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The Copenhagen PRODI project: preliminary results

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Summary
A randomized clinical trial concerning treatment of moderate obesity is described. The study compares: (a) conventional 1000 kcal (4.19 MJ) diet with diethylpropion permitted: (b) isocaloric partial meal replacement with protein powder, and diethylpropion permitted; and (c) pre-meal satiation with protein powder. Preliminary results indicate equally good weight losses by the three methods

Introduction

Protein powders for the treatment of moderate obesity have become extensively used by all social classes. In this popular use a distinction can be made between two patterns: partial meal replacement and pre-meal satiation.

In the treatment of morbid obesity protein powders has proved valuable, making possible a sufficient nutrition with less than 400 kcal (1.67 MJ). However, it is unknown if use of protein powders for partial meal replacement in a 1000 kcal (4.19 MJ) diet offers any advantages over conventional calorie restriction with natural foods as to weight loss or maintenance. It is also unknown whether use of the same quantity of protein powder before meals is superior to the before mentioned regimes. Furthermore, can anorexic drugs be replaced by a satiation effect of the protein powder?

Methodology and preliminary results

In order to throw light on these questions we have set up a randomized clinical trial comparing the above mentioned two protein powder applications to our standard 1000 kcal (4.19 MJ) regime. Figure 1 illustrates schematically the regimes, and Table 1 specifies the contents as to energy distribution. Our supplementary vitamin-mineral capsule is given elsewhere[1]. Criteria for entry are listed in Table 2, and flow chart is shown in Fig. 2. At the first medical control verbal and written instructions are given.

Patients allocated to PRODI 3 are told to 'eat as little as possible of

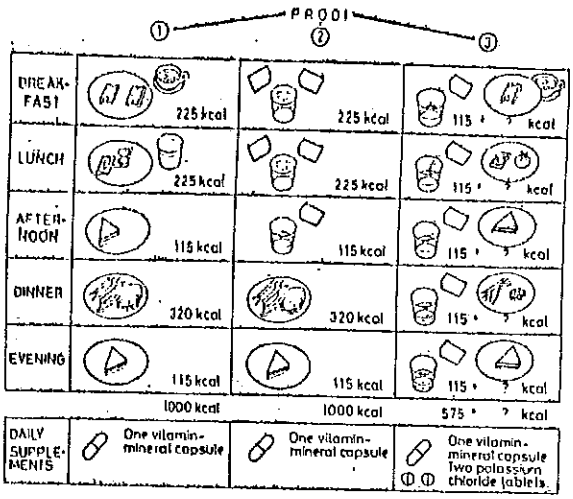

Fig. 1. Schematic representation of the regimes

Table 1. The PRODI project: daily intake. *The regimes comply with RDA's 1980[3] (calcium, phosphorus, magnesium, iron, zinc, iodine, vitamin A-D-E-C-B_1-B_2-B_6-B_{12}, biotin, niacin, and folic acid). * The regimes comply with Estimated Safe and Adequate Daily Dietary Intakes (ESADDI) 1980[3] (sodium, potassium, chloride, copper, manganese, chromium, selenium, molybdenum, vitamin K, biotin and pantothenic acid).

	Powder (116g) mg (kcal)	Orange juice (500 ml) mg (kcal)	Other foods mg (kcal)	Total in % of RDA 1980 %
PRODI 1 (1000 kcal)				
Protein	0 (0)	0 (0)	65,000(260)	♀ 147
				♂ 120
Lipid	0 (0)	0 (0)	36,000(324)	–
CHO	0 (0)	0 (0)	104,000(416)	–
Energy, total	(0)	(0)	(1000)	–
PRODI 2 (1000 kcal)*				
Protein	53,000(212)	5,000 (20)	55,000(220)	♀ 252
				♂ 206
Lipid	4,700 (42)	2,500 (23)	18,000(162)	–
CHO	22,000 (88)	45,000(180)	13,000 (52)	–
Energy, total	(342)	(223)	(434)	–
PRODI 3 (≥575 kcal)*				
Protein	53,000(212)	5,000 (20)	?	♀ ≥ 132
				♂ ≥ 107
Lipid	4,700 (42)	2,500 (23)	?	–
CHO	22,000 (88)	45,000(180)	?	–
Energy, total	(342)	(223)		–

Table 2. The PRODI project

Criteria for entry

1. Consecutive patients
2. 20 to 59% overweight[2]
3. Age 18 to 59 years
4. No sequelae after earlier abdominal obesity surgery
5. No contraindicating disease, eg malignancy
6. No pregnancy
7. No actual treatment with certain psycopharmacological drugs
8. Absence of – or stable – diuretic treatment
9. No alcohol or drug abuse
10. Co-operability
11. Informed consent

Criteria for continuation of the program after 3 months

1. Weight loss > 4 kg
2. > 10% overweight[2]

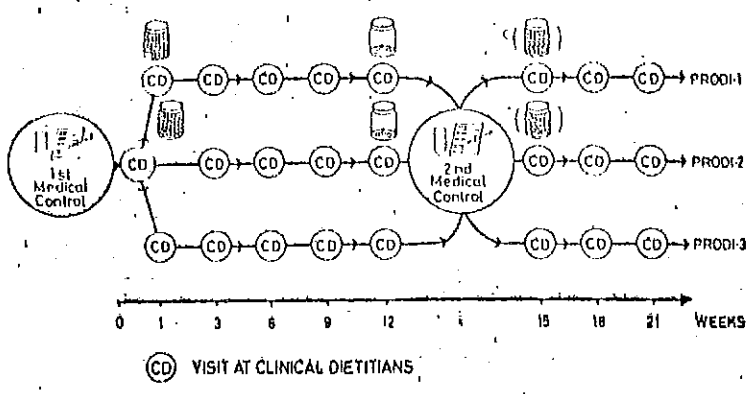

Fig. 2. PRODI flow chart

additional natural foods, if anything at all'. Anorexic drugs are excluded from PRODI 3, but 25 mg of diethylpropion is permitted maximally three times a day in PRODI 1 and 2.

Patients are not hospitalized but seen as out-patients by our clinical dieticians after 1, 3, 6, 9 and 12 weeks. At the second medical checkup the consumption of diethylpropion is quantified as a measure of hunger. If criteria for entry (numbers five to ten) are still fulfilled together with a weight loss greater than 4 kg and an actual overweight over 10 per cent[2] the program is continued in order to evaluate its long-term effect.

Our preliminary results show equally good weight losses on all three regimes (Fig. 3).

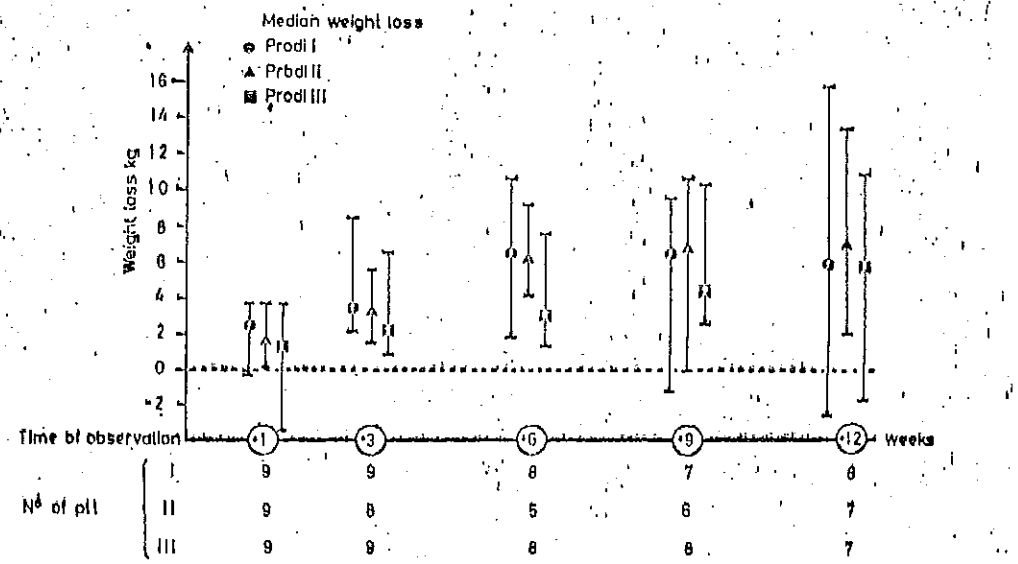

Fig. 3. PRODI preliminary results

Hopefully, the final results of the described trial will contribute to a clarification of the role of protein powders in the treatment of the moderate obesity. These new applications might also be of future value in maintaining a normalized weight obtained by more drastic regimes.

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