food t4	33	5.58	6	3.3	0	11	−2.112	.035
FCI sum t0	33	39.49	43	15.94	0	63		
FCI sum t4	33	33.8	33	16.61	0	72	−3.022	.003

SD, standard deviation.

Interval) (−0.03; 0.77)). The addition of age and sex did not change the results.

Participants' Experiences with the Therapy Module

The main results of the module 1 and 2 questionnaires, as well as the questionnaires on the implementation of the strategies in everyday life at t2, t3, and t4, are listed in Table 4. All participants were at least a little bit motivated to change their eating behavior, and 10 participants (30.3%) were somewhat or very motivated. Twenty-eight participants (84.8%) considered module 1 to be somewhat or very helpful in general; after module 2 participation, this number increased to 31 (94%). At t4, 21 participants (63.3%) had been further deploying the learned strategies a little, and 11 participants (33.3%) had been deploying the learned strategies sometimes or very often. All participants felt that they had benefited from the module "Eating More Consciously". Twelve participants (36.4%) benefitted a little, 14 participants (42.2%) benefitted somewhat, and 7 participants (21.2%) benefitted very much.

Discussion

Our study aimed to evaluate the "Eating More Consciously" module of a lifestyle intervention program for the prevention of medication-induced weight gain. The focus was on the satisfaction and acceptance of the participants as well as their subjective assessment of its usefulness.

In total, 33 patients completed the whole study and were included in the statistical analyses. Most participants were female (76%) and suffering from major depression (70%). Although data on feasibility was not collected from the therapists' perspective, the 2x 120-minute therapy sessions could well be integrated into a more comprehensive overall weight management program. The results of the exploratory questions, evaluating the participants' subjective attitudes and satisfaction, indicated that the perceived usefulness of the module was not associated with the extent of implementation of the strategies learned. In addition, the central pillars of the module (behavioral analysis and mindfulness) were rated as helpful by the patients and were further applied. Further results of the questionnaires on the module and the implementation of the strategies in everyday life illustrate the patients' motivation and interest in the topic of eating behavior, and most of the patients had already gained weight once as a result of medication, which was accompanied by a significant burden.

Table 3. Changes in Metabolic Blood Values Between t0 and t4

	N	Mean Value	Median	SD	Minimum	Maximum	*Z*	*P*
Cholesterol t0	33	195.94	196.00	38.65	116	294		
Cholesterol t4	33	190.88	178.00	40.21	124	293	−1.305	.192
HDL t0	33	62.06	60.00	18.48	27	111		
HDL t4	33	62.58	61.00	20.93	28	126	−0.054	.957
LDL t0	33	107.30	102.00	40.44	48	219		
LDL t4	33	103.85	92.00	41.01	28	218	−1.188	.235
Triglyceride t0	33	120.92	105.50	68.26	37	332		
Triglyceride t4	33	131.88	128.00	61.04	39	266	−1.707	.088
Fasting glucose t0	33	85.56	83.50	14.53	67	154		
Fasting glucose t4	33	85.97	85.00	6.89	71	101	−1.242	.214
HbA1c t0	33	5.28	5.30	.28	4.60	5.90		
HbA1c t4	33	5.32	5.30	.22	4.90	5.70	−0.907	.364

HDL, High Density Lipoprotein; LDL, Low Density Lipoprotein.

Table 4. Subjective Attitudes and Experiences of the Study Participants, and Results of the Module 1 and 2 Questionnaires and Questionnaires on the Implementation of the Strategies in Everyday Life

	Not At All (n/%)	A Little (n/%)	Somewhat (n/%)	Very Much (n/%)
Are you motivated to change your eating behavior?		13 (39.4)	10 (30.3)	10 (30.3)
How helpful was module 1 for you in general?		5 (15.2)	17 (51.5)	11 (33.3)
Do you want to implement any proposals in general?	1 (3.0) "no"			32 (97.0) "yes"
Have the exercises been helpful in influencing your eating behavior in a positive way?	3 (9.1)	16 (48.5)	9 (27.3)	5 (15.2)
Can you imagine to further deploying these strategies?	3 (9.1)	12 (36.4)	12 (36.4)	6 (18.2)
How helpful was module 2 for you in general?		2 (6.1)	15 (45.5)	16 (48.5)
Do you want to implement any proposals/methods/exercises?	1 (3.0) "no"			32 (97.0) "yes"
Have you been further deploying the learned strategies? (t2)	1 (3.0)	19 (57.6)	10 (30.3)	3 (9.1)
Do you feel that you have benefited from the module Eating Behavior? (t2)		11 (33.3)	15 (45.5)	7 (21.2)
Have you been further deploying the learned strategies? (t3)	3 (9.1)	19 (57.6)	9 (27.3)	2 (6.1)
Do you feel that you have benefited from the module Eating Behavior? (t3)	2 (6.1)	10 (30.3)	16 (48.5)	5 (15.2)
Have you been further deploying the learned strategies? (t4)	1 (3.0)	21 (63.6)	7 (21.2)	4 (12.1)
Do you feel that you have benefited from the module Eating Behavior? (t4)		12 (36.4)	14 (42.4)	7 (21.2)

We found discrete, but significant, changes in eating behavior and food craving after the 2-group module interventions (FEV domain "cognitive restraint" scores and FCI total scores), possibly confirming our hypothesis that the module would improve eating behavior.

As the FEV domain "cognitive restraint" shows cognitive control overeating behavior and the intervention was of a behavioral nature, the improvement is not surprising. Identifying thoughts and emotions leading to eating by using behavioral analyses presumably helped patients to be more aware of the internal and external motivations to overeat. This increased awareness probably led to higher cognitive control. Cognitive behavioral therapy is an efficacious approach for increasing cognitive restraint and reducing emotional eating,[40] and for learning to better self-regulate.[41] Mindfulness and mindful eating also have the potential to address problematic eating behaviors and may prevent weight gain.[26] A sustained effort to monitor and control food intake characterizes successful long-term weight maintenance, suggesting that self-regulation in the eating domain is essential for those with a tendency to gain weight. Weight management programs might be improved by the addition of cognitive training[42] and mindfulness-based approaches.[26] Overall data on specific cognitive interventions in weight management remain lacking.

The FEV domains "disinhibition" and "hunger", representing the extent of uncontrolled and emotional eating, did not significantly improve in the whole sample overall, although abnormalities in these domains were inclusion criteria for these domains and an improvement through the intervention could have been suspected. We suggest that a single intervention and 4 weeks of observation may be insufficient to effect change in these long-standing and unconscious behaviors. According to Barkham and colleagues,[43] everyone's behavior changes at different speeds, and, therefore, changes in eating behavior occur at different rates. This individuality is reflected in the clear improvement in patients who rated the eating behavior part 1 module as helpful and who viewed the learned exercises to be helpful in changing their eating behavior.

The significant improvement in overall food craving (with changes in craving for sweets and fast food as well as clear trends for fat and carbohydrates) may be related to the increase in cognitive control. We performed a post-hoc correlation analysis between the decrease in the FCI total score and the increase in the FEV domain cognitive restraint score between t0 and t4. The results showed a negative correlation that was not statistically significant, although it showed a trend toward significance (correlation coefficient −0.25; $P = .16$). The statistical power might not have been sufficient to identify an obvious effect.

Conversely, a decrease in food cravings may indicate a decrease in emotional eating, even if this was not reflected in the FEV scores. Emotions are often related to eating behavior, as food acts quickly and can thus weaken negative feelings and intensify positive feelings. Emotion-focused therapy aims to gain control over emotional processes and may be beneficial in limiting emotional eating as a result of mood dysfunction[44] and could therefore be a useful component in the further development of our therapy module. A mindful attitude can help break automatisms in the context of eating behavior, so patients can regain more control over their eating behavior. This is why mindfulness is a strategy often applied in the treatment of obesity[26] and why it was part of our intervention in module 2. Positive changes in emotional eating, following mindfulness interventions before weight loss is attempted, have the potential to change psychological factors that undermine weight loss efforts.[27] These findings highlight the importance of early intervention, especially in high-risk populations such as psychiatric patients. Given the negative effects of medication-induced weight gain on self-esteem, quality of life, and medication adherence, much more effort should be invested in prevention.[45] The development, implementation, and evaluation of prevention programs tailored to the specific needs and concerns of this patient population is essential. The long-term goal of the module "Eating More Consciously" is to help patients who demonstrate conspicuous eating behaviors and who are to receive medication associated with weight gain, as a preventative measure before the onset of weight gain and associated distress. The motivation of patients who show a predisposition but who have not yet experienced any physical or psychological accompanying symptoms continues to be a challenge.

The interrelationship between weight gain and psychiatric medications is well known and beyond the scope of this study. Nevertheless, we found that close to 70% of our participants were treated with weight gain-associated medications that might have influenced the

course of weight changes. Almost half of our participants were being treated with antipsychotic drugs, the use of which has increased in recent years, particularly for affective disorders,[46] despite the high risk for weight gain[47] and other possible adverse events. In many cases, these substances are without alternative, but a low-threshold use of these metabolically problematic substances should be discussed.

On average, participants in this study were overweight (BMI 28.8) at baseline. With a median weight change of 0.18% over the course of our study, there was no significant effect on weight. This may be due to the short observation period, as a profound behavior change cannot be expected in 4 weeks. However, weight changes and blood value changes were not the focus of the study.

Strengths and Limitations

Among the strengths of this study, in addition to the targeted selection of patients who exhibited abnormal eating behavior, were the weekly measurements of weight, as well as the follow-up measurements for the implementation of the learned strategies. Furthermore, the wide diagnostic and age range of patients at our university hospital leads to high external validity in general.

However, the results of this study must be considered in light of some limitations. First, there was no sample size calculation, resulting in reduced statistical power. Another major limitation was the heterogeneity of the study group concerning diagnoses and the use of psychotropic medications. Due to the lack of a control group, causality between changes in eating behavior and our intervention cannot be established, reducing internal validity. In addition, not all suitable patients participated in the study, so it remains unclear whether the patients who refused to participate or dropped out after module 1 would have shown a different course. Walburg et al[20] observed a correlation between weight loss and attendance rates. We found that there was a sample bias due to the exclusion of patients with acute psychosis, who are especially vulnerable to gaining weight from necessary medical treatment. Almost half of the subjects did not complete both modules, and only patients already motivated to work on their eating behavior participated in the study until the last follow-up. These issues may lead to limited external validity. Due to the high drop-out rate, attrition bias must also be discussed. It would be desirable to generate a higher number of patients and to prevent drop-out in the follow-up measurements. The difficulty in recruiting patients for this type of intervention is reflected in the participation rate achieved, and also demonstrates the general reluctance of this population group to participate in such health promotion interventions. The use of motivational interviewing[48] prior to group initiation, and also in the therapy sessions, could be an approach to overcome this challenge. The short duration of the study is another limitation to evaluating our module, although the duration reflected the time of an inpatient stay. In order to be able to make statements about sustainability in addition to short-term efficacy, a longer follow-up period would be favorable and needs to be considered in future projects.

The feasibility of the therapy module on the part of the therapists was not systematically recorded. For the questionnaire on the module "Eating More Consciously" as well as the questionnaire on the implementation of the learned strategies in everyday life—which were explicitly developed for the study—there is no information available on the quality criteria yet. Furthermore, only self-rating instruments were used. In addition, it is necessary to highlight the lack of knowledge regarding the potential consequences of the repeated administration of the questionnaires on their reliability.

Another limitation is that the possible influence of additional therapeutic interventions, exercise, or dieting was not considered. Likewise, data were not collected on whether and to what extent the patients exercised, or whether other weight management strategies, such as dieting, were carried out in parallel.

Conclusion

In conclusion, the module "Eating More Consciously" represents a promising avenue for behavioral intervention in weight management in patients with severe mental illness. Based on this one-arm pilot study, a preventive program is to be developed and evaluated that will specifically relate to the identified eating behaviors under treatment with weight gain-related medication. To achieve this, prospective, randomized, controlled trials with a larger sample size and a longer follow-up period are needed.

Availability of Data and Materials: *Data can be made available on request.*

Ethics Committee Approval: *This study was approved by the Ethics Committee of the Medical Faculty of the Ludwig-Maximilians-University (Approval No: 17-675; Date: 18.12.2017).*

Informed Consent: *Written informed consent was obtained from the participants who agreed to take part in the study.*

Peer-review: *Externally peer-reviewed.*

Author Contributions: *Concept - B.B.B., R.M.; Design - B.B.B., R.M.; Supervision - B.B.B., R.M.; Data Collection and/or Processing - M.S.S., N.A., B.B.B.; Analysis and/or Interpretation - C.G., M.S.S., N.A., J.E., B.B.B., R.M.; Literature Search - C.G., M.S.S., N.A., B.B.B.; Writing - C.G., N.A.; Critical Review - C.G., M.S.S, J.E., B.B.B., R.M.*

Acknowledgements: *We would like to thank all the participants, without whom it would not have been possible to carry out the study.*

Declaration of Interests: *The authors have no conflicts of interest to declare.*

Funding: *The authors declare that this study received no financial support.*

References

1. World Health Organization. Obesity and overweight; 2022. Available at: https://www.who.int/news-room/fact-sheets/detail/obesity-and-overweight. .Accessed 31.01.2022.
2. Chao AM, Wadden TA, Berkowitz RI. Obesity in adolescents with psychiatric disorders. *Curr Psychiatry Rep*. 2019;21(1):3. [CrossRef]
3. Lawrence D, Kisely S. Inequalities in healthcare provision for people with severe mental illness. *J Psychopharmacol*. 2010;24(4)(suppl):61-68. [CrossRef]
4. Carney CP, Jones LE. Medical comorbidity in women and men with bipolar disorders: a population-based controlled study. *Psychosom Med*. 2006;68(5):684-691. [CrossRef]
5. Evans DL, Charney DS. Mood disorders and medical illness: a major public health problem. *Biol Psychiatry*. 2003;54(3):177-180. [CrossRef]
6. Capasso A, Putrella C, Milano W. Recent clinical aspects of eating disorders. *Rev Recent Clin Trials*. 2009;4(1):63-69. [CrossRef]
7. Osborn DPJ, Nazareth I, King MB. Physical activity, dietary habits and Coronary Heart Disease risk factor knowledge amongst people with severe mental illness: a cross sectional comparative study in primary care. *Soc Psychiatry Psychiatr Epidemiol*. 2007;42(10):787-793. [CrossRef]
8. Roick C, Fritz-Wieacker A, Matschinger H, et al. Health habits of patients with schizophrenia. *Soc Psychiatry Psychiatr Epidemiol*. 2007;42(4):268-276. [CrossRef]

9. Verhaeghe N, De Maeseneer J, Maes L, Van Heeringen C, Annemans L. Effectiveness and cost-effectiveness of lifestyle interventions on physical activity and eating habits in persons with severe mental disorders: A systematic review. *Int J Behav Nutr Phys Act*. 2011;8(1):28. [CrossRef]
10. Dent R, Blackmore A, Peterson J, et al. Changes in body weight and psychotropic drugs: A systematic synthesis of the literature. *PLoS One*. 2012;7(6):e36889. [CrossRef]
11. Barton BB, Segger F, Fischer K, Obermeier M, Musil R. Update on weight-gain caused by antipsychotics: a systematic review and meta-analysis. *Expert Opin Drug Saf*. 2020;19(3):295-314. [CrossRef]
12. Parsons B, Allison DB, Loebel A, et al. Weight effects associated with antipsychotics: a comprehensive database analysis. *Schizophr Res*. 2009;110(1-3):103-110. [CrossRef]
13. Musil R, Obermeier M, Russ P, Hamerle M. Weight gain and antipsychotics: a drug safety review. *Expert Opin Drug Saf*. 2015;14(1):73-96. [CrossRef]
14. Stauffer VL, Lipkovich I, Hoffmann VP, Heinloth AN, McGregor HS, Kinon BJ. Predictors and correlates for weight changes in patients co-treated with olanzapine and weight mitigating agents; a post-hoc analysis. *BMC Psychiatry*. 2009;9(1):12. [CrossRef]
15. Simon MS, Barton B, Zagler A, et al. Lifestyle behaviors, metabolic disturbances, and weight gain in psychiatric inpatients treated with weight gain-associated medication. *Eur Arch Psychiatry Clin Neurosci*. 2023;273(4):839-851. [CrossRef]
16. Munsch S, Biedert E, Keller U. Evaluation of a lifestyle change programme for the treatment of obesity in general practice. *Swiss Med Wkly*. 2003;133(9-10):148-154. [CrossRef]
17. Maayan L, Correll CU. Management of antipsychotic-related weight gain. *Expert Rev Neurother*. 2010;10(7):1175-1200. [CrossRef]
18. Alvarez-Jiménez M, Hetrick SE, González-Blanch C, Gleeson JF, McGorry PD. Non-pharmacological management of antipsychotic-induced weight gain: systematic review and meta-analysis of randomised controlled trials. *Br J Psychiatry*. 2008;193(2):101-107. [CrossRef]
19. Taylor VH, McIntyre RS, Remington G, Levitan RD, Stonehocker B, Sharma AM. Beyond pharmacotherapy: understanding the links between obesity and chronic mental illness. *Can J Psychiatry*. 2012;57(1):5-12. [CrossRef]
20. Walburg FS, van Meijel B, Hoekstra T, et al. Effectiveness of a lifestyle intervention for people with a severe mental illness in Dutch outpatient mental health care: A randomized clinical trial. *JAMA Psychiatry*. 2023;80(9):886-894. [CrossRef]
21. Martínez-Ortega JM, Funes-Godoy S, Díaz-Atienza F, Gutiérrez-Rojas L, Pérez-Costillas L, Gurpegui M. Weight gain and increase of body mass index among children and adolescents treated with antipsychotics: a critical review. *Eur Child Adolesc Psychiatry*. 2013;22(8):457-479. [CrossRef]
22. Alvarez-Jiménez M, González-Blanch C, Vázquez-Barquero JL, et al. Attenuation of antipsychotic-induced weight gain with early behavioral intervention in drug-naive first-episode psychosis patients: A randomized controlled trial. *J Clin Psychiatry*. 2006;67(8):1253-1260. [CrossRef]
23. Zipursky RB, Gu H, Green AI, et al. Course and predictors of weight gain in people with first-episode psychosis treated with olanzapine or haloperidol. *Br J Psychiatry*. 2005;187:537-543. [CrossRef]
24. Vandenberghe F, Gholam-Rezaee M, Saigí-Morgui N, et al. Importance of early weight changes to predict long-term weight gain during psychotropic drug treatment. *J Clin Psychiatry*. 2015;76(11):e1417-e1423. [CrossRef]
25. Evans S, Newton R, Higgins S. Nutritional intervention to prevent weight gain in patients commenced on olanzapine: a randomized controlled trial. *Aust N Z J Psychiatry*. 2005;39(6):479-486. [CrossRef]
26. Warren JM, Smith N, Ashwell M. A structured literature review on the role of mindfulness, mindful eating and intuitive eating in changing eating behaviours: effectiveness and associated potential mechanisms. *Nutr Res Rev*. 2017;30(2):272-283. [CrossRef]
27. Lattimore P. Mindfulness-based emotional eating awareness training: taking the emotional out of eating. *Eat Weight Disord*. 2020;25(3):649-657. [CrossRef]
28. Bays JC. *Achtsam Essen. Vergiss Alle Diäten und Entdecke die Weisheit Deines. Körpers*. Kolarik C, 2009.
29. Stunkard AJ, Messick S. The three-factor eating questionnaire to measure dietary restraint, disinhibition and hunger. *J Psychosom Res*. 1985;29(1):71-83. [CrossRef]
30. Pudel V, Westhöfer J, zum Essverhalten F. *Verlag für Psychologie Dr C J Hogrefe*. 1991.
31. Löffler A, Luck T, Then FS, et al. Eating behaviour in the general population: an analysis of the factor structure of the German version of the three-factor-eating-questionnaire (TFEQ) and its association with the body mass index. *PLoS One*. 2015;10(7):e0133977. [CrossRef]
32. White MA, Whisenhunt BL, Williamson DA, Greenway FL, Netemeyer RG. Development and validation of the food-craving inventory. *Obes Res*. 2002;10(2):107-114. [CrossRef]
33. Platzer M, Fellendorf FT, Bengesser SA, et al. The relationship between food craving, appetite-related hormones and clinical parameters in bipolar disorder. *Nutrients*. 2020;13(1), [CrossRef]
34. Taylor M. A review of food craving measures. *Eat Behav*. 2019;32:101-110. [CrossRef]
35. Alberti KGMM, Eckel RH, Grundy SM, et al. Harmonizing the metabolic syndrome: a joint interim statement of the International Diabetes Federation Task Force on Epidemiology and Prevention; National Heart, Lung, and Blood Institute; American Heart Association; World Heart Federation; International Atherosclerosis Society; and International Association for the Study of Obesity. *Circulation*. 2009;120(16):1640-1645. [CrossRef]
36. Assmann G, Schulte H, Cullen P, Seedorf U. Assessing risk of myocardial infarction and stroke: new data from the Prospective cardiovascular Münster (PROCAM) study. *Eur J Clin Investig*. 2007;37(12):925-932. [CrossRef]
37. World Health Organization. *Obesity: preventing and managing the global epidemic: report of a WHO Consultation on Obesity, Geneva, 3-5 June 1997*. 1997;1998:9.
38. World Health Organization. *Waist circumference and waist–hip ratio: report of a WHO expert consultation, Geneva, 8–11 December 2008*. 2011.
39. Altman DG, Bland JM. Parametric v non-parametric methods for data analysis. *BMJ*. 2009;338:a3167. [CrossRef]
40. Jacob A, Moullec G, Lavoie KL, et al. Impact of cognitive-behavioral interventions on weight loss and psychological outcomes: A meta-analysis. *Health Psychol*. 2018;37(5):417-432. [CrossRef]
41. Johnson F, Pratt M, Wardle J. Dietary restraint and self-regulation in eating behavior. *Int J Obes (Lond)*. 2012;36(5):665-674. [CrossRef]
42. Higgs S, Spetter MS. Cognitive control of eating: the role of memory in appetite and weight gain. *Curr Obes Rep*. 2018;7(1):50-59. [CrossRef]
43. Barkham M, Rees A, Stiles WB, Shapiro DA, Hardy GE, Reynolds S. Dose-effect relations in time-limited psychotherapy for depression. *J Consult Clin Psychol*. 1996;64(5):927-935. [CrossRef]
44. Koning E, Vorstman J, McIntyre RS, Brietzke E. Characterizing eating behavioral phenotypes in mood disorders: a narrative review. *Psychol Med*. 2022;52(14):2885-2898. [CrossRef]
45. Fink A, Cieslak S, Rosenbach F. [Non-pharmacological interventions for the prevention of weight gain in schizophrenic patients treated with antipsychotic medication]. *Psychiatr Prax*. 2015;42(7):359-369. Nichtpharmakologische Interventionen zur Prävention von Gewichtszunahme bei schizophrenen Patienten unter antipsychotischer Medikation. [CrossRef]
46. Seifert J, Engel RR, Bernegger X, et al. Time trends in pharmacological treatment of major depressive disorder: results from the AMSP Pharmacovigilance Program from 2001-2017. *J Affect Disord*. 2021;281:547-556. [CrossRef]
47. Schneider M, Pauwels P, Toto S, et al. Severe weight gain as an adverse drug reaction of psychotropics: data from the AMSP project between 2001 and 2016. *Eur Neuropsychopharmacol*. 2020;36:60-71. [CrossRef]
48. Emmons KM, Rollnick S. Motivational interviewing in health care settings. Opportunities and limitations. *Am J Prev Med*. 2001;20(1):68-74. [CrossRef]