

Article

A randomized controlled study to evaluate the effects of lifestyle intervention program for patients with severe mental illness taking Second Generation Antipsychotics (SGAs) in body weight management and monitoring their Body Mass Index (BMI)

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Abstract: Background: Second generation antipsychotics (SGAs) are strongly associated with accelerated body weight gain resulting in overweight and obesity in patients with severe mental illness (SMI). Evidence found that lifestyle interventions used behavioral techniques to improve dietary habits and increase physical activity can reduce the increase in patients' body weight and BMI. Methods: Randomized Controlled Trial (RCT) on 54 patients with severe mental illness were randomized with 27 patients joined in the Lifestyle Intervention group (LIP) and 27 patients in treatment as usual group (TAU) from September/2018 to October/2019. The intervention group attended the educational talks on medication, diet control and physical exercise and use of a daily record. Result: After twelve months, the LIP presented a decrease of 1.25kg (CI 95% -0.73 to 3.24) and treatment as usual TAU presented with a significant increase of 1.65kg CI 95% -2.84 to -0.45) (p=0.009). The BMI of the LIP showed a decrease of 0.51kg/m2 (CI 95% -0.29 to 1.33) and the TAU presented an increase of 0.66kg/m2. Conclusion: The TAU shows a significant increase of body weight while the LIP group had a decrease in body weight under the Life Intervention program. This study was not intended for patients to reduce body weight, rather to prevent their body weight to increase and enhance their quality of life through understanding physical health, exercise and dietary habit.

Keywords: second generation antipsychotic, severe mental illness, body mass index, randomize controlled trial, lifestyle intervention, body weight management.

Introduction

Second generation antipsychotics (SGAs) are strongly associated with accelerated weight gain resulting in overweight of patients with severe mental illness (SMI). Severe mental disorders include Schizophrenia and related conditions, bipolar disorders, and moderate and severe depression. Severe mental disorders affect more than 4% of the adult population according to the World Health Organization. People with SMI die on average 10-20 years earlier than the general population. Most deaths are due to preventable physical diseases, especially cardiovascular disease, respiratory disease and infections [1]. Weight gain is one of main side effects of SGAs which will cause obesity, high risk of cardiovascular diseases and metabolic syndrome that will also cause patients to discontinue treatments and increasing risk of relapse [2, 4]. This RCT study aims to test the lifestyle intervention program for patients with SMI taking SGA to maintain their body weight and BMI, and also enhance their drug adherence, self-esteem and quality of life

Background

First-generation antipsychotics (FGAs), also known as "typical antipsychotics," were developed in the 1950s. Second-generation antipsychotics (SGAs), also known as "atypical antipsychotics," emerged in the 1980s [3]. FGAs were first developed for the treatment of psychosis (e.g., schizophrenia). Since then, they have also been proven effective in the treatment of other conditions including acute mania, agitation, and bipolar disorder. Second generation antipsychotics (SGAs) have shown several advantages over first generation antipsychotics (FGA) in terms of positive, negative, cognitive and affective symptoms and a lower propensity for extrapyramidal side effect [3]. The common FGAs and SGAs are listed in the Appendix A. SGAs have been proven effective for treating a variety of psychiatric conditions by blocking the cerebral dopamine pathways. However, evidence has shown that SGAs are strongly associated with accelerated weight gain resulting in overweight and obesity in patients with SMI [4]. Overweight, hyperglycaemia and hyperlipidaemia are risk factors for cardiovascular events, such as myocardial infarction and stroke, and commonly found in patients with SMI because they also prone to other major risk factors such as smoking and a sedentary lifestyle [5]. Studies have shown obese patients distress over-weight gain was the primary mediator of non-compliance [6].

Systematic literature review find that most lifestyle interventions used behavioral techniques to moderate dietary intake habits and increase physical activity [7]. Twelve studies report significant improvements in weight loss or metabolic syndrome [7]. Lifestyle educational intervention has shown significant effects in weight reduction among the US population. It is found that thirty-one patients with schizophrenia or schizoaffective disorder participated in a 12-week weight control program that incorporated nutrition, exercise, and behavioral interventions [8]. The intervention group had a mean weight loss of 2.7kg and a mean reduction of 0.98 BMI points, whereas the control group had a mean weight gain of 2.9kg and a mean gain of 1.2 BMI points. Another study which randomized 70 patients treated with Olanzapine to receive either psychoeducation or no intervention [9]. Weight changes between the two groups were statistically significant; mean weight loss for the

treatment group was 0.27 kg and mean weight gain for the non-treatment group was 4.35 kg.

There is a paucity of Asian randomized controlled trials on weight loss, such as Taiwan and China. A study of 53 schizophrenia patients in Taiwan in a 6-month weight management program consisting of dietary control administered by a dietitian focusing on reducing calorie intake and engaging in physical activity [10]. Results showed that participants in the weight management group lost significantly more weight [10]. Another study of 64 schizophrenia subjects in China in an outpatient mental health clinic at an academic medical center focusing on change in weight and BMI at 12-weeks. Results showed that lifestyle intervention participants loss significantly more weight [11].

There has been research in lifestyle intervention inducing weight loss. However, the outcomes of the interventions were limited by factors, an emphasis in the Caucasian population, and small number of studies using Asian participants, small sample size and short study duration. Further research on the lifestyle intervention on Asian patients with serious mental illness under the treatment of SGA is needed.

Objectives

- a) To estimate the effect of the lifestyle program for the patients with SMI taking SGA on their body weight and BMI
- b) To explore the relationship of the maintenance of the body weight and BMI of patients with SMI taking SGA on their drug adherence, self-esteem and quality of life

Materials and Methods

An experimental randomized controlled trial was undertaken. The program was commenced in one year, from September/2018 – October/2019. The RCT was conducted at the Community Psychiatric Services office at one of largest geographical regions of Hong Kong in the New Territories West Cluster. There were more than 5000 patients with mental health problems serving in the center in a year. The Lifestyle Intervention group (LIP) patients were carried out the educational talks in the 1st and 12th month in two group sessions. Seven individual discussion sessions were arranged in 2nd, 4th, 5th, 7th, 8th, 10th, 11th month provided by individual case managers. Three group sessions in 3rd, 6th & 9th month were provided for group sharing and discussion. The control group (TAU) patients were followed the routine treatment and care by the case managers (illustrated in Table 1).

The educational talk group sessions for the LIP which involved measurement of BMI and other psychological assessments in the baseline and final group sessions. In the first group session, there was educational talks by the psychiatric nurses on SGA side effects, diet control and physical exercise. A booklet for daily record of physical exercise and diet intake was given to the participants. Case sharing and summarizing the knowledge of the whole program were provided in the final sharing session in the 12th month.

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Individual sessions were also conducted during home visits by the case managers to encourage participants to adhere the physical exercise and diet control through reviewing the record of the booklet and refreshing their knowledge and persistence in the program

Sharing sessions were able to allow peers to know others' situation empathically through emotional and psychological support and facilitation from the case managers.

The TAU group patients involved in both BMI and psychological assessments in the baseline and final group sessions. No educational talk and booklet was provided.



Table 1. 12-month Lifestyle Intervention Program

1 (120) Warm up games. Educational talk on side effects of SGA, diet control and physical exercise, booklet distribution, baseline asse 2 (30) Individual session and prompting on regular exercise and use of booklet 3 (60) Participation games. Group members sharing and discussion 4 (30) Individual session on medication adherence, review of booklet 5 (30) Individual session on diet control, review of booklet	nth/ duration (min) Co	Contents details
3 (60) Participation games. Group members sharing and discussion 4 (30) Individual session on medication adherence, review of booklet	20) W	Varm up games. Educational talk on side effects of SGA, diet control and physical exercise, booklet distribution, baseline assessment
4 (30) Individual session on medication adherence, review of booklet	(0) In	ndividual session and prompting on regular exercise and use of booklet
	50) Pa	Participation games. Group members sharing and discussion
5 (30) Individual session on diet control, review of booklet	60) In	ndividual session on medication adherence, review of booklet
	i0) In	ndividual session on diet control, review of booklet
6 (60) Participation games. Group members sharing and discussion	50) Pr	Participation games. Group members sharing and discussion
7 (30) Individual session on physical exercise, review of booklet	30) In	ndividual session on physical exercise, review of booklet
8 (30) Individual session on healthy lifestyles, review of booklet		ndividual session on healthy lifestyles, review of booklet
9 (60) Participation games Group members sharing and discussion		
10 (30) Individual session on quality of life, review of booklet		
11 (30) Individual session on healthy lifestyles, review of booklet		
12 (120) Group sharing, final assessment, evaluation and certification given		

Participants

Participants were searched from the Information Management System (IMS) in the Community Psychiatric Services (CPS), a total 5219 patients under cared by CPS in the recruiting period. The search including the age range and diagnosis which fulfilling with the inclusion criteria. Information sheets were explained and provided to participants and consent forms were signed by participants. All the participants were free to leave the study at any time if they wished. All the data was kept in privacy and confidential in locked cabinet in CPS.

There were 705 patients were found eligible in the study and 72 patients were eligible to participate in the study. Inclusion criteria were: $\frac{1}{2} \left(\frac{1}{2} \right) = \frac{1}{2} \left(\frac{1}{2} \right) \left(\frac{1}{2$

- (a) patient aged 18 to 55,
- (b) suffers from Severe Mental Illness (SMI) including schizophrenia and related spectrum illness, bipolar affective disorder and psychotic depression, using ICD-10 criteria,
 - (c) taking SGAs,
 - (d) able to speak and read Chinese;

(e) shows his/her awareness of body weight and consented to engage the program.

Exclusion criteria were:

- (a) patients with co-morbid diagnoses with eating disorder,
- (b) patients with substance dependency syndromes, personality disorders, intellectual disability,
 - (c) patients referred for crisis intervention,
- (d) woman with pregnancy or planning to have pregnancy within 1 year
- (e) patients who had diabetes, hypertension, heart disease, osteoarthritis, osteoporosis or BMI greater than or equal to 35.
 - (f) patients with unstable mental state

The assigned investigator(s) reviewed the patients' mental and physical conditions that were suitable for the study in the baseline assessment. The mental state of the patients was assessed by the case managers using the Brief Psychiatric Rating Scale (18-items) [12] and ensured that the total score did not higher than 41 (Moderately ill level). Items were rated on a 7-point Likert scale (1=present, 2=very mild,

3=mild, 4=moderate, 5=moderate severe, 6=severe, 7=extremely severe): the higher the score, the more severe the mental symptoms.

Participants were randomly assigned to the LIP and TAU groups. Participants were assigned a number. By using the True Random Number Generator in the Random.org, it generated 36 participants into the intervention group first and then the rest 36 participants in the control group. The participants, investigators, and research assistant, those assessing/analyzing the outcome(s) were blind (or masked) to the group assignment.

Ethical consideration

The study was approved solely by the New Territories West Cluster Clinical & Research Ethics Committee (NTWC CREC) under the Hospital Authority (NTWC/CREC/18054). All the procedures and requirements were followed the standard operating procedure (SOP) and the Declaration of Helsinki. All participants received an explanation of the study before providing written consent. Informed consents were obtained from all participants. Co-investigators provided a clear and comprehensive explanation of all aspects of the research proposal to participants.

The participants' personal information was based on anonymity and only individual case numbers were shown in the outcome measures and treated confidential in the whole study.

Outcome measures

The primary outcome was the body mass index (BMI). BMI was calculated as weight in kilograms divided by the square of the height in meters. It would be measured in the regular intervals in 1 year. The following instruments were used to collect outcome data in both intervention and control groups. Waist circumference (cm) and waist-hip ratio were also used to measure the patients' general health conditions. The measurement was adopted the expert method illustrated by the World Health Organization (WHO) in 2008 [13].

The secondary outcomes based on patient's survey assessed at baseline and repeated at 1 year, including the Chinese version of the World Health Organization Quality of Life - BREF (WHOQOL-BREF) [14], Chinese version of Rosenberg self-esteem scale [15], the Drug Attitude Inventory (DAI-10) [16], the Level of Understanding towards Health Awareness, Lifestyle and Dietary Behavior [17]. The blood sugar levels and cholesterol level were searched from the Hospital Authority Electronic Patient Record (EPR) and recorded in the participants' data sheet.

Data analysis

Demographic data were collected from participants including age, gender, diagnosis and current SGAs taking for chi-square test.

Apart from these, all the following data were using Paired T-tests to compare the initial and final results:

- A. Baseline and annual assessment of body weight (BW) and body mass index (BMI).
- B. Baseline and annual assessment of waist circumference (WC), Blood sugar levels and cholesterol levels
- C. The differences in the pre and post of quality of life BREF (WHOQOL-BREF), Rosenberg self-esteem scale and the level of understanding towards Health Awareness, Lifestyle and Dietary Behavior to each question would be tested using Pair-T tests. Results were presented as percentages and the corresponding P value.

An "intention to treat" (ITT) analysis, per protocol analysis, or both would be presented. An ITT analysis is preferred as it compares all subjects in the groups to which they were originally randomly assigned (despite withdrawal, treatment failure or cross-over). An alpha level of 0.05 was set for all statistical tests. Statistical analysis was conducted using Statistical Package for Social Sciences, version 24 (SPSS Inc. Released 2019).

Results

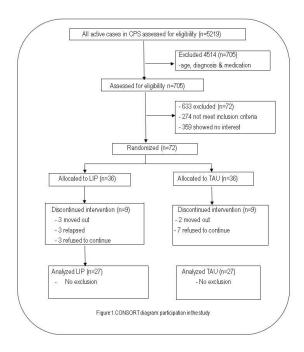
Randomization

Seventy two patients were recruited in the study, 36 were randomly allocated to the Lifestyle intervention program (LIP) and 36 patients to the treatment as usual (TAU). Figure 1 shows the CONSORT diagram of events among participants of the study. Overall there were 18 dropouts in the 12-month follow up. Nine patients in (LIP) did not attend all the sessions with the following reasons. Three patients had moved to other areas, three patients had relapse and three patients refused to continue treatment. Nine patients in (TAU) did not attend the sessions with two patients moved out and 7 patients refused to continue. All the 27 patients from each group were completed the sessions and results were analyzed.

Quantitative analysis

A total of 72 patients were randomized into two groups and finally there were 27 patients in (LIP) and 27 in (TAU) after 12-month interventions. The drop-out rate was 25 % as patients were voluntarily joined in and could be left the group anytime. Moreover, the program last about 1 year and some patients did not have free time to join all the sessions. The drop-out rate was comparable to other studies findings. The average drop-out rate for psychosocial program is 30.4 whereas for physical exercise programs are higher from 25% to 50% [18, 19]. Table 2 show that the social, demographic and diagnostic characteristics did not have significant difference between the two groups except on the gender. More female patients were recruited in the LIP, more than 80% were female whereas only 55% in the TAU. All the patients were taken second generation antipsychotics (Amisulpride, Aripiprazole, Clozapine, Olanzapine, Paliperidone, Quetiapine and Risperidone). We found no difference between both groups regarding the type of antipsychotic taken. Table 3 showed at baseline both groups were similar regarding clinical and metabolic parameters such as weight, waist measurement, blood

glucose, total cholesterol (p>0.05). The baseline BMI (kg/m2) of the two groups showed presence of being overweight, and the LIP was significantly higher (27.04kg/m2) than the TAU (25.01kg/m2) (p<0.05). Moreover, the QoL of health was significant lower in the LIP (2.6) than the TAU (3.1) (p<0.05).



Intervention adherence

Patients participated in the study were followed up by the co-investigators who had contacted them in case of absence in the session. The means of attendance was 2.44 sessions (SD: 1.42), 96% of patients had attended one or more psychoeducational group session (5 sessions).

Changes over time

After twelve months, the LIP (n=27) presented a decrease in body weight of 1.25kg (CI 95% -0.73 to 3.24) and TAU (n=27) presented an increase of 1.65kg (CI 95% -2.84 to -0.45), and this increase was statistically significant for the TAU (p=0.009).

The BMI of the LIP showed a decrease of 0.51 kg/m2 (CI 95% - 0.29 to 1.33) and the TAU presented an increase of 0.66 kg/m2 (CI 95% - 1.11 to -0.21; p=0.005).

Blood sugar level increased in both groups over time after twelve months, however the increase was not statistically significant between the two groups (p>0.05).

The total cholesterol level of the LIP showed a decrease of 0.1 (CI 95% -0.15 to 0.36) while the TAU showed an increase of 0.03 (CI 95% -0.05 to 0.08) after twelve months, however the changes was not statistically significant between the two groups (p>0.05).

The waist circumference of the LIP showed a significant decrease of 3.10 cm (CI 95% 3.10 to 6.04; p =0.013) after twelve months, and the TAU presented an increase of 2.03 cm (CI 95% -4.08 to 0.009; p = 0.051). However, the changes were not statistically significant between the two groups (p>0.05).

The drug inventory of the LIP showed a significant increase of 1.55 unit (CI 95%-3.08 to -0.03; p =0.046) after twelve months, and the TAU presented a decrease of 0.11 unit (p >0.05). The changes were not statistically significant between the two groups (p>0.05).

The WHO-QoL health (an increase of 0.62 unit; CI 95% -1.04 to -0.21; p = 0.004), WHO-QoL physical (an increase of 7.70 unit; CI 95% -14.41 to -0.99; p = 0.026) and WHO-QoL psychological (an increase of 15.11 unit; CI 95% -24.66 to -5.55; p = 0.003) of the LIP showed a significant increase after twelve months. But the changes of the TAU were not statistically significant (p>0.05). And the changes were not statistically significant between the two groups (p>0.05).

In addition, there were no differences over time in Rosenberg selfesteem scale and WHO-QoL overall for the two groups, the results were shown in Table 4.

Changes between groups

After twelve months there were no differences between groups in body weight, BMI, waist, blood sugar and total cholesterol (p>0.05). But there were significant differences between the two groups on WHO-QoL psychological (LIP 110.22, TAU 98.37; p=0.039), understand health domain (LIP 20.88, TAU 19.18; p=0.052) and understand diet domain (LIP 30.00, TAU 26.51; p=0.03).



Table 2. The social, demographic and clinical characteristics of patients at baseline (n=54)

Characteristics	LIP (n=27)	TAU (n=27)	X ²	Р
Female/Male	22/5	15/12	4.20	0.041†
Age	44.3	39.81		0.069
Housing public/private	20/7	18/9	0.35	0.551
Living alone/family/others	7/20/0	7/19/1	1.02	0.598
Diagnosis			5.40	0.493
Schizophrenia	18	16		
Delusional disorder	0	2		
Schizoaffective disorder	3	1		
Psychosis	2	5		
Bipolar affective disorder	2	2		
Psychotic depression	1	0		
Depression	1	1		
SGAs			2.98	0.810
Amisulpride	5	2		
Aripiprazole	7	5		
Clozapine	5	3		
Olanzapine	9	7		
Paliperidone	5	7		
Quetiapine	5	4		
Risperidone	2	4		

^{*}Statistical analyze were performed using the Chi-squared test and t-test for age. † Significant difference on the gender between two groups

Discussion

The randomized controlled trial (RCT) on the effects of the lifestyle intervention program for patients with severe mental illness taking SGAs in body weight management, amid a paucity of studies on Asian subjects. At the end of the intervention there were no significant difference between groups on body weight, BMI, waist, blood sugar and total cholesterol. However, the LIP group had maintained their body weight while the TAU group had increased significantly in body weight over 12-month time. Patients who received the LIP had lost 1.25kg and the patients under TAU had gained 1.65kg, and this difference was statistically significant for the TAU patients. If we compared the two groups, the difference would be 3.0 kg. Moreover, the LIP group had maintained their BMI and the TAU group had gained significantly 0.66kg/m2. The waist circumference of the LIP group decreased and the TAU patients had increased. Therefore, the intervention group maintained their weight and BMI and presented a tendency to decrease weight and reduce their waist circumference after twelve months. Apart from the effects of the metabolic parameters, the two groups were differed on psychological indicators including the WHO-QoL psychological domain and the level of understanding towards health

and diet. Specifically, the LIP had higher WHO-QoL and a higher level of understanding towards health and diet as compared to the TAU patients which would be very important for patients to maintain their heathy lifestyles in the future to tackle the exterior barriers in finding healthy food in the market and interior barriers such as eating habits and social interaction. [20]

The limitation of this study includes small sample size which precluded adequate power to determine the effects of lifestyle intervention. Due to limit number of male patients willing to join in the study and the randomization was difficult. There were higher number of female patients in the LIP group. Case managers did not have special training in the lifestyle intervention which might influence the result. The study could not be blind to the patients and the case managers. Blinding with respect to a pragmatic intervention such as physiotherapy and exercise prescription is more difficult [21]. Practical limitation as the participants knew them they were in the intervention group.

There is a paucity of Asian randomized controlled trials on weight loss, especially among patients with severe mental illness taking SGAs in body weight management. This study was the first of its kind on lifestyle

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Table 3. Comparison of the patients (n=54) at baseline, stratified by intervention and control

Outcome measures	LIP (n=27)	TAU(n=27)	P value
Mean weight kg	70.9 (12)	67.2 (13)	0.282
Mean BMI Kg/m ²	27 (3)	25(4)	0.042†
Blood sugar (mmol/L)	5.5 (0.7)	5.39(1)	0.641
Total cholesterol(mg/dl)	5.2 (1)	5(1)	0.465
Waist circumference (cm)	91.9(12	87.4(11)	0.156
RSE	22.6(4.9)	23 (3.9)	0.741
DAI	4.2(3)	3.9(5)	0.790
QoL health	2.6(0.9)	3.1(0.7)	0.026†
QoL physical	92.7(19)	96.7(15)	0.394
QoL psychological	95.1(25)	99.2(17)	0.627
QoL environment	104(21)	106.6(18)	0.474
Understand health	20.5(3)	20(2)	0.237
Understand life	28.1(4)	26.8(4)	0.250
Understand diet	27.5 (6)	26 (3)	0.250

^{*}Data were presented as mean and SD number in brackets. Statistical analyze were performed using Unpaired t-test. † Significant difference on BMI and QoL Health between two groups

intervention program for patients with severe mental illness taking SGAs. Further studies should be included physical activity sessions in combination with psychoeducational intervention in body weight management. That would possibly exert a stronger impact on both physiological and psychological parameters in managing body weight for patients with severe mental illness taking SGAs than either educational or physical activity intervention alone.

Table 4 Results of outcome measures after 12-month follow-up by LIP (n=27) and TAU (n=27). Results of comparisons of differences between baseline and follow-up measurements.

Outcome measures	Baseline	12-month	Differences	P value
Weight Kg				
LIP (n=27)	70.9 (12)	69.6(13)	-1.25 (7.96)	0.837
TAU (n=27)	67.2 (13)	68.8 (13)	1.65 (8.22)	
BMI Kg/m ²				
LIP (n=27)	27 (3)	26.5 (3)	-0.51 (1.91)	0.449
TAU (n=27)	25 (4)	25.6 (4)	0.66 (2.52)	
Blood sugar (mmol/L)				
LIP (n=27)	5.5 (0.7)	5.6 (1)	0.10 (0.60)	0.532
TAU (n=27)	5.39 (1)	6.1 (3)	0.71 (2.28)	
Total cholesterol(mg/dl)				
LIP (n=27)	5.2 (1)	5.1 (1)	-0.10 (0.63)	0.948
TAU (n=27)	5 (1)	5.1 (1)	0.03 (0.63)	
Waist circumference (cm)				
LIP (n=27)	91.9 (12)	88.8 (11)	-3.10 (7.33)	0.837
TAU (n=27)	87.4 (11)	89.5 (11)	2.03 (6.95)	

	-	-	-	-
Outcome measures	Baseline	12-month	Differences	P value
RSE				
LIP (n=27)	22.6 (4.9)	21.2 (4.2)	-1.40 (2.95)	0.140
TAU (n=27)	23 (3.9)	22.8 (3.8)	0.20 (2.43)	
DAI				
LIP (n=27)	4.2 (3)	5.8 (2)	1.55 (1.84)	0.083
TAU (n=27)	3.9 (5)	3.8 (5)	-0.11 (3.16)	
QoL health				
LIP (n=27)	2.6 (0.9)	3.2 (0.9)	0.62 (0.56)	0.875
TAU (n=27)	3.1 (0.7)	3.2 (0.7)	0.10 (0.44)	
QoL physical				
LIP (n=27)	92.7 (19)	100.4 (18)	7.70 (11.73)	0.258
TAU (n=27)	96.7 (15)	94.8 (18)	1.92 (10.81)	
QoL psychological				
LIP (n=27)	95.1 (25)	110.2 (22)	15.11 (15.13)	0.039+
TAU (n=27)	99.2 (17)	98.3 (18)	-0.90 (11.10)	
QoL environment				
LIP (n=27)	104 (21)	110.9 (22)	6.90 (13.63)	0.208
TAU (n=27)	106.6 (18)	103.8 (18)	-2.81 (11.38)	
Understand health				
LIP (n=27)	20.5 (3)	20.8 (3)	0.38 (1.89)	0.052
TAU (n=27)	20.9 (2)	19.1 (2)	-1.72 ((1.26)	
Understand life				
LIP (n=27)	28.1 (4)	29.4 (5)	1.32 (3.00)	0.062
TAU (n=27)	26.8 (4)	26.5 (5)	0.33 (3.00)	
Understand diet				
LIP (n=27)	27.5 (6)	30.0 (6)	2.53 (3.79)	0.030+
TAU (n=27)	26 (3)	26.5 (4)	0.46 (2.40)	

^{*}Data were presented as mean and SD number in brackets. Statistical analyze were performed using Paired t-test. † Significant difference on Qol Psychological and Understanding diet

Conclusions

This study provided evidence of the feasibility and efficacy of a lifestyle intervention for patient with severe mental illness taking SGAs medication in body weight management. This study was not intended for patients to reduce body weight, rather to prevent the body weight to increase. It was reasonable to suppose that lifestyle interventions would be important for long-term strategies to prevent and manage adverse effect of weight gain, as well as enhancing their quality of life.

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on the food samples and preparation, transportation, booklet printing & design. (1 US dollar = $7.81\,\mathrm{HK}$ dollar)

Author Contributions: "Fanny SM Ip and Daniel YF Cho conceived and designed the experiments; Fanny SM Ip, KM Ng, KY Lai, WS Yuen performed the interventions and education; Fanny SM Ip and Wanda Siu analyzed the data; KT Leung contributed resource management and administrative support; Fanny SM Ip and Daniel YF Cho. wrote the paper.

Conflicts of Interest: "The authors declare no conflict of interest."

Appendix A

List of common FGAs and SGAs

FGAs	SGAs		
Chlorpromazine	Amisulpride		
Flupentixol	Aripiprazole		
Fluphenazine	Clozapine		
Haloperidol	Olanzapine		
Perphenazine	Paliperidone		
Thioridazine	Quetiapine		
Trifluoperazine	Risperidone		
Zuclopenthixol	Ziprasidone		

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