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Early Intervention in the Real World

Evaluating an individualized lifestyle and life skills intervention to prevent antipsychotic-induced weight gain in first-episode psychosis

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Abstract

Aim: Initiating antipsychotic medication frequently induces rapid, clinically significant weight gain. We aimed to evaluate the effectiveness of a lifestyle and life skills intervention, delivered within 4 weeks of antipsychotic medication initiation, in attenuating weight gain in youth aged 14–25 years with first-episode psychosis (FEP).

Methods: We undertook a prospective, controlled study in two early psychosis community services. Intervention participants (n = 16) received a 12-week individualized intervention delivered by specialist clinical staff (nurse, dietician and exercise physiologist) and youth peer wellness coaches, in addition to standard care. A comparison group was recruited from a similar service and received standard care (n = 12).

Results: The intervention group experienced significantly less weight gain at 12 weeks compared to standard care (1.8 kg, 95% CI –0.4 to 2.8 vs. 7.8 kg, 4.8–10.7, $P < 0.001$). Thirteen per cent (2/16) of the intervention group experienced clinically significant weight gain (greater than 7% of baseline weight), while 75% (9/12) of the standard care group experienced this level of weight gain. Similar positive effects of the intervention were observed for waist circumference.

Conclusions: A lifestyle and life skills intervention delivered as part of standard care attenuated antipsychotic-induced weight gain in young people with FEP. The intervention was acceptable to the young people referred to the service. Such interventions may prevent the seeding of future disease risk and in the long-term help reduce the life expectancy gap for people living with serious mental illness.

Key words: first-episode psychosis, lifestyle intervention, weight gain.

INTRODUCTION

People with severe mental illness suffer from a 20-year shortfall in life expectancy.[1] This disparity in life expectancy is largely due to premature cardiovascular disease (CVD), underpinned by metabolic disorders including diabetes and hyperlipidaemia. This disparity in life expectancy has been termed a scandal for countries embracing the notion of equity in access and quality of medical attention for all citizens.[1] Moreover, the mortality gap has widened, suggesting this population has not gained the health benefits experienced by the general population from improved CVD treatment and health initiatives to reduce CVD risk and reduce smoking.[2]

The antecedents to CVD appear early in the course of treatment with antipsychotic medications. Young people with first-episode psychosis (FEP) commencing antipsychotic medications can

experience weight gain and obesity, hyperlipidaemia, insulin resistance, hypertension and metabolic syndrome, which often develop rapidly, within 12 weeks of commencing antipsychotic medications.[3–5] Such changes are also observed in children and adolescents prescribed second-generation antipsychotics.[6]

Weight gain in young people with FEP is a major factor mediating the adverse cardiometabolic health in this population. Prevention of weight gain following initiation of antipsychotic medication, if achievable, would mitigate heightened cardiometabolic risk and future disease seeding.[4,6,7] Despite increased awareness of the cardiometabolic sequelae of antipsychotic treatment in youth with FEP, and the recent development of screening and monitoring tools,[8,9] there have been few trials that have demonstrated positive results in youth with FEP recently commenced on antipsychotic medications.[3,10,11] For example, a healthy living intervention for users of early psychosis services with a body mass index (BMI) of 25 or above, comprising both motivational and behavioural components with minimal face-to-face contact (nine sessions), did not significantly reduce BMI at 12 months.[12] However, strong evidence for the efficacy of lifestyle interventions in established illness was provided by a recent large-scale study in obese patients with serious mental illness that found sustained weight loss over 18 months using a behavioural intervention.[13]

Whether antipsychotic-induced weight gain can be prevented among young people with FEP remains unclear. To address this question, the present study examined the efficacy of the Keeping the Body in Mind (KBIM) programme, a holistic, individualized lifestyle and life skills intervention for the prevention of weight gain in youth with FEP recently commenced on antipsychotic medications. Results from those who completed the 12-week intervention were compared with results obtained in another sample recruited from a FEP service that offered guideline-based best-practice care, but did not offer additional lifestyle and life skills interventions.

METHODS

Design

The study was conducted across two community-based FEP services in Sydney, Australia, and received ethical approval from the South Eastern Sydney Local Health District Human Research Ethics Committee (Reference No. 13/040; LNR/13/POWH/85). The study was conducted between February 2013 and February 2014. Referral into the KBIM intervention was offered to all FEP youth treated at the Bondi Centre (South Eastern Sydney Local Health District). The second site, based at the Liverpool Mental Health Centre (South Western Sydney Local Health District), provided guideline-based best-practice standard care for FEP, without specific programmes or resources targeting healthy lifestyle. Only routine clinical measures were obtained at the comparison site and hence only these measures could be compared across both sites.

Participants

Figure 1 shows the enrolment process. A total of 53 clients were referred to the two FEP services during the recruitment period. Baseline and 12-week follow-up data were obtained for 28 clients across both community-based early psychosis treatment programmes. Inclusion criteria were: (i) diagnosis of FEP, defined as schizophreniform psychosis, schizophrenia, schizoaffective disorder, delusional disorder, brief psychotic disorder, bipolar affective disorder, or depression with psychotic features according to DSM-IV-TR (Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition, Text Revision) criteria; and (ii) treatment with antipsychotic medication for less than 4 weeks prior to baseline assessment. Exclusion criteria were: (i) medically unfit to exercise as determined by treating clinician and (ii) previous antipsychotic medication treatment for longer than 4 weeks.

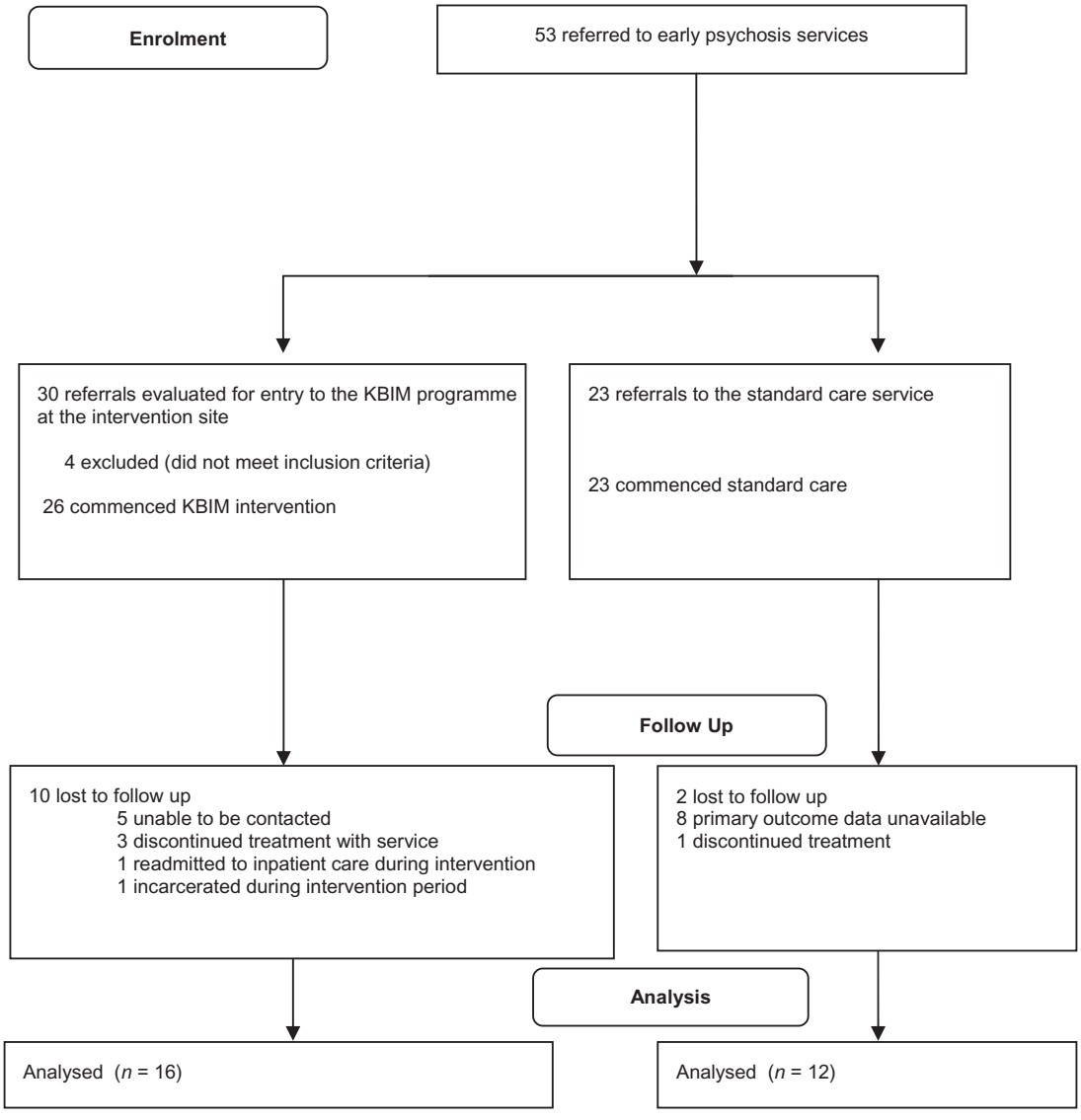
Intervention

A team that included a clinical nurse consultant, a dietician, an exercise physiologist and youth peer wellness coaches delivered the KBIM intervention. Psychiatrists (JC and MK) and an endocrinologist (KS) provided additional medication review and advice. The intervention comprised three interrelated components including health coaching, dietetic support and supervised exercise prescription, and was individualized based on best-practice recommendations in order to maximize adherence.

Health coaching

The clinical nurse consultant provided a motivational framework to assist clients with adherence. Specifically, this involved goal identification and structured motivational interviewing to maximize

FIGURE 1. Study profile.



attendance and increase motivation to participate in the intervention programme.[14]

Dietetic support

Weekly dietetic consultations based on the Australian Dietary Guidelines[15] were offered. These focused on nutritional adequacy and energy balance to ensure requirements for key nutrients were met, while promoting energy intake restraint to prevent weight gain. The individual consultations also included education modules focused on weight management, food quality, portion control, nutrition labels, shopping lists, setting up a healthy kitchen and cooking skills. The dietician, in conjunction with a caseworker, also modelled the key skills needed to choose, purchase ingredients and prepare healthy meals via weekly shopping tours and cooking classes held at the community health centre.

Exercise programme

The World Health Organization's recommendations for physical activity participation[16] and the American College of Sports Medicine resistance training guidelines[17] were used to specify exercise programming for the KBIM intervention group. The exercise physiologist tailored individual programmes, utilizing results of baseline fitness testing, and taking into account variations in motivation, individual goals and fluctuations in psychiatric symptomatology.[18] The aim of the exercise intervention was to increase physical activity participation in line with the

Australian Physical Activity guidelines. Given the wide range of physical activity participation at baseline assessment, interventions were tailored to ensure that the intensity and volume were challenging while maximizing enjoyment and taking into account the goals of individual participants (e.g. 60–75% of VO_2 peak for aerobic and moderate to high intensity resistance training). KBIM participants had access to a supervised gym within the community health centre, with access to treadmills, stationary bikes and resistance training equipment.

Youth peer wellness coaches

Two young people with lived experience of the impact of antipsychotic-induced weight gain participated in cooking classes and attended exercise sessions in the gym. They were both able to act as positive role models for KBIM participants, and provided motivation and encouragement for participants to maintain their engagement with the programme.

Antipsychotic medication switching

In addition to usual psychiatric care, medical staff in the intervention group reviewed clients who gained more than 5 kg following the initiation of antipsychotic treatment to consider switching to more weight neutral medication.[19] At the same time, consideration was given as to whether metformin should be prescribed in addition to the KBIM-structured lifestyle intervention, according to emerging treatment recommendations,[20,21] and whether any antipsychotic polypharmacy should be rationalized.[22]

Standard care

The comparison group received standard care involving individual mental health case management with medical assessment and antipsychotic prescription based on standard clinical guidelines.[23]

Outcome measures

Data were collected at baseline (upon referral to the service) and after 12 weeks of care. Body weight was measured with clients barefoot and in light street clothes to the nearest 0.1 kg. Height was measured with a stadiometer to the nearest 1 cm and BMI was calculated (weight/height squared, kg/m^2). Waist circumference was measured to the nearest 1 cm, midway between 12th rib and iliac crest. Blood pressure was measured with a sphygmomanometer with the client in the seated position and after 10-min rest (mm Hg). Blood was collected following a 10-h overnight fast, and fasting lipid profile (high-density lipoprotein, low-density lipoprotein, triglycerides, total cholesterol) and fasting blood glucose were analysed. Blood and anthropometric measures were obtained on the same day at the standard care site. At the intervention site, blood measures were taken as soon as practicable after anthropometry, or else the most recently obtained pathology results obtained during inpatient admission were utilized.

The KBIM intervention site also administered a limited battery of clinically relevant measures including: the Rosenberg Self-Esteem Scale,[24] Pittsburgh Sleep Quality Index (PSQI),[25] Global Assessment of Functioning (GAF),[26] Health of Our Nation Outcome Scale (HoNOS),[27] Medication Adherence Rating Scale (MARS),[28] a food frequency questionnaire assessing nutrition status (including micro- and macronutrient intake),[29] and exercise capacity, including sub-maximal oxygen consumption (VO_2max)[30] and self-reported physical activity levels (IPAQ-SF).[31]

Statistical analyses

The impact of the KBIM intervention versus standard care on weight, BMI, waist circumference and biochemical measures was examined using repeated measures ANCOVA with between-group factor (site) and within-subject factor (time), using baseline measures as a covariate. Pearson chi-square analyses were undertaken for categorical variables. Paired-sample *t*-tests were used to compare pre- and post-intervention scores for continuous variables assessed at the intervention site only. Analyses were conducted using SPSS version 22 software package (Chicago, IL, USA). Partial eta-squared (η_p^2) effect sizes were calculated for the site by time interaction effect for the primary outcome measures.[32]

RESULTS

The final sample consisted of 28 participants (17 men, 11 women) with a mean age of 20.7 years (SD = 2.2, range 17–25). Baseline characteristics were similar for participants at the intervention and standard care sites (Table 1), although the proportion of female participants in the intervention group was greater than in the standard care group (56% vs. 17%, $P = 0.04$). The intervention group reported tobacco use well below the rates observed in recent systematic reviews in this population,[33] while tobacco use in the standard care group was similar

TABLE 1. Baseline characteristics of 28 participants; *N* (%)

		KBIM (n = 16)	Standard care (n = 12)	Statistical test	P-value
Demographic					
Age	Mean (SD)	20.0 (2.3)	21.7 (1.9)	$T = 2.1$	0.05
Female		9 (56)	2 (17)	$\chi^2 = 4.5$	0.04
Ethnicity	*n* (%)				
Asian		4 (25)	5 (42)		
Indigenous		2 (13)	2 (16)	$\chi^2 = 8.2$	0.22
Caucasian		10 (62)	5 (42)		
Smoking	*n* (%)	2 (13)	5 (42)	$\chi^2 = 1.8$	0.18
DSM-IV diagnoses	*n* (%)				
Schizophreniform		9 (56)	5 (42)		
Bipolar affective disorder		4 (25)	5 (42)	$\chi^2 = 1.0$	0.79
Major depression with psychosis		2 (13)	1 (8)		
Schizophrenia		1 (6)	1 (8)		
Psychotropic medications	*n* (%)				
Mood stabilizer					
Lithium		3 (19)	1 (8)	$\chi^2 = 0.6$	0.42
Sodium valproate		1 (6)	6 (50)	$\chi^2 = 7.0$	0.01
Antipsychotic					
Risperidone		4 (25)	8 (67)	$\chi^2 = 4.9$	0.03
Quetiapine		5 (31)	0 (0)	$\chi^2 = 4.6$	0.04
Olanzapine		4 (25)	3 (25)	$\chi^2 = 0.0$	0.67
Aripiprazole		1 (6)	1 (8)	$\chi^2 = 0.0$	0.68
Paliperidone		2 (13)	0 (0)	$\chi^2 = 1.6$	0.32
Antidepressant (all classes)		4 (25)	3 (25)	$\chi^2 = 0.0$	0.67
Anthropometric and metabolic measures					
Weight (kg)	Mean (SD)	68.8 (13.6)	75.8 (18.8)	$T = 1.2$	0.26
Body mass index (BMI) (kg m^{-2})	*n* (%)				
Normal (18.5–24.9)		10 (63)	7 (59)	$\chi^2 = 1.4$	0.5
Overweight (25–29.9)		6 (38)	4 (33)		
Obese (>30)		0 (0)	1 (8)		
Waist circumference (cm)	Mean (SD)	84.3 (10.8)	83.7 (9.1)	$T = 0.33$	0.74
'At risk' waist circumference†	*n* (%)	9 (56)	0 (0)	$\chi^2 = 9.9$	0.002
Time in service prior to baseline assessment (days)	Mean (range)	12.1 (1–24)	16.8 (4–31)	$T = 1.5$	0.15
Elevated systolic BP (≥130 mm Hg)	*n* (%)	2 (13)	4 (36) (n = 11)	$\chi^2 = 2.1$	0.16
Elevated diastolic BP (≥85 mm Hg)	*n* (%)	1 (6)	2 (18) (n = 11)	$\chi^2 = 0.9$	0.36
Low HDL (<1.03 mmol/L male; <1.29 female)	*n* (%)	4 (25)	1 (10) (n = 10)	$\chi^2 = 0.9$	0.34
Elevated LDL (>4.0 mmol/L)	*n* (%)	0 (0)	1 (10) (n = 10)	$\chi^2 = 1.7$	0.39
Elevated triglycerides (≥1.7 mmol/L)	*n* (%)	0 (0)	2 (18) (n = 11)	$\chi^2 = 3.1$	0.16
Impaired fasting BSL (>7.0 mmol/L)‡	*n* (%)	0 (0)	0 (0) (n = 10)	–	

†Female ≥80 cm, male ≥90 cm for SE Asian, Japanese, Central or South American or ≥94 cm for Europid.
‡Missing data for n = 1.
BMI, body mass index; BP, blood pressure; BSL, Blood sugar level; HDL, high-density lipoprotein; IDF MetS, International Diabetic Federation metabolic syndrome; KBIM, Keeping the Body in Mind programme; LDL, low-density lipoprotein.

to that usually reported among FEP youth. At the intervention site, a minority of referrals to the community-based service were made following an inpatient admission (6/16: 38%). In contrast, the majority of referrals to the standard care service had been hospitalized prior to beginning specialized community-based care (9/12: 75%; $\chi^2 = 3.9$, $P = 0.05$), reflecting differing pathways to care in the two services.

Psychotropic medication use at baseline is shown in Table 1. Risperidone was most commonly prescribed (43%, $n = 12$), followed by sodium valproate (26%, $n = 7$), olanzapine (26%, $n = 7$), quetiapine (19%, $n = 5$) and lithium (15%, $n = 4$). Site differences were evident: sodium valproate was prescribed more frequently in the standard care participants, consistent with higher rates of bipolar disorder among this group (50% vs. 6%, respectively, $\chi^2 = 7.0$, $P = 0.01$). There was more frequent prescription of quetiapine in the intervention participants (31% vs. 0%, $\chi^2 = 4.6$, $P = 0.04$) and risperidone in the standard care participants (67%

vs. 25%, $\chi^2 = 4.9$, $P = 0.03$); however, these two antipsychotics have similar propensity for weight gain[19] and their differential use at the two sites was unlikely to influence the primary outcomes. Only limited changes in antipsychotic medication prescribing were documented in the KBIM intervention participants during the 12-week intervention. Eight participants (50%) had no change in medication, and one participant was switched from olanzapine to risperidone at week 5 due to lack of efficacy for psychotic symptoms. Changes in antipsychotic dosage occurred in the remaining participants (25% decreased, 19% increased) during the course of the intervention. There was no antipsychotic polypharmacy at either site during the 12-week follow-up period.

Baseline weight, waist circumference and BMI were similar in the intervention and standard care groups (Table 1). Baseline BMI was normal in the majority of participants; however, 32% had waist circumferences that met the International Diabetes Federation at-risk criteria,[34] all of whom were in the intervention group. Mean participation rates in the individual components of the KBIM intervention were 8 dietary sessions (range = 5–10) and 11 supervised exercise sessions (range = 3–25).

The KBIM intervention resulted in substantially lower weight gain compared to standard care (1.8 kg (95% CI −0.4 to 2.8) vs. 7.8 kg (4.8–10.7), Site × Time interaction, $F(1, 25) = 19.6$, $P < 0.001$, $\eta_p^2 = 0.44$) (see Table 2). There was no significant change in BMI in the KBIM intervention group (0·4 kg m^{-2} (−0.1–0.9)) while there was a significantly greater increase in BMI with standard care (2.6 kg m^{-2} (1.6–3.6), Site × Time interaction, $F(1, 25) = 23.3$, $P < 0.001$, $\eta_p^2 = 0.48$). There was a non-significant increase in waist circumference of 0.1 cm (−2.1 to 2.2) in the KBIM intervention group; in contrast, there was a significant waist circumference increase with standard care (7.1 cm (4.8–10.7), Site × Time interaction, $F(1, 25) = 22.4$, $P < 0.001$, $\eta_p^2 = 0.47$).

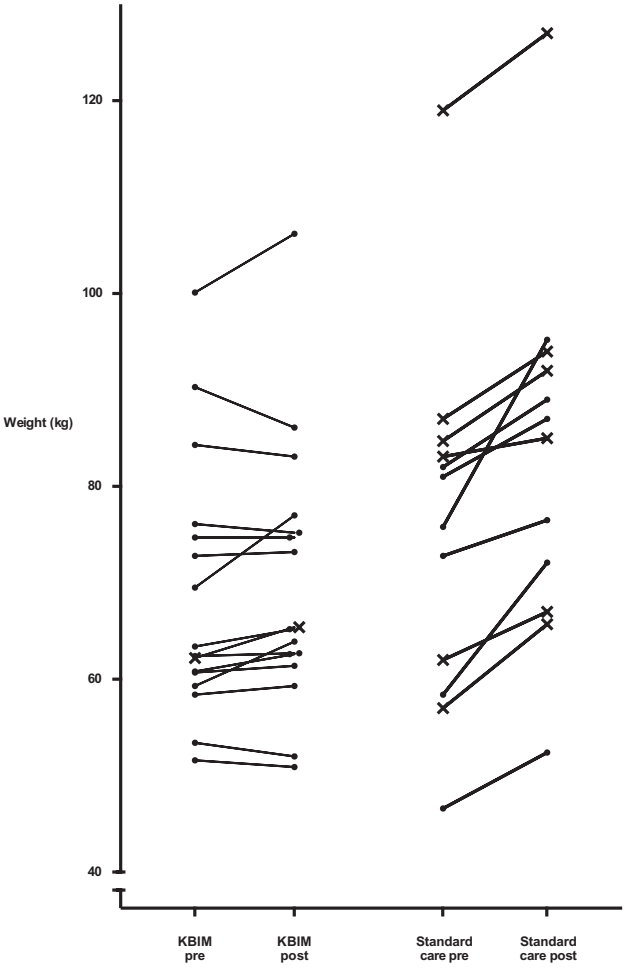
The rate of clinically significant weight gain, defined as >7% of baseline weight, was 13% in the KBIM intervention, compared to 75% in standard care ($\chi^2 = 11.2$, $P = 0.001$). Figure 2 illustrates the individual patterns of weight change in all participants. As sodium valproate prescribing was significantly more frequent in the standard care group, and has been linked with increased weight in youth with FEP,[35] we addressed the potential impact of the use of valproate on this measure by examining individual changes in weight among those prescribed sodium valproate compared to the rest of the sample in which this medication was not used. This demonstrated that the significant weight increase

TABLE 2. Mean within-group change and repeated measures ANOVA

Mean (SD)	KBIM (n = 16)			Standard care (n = 12)			Repeated measures ANCOVA
	Pre	Post	Mean within-group change (95% CI)	Pre	Post	Mean within-group change (95% CI)	Site × Time interaction
Weight (kg)	68.8 (13.6)	69.9 (13.9)	1.8 (−0.4to2.8)	75.8 (18.8)	83.6 (19.0)	7.8 (4.8–10.7)**	$F(1, 25) = 19.6$ ($P < 0.001$)
BMI (kg m^{-2})	23.5 (3.2)	23.9 (3.2)	0.4 (−0.1to0.9)	24.8 (3.3)	27.4 (3.1)	2.6 (1.6–3.6)**	$F(1, 25) = 23.3$ ($P < 0.001$)
Waist circumference (cm)	84.3 (10.8)	84.4 (10.3)	0.1 (−2.1to2.2)	83.0 (9.1)	90.1 (9.4)	7.1 (4.8–9.4)**	$F(1, 25) = 22.4$ ($P < 0.001$)
Systolic blood pressure (mm Hg)	116.8 (11.6)	116.1 (5.8)	−0.6 (−6.1to4.8)	*	*	–	–
Diastolic blood pressure (mm Hg)	73.9 (7.7)	70.8 (5.3)	−3.1 (−6.5to0.3)	*	*	–	–
HDL cholesterol (mmol/L)	1.4 (0.2)	1.4 (0.4)	0.1 (−0.1to0.2)	1.4 (0.4)†	1.3 (0.3)†	−0.1 (−0.3 to 0.2) NS	$F(1, 22) = 1.4$
LDL cholesterol (mmol/L)	2.7 (0.9)	2.7 (0.9)	0.0 (−0.3to0.3)	2.5 (1.0)†	2.6 (0.9)†	0.0 (−0.6 to 0.7) NS	$F(1, 22) = 0.0$
Triglyceride (mmol/L)‡	0.85 (0.3)	0.86 (0.4)	0.0 (−0.2to0.2)	1.1 (0.7)§	1.4 (1.1)§	0.3 (−0.5 to 1.0) NS	$F(1, 23) = 1.6$
Total cholesterol (mmol/L)	4.4 (1.1)	4.5 (1.1)	0.1 (−0.3to0.6)	4.3 (1.0)§	4.5 (1.1)§	0.2 (−0.2 to 0.7) NS	$F(1, 23) = 0.1$
Glucose (mmol/L)	4.8 (0.4)¶	4.8 (0.4)¶	−0.1 (−0.3to0.2)	4.7 (0.4)††	5.1 (0.8)††	0.4 (−0.2 to 0.9) NS	$F(1, 23) = 2.5$

*Data not available for post-test blood pressure in the standard care group, so both pretest and post-test data on blood pressure are omitted. **$P < 0.001$.
†n = 9.
‡Site $F(1, 23) = 7.9$, $P = 0.01$; when covaried for baseline weight, the group difference for triglycerides was no longer statistically significant ($P = 0.12$).
§n = 10.
¶n = 15.
††n = 11.
BMI, body mass index; HDL, high-density lipoprotein; LDL, low-density lipoprotein; NS, non-significant.

FIGURE 2. Individual scatter plot for weight at baseline and 12-week follow up for KBIM (left panel) and standard care (right panel) participants. (X) Participant prescribed sodium valproate. [Correction added on 22 May 2015, after first online publication: Figure 2 has been corrected to show the accurate number of participants who received sodium valproate at both KBIM and standard care sites.]



that was observed in the standard care group was evident across the entire cohort, not only in those participants who were prescribed sodium valproate. Metformin was not prescribed for any of the KBIM intervention participants.

There was no significant change in fasting lipids or glucose in either group, despite the standard care group experiencing clinically significant weight and waist circumference gains.

Additional outcome measures in KBIM participants

Table 3 reports the pre-, post- and mean within-group change for outcomes assessed only at the KBIM site. Significant improvements in functional and clinical outcome measures were observed (GAF: 16.1 (12.3–19.8); $P < 0.001$; HoNOS: –3.8 (–7.1 to –0.5); $P < 0.05$) along with improved self-reported sleep quality (PSQI: –1.6 (3.1 to –0.1); $P < 0.05$). There was a clinically significant reduction in energy consumption (–507.9 kcal/day (95% CI –751.6 to –264.2); $P < 0.001$), while aerobic capacity (VO_2max; 4.2 mL kg^{-1} min^{-1} (1.3–7.2); $P < 0.01$) and self-reported minutes of physical activity per week (IPAQ-SF: 1239.2 min/week (243.7–2234.6); $P < 0.05$) increased significantly. No statistically significant changes were observed for self-rated self-esteem (Rosenberg Self-Esteem Scale) or medication adherence (MARS).

DISCUSSION

The KBIM intervention was effective in attenuating weight gain in youth receiving antipsychotic medication for FEP over 12 weeks, with only 13% of the participants experiencing clinically significant weight gain. In contrast, the majority (75%) of participants who received standard care gained a clinically significant amount of weight and had markedly increased waist circumference over the same time period, consistent with results seen in previous studies of FEP youth receiving standard care.[3] Despite the relatively small numbers of participants for whom follow-up data were available at both sites, the magnitude of the intervention effect was large, as indicated by the substantial percentage of variance in primary outcome measures that was accounted for by the significant Site × Time interactions (44–48%). The KBIM intervention, while it included individualized education and advice for healthy eating and physical activity, additionally supported lifestyle change through life skills acquisition. For example, we employed group-based cooking and shopping activities that demonstrated how to purchase and prepare meals using healthy, affordable ingredients.

There was no significant change in fasting lipids or glucose in either group at 12 weeks, despite clinically significant weight and waist circumference increases occurring in the standard care participants. Our findings differ from prior studies that show early glucose homeostasis dysregulation and blood glucose and/or blood lipid changes after short-term antipsychotic treatment with second-generation antipsychotic medications.[6,36] The absence of such changes in our data may reflect lower sensitivity to the metabolic effects of antipsychotics in a youth sample compared to a younger cohort,[6] and/or the less frequent use of antipsychotics with greater weight gain propensity (e.g. olanzapine) in the current study.

TABLE 3. Additional outcome measures only assessed in the KBIM group (n = 16)

	Mean (SD)		Mean change (95% CI)	Paired samples t-test
	Pre	Post		
Global Assessment of Functioning (GAF)	54.6 (7.8)	70.7 (9.9)	16.1 (12.3–19.8)	$t(15) = 9.0$***
Health of our Nation Outcome Scale (HoNOS)	9.9 (3.4)	6.1 (5.4)	−3.8 (−7.1 to −0.5)	$t(15) = 2.5$*
PSQI Sleep Quality (0–21)	7.7 (3.6)	6.1 (2.3)	−1.6 (−3.1 to −0.1)	$t(15) = 2.3$*
Energy intake (kcal/day)	2015.7 (535.8)	1507.8 (471.5)	−507.9 (−751.6 to −264.2)	$t(15) = 4.4$***
VO_2 (relative) (mL kg^{-1} min^{-1})	30.6 (6.5)[%]	34.9 (9.1)[%]	4.2 (1.3–7.2)	$t(13) = 3.1$**
MET min/week [%] (IPAQ-SF)	788.4 (655.0)†	2027.6 (1740.0)†	1239.2 (243.7–2234.6)	$t(14) = 2.7$*
Rosenberg Self-Esteem Scale (0–30)	18.4 (6.9)	19.1 (5.4)	0.7 (−1.4 to 2.8)	$t(15) = 0.7$
Medication adherence (MARS: 0–10)	7.9 (1.9)	8.3 (1.8)	0.4 (−0.4 to 1.2)	$t(15) = 0.3$

*$P < 0.05$; **$P < 0.01$; ***$P < 0.001$.
†n = 15 due to one man having physical injury limiting PA participation.
[%]n = 14 due to one man having physical injury limiting PA participation and one woman not completing follow-up VO_2 assessment.
KBIM, Keeping the Body in Mind programme.

The KBIM participants also experienced significant improvements in the specific outcomes targeted by the intervention: total energy intake was significantly reduced, while improvements were seen in aerobic fitness and self-reported physical activity. The improvement in self-reported sleep quality is consistent with studies in other populations that found a significant impact of exercise on sleep quality[37]; however, the pragmatic 'real-world' nature of this evaluation does not enable us to attribute this improvement to the specific elements of the KBIM intervention.

Limited changes in psychotropic medication use occurred during the KBIM intervention, suggesting that such changes were unlikely to account for the non-significant weight gain at the intervention site. There was no significant change in the relatively high levels of medication adherence recorded at baseline and follow-up assessments, so that variation in adherence was unlikely to have contributed to the positive outcomes in the intervention group.

As a real-world study, the use of antipsychotics at both sites reflected the practice of the prescribers. While clinicians in the specialist community-based FEP services aimed to avoid the use of antipsychotic medications with a high potential for weight gain, young people were frequently commenced on antipsychotic, mood stabilizer and antidepressant drug regimens with high weight gain potential while admitted to acute inpatient units. The rate of antidepressant prescription was similar across both sites, and it is unlikely that the use of antidepressants made a substantial contribution to the differential outcomes for weight, waist circumference and BMI described in the manuscript.

Higher rates of overweight and obesity have been observed in women compared with men with FEP,[38] so that a greater propensity for weight gain in the KBIM intervention sample, where the proportion of women was higher than in the standard care group, may have been predicted. This was not the case, with only one female and one male KBIM participant experiencing clinically significant weight gain during the 12-week follow-up period. Attrition rates were similar for the two sites (KBIM intervention: 62%; standard care: 52%), and reflect the challenges frequently experienced in establishing and maintaining engagement during FEP treatment.[39]

The current study was a pragmatic evaluation of a novel intervention, delivered in one service setting, with comparison data obtained from another early intervention service providing guideline-based best-practice standard care without the additional specialist lifestyle intervention components. It is possible that sociodemographic differences exist between the populations from which each service drew its clients, which may have impacted the results obtained. It is important to note that the anthropometric changes observed at 12 weeks in those receiving standard care were consistent with results seen in previous systematic reviews.[40]

Early weight gain and increased cardiometabolic risk factors will seed future poor health outcomes in youth with psychosis[4,6,7] unless effective interventions are implemented. International initiatives to achieve parity in physical health expectations for young people with psychosis have been developed and outlined in the Healthy Actives Lives (HeAL) declaration (http://www.iphys.org.au). The HeAL declaration specifies targets that address antipsychotic-induced weight gain, poor nutrition, low levels of physical activity and high rates of tobacco use. It is notable that the low rate of clinically significant weight gain in the KBIM intervention sample at 12 weeks (13%) exceeds the target proposed in the HeAL declaration for weight gain

over the first 2 years of treatment (25% or less). Questions that need to be addressed in further longitudinal follow-up studies include how to minimize weight gain over the longer term, and what intensity of lifestyle intervention support is needed to maintain positive cardiometabolic health in youth with FEP.

Additional resources were required to deliver the KBIM; however, the benefits that were obtained were not limited to the primary and secondary outcomes described in this evaluation. The greater degree of engagement with the service that participants described and mental health staff confirmed[41] should translate into better outcomes in terms of symptom control and psychosocial functioning.

In summary, a 12-week combined lifestyle and life skills intervention attenuated antipsychotic-induced weight gain in youth with FEP. Asking mental health clinicians to provide information about diet and exercise may be insufficient to prevent the substantial weight gain and decline in cardiometabolic health associated with antipsychotic use. Implementing effective lifestyle and life skills interventions from the initiation of treatment as part of routine care in youth with FEP may be a critical step in reducing the life expectancy gap for people living with serious mental illness.

CONTRIBUTORS

JC, KS and PBW obtained funding. JC, KS and PBW designed the study with input from AW, SR and ST. JC, MK and KS provided clinical supervision. AW, SR and ST collected data. SR, ST and PBW analysed the data. JC, KS and PBW led data interpretation. JC, KS and PBW led manuscript preparation with input from SR, AW and ST. All authors contributed to successive drafts.

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