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Randomised controlled trial of novel, simple, and well supervised weight reducing diets in outpatients

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Abstract

Objectives To investigate the contribution of novelty and simplicity to compliance with a low energy diet among obese outpatients.

Design Three arm randomised trial for 16 weeks.

Setting NHS hospital obesity clinic.

Subjects 45 patients aged over 17 years with a body mass index >27 who were not diabetic, pregnant, or lactating.

Interventions Conventional 3.4 MJ diet (control), isoenergetic novel diet of milk only, or milk plus one designated food daily. Follow up visit every 4 weeks.

Main outcome measure Weight loss.

Results Mean weight loss (kg) after 16 weeks on control, milk only, and milk plus diets was 1.7 (95% confidence interval -0.3 to 3.7), 9.4 (5.9 to 12.9), and 7.0 (2.7 to 11.3) respectively. Weight loss on the novel diets was significantly greater than on the control diet.

Conclusions Dietary treatment can achieve as much weight loss in obese outpatients over 16 weeks as has been reported for the most successful drug treatment, but compliance with the prescribed diet is poor unless the diet is novel and simple.

Introduction

Outpatient dietary weight reduction for obesity is unsatisfactory,^{1,2} but inpatient dieting is extremely effective.³ Obese patients lose weight more rapidly as inpatients than as outpatients when nominally on the same diet, which can be explained only by compliance.⁴ Some of the most impressive weight losses achieved by outpatient dietary treatment have been in the placebo control arm of drug trials.^{5,6} The ambience of a

controlled drug trial seems to be conducive to high compliance with dietary treatment and hence good weight loss. The patient is reviewed regularly and believes that the treatment is something novel which may succeed.

This study was designed to test the hypothesis that prescription of simple, novel diets would result in higher levels of compliance and weight loss in an outpatient setting over 16 weeks. Patients were randomised to one of three diets, each of which was designed to produce an initial energy deficit of 4-7 MJ a day.

Subjects and methods

Recruitment and randomisation

All new patients aged over 17 attending an obesity outpatient clinic at St Bartholomew's Hospital between 1 November 1993 and 13 May 1994 were eligible if their body mass index (weight (kg)/(height (m)²) was >27 and they were not diabetic, pregnant, or lactating. Eligibility was assessed by JSG, who was blind to the subsequent allocation of treatment.

All patients had their weight and height measured by the clinic nurse and were given appointments to return to the clinic every four weeks for 16 weeks. At the first visit JSG took a medical history and did a physical examination. CDS then performed the initial randomisation, gave dietary advice, and explained how to record dietary intake. Randomisation was achieved by using blocks of six sealed, opaque envelopes (equal allocation) from which sequential patients chose one. Exact blocking was disturbed because a partly used block of envelopes was mislaid. At subsequent visits

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Randomisation and follow up of patients in trial

patients were seen by JSG, and CDS and CW reviewed the food records and provided advice about the diet. CW administered psychological rating scales and a questionnaire (results not reported).

Interventions

Energy free fluid intake was unrestricted in all diets.

Control—A conventional balanced diet composed of a variety of normal foods designed to supply about 3.4 MJ daily with at least 36 g protein.

Milk only—A variable combination of full cream or semi-skimmed milk and unsweetened yoghurt to provide the energy equivalent of the control diet. This diet was novel and simple but very restrictive.

Milk plus—This was the milk only diet with the addition of an unlimited amount of a single food

selected by the patient on each day of the week. Of these seven extra foods, three were a fruit or vegetable, two were a high protein food, and two were a “favourite” food. The seven foods were repeated on the same day of successive weeks. It was intended to give the patient greater power to decide the nature of the diet without greatly affecting its nutritional characteristics. On average, this diet supplied 5.6 MJ.

Statistical analysis

We performed an intention to treat analysis (using last available weight) and an analysis of patients attending at both week 4 and 16. Confidence intervals are based on *t* tests, assuming unequal variances for comparisons. Mann-Whitney tests, performed because positive skew was introduced in the intention to treat analysis, did not alter significance; means are presented for simplicity.

Results

Sixty four patients met the criteria for the trial (figure). After the protocol was explained 19 patients declined to be randomised, leaving 45 patients. Baseline characteristics were similar in the three groups (table 1) and a similar proportion in each group completed the trial. The table shows the weight loss from baseline at four and 16 weeks and table 2 shows the mean differences between the groups.

Discussion

This trial was a realistic test of what can be achieved by dietary treatment alone for obese patients in NHS facilities. The patients were typical of those referred by general practitioners to a hospital obesity clinic⁷: they travelled to the clinic at their own expense, neither paid nor received money, and bought the food they ate at normal retail outlets. No drug or surgical treatment was offered and no exercise or behavioural therapy programmes were provided.

Within the limitations of a trial lasting only 16 weeks our results support the received wisdom that

Table 1 Mean (SD) baseline characteristics and weight loss of patients who were randomised to control, milk only, and milk plus diets. Results shown for all randomised patients (intention to treat analysis) and for those completing trial

Group	Control		Milk only		Milk plus	
	Randomised (n=14)	Completed (n=9)	Randomised (n=14)	Completed (n=11)	Randomised (n=17)	Completed (n=11)
Sex (M/F)	3/11	1/8	3/11	2/9	4/13	3/8
Age (years)	39.5 (13.9)	38.1 (15.0)	45.2 (14.8)	46.0 (14.3)	41.1 (11.5)	41.4 (13.4)
Weight (kg)	122 (38)	118 (33)	116 (17)	114 (17)	129 (26)	127 (28)
Body mass index	43.0 (9.2)	41.4 (9.0)	43.1 (7.7)	42.6 (8.1)	46.6 (9.1)	44.9 (9.3)
Weight loss at 4 weeks (kg)						
Mean (SD)	0.9 (2.7)	1.4 (3.4)	6.4 (3.5)	7.4 (2.4)	2.8 (3.3)	4.3 (3.2)
Range	−3.7 to 7.9	−3.7 to 7.9	0.0 to 11.5	3.3 to 11.5	−0.7 to 10.5	−0.7 to 10.5
Weight loss at 16 weeks (kg)						
Mean (SD)	1.7 (3.5)	2.6 (4.1)	9.4 (6.1)	11.2 (5.2)	7.0 (8.4)	8.2 (7.4)
Range	−0.9 to 10.7	−0.9 to 10.7	−0.4 to 18.6	−0.4 to 18.6	0.0 to 25.6	−0.7 to 24.5

Table 2 Mean difference (95% confidence interval) in weight loss between patients randomised to control, milk only, and milk plus diets. Results shown for all randomised patients (intention to treat analysis) and for those completing trial

	Milk only v control		Milk plus v milk only		Milk plus v control	
	Randomised	Completed	Randomised	Completed	Randomised	Completed
4 weeks	5.5 (3.1 to 7.9)	6.1 (3.2 to 8.9)	−3.6 (−6.0 to −1.1)	−3.1 (−5.6 to −0.6)	1.9 (−0.3 to 4.1)	2.9 (−0.2 to 6.1)
16 weeks	7.7 (3.8 to 11.6)	8.6 (4.2 to 12.9)	−2.4 (−7.7 to 2.9)	−3.0 (−8.7 to 2.7)	5.3 (0.7 to 9.9)	5.6 (0.0 to 11.1)

Key messages

- Energy reducing diets often work poorly in obese outpatients, although they are effective for inpatients
- In this study patients put on a milk only diet had significant weight loss
- Weight loss was comparable with that achieved by drugs
- Patients are more likely to respond to a simple diet which they have not tried before than to advice on conventional diets

“diets do not work,” at least as far as the conventional balanced reducing diet is concerned. The milk only diet was simple and patients had not tried it before. Patients completing the trial in this group achieved the highest overall mean weight loss (11.2 kg in 16 weeks), which is greater than the mean weight loss in one year in trials of dexfenfluramine,⁸ sibutramine,⁹ or orlistat.^{10 11} Patients consuming only milk might be expected to become deficient in some vitamins and iron, but this was not found in another longer trial⁴; constipation was the only serious side effect reported.

We expected that patients on the milk plus diet would have a greater weight loss than those on the milk only diet as it was still simple but much less boring and patients were more likely to comply with it. The milk plus diet is also theoretically superior as it provides a greater variety of nutrients and an energy deficit of about 4 MJ/day instead of a 7 MJ/day deficit on milk only, which would cause an excessive loss of lean tissue.⁴ Analysis of compliance (not reported) showed that it was similar for the two milk diets but much lower for the conventional diet.

We are not advocating milk only as a general long term reducing diet for obese outpatients, because in the long term it will cease to be novel and compliance will fall. Probably the best strategy is to rotate diets, just as rotation of anorectic drugs achieves greater long term weight loss than continuous use of a single drug.¹²

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Effect of government recommendations on methadone prescribing in south east England: comparison of 1995 and 1997 surveys

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On instruction from the Minister of Health, the Department of Health in England convened a task force on the effectiveness of treatment services for drug misusers, and widely distributed its recommendations in 1996.¹ Methadone constituted 96% of all opiate prescriptions dispensed to drug misusers.^{2 3} The task force specifically recommended that (a) methadone tablets should no longer be prescribed for the treatment of drug misuse; (b) daily dispensing should be used to prevent diversion of drugs; and (c) the optimal dosage for methadone maintenance treatment was probably between 50 mg and 100 g daily.¹

Much of the drug problem of England and Wales is concentrated in London,^{4 5} with 23% of all methadone

prescriptions in the area being from the Thames regions.³ We report the extent to which changes in line with the three recommendations of the task force occurred in the Thames regions between 1995 and 1997.

Methods and results

Data were collected nationally on prescriptions dispensed to drug misusers by community pharmacists in 1995^{2 3} and for south east England again in 1997 (first mailshot only)—that is, one year before and one year after the publication of the task force's recommendations. One in four community pharmacies was randomly selected for the 1995 national

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