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Formula Diet Plus Free Additional Food Choice up to 1000 Kcal (4.2 MJ) Compared with an Isoenergetic Conventional Diet in the Treatment of Obesity. A Randomised Clinical Trial

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ABSTRACT Eighty-six patients aged between 18 and 59 years with more than 20% overweight were assigned to one of two slimming diets. The test group had an obligatory basis (388 kcal, 1.6 MJ) of a complete formula diet (NUPO®) and were allowed a totally free additional choice of food and drink up to 1000 kcal (4.2 MJ), including sweets and alcohol. The control group had a conventional isoenergetic diet excluding all less valuable items ('empty calories'), but were permitted to take an anorectic drug. All patients were instructed and controlled in groups, which saved resources and had psychological advantages. In both regimens, dietary instruction was conducted within a new educational system based on isoenergetic, exchangeable units of every-day food and drink, visualised as illustrated symbols (counters). After 12 weeks, weight loss was insignificantly better on conventional diet (8.9 kg) than in the test group (7.5 kg). By contrast, the latter group had a better compliance, as evidenced by a significantly smaller drop out rate ($p < 0.05$). Repeated registration of energy intake showed that the consumption of 'empty calories' was moderate in the test group, amounting to ab. 10%, and that excess intake was primarily due to an increased consumption of foods rich in fibre. Complaints of side effects were negligible in both groups. The counter diet system made instruction and control easy. We conclude that a free qualitative food choice, made possible by the sufficiency of the formula diet as a basis, is a realistic, effective, and responsible alternative to conventional dietary treatment of obesity.

INTRODUCTION

The formula diet NUPO® meets all international recommendations [1] for daily intakes of protein, essential amino and fatty acids, vitamins, minerals and trace elements within a daily energy intake of only 388 kcal (1.6 MJ). A very low calorie (VLCD) regimen with NUPO® as sole source of nutrition for many months has caused great weight loss without risk in patients with severe obesity [1, 2]. Provided that the prescribed amount of nutrition powder is taken it is justifiable to allow a free choice of additional foods, including less valuable items, as long as the energy allowance is small enough to induce weight loss. Renunciation of popular foods and beverages such as cake, sweets, wine and spirits is one major reason why many patients do not attempt to diet or, if they do, show poor compliance. For these reasons we felt justified in evaluating a 1000 kcal (4.2 MJ) regimen in which a fundament of formula diet is obligatory while at the same time the patients are totally free to manage the remaining energy allowance.

The control group was prescribed an isonergetic conventional slimming diet. This group was allowed diethylpropion in self-governed moderate dosage. Another purpose of the trial was to test a recently developed dietary system based on visual symbols of isoenergetic units (counters).

PATIENTS AND METHODS

Subjects

Ninety-one consecutive patients with an overweight of more overweight $\geqslant 20\%$ [3] were considered for entry. Five patients were excluded: four did not meet our criteria for age or degree of overweight, one could not accept the nutrition powder. Characteristics of included patients are shown in Table 1.

The patients were equally randomised to the two regimens. The allocation was made in blocks, as the patients were started in three series. Patients who failed to appear on two consecutive appointments were considered to have left the trial.

Table 1 Patient characteristics at entrance to study (medians with ranges in brackets)

	Sex females/males	Age years	Height cm	Body weight kg	Overweight (2) %
Group A (Conventional diet, diethylpropion allowed)	35/9	41 (18–59)	165 (152–192)	93.0 (72.3–158.4)	51 (22–127)
Groub B (nutrition powder plus free food choice)	34/8	41 (18–59)	166 (150–187)	94.0 (64.5–177.5)	45 (20–134)
Significance of difference (p)		0.68	0.39	0.99	0.42

Methods

Before treatment, patients were instructed in a dietary system based upon visualised symbols of fairly big isoenergetic and thus freely exchangeable units of food and drink (the 'counter system'): All nutrients were fractionised in units of ab. 62.5 kcal (0.26 MJ), and were summarily classified in three groups designated by colour: Blue for high protein content, green for high content of starch and fibre; and red for high content of sugar, fat or alcohol.

A large number (180) of units were illustrated in small coloured pictures (counters). Figures 1 and 2 show examples of counters. The total repertory comprised 180 symbols. Of these, 36 were blank, to be used for duplication or repetition. The patients were issued with lists showing the equivalent in counters of an ordinary portion of most kinds of food and drink.

Diet A. Patients in this group were given only blue and green symbols, and red units were not allowed. Sixteen units were at disposal. At least four or five of these must be blue. A daily maximum of 75 mg of diethylpropion was allowed.

Diet B. Patients in this group were issued with counters of all three colours. The mandatory basis consisted of five sachets of nutrition powder yielding 388 kcal (1.6 MJ). For declaration, see reference [1]. This left 10 units (612 kcal, 2.6 MJ) for free disposal, including less valuable items (red counters). Anorectics were not allowed.

Fig. 1 Examples of visualised isoenergetic units of food and drink (counters). Upper and middle row: visualisation by portioning. Lower row: Dietary instruction on back of counters.

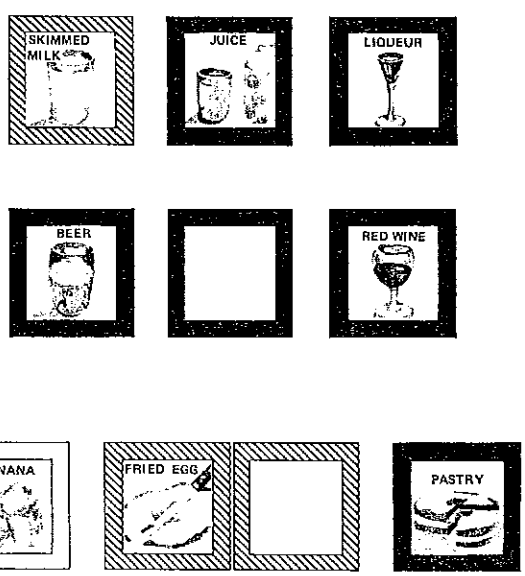

Fig. 2 Examples of visualised isoenergetic units of food and drink (counters). Upper and middle row: visualisation by means of receptacle. Lower row: visualisation by division (cutting). Empty counters for duplication.

Dietary instruction was given in groups by two alternating dieticians, the A and B group being kept separate. Weight control took place after 1, 2, 4, 6, 8, 10 and 12 weeks. Before treatment, blood Hb, and serum sodium, potassium, uric acid, glucose, lactic acid dehydrogenase and alkaline phosphatase were checked. The patients performed a 7 days registration of ingested food and drink. The recordings were validated through interviews by the dieticians.

Ethics

Participants gave informed consent. The protocol respected the Helsinki II declaration and was approved by the local ethical committee.

Statistics

Number of patients — 45 in each group — was decided on from variations and weight losses in a previous study [4], the risk of type 1 and type 2 errors being fixed at 5%. The Mann-Whitney ranksum test or the Chi-square test were used in comparing groups. Paired data were tested for significant differences with Pratt's test [5]. Data are given as medians with total range in paranthesis.

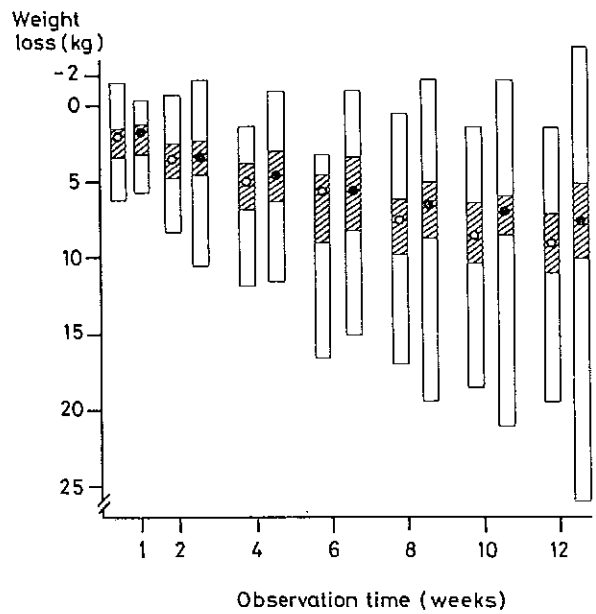

Fig. 3 Weight loss in group A (left) and group B (right). The bars represent total ranges, the hatched areas give 50% central observations, and the dots, open (group A) or solid (group B), indicate median weight losses. No significant group differences were observed.

RESULTS

Of 44 group A patients, 34 (77%) went through with all 12 weeks, while 40 of 42 groups B patients (95%) completed. This difference is significant ($p < 0.05$).

Weight loss was considerable in both groups (Fig. 3), and somewhat greater in group A, but not significantly so ($p = 0.06$). After 12 weeks median weight loss in group A was 8.9 kg (range, 2.2–19.6), and in group B 7.5 kg (range, — 2.6–25.5).

Table 2 shows that energy intake at the first registration (week 2) was identical in the two groups. At the second registration (week 10), energy intake was insignificantly lower in A than in B. Energy intake via ordinary items increased in both groups from the 2nd to the

Table 2 Results of food registrations after 2 and 10 weeks of treatment. The table gives medians with total ranges in brackets. Significant differences between groups are indicated with asterisks, and significant changes from 2nd to 10th week are indicated with a plus sign.

Time of registration	Group	Units of 62.5 kcal (0.26 MJ)			Energy total (kcal)	
		blue counters	green counters	red counters	exclusive NUPO	inclusive NUPO
Week 2	A	6.4 (3.0–9.5) *	6.6 (2.4–10.2) *	0.0 (0.0–0.6) *	844 (384–1288) *	844 (384–1288)
	B	3.2 (1.0–10.3)	3.2 (0.6–5.7)	0.6 (0.0–3.4)	460 (163–888)	848 (551–1276)
Week 10	A	7.2 (3.3–11.0) *	6.8 (3.2–10.7) *	0.0 (0.0–2.0) *	917 (403–1120) *	917 (403–1120)
	B	4.2 (1.1–7.9)	3.7+ (0.9–9.0)	0.7 (0.0–5.2)	578+ (163–1121)	966+ (551–1509)

10th week, but only significantly so for group B ($p < 0.01$). At the two registrations, median energy intake was 16 and 8% lower than prescribed in group A, and 15 and 3% lower than prescribed in group B. Thirty-five patients in group B delivered usable registrations for a total of 430 days. Ten patients stated that they had used the formula diet as the sole source of nutrition for a total of 20 days. Twenty-three patients admitted that for 59 (14%) of the days they had taken less than the prescribed amount of nutrition powder. Among the patients in group A, who were not allowed red units, 14 and 24% had consumed 'empty calories' at the first and second registration, respectively. This increase was not significant. In group B the proportion of red units of the energy intake at first and second registration was 10% and 8.5% (range, 0–55% and 0–34%).

The consumption of blue and green units was ab. twice as great in group A as in group B ($p < 0.0001$). At both first and second registration four patients in group A (11%) consumed less than four blue units per day. The consumption of blue units rose insignificantly between the first and the second registration ($0.10 > p > 0.05$), while the increase was significant for the green units ($p < 0.01$).

Eight patients made no use of diethylpropion, 15 used from 0–100 tablets, 11 from 100–200 tablets, and 10 patients used from 200–300 tablets.

There were no clinical side effects of any importance. A few patients in both groups complained of constipation. A maximum of 3 dietician hours were used at the introduction. A total of 51 hours were spent in further instruction and in control. For comparison, 209 hours would have been necessary in conventional individual treatment with 15 minute control visits with the same frequency. Group treatment thus saved more than 75% in resources.

DISCUSSION

The primary aim of the trial was to evaluate a slimming regimen which allowed food and drink of less nutritional sufficiency, but of high hedonic value. On this regimen, weight losses were somewhat less than after prescription of an isoenergetic traditional diet. The difference bordered on statistical significance, but should be viewed in the light of two important facts: First, the group on the traditional regimen received an anorectic. Second, in this group there were significantly more patients who dropped out, and these can be assumed to have had poor weight losses. In both groups weight losses were at least as good as on an ordinary 1.000 kcal diet accompanied by traditional instruction [4]. We deliberately chose to allow an anorectic to the A group in order to put the new regimen to a sharp test. Without that we assume that the drop-out rate on conventional diet would have been even greater. The purpose of comparing two isoenergetic slimming regimens is to evaluate compliance in the widest sense of the word. Compliance is not only measured in drop out rate and weight loss, but also by estimating the actual adherence to the diet prescribed. Our registrations showed that energy intake in both groups increased as the trial proceeded, and that this increase was significant in the group who was allowed 'empty calories'. However, the increase was not caused by these items, but by more consumption of the green fibre units, presumably in an attempt to obtain satiety. This can be said to be a relatively harmless form of non-compliance. Incidentally, the median consumption of red units was moderate, less than one unit per day, corresponding to less than 10% of the energy intake. By contrast, it is worth noticing that even a thorough prescription of a traditional regimen safeguarded neither against insufficient protein intake nor against the consumption of sweets and alcohol. So far, a slimming regimen giving access to 'empty calories' has not been tested in a randomised clinical trial. This study has shown such a regimen to be effective and safe. Only some obese persons are obese because they overeat on sweets or fats, or because they abuse alcohol, and even for these patients it is arguable whether a total prohibition is a realistic policy. All things being equal, it seems better to be of normal weight with questionable eating habits than to remain obese with the same habits. Even more important: many obese people are not hyperphagic and have a 'normal' relationship to food and drink of hedonic and social value. These items are not the reason for their obesity, and foregoing of these enjoyments constitutes an undesirable increase of the strain imposed by the energy restriction in itself.

The second main purpose of the trial was to evaluate a dietary instruction where food and drink are visualised in fairly large isoenegetic and freely interchangeable units. A conventional and detailed instruction of a varied and nutritionally sufficient slimming diet is time-consuming, and the patients' understanding of it is often poor. Recipes must be read, calories counted, and items often weighed. Our patients found it easy to work with the pre-made units. As in previous trials [1, 2] we found great practical and psychological advantages in the group organisation.

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