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PAPER

Effect of normal-fat diets, either medium or high in protein, on body weight in overweight subjects: a randomised 1-year trial

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BACKGROUND: We have previously reported that a fat-reduced high-protein diet had more favourable effects on body weight loss over 6 months than a medium-protein diet.
OBJECTIVE: To extend this observation by a further 6–12 months less stringent intervention and a 24 months follow-up.
DESIGN: A randomised 6 months strictly controlled dietary intervention followed by 6–12 months dietary counselling period, and a subsequent 24 months follow-up, comparing an *ad libitum*, fat-reduced diet (30% of energy) either high in protein (25% of energy, HP) or medium in protein (12% of energy, MP).
SUBJECTS: A total of 50 overweight and obese subjects (age: 19–55 y; BMI: 26–34 kg/m^2).
MEASUREMENTS: Change in body weight, body composition and blood parameters.
RESULTS: After 6 months, the HP group ($n=23$) achieved a greater weight loss than the MP group ($n=23$) (9.4 *vs* 5.9 kg) ($P<0.01$). After 12 months, 8% had dropped out in the HP *vs* 28% in the MP group ($P<0.07$). After 12 months, the weight loss was not significantly greater among the subjects in the HP group (6.2 and 4.3 kg), but they had a 10% greater reduction in intra-abdominal adipose tissue and more in the HP group (17%) lost >10 kg than in the MP ($P<0.09$). At 24 months, both groups tended to maintain their 12 months weight loss, but more than 50% were lost to follow-up.
CONCLUSION: A fat-reduced diet high in protein seems to enhance weight loss and provide a better long-term maintenance of reduced intra-abdominal fat stores.
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Keywords: high-protein diet; *ad libitum* diet; overweight; body composition; weight loss; weight maintenance

Introduction

In the past 2–3 decades, dietary recommendations have aimed at reducing the total dietary fat intake to less than 30% of the energy intake (30 E%). This concept has been used to induce and maintain weight loss in obese subjects by administration of fat-reduced diets consumed *ad libitum*.[1,2] The balance, between the non-fat components of the diet, carbohydrate and protein, is also important and currently recommendations for increased consumption of protein are among the most common approaches of popular diets.[3] On the basis of the results of short-term studies, protein seems to be superior to carbohydrate in promoting both satiety[4–9] and diet-induced thermogenesis.[10–12] If this is also true in the long term, replacing some of the dietary carbohydrate by protein should improve the weight loss and maintenance obtained by using normal-fat diets under *ad libitum* conditions.

Only few studies lasting more than 6 months have previously addressed the optimal content of dietary protein and carbohydrate for weight loss, and thus more long-term studies elucidating this are needed. We conducted a 6 months strictly controlled trial with the object of testing two *ad libitum* fat-reduced diets, one high and one medium in protein, in overweight and obese subjects.[13] The trial showed that replacement of some dietary carbohydrate by protein improved weight loss and body composition. We now report a 6–12 months extension and a 24 months

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follow-up of that trial, with effects on dropout rate, body weight and composition, intra-abdominal depot and blood parameters.

Methods

Subjects and design

A total of 50 overweight and obese (BMI, 25–35 kg/m^2) men and women aged 18–56 y were included in the study. The characteristics of the subjects are given in Table 1. Subjects were randomly assigned to a medium-protein diet (12% of energy, MP) or a high-protein diet (25% of energy, HP) both normal in fat (<30 E%). A control group consuming a habitual *ad libitum* diet was included in the first 6 months, and is reported elsewhere.[13] Macronutrient composition of the diet in the intervention groups was strictly controlled but energy intake was *ad libitum*. The subjects were instructed not to change their physical activity patterns or smoking habits during the study. Physical characteristics including body composition were measured at baseline. The outcome measures were changes in body weight and body composition, proportion of subjects achieving a weight loss greater than 5 and 10 kg, and blood parameters.

The study was conducted as a 6 months strictly controlled dietary intervention with provision of food from a purpose-built shop (February 1995 to September 1995), followed by dietary counselling every second week from month 6 to 12. All subjects were re-contacted for a subsequent, initially unscheduled follow-up approximately 12 months after their last dietary counselling session.

Approval was obtained from the Municipal Ethical Committee of Copenhagen and Frederiksberg. The study was performed in accordance with the Helsinki II Declaration, and each subject signed an informed consent document before the study commenced.

Dietary intake and compliance

6 months provision of food. A 50 m^2 shop with approximately 900 different food items was built at the Department of Human Nutrition. All food was collected from the shop during the first 6 months. A computerised system was developed for registration of the selection made at each visit to the shop. All food items were bar-coded and a dietitian scanned the barcodes of all the chosen items to monitor macronutrient composition of the diet. When necessary the dietitian assisted in altering the selection made to meet the prescribed macronutrient composition. The calculated energy content of the chosen groceries was not made known to the subjects. The experimental shop facility is described in detail in earlier publications.[13,14]

Table 1 Physical characteristics of subjects at baseline

	Medium protein (n = *25*)	*High protein* (n = *25*)
Age (y)	39.4 (35.3–43.6)	39.8 (35.8–43.8)
Gender (M/F)	6/19	6/19
Smoking[a]	9 (5.7)	9 (8.0)
Body weight (kg)	88.6 (84.5–92.7)	87.0 (83.0–90.9)
Height (m)	1.70 (1.67–1.72)	1.70 (1.67–1.73)
BMI (kg/m^2)	30.8 (29.9–31.6)	30.0 (29.1–30.9)

Values are means with 95% CI. There were no differences between groups by *t*-test. [a]Number of smokers in group (number of cigarettes smoked per day).

6–12 months dietary counselling. During the 6–12 months dietary counselling period, the subjects maintained and controlled the established dietary alteration themselves. The close contact with the dietitians at the Department continued, as the subjects in the MP and HP groups participated in group-specific behaviour therapy sessions every second week.

Compliance to the diet. The average dietary intake during the 6 months provision of food period was registered by the shop computer system. Both groups completed a 7-day dietary record at baseline and after $7\frac{1}{2}$, 9 and 12 months intervention. The dietary records were calculated by using the DANKOST 2000 package (National Food Agency of Denmark, Søborg, Denmark) and a database specific for the Danish diet (Levnedsmiddeltabeller; National Food Agency of Denmark). Compliance to the diets was measured by 24-h urinary nitrogen (24-h UN) excretion. This method is validated in an earlier publication.[14] Urine was collected prior to the dietary intervention and at the start of each month during the 12 months of dietary intervention.

Anthropometrical measures

Body weight was measured weekly in both intervention groups during the 6 months provision of food, and every second week during the 6–12 months counselling period, and once at the 24 months follow-up. All subjects were weighed on a decimal scale (Seca model 707, Copenhagen, Denmark) wearing only light clothing.

Body composition was determined by a dual-energy X-ray absorptiometry (DXA) scanning (Hologic 1000/W, software version 5.61; Hologic Inc., Waltham, MA, USA) at baseline and after 6 and 12 months of dietary intervention. Subjects wore only underwear and a cotton T-shirt during the scan. For quality control spine phantoms were scanned daily, and for calibration a Hologic body composition calibration phantom was scanned simultaneously at each examination. The intraindividual coefficient of variation (CV) was determined from measurements on 18 weight-stable controls at 8-week intervals. The CV for fat mass (FM) was 3.6 and 1.9% for fat-free mass (FFM). Intra-abdominal adipose tissue (IAAT) was estimated from DXA scans, and anthropometry by the equation IAAT (cm^2) = $-208.2 + 4.62$ (sagittal diameter, cm) + 0.75 (age, y) + 1.73 (waist, cm) + 0.78 (trunk fat%), given by Treuth *et al*.[15] Waist and hip circumferences were measured on undressed subjects using a tape measure, with the subjects in a standing posture.

Assays

Blood samples of glucose were drawn into test tubes containing EDTA/fluoride and kept on ice. Samples of insulin were drawn into tubes with no additives. Plasma glucose was analysed by standard enzymatic methods (Boehringer Mannheim GmbH Diagnostica, Copenhagen, Denmark). Insulin concentrations in serum were measured by ELISA (DAKO, Copenhagen, Denmark). Descriptions of blood samples of triacylglycerol (TG), HDL, cholesterol and FFA are reported elsewhere.[13]

Statistical analysis

All results are given as means with 95% confidence intervals (CIs) or ±s.e.m. or as median (interquartile range) for variables with a screwed distribution. Normal distribution was achieved after log transformation of screwed data. Differences between the groups at baseline were tested by unpaired *t*-test. During the intervention, the differences between the groups in dietary, anthropometrical and blood parameters were tested by analysis of variance (ANOVA), with baseline values and body weight changes as covariates when relevant. Differences in the proportion of dropout and subjects achieving a certain weight loss (>5 and >10 kg) after 6, 12 and 24 months were tested by χ^2 test. The level of significance was set at $P<0.05$. All statistical tests were performed by SPSS version 11.0 (SPSS Inc., Chicago, IL, USA).

Results

During the 6 months provision of food, only two subjects dropped out of each intervention group. After 12 months of dietary intervention, seven (28%) in the MP group and two (8%) in the HP group had dropped out ($P<0.07$). At the 24 months follow-up, 19 (76%) subjects in the MP group and 14 (56%) in the HP group no longer attended (NS).

Dietary intervention

The average dietary intake in the MP and HP groups during the 6 months provision of food and the 6–12 months counselling period is shown in Table 2. At baseline, there were no significant differences between the groups. During the 6 months provision of food, the average protein intake increased from 89.1 (81.1–97.2) to 127.6 g/day (117.0–138.2) corresponding to an increase of 8.2% of total energy in the HP group. The protein-E% decreased by 3.1% in the MP group and the difference in the protein-E% between the two groups was significant during the 6 months intervention ($P<0.0001$). During the dietary counselling period, the protein-E% remained higher in the HP than in the MP group (Table 2), which was also reflected in a significant difference in 24-h urinary nitrogen excretion between the groups through out the study (time × group interaction: $P<0.001$) (Figure 1).

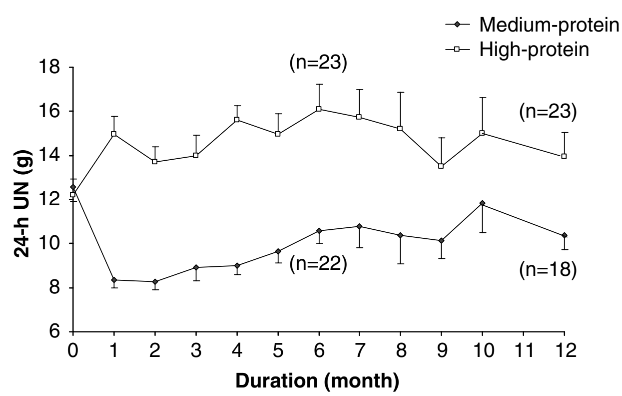

Figure 1 24-h urinary nitrogen excretions (24-h UN) from baseline to month 12. Values are means±s.e.m. The difference between the groups was significant from month 1 to 12 (time × group interaction: $P<0.001$) by ANOVA.

Table 2 Dietary intake at baseline, during 6 months provision of foods, after $7\frac{1}{2}$, 9, and 12 months of dietary intervention in the medium-protein (MP) and high-protein (HP) groups

	Baseline (n = *50*)	P[a]	*0-6 months*[b] (n = *46*)	P	$7\frac{1}{2}$ *months* (n = *44*)	P	*9 months* (n = *41*)	P	*12 months* (n = *41*)	P
Energy (MJ/day)[c]										
MP	9.9 (8.8–11.0)	NS	10.8 (10.1–11.5)	0.001	9.3 (8.2–10.3)	NS	8.9 (7.9–9.8)	NS	8.2 (7.4–9.0)	NS
HP	9.5 (8.6–10.5)		9.0 (8.2–9.7)		9.4 (8.5–10.3)		9.6 (7.2–11.9)		8.4 (7.6–9.3)	
Protein (E%)										
MP	15.1 (13.9–16.4)	NS	12.0 (11.9–12.2)	<0.0001	13.5 (12.5–14.5)	<0.0001	13.1 (12.1–14.2)	0.0001	13.9 (13.0–14.7)	<0.0001
HP	16.1 (15.1–17.2)		24.3 (24.0–24.5)		21.8 (19.9–23.7)		24.8 (19.7–29.9)		21.2 (19.5–22.8)	
Carbohydrate (E%)										
MP	44.5 (41.9–47.1)	NS	58.6 (58.3–58.9)	<0.0001	57.2 (53.3–61.0)	0.0005	58.1 (54.8–61.3)	<0.0001	54.7 (51.0–58.4)	0.005
HP	45.6 (43.3–48.0)		46.3 (45.9–46.7)		48.5 (45.3–51.7)		45.1 (41.7–48.5)		48.9 (46.4–51.4)	
Fat (E%)										
MP	40.3 (37.9–42.8)	NS	29.4 (29.1–29.7)	NS	29.3 (25.9–32.8)	NS	28.8 (25.6–32.0)	NS	31.4 (28.1–34.8)	NS
HP	38.2 (36.0–40.5)		29.5 (29.2–29.8)		29.7 (27.1–32.3)		30.1 (27.0–33.3)		30.0 (27.1–32.8)	

Values are means with 95% CI. Data are based on 7-day dietary records. *P*: *P*-values between groups were derived by ANOVA with baseline as covariates. [a]*P*-values at baseline by unpaired *t*-test. [b]Values are registered by the shop computer system during the 6 months provision of food, calculated as mean daily values. [c]Energy intake is adjusted for alcohol.

The carbohydrate-E% increased in the MP group, but remained unchanged in the HP group and the difference between the groups was significant during all 12 months of dietary intervention (Table 2). No difference in fat-E% between the groups was found. Consistent with the greater weight loss, the average energy intake was lower in the HP than in the MP group during the 6 months provision of food ($P = 0.001$), but no difference was found during the counselling period.

Anthropometrical measures

The anthropometrical measures in the two intervention groups are shown in Table 3. There were no significant differences between the groups at baseline. After 6 months, the HP group had a 3.5 (0.8–6.2) kg greater weight loss than the MP group ($P < 0.05$). During the following 6–12 months period, the weight regain was higher in the HP than in the MP group ($P < 0.05$) (Figure 2). After 12 months, the average weight loss from baseline was 6.2 (3.8–8.6) and 4.3 (2.2–6.4) kg in the two groups and the difference between the groups was no longer significant. At the 24 months follow-up visit, the maintained weight loss was doubled in the HP than in the MP group (6.4 (2.6–10.2) *vs* 3.2 (−1.5–7.9) kg), but the difference was not significant due to the low number of subjects attending this visit. We also analysed the results with an intention-to-treat analysis based on the last observation carried forward, that is, the data obtained at the time of the last follow-up for those who did not complete the study. This analysis did not change the outcome as compared to the completer analysis.

After 6 months, 78% (18/23) in the HP and 61% (14/23) in the MP group had lost more than 5 kg (NS), while 39 (9/23) *vs* 13% (3/23) had lost more than 10 kg ($P < 0.05$) (Figure 3). After 12 months, 57% (13/23) in the HP and 50% (9/18) in the MP group had lost more than 5 kg (NS). In the HP group, 17% of the subjects (4/23) had lost more than 10 kg, whereas none in the MP group had achieved this ($P = 0.09$). After 24 months, the proportion of subjects with >5 kg weight loss in the HP and MP groups was similar (55 (6/11) and 50% (3/6), respectively (NS)), while 18% (2/11) in the HP and none in the MP group had lost more than 10 kg (NS).

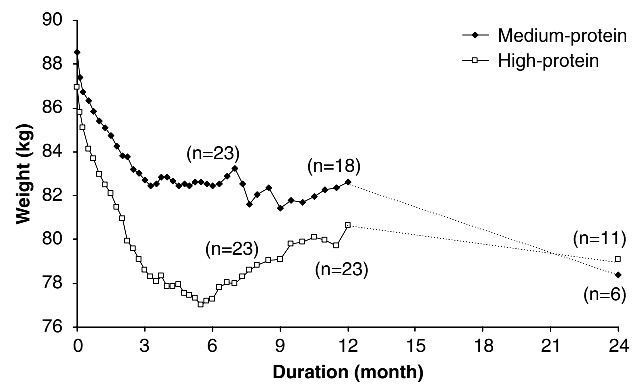

Figure 2 Changes in body weight during strictly controlled dietary intervention (months 0–6), dietary counselling (months 6–12) and at 24 months follow up. Values are means. n = number of subjects at given time (missing values are interpolated).

Table 3 Changes from baseline in anthropometrical measures in the medium-protein (MP) and high-protein (HP) groups at baseline and after 6 and 12 months of dietary intervention

	Baseline (n = 50)	P[a]	*6 months (n = 46)*	P	*12 months (n = 41)*	P
Body weight (kg)						
MP	88.6 (84.5–92.7)	NS	−5.9 (−4.2 to −7.7)	0.008	−4.3 (−2.2 to −6.4)	NS
HP	87.0 (83.0–90.9)		−9.4 (−7.2 to −11.6)		−6.2 (−3.8 to −8.6)	
BMI (kg/m^2)						
MP	30.8 (29.9–31.6)	NS	−2.1 (−1.5 to −2.7)	0.007	−1.5 (−0.8 to −2.8)	NS
HP	30.0 (29.1–30.9)		−3.3 (−2.5 to −4.0)		−2.2 (−1.2 to −3.0)	
FM (kg)						
MP	30.5 (27.4–33.6)	NS	−4.3 (−2.9 to −5.6)	<0.0001	−3.1 (−1.4 to −4.7)	NS
HP	28.5 (25.6–31.4)		−7.6 (−5.7 to −9.4)		−4.6 (−2.7 to −6.6)	
LBM (kg)						
MP	54.4 (50.2–58.5)	NS	−0.8 (−1.6 to 0.0)	NS	−0.4 (−1.2 to 0.4)	NS
HP	54.6 (50.6–58.7)		−1.2 (−0.3 to −2.0)		−0.9 (−1.8 to 0.0)	
Waist (cm)						
MP	99.1 (95.1–103.1)	NS	−4.2 (−1.5 to −6.9)	0.004	−1.8 (−5.5 to −1.8)	0.0006
HP	97.7 (94.5–101.0)		−10.1 (−8.0 to −12.3)		−8.4 (−6.3 to −10.5)	
W/H						
MP	0.88 (0.83–0.92)	NS	0.00 (−0.02 to 0.02)	0.007	+ 0.01 (−0.03 to 0.04)	0.001
HP	0.88 (0.85–0.92)		−0.04 (−0.03 to −0.06)		−0.04 (−0.02 to −0.06)	
IAAT (cm^2)						
MP	126.3 (115.4–137.2)	NS	−18.3 (−9.8 to −26.8)	0.002	−10.5 (−0.1 to −20.8)	0.03
HP	120.3 (111.0–129.7)		−35.9 (−28.3 to −43.5)		−22.0 (−15.0 to −29.0)	

Values are means with 95% CI. FM: fat mass; LBM: lean body mass; IAAT: intra-abdominal adipose tissue. *P*: *P*-values between groups were derived by ANOVA with baseline as covariates. [a]*P*-values at baseline by unpaired *t*-test.

Body composition. After 6 months, the HP group experienced a greater loss of body FM compared to the MP group ($P<0.0001$) (Table 3). During the following 6–12 months, FM increased in both groups and no longer there was any difference between the groups. After 6 months, the HP group had a greater decrease in waist-to-hip ratio (W/H) compared to the MP group ($P<0.01$), due to a greater decrease in waist circumference ($P<0.01$). After 12 months, the HP group still maintained a greater decrease in waist ($P<0.001$) and W/H ratio ($P=0.001$) compared to the MP group. The decrease in IAAT was greater in the HP group than the MP group both after 6 months ($P<0.01$) and 12 months intervention ($P<0.05$). The difference in IAAT between the groups was maintained after adjustment for body weight loss ($P<0.05$). Gender influenced IAAT ($P<0.05$), but no difference between the groups was detected, due to too few male subjects. No significant differences between the groups with respect to lean body mass were found during the intervention.

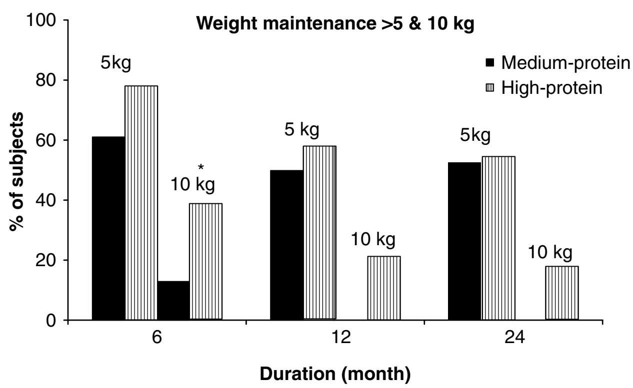

Figure 3 Proportion of subjects having lost and maintained >5 and 10 kg body weight after 6, 12 and 24 months of dietary intervention. Comparisons between groups were made by χ^2 test. Difference between medium- and high-protein groups: *$P<0.05$.

Blood parameters

No differences were seen in any of the blood parameters between the MP and HP groups at baseline and after 6 or 12 months of dietary intervention with the exception of FFA (Table 4). After 6 months, the FFA concentration was significantly lower in the HP than in the MP group ($P=0.01$). These results were unaltered after adjustment for changes in body weight.

Discussion

The results of the extended 6–12 months dietary counselling show that the weight loss achieved during the 6 months strictly controlled dietary intervention was difficult to maintain when the free provision of food was stopped, even when the subjects attended regular counselling sessions (every second week). During the counselling period, the HP group experienced a greater weight regain and the difference between the groups was no longer significant. However, the HP group seemed more successful than the MP group, although not significantly so, both in achieving a weight loss of more than 5 or 10 kg and in maintaining this weight loss.

Despite the weight regain, the HP group still had a greater reduction in waist circumferences, W/H and IAAT after 12 months, which indicates a maintained reduction in the intra-abdominal fat depot. The amount of adipose tissue

Table 4 Serum concentrations of fasting blood parameters in the high-protein (HP) and medium-protein (MP) groups at baseline and after 6 and 12 months dietary intervention

	Baseline (n = 50)	P[a]	*6 months (n = 46)*	P	*12 months (n = 41)*	P
Glucose (mmol/l)						
MP	4.9 (4.6–5.4)	NS	4.9 (4.7–5.3)	NS	5.2 (4.9–5.5)	NS
HP	4.9 (4.6–5.2)		4.9 (4.6–5.1)		5.0 (4.6–5.3)	
Insulin (pmol/l)						
MP	50 (28–61)	NS	43 (37–54)	NS	61 (34–76)	NS
HP	42 (32–78)		34 (25–62)		47 (27–92)	
Cholesterol (mmol/l)						
MP	5.13 (4.6–5.5)	NS	5.16 (4.3–5.6)	NS	5.81 (5.3–6.1)	NS
HP	4.86 (4.2–5.3)		4.55 (4.1–4.7)		4.96 (4.4–5.5)	
HDL (mmol/l)						
MP	1.37 (1.1–1.5)	NS	1.16 (1.0–1.4)	NS	1.28 (1.2–1.6)	NS
HP	1.35 (1.1–1.6)		1.32 (1.1–1.4)		1.47 (1.1–1.6)	
TG (mmol/l)						
MP	1.30 (1.0–1.7)	NS	1.41 (1.0–2.1)	NS	1.63 (1.3–1.9)	NS
HP	1.34 (1.1–1.7)		1.19 (0.7–1.5)		1.29 (0.9–1.5)	
FFA (μmol/l)						
MP	435 (296–626)	NS	434 (311–561)	0.01	434 (315–533)	NS
HP	500 (324–658)		294 (232–457)		384 (232–493)	

All blood parameters are expressed as median (interquartile range). *P*-values between groups were derived by ANOVA with baseline values as covariates. [a]*P*-values between groups at baseline by unpaired *t*-test.

located in the intra-abdominal region is more tightly correlated with metabolic complications in obese patients than is subcutaneous fat.[16–18] The distribution of fat mass in the intra-abdominal depot may be influenced by gender[19] and cortisol. The mechanism by which the HP diet reduced the intra-abdominal fat is not known, but it is interesting that the effect was maintained after adjustment for weight loss, which suggests that the finding cannot be explained by the slightly greater weight loss in the HP group. Whether an HP diet influences the concentration of cortisol remains to be determined.

Few other trials of more than 2 weeks duration with inclusion of a control group have studied the effect of a high intake of protein on weight loss. Moreover, the diets in these studies were often hypoenergetic[20–25] and ketogenic,[21,22,24,25] so comparison with the present long-term *ad libitum* study is difficult. A study of 4 weeks duration confirmed that an HP diet (45 protein-E%, 25 carbohydrate-E% and 30 fat-E%) with a daily energy intake corresponding to 80% of resting energy expenditure could cause a greater weight loss compared to an MP diet.[26] In another 6-day study, an HP diet resulted in a 20% greater weight loss than a mixed diet, but the weight loss was attributed to loss of fluid.[21] Other studies of 3–10 weeks duration could not detect any difference in body weight or body composition.[20,22–25] This could be partly due to the fixed hypoenergetic intake of 1.7–5.0 MJ/day in these studies, which eliminates the differential effects of carbohydrate *vs* protein on appetite control to exert their effects.

The mechanisms responsible for the larger weight loss caused by an HP diet may be attributed to a greater satiety and fullness, and also the thermogenic effect of protein.[10] However, the exact mechanisms remain unclear. A number of studies have compared subjective hunger and satiety in the hours following consumption of a single high-protein meal and/or a control meal. These studies have reported an effect of high-protein diets on increased satiety[4–8] except for one study.[27] Although not conclusive, the body of evidence from these studies suggests that high-protein meals have the potential to suppress hunger and to induce more satiety than carbohydrate or fat. However, it should be noted that not all of these studies were controlled for dietary factors with a potential influence on satiety, such as fibre content, glycaemic index, variety and palatability. Stubbs *et al*,[9] whose study was very tightly controlled, identified a greater satiety effect of protein, although no difference in subsequent energy intake was noted.

In the present trial, the HP diet induced a lower energy intake during the provision of food likely due to the satiating effect of protein. However, the lower energy intake seen in the HP group was not maintained during the counselling period. The energy intake measured from 7-day dietary records in the present study is possibly underestimated and should make reservation, as subjects tend to eat less or just report less during the period of dietary reporting.[28,29] Additionally, the protein-E% in both groups reverted slightly towards baseline levels during months 6–12, but the difference between the groups was significant throughout most of the trial as confirmed by the difference in 24-h urinary excretion.

It is also likely that the enhanced weight loss seen in the HP group may be attributed to a lesser reduction in resting energy expenditure and/or a greater food-derived thermogenesis. Several studies have found that an HP diet isoenergetic with a diet high in carbohydrate produces a higher 24-h energy expenditure,[10–12] even despite a lower energy intake.[10]

Compliance in the present study was relatively high compared to other weight reduction studies,[30] as shown by the fact that urinary nitrogen excretion remained within the predicted levels, and only few subjects dropped out (very few in the HP group) during months 6–12, while most subjects were lost at the (initially unscheduled) follow-up at month 24. The lack of attendance of the remainders (mainly in the MP group) could be due to an unsatisfactory weight loss, or to relapse, and the real body weight and body composition of the two intervention groups remain unknown.

A limited dietary variety is known to decrease energy intake.[31] The variety of food in the present study was high as the grocery store had approximately 900 items, and as the subjects shopped in commercial stores during the counselling period. The variety of food in other studies differs considerably: two used a liquid formula,[24,25] two were comprised of a very limited variety of food[21,22] and the remainder had a more varied menu, but still limited compared to the present study.[20,23,26] A limited variety of food is unlikely to play a role in the present study.

It is possible that the provision of free food during the dietary intervention period played a role in the resumption of habitual diets during the counselling period. Firstly, low-fat foods are generally assumed to be more expensive than high-fat foods. Secondly, the subjects may have been highly compliant due to economic incentive. In addition, the subjects went back to buying their foods in stores where they shopped before the intervention, which could cause a return to old dietary habits. However, a study where obese subjects participated in 18 months behavioural weight control programmes that differed only with respect to the way the food was provided to the subjects—no food provision, meal plans, provision of food (paid by the subjects), or food provided for free[32]—found that weight losses were similar in the three latter groups, but significantly different from the group receiving the behavioural programme alone. It was concluded that counsellors should structure the environment for the obese patients in order to achieve permanent dietary changes and increased weight loss, but no further benefit was seen when food was provided free of charge.[32] Furthermore, after 1 y with no treatment, there was no difference between the groups and it was concluded that maintaining weight loss in obese patients is a difficult and persistent problem.[33] In the present study, subjects were expected to benefit more from skills acquired in selecting foods of the prescribed dietary composition during 6 months of dietary counselling, but this did not seem to be true in the long term, as seen by the quick relapse. Moreover, although the subjects in the present study reported a high compliance regarding the intake of protein, it is not known whether the diet remained fat-reduced during the counselling period, and so failure to maintain a weight loss may be attributable in part to a lack of adherence to a fat-reduced diet.

In the absence of scientific consensus with respect to the optimal macronutrient composition for weight loss, non-scientific prescriptions have flourished and are frequently used by individuals wishing to lose weight. Many of these have focused on dietary protein and have advocated consumption of high-protein diets.[3] The HP diet in the present study is very different from these popular diets as the protein intake was lower, and fat content much lower than the popular high-protein diets, such as The Atkins,[34] Protein power,[35] Sugar Busters[36] and the Zone diet.[37] The Atkins and Protein Power are the most radical diets and they advocate a high intake of protein (~35 E%) and fat (>50 E%), and an extremely restricted intake of carbohydrate (<10 E%). The Sugar Busters and the Zone diets advocate a similar intake of protein, carbohydrate and fat (28 E%, 40 E% and 32 E%) as the HP diet in the present study. However, the diet in our study differs from these two by not accounting for high-glycaemic carbohydrates, as in Sugar Busters, and not excluding most grain products, starchy vegetables and some fruits, as in the Zone diet.[38]

Recently, two studies found that a low-carbohydrate diet (The Atkins' diet), without restriction in calories or in fat and protein, induced more than a two-fold greater reduction in body weight[39,40] and fat mass[39] than a conventional low-fat diet (<30 E%) during 6 months intervention. However, in the trial by Foster *et al*, the positive effects of the low-carbohydrate diet were no longer present after 12 months intervention, due to poor adherence and high attrition. The outcomes in these trials were very similar to the ones seen in the present trial. Notably, the diets were very similar to the Atkins' diet[34] and as the fat intake comprised >50% of the total energy intake the dietary composition was very different from ours.

It has been suggested that high-protein diet may have unfavourable health implications. However, we have previously reported that the HP diet in the present trial had no adverse effect on calcium homeostasis,[41] renal function[42] or risk factors of cardiovascular disease (CVD)[13,43] after 6 months intervention. Furthermore, we found no unfavourable effects of an HP diet on the blood lipids related to CVD after 12 months intervention; on the contrary, we found a decrease in the intra-abdominal tissue. Moreover, the HP diet induced a significant decrease in FFA after 6 months intervention, possibly due to an increase in lipid oxidation; however, this difference was not significant after 12 months.

In conclusion, the present study suggests that a protein content up to 25% of total energy is favourable for inducing weight loss and does not adversely affect weight maintenance. In addition, the beneficial effect on intra-abdominal tissue was maintained after 12 months, and may have important implications in the prevention of complications of obesity. However, an HP diet may have adverse effects on other health aspects in the long run and this should be addressed in more detail in future long-term trials.

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