Intentional Weight Loss in Overweight and Obese Patients With Severe Mental Illness: 8-Year Experience of a Behavioral Treatment Program

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Objective: Obesity is 2 to 3 times more common among people with severe mental illness and has adverse effects on physical and psychological health. We report the experience from the first 8 years of a self-referring weight management clinic.

Method: From 2000 to 2008, 113 patients with severe mental illness (according to *ICD-10* criteria) with a mean ± SE age of 43.8 ± 1.7 years (range, 22–71 years) referred themselves to this clinic. The patients were seen in weekly group sessions lasting 1 hour that involved weight measurement, discussion, and education. The response to the program was assessed by the paired Student *t* test and linear analysis corrected for repeated measures.

Results: Mean ± SE baseline weight was 90.1 ± 1.6 kg (body mass index [BMI] = 32.2 ± 0.5 kg/m^2). Fifty subjects of the 142 total patient episodes (35%) dropped out within the first 3 months. Sixty-four subjects completed 1 year of the program, and 35 have attended for 2 years or longer. There were progressive statistically significant reductions in mean weight and BMI throughout the duration of monitoring, with no suggestion of a plateau. The mean ± SE final weight loss was 7.2 ± 0.6 kg. Weight loss was correlated only with the number of sessions attended ($r = 0.42$, $P < .0001$).

Conclusions: Lifestyle advice within a group setting may be effective in long-term management of obese and overweight patients with severe mental illness.

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The worldwide prevalence of obesity has increased dramatically over the last 25 years and is a major cause of premature mortality and morbidity.[1,2] Obesity is more common among those with severe mental illness (SMI),[3–5] including treatment-naive cohorts.[6]

The treatment of obesity is a major challenge for society and in people with SMI.[7] Unfortunately, there is much therapeutic nihilism in mental health services regarding obesity management, but this view has been challenged by a number of recent observational studies and randomized control trials, supported by a Cochrane review, which have shown that lifestyle interventions are possible in those with severe mental illness, at least in the short term.[8,9] Although these reports are encouraging, studies of interventions over a longer duration are needed to assess whether early weight loss is sustainable.

This service evaluation describes the longer term effectiveness of a weight management clinic over a period of up to 8 years in people with severe mental illness that uses a simple model that could be replicated in other settings and potentially be cost-effective. An earlier analysis reported the 4-year data.[10]

METHOD

The Cromwell House weight management clinic, located in Manchester, United Kingdom, was set up in May 2000 at the request of a small group of patients with SMI and is believed to be the longest running such service in the world. The format of the clinic was designed in consultation with the initial group of patients, but more recent attendees are invited to make comments about the running of the clinic.[10]

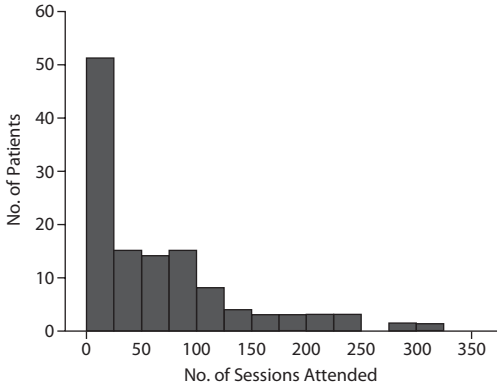
It was initially staffed by a community psychiatric nurse (J.P.) and an occupational therapist. In 2007, the responsibility for the clinic passed from J.P. to a group worker and community care workers. This program was made available to people with SMI who were receiving psychotropic medications, were concerned about their weight, and were able to refer themselves to this clinic.

The patients were seen in a weekly group session, held on Thursday at lunchtime, a time chosen to make the clinic accessible for people with SMI. A group session was used to reduce staffing time and to allow patients to discuss their challenges and successes and, therefore, help each other.

Attendance at the sessions was voluntary, and patients, thus, attended the clinic for as few or as many sessions as they chose. Several patients re-referred themselves to the group after a break of more than 3 months. These were considered as new patient episodes.

Baseline demographic details were obtained, including age, sex, height measured using a wall-mounted stadiometer, psychiatric diagnosis (according to *International Classification of Diseases, Tenth Revision* criteria), and medication. Weight was measured in private using imperial measures to the nearest half pound rather than metric measures at the request of the patients at the initial and each follow-up visit. The digital scales were accurate to 0.05 kg (2 ounces imperial) and routinely checked for accuracy at least 4 times a year. Patients were told how much weight they had lost or gained to the nearest half pound and were given their actual weight on a card to maintain individual privacy. These data

Figure 1. Distribution of the Number of Sessions Attended by Each Patient



were also entered into the database that was used to assess the clinic's success.

After weighing, there was a 15-minute period for group discussion and feedback, which was facilitated by the group leader. The group voluntarily shared details of their weight change together with personal dietary experiences from the previous week. Each patient was asked to keep a dietary record, which was used individually or within the group to negotiate a single change in the person's diet for the following week depending on the individual's weight loss, such as a switch to nonsugary soft drinks. Other changes included eating more fruit and vegetables, changing to semi or skimmed milk, using artificial sweetener instead of sugar in tea and coffee, frying less, using low fat spread instead of butter or using less butter, and drinking less alcohol.

The final 30 minutes were used for a series of 8 rotational topics, which addressed issues such as healthy eating, exercise, self-esteem, meal planning and demonstrations, motivation, and evaluation. Written materials were not used within the clinic. The topics were presented in a flexible and informal manner by the group leader, and additional sessions were incorporated to address specific weight issues, such as Christmas, Easter, birthdays, and school holidays. Patients did not receive any written materials within the clinic.

As this was a service evaluation, no specific control group was included in this analysis. The service evaluation was undertaken in accordance with guidance from the National Research Ethics Service. In line with this guidance, approval for the study was obtained from the managers of the Greater Manchester West Mental Health Trust, but participants were not required to provide written informed consent.

Statistical Analysis

All imperial measures were converted to metric. As weight and weight loss were normally distributed, parametric statistical methods were used. All analyses were performed using the Statistical Package for the Social Sciences version 14.0 for Windows (SPSS Inc, Chicago, Illinois). Results were considered statistically significant if the *P* value was less than .05. The results are given as mean ± SE. The response to the program was assessed by the paired Student *t* test and linear analysis corrected for repeated measures. The effect of sex and psychotic medication was assessed by analysis of variance. The effect of number of sessions attended and age was determined by linear analysis.

A value of 7% change in body weight was used to define clinically significant weight loss. This change is the accepted norm value used by both the US Food and Drug Administration and European Medicines Agency, and such data are often presented in the summary of product characteristics or product label of antipsychotics.

Table 1. Drug Therapy of Patients With Schizophrenia or Affective Disorders Attending the Weight Management Clinic

Treatment	Schizophrenia (n = 89), n	Affective Disorders (n = 23), n
Atypical antipsychotic monotherapy		
Olanzapine	22	0
Quetiapine	5	1
Risperidone	5	0
Clozapine	8	0
Amisulpride	4	0
Typical antipsychotic monotherapy		
Chlorpromazine	2	0
Flupenthixol	3	0
Fluphenazine	3	0
Antidepressant monotherapy		
Citalopram	0	3
Lithium	0	7
Sertraline	0	1
Mirtazapine	0	1
Duloxetine	0	2
Multiple psychotropic drugs		
2 drugs	14	5
3 drugs	13	2
> 3 drugs	10	1

RESULTS

Since May 2000, 46 men and 67 women have been enrolled into the program. The mean ± SE age of the patients was 43.8 ± 1.7 years (range, 22–71 years). Fourteen patients dropped out from the weight management program and rejoined the program more than 3 months after leaving the program. Six patients enrolled in the program 3 times, and 1 person enrolled 4 times, giving a total of 142 patient episodes. The number of sessions attended per episode ranged from 1 to 315 (mean ± SE = 61.0 ± 6.8, median = 48) (Figure 1).

Eighty-nine patients had schizophrenia, 23 had an affective disorder, and 1 had suffered a brain injury. The patients' treatments are shown in Table 1. The brain injury subject was receiving carbamazepine and paroxetine.

The mean ± SE baseline weight for the first visit to the clinic was 90.1 ± 1.6 kg (body mass index [BMI] 32.2 ± 0.5 kg/m^2). Upon enrollment, 11 patients had a normal BMI (≥ 19 kg/m^2 but < 25 kg/m^2), 44 were overweight (BMI 25–30 kg/m^2), and 87 were obese (BMI > 30 kg/m^2).

The patients who rejoined the clinic had gained a mean ± SE of 11.7 ± 1.8 kg in the interim between leaving and reregistering with the program. Those rejoining the clinic were heavier than those joining for the first time (96.6 ± 3.7 kg vs 88.4 ± 1.8 kg, *P* = .04), but there was no

Table 2. Number of Patients Remaining in the Program Over Time

		Patients Remaining in Program Over Time, n										
Year of Recruitment	n	4 wk	3 mo	6 mo	1 y	2 y	3 y	4 y	5 y	6 y	7 y	8 y
2000	31	31	28	26	25	17	12	7	7	5	4	4
2001	22	21	16	11	8	3	2	2	2	2	2	…
2002	28	27	16	14	11	16	5	5	4	0	…	…
2003	31	23	15	14	14	7	5	4	1	…	…	…
2004	12	11	8	6	3	2	1	0	…	…	…	…
2005	6	6	4	1	1	0	0	…	…	…	…	…
2006	7	7	2	2	1	0	…	…	…	…	…	…
2007	5	4	3	3	1	…	…	…	…	…	…	…
Total	142	130	92	75	64	35	25	18	14	7	6	4
Denominator	142	142	142	142	142	137	130	124	112	81	53	31
Percentage	100	92	65	53	45	26	19	15	13	9	11	13

statistical difference in BMI (33.7 ± 1.4 kg/m^2 vs 31.8 ± 0.5 kg/m^2, $P = .2$).

Twelve patients (8%) dropped out of the program within 4 weeks, and a further 38 withdrew between 4 and 12 weeks. Thus, dropouts within the first 3 months were 35%. The numbers involved with longer follow-up are shown in Table 2. There was no difference in drop-out rate between genders and between those with schizophrenia compared with bipolar illness. However, those who had dropped out in the first year were younger (40.6 ± 1.6 years vs 47.6 ± 1.6 years, $P = .002$). There was no difference in baseline weight and weight loss during the program between those who had dropped out in the first year and those who remained in the program.

Weight Loss

There was a continual statistically significant reduction in mean weight, BMI, and percentage of weight loss throughout the duration of the study, with no suggestion of a plateau (Figure 2). By 3 months into the program, 86 of the 92 patients (93%) still attending had lost some weight. The number of patients achieving a 7% weight loss is shown in Table 3, and the final BMI category is shown in Table 4. By the end of the patient episode, 92% (n = 130) had lost some weight, 4% (n = 6) had maintained their initial weight, and only 4% (n = 6) had gained weight. Thirty-six had a normal BMI, and the number who remained obese had fallen from 87 to 57. The mean final weight loss was 7.2 ± 0.6 kg. This final weight was determined at cessation of clinic attendance, and, hence, time-points for this final outcome cover the whole 8-year period, depending upon the length of attendance.

Determinants of Weight Loss

There was no significant difference in percentage of weight loss between men and women. There was no correlation between percentage of weight loss and either baseline weight or BMI. Younger people lost weight faster in the first 3 months, as demonstrated by an inverse correlation between age and percentage of weight loss in the first 3 months ($r = 0.238$, $P = .022$), but this difference was no longer significant after 6 months.

There was no significant difference in percentage of weight loss between patients who were new to the program or rejoining the program after a break of 3 months or more.

Weight loss was correlated with the number of sessions attended ($r = 0.42$, $P < .0001$). On average, patients lost 0.34 ± 0.07 kg per session.

There was no significant difference in percentage of weight loss between those with schizophrenia and those with affective disorders. There was no difference in weight loss between patients receiving typical or atypical antipsychotic drugs in the first year, but, thereafter, the observed weight loss was greater in those receiving atypical antipsychotics, although the numbers by this stage are small. There was no significant difference in weight loss between those taking multiple drugs rather than monotherapy ($P = .26$).

DISCUSSION

Our experience of the first 8 years of the voluntary Cromwell House weight management clinic has shown that long-term weight loss is achievable in well-motivated patients with SMI, irrespective of age, initial BMI, diagnosis, and treatment. The achieved weight loss has been at least as great as the effectiveness of lifestyle modification programs within the general population,[11] suggesting that simple lifestyle interventions can be successful in the long term in people with SMI.

There is a clear need for effective treatment and prevention of obesity in people with SMI given the increased prevalence of obesity in SMI compared with the general population.[3–5] Obesity occurs early in the natural history of SMI; a significant proportion of people with first-episode psychosis are overweight prior to any treatment, and weight gain occurs following treatment initiation; 17% of patients with schizophrenia in the European First-Episode Schizophrenia Trial were overweight at baseline prior to treatment, and between 37% and 86% had gained more than 7% of their initial body weight during the first year of treatment, depending on medication choice.[12] Similarly, in a Spanish first-episode schizophrenia cohort, weight increased rapidly during the first treatment year, resulting in overweight in 34.7% and obesity in 25.7%.[6] The baseline BMI in our cohort was comparable to that seen in the Clinical Antipsychotic Trials of Intervention Effectiveness study[5] and the UK "Well-Being Support Programme" study, which evaluated a physical health program in 966 people with SMI.[13]

While there are justifiable concerns about treatment-emergent–induced weight gain,[14] the development of obesity

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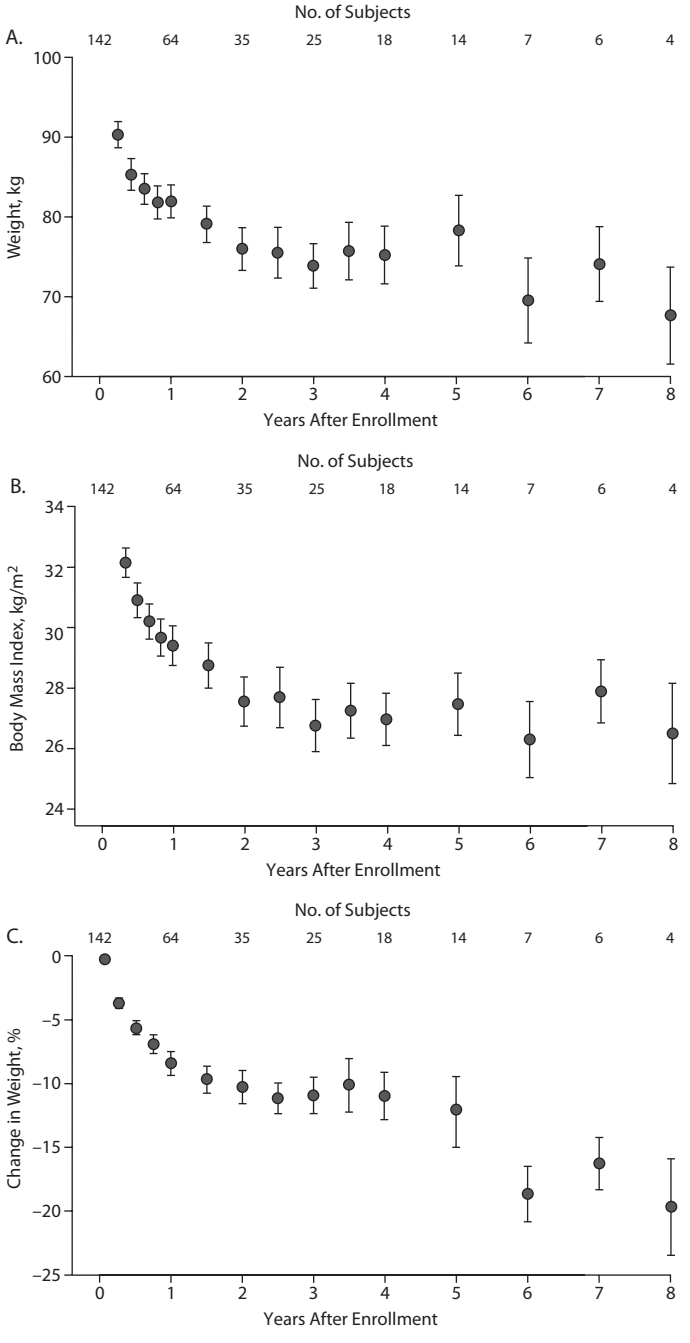
Figure 2. (A) Weight Loss, (B) Reduction in Body Mass Index, and (C) Percentage of Weight Loss With Time Seen in the Patients Attending the Cromwell House Weight Management Clinic[a]



[a]Results are mean ± SE.

in SMI results from the complex interaction of the genotype and the early and adult environment of the person with mental illness, the mental illness itself, and treatment.[15]

The pessimism surrounding treatment has been challenged by a number of recent observational studies and randomized controlled trials of lifestyle and pharmacologic interventions.[8,9,16] A recent meta-analysis of 10 randomized trials involving 482 patients comparing nonpharmacologic interventions for 2–6 months with usual treatment found a statistically significant reduction in mean body weight of around 2.5 kg for those in the nonpharmacologic intervention groups with no evidence of heterogeneity.[8]

Although these results are encouraging, the management of obesity is a lifelong venture. Most previous studies are short term with few randomized studies extending beyond 12 weeks, and, hence, their applicability to the long-term nature of SMI remains unknown. The results of our current analysis extend our previous 4-year report[10] and show that with continued support, people with SMI are able to maintain weight reduction in the long term provided they remain under follow-up.

Rossner[17] proposed that there should be 4 targets for weight loss: first, there should be prevention of further weight gain; this is particularly relevant to this group of patients as individuals who gained weight with time. The second target is to start to lose weight followed by weight loss of ~ 5%–10% to achieve improvements in cardiovascular disease (CVD) risk factors. A recent meta-analysis of long-term weight loss studies in obese adults showed that this degree of weight loss achieved through lifestyle therapy was associated with a reduction in blood pressure, dyslipidemia, and hyperglycemia, although these benefits appear to occur mainly in people with CVD risk factors.[18] There have been few studies examining the effect of lifestyle intervention programs on CVD risk factors in people with SMI. In the UK Well-Being Support Program, however, there were significant improvements in hypertension, cigarette smoking, poor diet, and lack of exercise.[19]

The final target is restoration of weight into the normal range. Recently, there has been debate about the optimal target, as some studies have found that the lowest mortality rates are seen in those in the overweight range (25–29.9 kg/m^2).[20,21] These data are often confounded by smoking and weight loss associated with illness, and when these individuals are excluded, the relationship between BMI and mortality becomes linear.[22] It is, therefore, important to consider the effects of intentional weight loss. A systematic review of 8 studies found evidence that intentional weight loss has long-term benefits on all-cause mortality for women.[23] The impact of weight loss in men on mortality was less clear, with some studies indicating weight loss to be detrimental. By contrast, weight loss improves mortality in people with diabetes irrespective of gender.

Cardiovascular disease risk factors are highly prevalent and often undiagnosed in those people with SMI, and in those with CVD risk factors, it seems appropriate to aim for a normal BMI where possible[5,24]; however, it may be reasonable to accept a target of 25–30 kg/m^2 for those without CVD risk factors. Further research in patients with SMI is required to verify if these findings based in the general population apply in schizophrenia.

There are several factors that may be responsible for the achieved weight loss in this clinic. The model of care offers a multimodal program that incorporates nutrition, exercise,

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Table 3. Number and Percentage of Individuals Achieving 7% Weight Loss or Change of Body Mass Index to < 25 kg/m^2 Over Time

Patient Group	12 wk	6 mo	1 y	2 y	3 y	4 y	5 y	6 y	7 y	8 y
No. attending	92	75	64	35	25	18	14	7	6	4
No. achieving 7% weight loss	11	27	39	28	19	14	13	7	6	4
Percentage achieving 7% weight loss	12	36	61	80	76	78	93	100	100	100

Table 4. Patients Within BMI Categories[a] at Commencement and End of Patient Episode

	Initial BMI Category		
Final BMI Category	Normal (n = 11), n	Overweight (n = 44), n	Obese (n = 87), n
Normal	11	18	7
Overweight	0	25	24
Obese	0	1	56

[a]BMI categories: normal (BMI < 25 kg/m^2), overweight (BMI = 25–30 kg/m^2), and obese (BMI > 30 kg/m^2).
Abbreviation: BMI = body mass index.

and some degree of behavioral interventions on the premise that weight management should not be viewed in isolation and is best combined with a holistic approach to lifestyle management. As such, there may be additional benefits over and above those associated with weight loss.[10] The emphasis placed on physical activity would reasonably be expected to improve physical fitness, which is independently associated with decreased cardiovascular disease,[25] decreased diabetes,[26,27] and increased longevity.[28]

Our patients were able to refer themselves to the clinic and, therefore, are likely to comprise the most motivated people. In this regard, it is important to note that the achieved weight loss did not vary with year of recruitment, as it is possible that the original members of the program may have been the most motivated to lose weight. The fall in new members reflects the Cromwell House patient population; the earlier recruits were existing patients while the more recent patients had only been newly referred to the service.

The clinic first utilized a group approach as a pragmatic way forward in terms of cost-effectiveness, but the group setting and peer support was also appreciated by many participants. The Irish Solutions for Well-Being program, which also involves a group-based model of care, has reported similar results to our own.[29]

The lifestyle changes made by the patients were not imposed by health care professionals but were chosen by the subjects themselves. Finally, many of the initial health behaviors, such as a high intake of sugary carbonated beverages, were highly amenable to change. The stepwise change also made the process relatively simple, achievable, and sustainable.

The program appeared to be effective for all participants, as there was no significant difference in weight loss with any demographic feature, psychiatric illness, or treatment. The only predictor of weight loss was continued attendance at the clinic, emphasizing the need to engage the patients in the process and to design programs without a defined endpoint.

This service evaluation has a number of limitations. Although weight is an important outcome in its own right, the purpose of weight reduction is to prevent long-term morbidity and mortality associated with obesity, and these were not assessed. Furthermore, we did not measure CVD risk factors or waist circumference, a proxy for visceral obesity that better correlates with CVD morbidity and other relevant CVD risk factors. Future weight and lifestyle management programs need to evaluate whether such programs reduce these tangible endpoints.

This service evaluation may be subject to bias, such as the patients were likely to be well motivated and perhaps less psychiatrically unwell than others. As such, it may be difficult to extrapolate these findings to wider patient populations. Nevertheless, we believe that the principles employed in the Cromwell House clinic can be used to treat other patients with SMI who are worried about their weight.

By design, the study did not contain a control group, and so it is unknown whether a similar group of patients would have lost or gained over the same time period without any intervention at all. The weight gain in those who left and rejoined the clinic, however, suggests that it is unlikely that weight loss would have happened without the clinic. It is also conceivable that a more intensive intervention may have provided better results. Although complex intervention trials are difficult to undertake, ideally longer term randomized controlled studies are needed to assess the clinical and cost effectiveness of the lifestyle interventions.

Experience of the clinic would suggest that this approach is not suitable for all outpatients, as around 50% of people dropped out within a year. We do not have the reasons for clinic discontinuation, but it is unlikely that mental state will remain unchanged over a long-term period of evaluation. A similar dropout rate was observed in the Irish program,[29] but in programs such as the UK Well-Being Support Program that have utilized more intensive nursing engagement, patient retention rates were 80% at 2 years.[19]

The alternative options available for these individuals are limited, although a wide range of unapproved pharmacologic treatments have been tried to treat or prevent antipsychotic-induced weight gain.[16] Most treatments have only limited effectiveness with only modest weight loss, and some studies have reported adverse changes in mental state. There is preliminary evidence from short-term studies that metformin may attenuate weight gain in patients taking antipsychotics.[30] A recent systematic review including 495 patients found that metformin led to reduction in weight or attenuation of weight gain in 10 out of 11 studies.[31] While longer, more definitive trials are needed, metformin may be considered in patients with additional risk factors, such as a personal or family history of metabolic dysfunction.[32]

In conclusion, this study has shown that weight loss is achievable over the long term in people with severe mental illness. The only significant correlation with weight loss

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was continued engagement with the clinic. This has clinical implications for programs that use a prespecified treatment duration.

Drug names: carbamazepine (Carbatrol, Equetro, and others), citalopram (Celexa and others), clozapine (FazaClo, Clozaril, and others), duloxetine (Cymbalta), lithium (Eskalith, Lithobid, and others), metformin (Riomet, Fortamet, and others), mirtazapine (Remeron and others), olanzapine (Zyprexa), paroxetine (Paxil, Pexeva, and others), quetiapine (Seroquel), risperidone (Risperdal and others), sertraline (Zoloft and others).

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Potential conflicts of interest: **Dr Bushe** is an employee of and a stock shareholder of Eli Lilly. **Dr Holt** has received fees for lecturing, consultancy work, or attendance at conferences from the following companies: Eli Lilly, Bristol-Myers Squibb, AstraZeneca, and GlaxoSmithKline. **Mr Pendlebury** has received honoraria from several pharmaceutical companies for lecturing on weight management and physical health; is an employee of the National Health Service; and has received honoraria from and is on the speaker/advisory boards for Eli Lilly, Bristol-Myers Squibb, and Janssen-Cilag. **Dr Wildgust** is the director at Hiram Consulting, Ltd; and has undertaken consultancy work for and is a stock shareholder of Eli Lilly.

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