

A comparison of two very-low-calorie diets: Protein-sparing-modified fast versus protein-formula-liquid diet^{1,2}

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ABSTRACT This study investigated the acceptability of two very-low-calorie diets in 16 moderately overweight persons participating in a weight reduction program. Subjects were prescribed a 1000–1200 kcal balanced diet the first month and asked to complete appetite and mood scales on a weekly basis. They were then randomly assigned to either a protein-sparing-modified fast (PSMF) or a protein-formula-liquid diet, each of which provided about 400 kcal daily. Analysis of the appetite data showed that PSMF subjects reported significantly less hunger and preoccupation with eating than did liquid diet subjects during 2 of the 4 weeks on very-low-calorie diet. Subjects in both conditions reported significant reductions in anxiety. Results are discussed in terms of possible advantages of PSMF. *Am J Clin Nutr* 1985;41:533–539.

KEY WORDS Low calorie diet, appetite, psychological effects of dieting, protein-supplemented fast

Introduction

Very-low-calorie diets providing protein of high biologic value hold major promise in the treatment of moderate and severe obesity. These diets produce average weight losses of 20 kg in 12 weeks and appear to be safe when conducted under proper medical supervision (1). This safety contrasts with the more than 58 fatalities associated with the use of liquid protein diets in 1976 and 1977 (2, 3).

Current very-low-calorie diets are of two types. The protein-sparing-modified fast (PSMF), developed by Blackburn, Bistrian, and colleagues, provides 1.5 g of protein per kilogram of ideal body weight (4–6). Protein is obtained from lean meat, fish, and fowl. Carbohydrate is prohibited, and fat is restricted to that present in the protein source. The other type of diet relies on a milk- or egg-based protein formula, served as a liquid diet. These commercially prepared diets provided a daily ration of 33 to 70 g of protein, 30 to 45 g of carbohydrate, and about 2 g of fat. Both types of diets must be supplemented with vitamins and minerals (1).

Proponents of the PSMF argue that the diet teaches patients to successfully handle conventional foods (in the form of meat, fish, and fowl) and facilitates a smooth transition from the reducing diet to a maintenance diet of conventional foods. Proponents of protein-formula-liquid diets contend, however, that this approach promotes better dietary adherence because conventional foods are totally avoided. The two diets produce similar weight losses but there have been no controlled trials comparing their relative merits. Accordingly, little is known about possible differences in the acceptability of and adherence to the two diets, or hunger and physical complaints associated with them. The present study was designed to provide important information about these and other effects of the diets and to enable, if possible, a choice between them.

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Method

Subjects

This study was part of a larger investigation of combined treatment by behavior modification and very-low-calorie diet (7). Subjects were 17 women and 2 men with an average weight of 106.4 kg, percentage overweight of 82.3, and age of 38.1 years. Subjects were self-referred. All subjects underwent a medical examination which included a history, physical examination, electrocardiogram, complete blood count, screening chemistries panel, and tests of thyroid function. Reasons for exclusion from the study included a recent myocardial infarction, a history of cerebrovascular, kidney, or liver disease, cancer, Type I diabetes, and pregnancy. This research protocol was reviewed and approved by the Committee on Studies Involving Human Beings of the University of Pennsylvania School of Medicine.

Procedure

Month 1 (baseline): Balanced-calorie diet. Subjects were treated on an individual, weekly basis (by TAW) for the first month and were prescribed a balanced diet of 1000–1200 kcal (1500 kcal for men). Diets were tailored to individual food preferences, but subjects were asked to consume no more than 30% of calories from fat. They kept daily diet diaries in which they recorded all foods eaten and their caloric value. Diaries were examined each session to determine food selection and adherence.

Month 2: Very-low-calorie diet. For the second month, subjects were assigned to one of four groups on the basis of scheduling convenience and then randomly assigned by group to one of two very-low-calorie diets. Two groups (N = 9) were prescribed the PSMF (4–6). Subjects were provided a list of protein servings which included lean meat, fish, and fowl, from which they selected three servings a day. Each serving yielded 20 to 25 g of protein, for a daily total of 60 to 75 g. Subjects were asked to consume no more than 450 kcal a day and to avoid all other foods, with the exception of bouillon (to prevent salt depletion) and noncaloric beverages. They were prescribed a daily multi-vitamin capsule and potassium (40 Meq) and calcium (600 mg) supplements and were asked to drink at least 1.5 liters of water a day.

Two other groups of subjects (N = 10) were prescribed a protein-formula-liquid diet (Optifast 70; Sandoz Nutrition Co; Minneapolis, MN) which provided 420 kcal daily in the form of 70 g of protein, 30 g of carbohydrate, and 2 g of fat. These subjects were asked to observe the same dietary restrictions as those on the PSMF diet and to take the same vitamin and mineral supplements.

During this month, subjects continued to keep diet diaries in which they were requested to record all foods eaten, including prohibited foods, and their caloric value. Diaries were examined for adherence by the group leaders (KDB, AJS, & TAW) in the weekly meetings. All groups were conducted following the same written protocol. Every other week, subjects were examined by an internist (SCD), who reviewed their clinical condition, electrolytes, and tests of liver and thyroid function. (No significant problems were observed.)

Measures

Weight. Weight was measured weekly using a balance-beam scale.

Appetite. Beginning the second week of the 1-month baseline, subjects rated their hunger, preoccupation with eating, liking of their diet, and the disruptiveness of their diet using a set of four bipolar, visual analogue scales (8). Responses to four questions were requested: “How hungry did you feel today?”; “How much did you think about wanting to eat today?”; “How much did you like your meals today?”; and “To what extent did your meals disrupt your normal, social eating (eating with family, friends, etc)?”. Scales were completed three times each week at home at approximately 8 PM throughout the study.

Psychological functioning. Subjects completed the Beck Depression Inventory (BDI) (9) weekly throughout the study, beginning the second week of baseline. They completed the State-Trait Anxiety Inventory (STAI) (10) during the fourth baseline week and weekly thereafter.

Physical complaints. While receiving the very-low-calorie diet, subjects rated on a weekly basis the extent to which they experienced various physical complaints reported to occur on such diets (11). These included: cold intolerance, constipation, diarrhea, dizziness, dry skin, vomiting, and weakness/fatigue. The intensity of these symptoms was rated on a 4-point scale: 1 = not at all; 2 = slight amount; 3 = moderate amount; 4 = great amount.

Attrition. Three subjects failed to complete the appetite and mood scales for 2 of 4 weeks on very-low-calorie diet. Data for these subjects (2 PSMF, 1 liquid diet) were therefore eliminated from the statistical analyses. The weight losses and other test results of these three subjects did not differ significantly from those of the remaining 16 subjects, all of whom provided complete data sets.

Results

Weight change

Month 1. Subjects lost an average of 4.2 kg (SD = 2.9) during the baseline month on the 1000–1200 kcal diet. Subjects had not been assigned to diet conditions at this point; however, weight losses for the prospective PSMF and liquid diet subjects were very similar—4.4 and 4.1 kg, respectively (ns).

Month 2. PSMF and liquid diet subjects weighed 108.8 and 99.5 kg, respectively, at the start of the very-low-calorie diet (ns). Weight losses during the month did not differ significantly between the two conditions, either overall (8.7 and 7.3 kg, respectively) or on a weekly basis. For weeks 1, 2, 3, and 4, losses were 3.0, 2.0, 1.4, and 1.6 kg, respectively.

Appetite

Analyses of baseline data. The three scores obtained each week on each appetite mea-

sures were averaged to provide weekly values for each of the three baseline weeks. A MANOVA with repeated measures indicated that subjects' scores on the four appetite measures did not change significantly from week 1 values during either of the two subsequent baseline weeks (all values, $p > .10$). Nor were significant differences observed between the two groups on any of these measures at any time during baseline (all values, $p > .10$). Therefore, the nine scores obtained on each measure during baseline were averaged to provide a single "baseline" value. A second MANOVA indicated that the two groups did not differ significantly on any of these "baseline" values, which are shown in Table 1 (all values, $p > .10$).

The three scores obtained each week during the very-low-calorie diet were averaged to provide weekly values. Differences between the two groups were analyzed using analysis of covariance, with the baseline value as the covariate. (Analysis of covariance was used because there were small differences between the two groups on baseline values, even though these differences were not statistically significant.)

Hunger. Figure 1 shows that the PSMF subjects reported decreased hunger on the

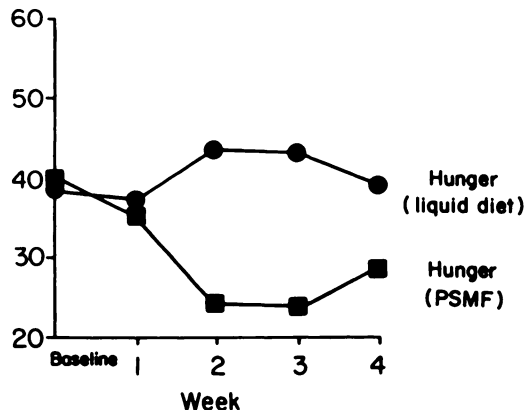


FIG 1. Comparison of reports of hunger in subjects assigned to PSMF and liquid diet. High scores indicate greater hunger (ie, 0 = none at all, 80 = very great amount).

very-low-calorie diet, whereas liquid diet subjects generally reported increased hunger. These differences reached statistical significance during the second and third weeks, $F(1,13) = 9.05, p < .01$ and $F(1,13) = 17.94, p < .001$, respectively. Separate within-subjects analyses revealed that the differences between groups were attributable to significant reductions from baseline hunger in the PSMF subjects at weeks 2 and 3 (both values, $p < .008$); hunger ratings of liquid diet subjects did not change significantly from baseline at any time.

Preoccupation with eating. Changes on this measure were similar to those for "hunger" (see Fig 2). PSMF subjects reported decreased preoccupation with eating, whereas liquid diet subjects generally reported increased preoccupation. Differences approached statistical significance at the second week, $F(1,13) = 3.76, p < .07$, and reached significance at the third week, $F(1,13) = 4.91, p < .05$. The within-subjects analyses revealed that ratings of PSMF subjects differed significantly from baseline at week 2 ($p < .009$), but not at weeks 3 or 4, despite the similarity of the mean values; ratings of liquid diet subjects did not differ significantly from baseline at any time.

Acceptability of diets. Figure 3 shows that, with the exception of the first week, PSMF subjects generally liked their very-low-calorie diet as much as the preceding 1000 kcal

TABLE 1
Weekly self-ratings on appetite measures during baseline and very-low-calorie diet

Measure	Time of Assessment	PSMF		Liquid Diet	
		Mean	SEM*	Mean	SEM
Hunger	Baseline	39.3	3.4	38.7	3.5
	Wk 1	35.0	8.4	36.4	6.0
	Wk 2	24.0	3.8	44.0	5.7
	Wk 3	24.1	4.9	44.6	4.6
	Wk 4	29.3	5.2	41.7	6.6
Preoccupation	Baseline	34.5	4.3	44.0	5.1
	Wk 1	31.3	6.1	40.6	6.3
	Wk 2	25.7	3.9	47.7	7.2
	Wk 3	25.7	7.0	47.9	5.7
	Wk 4	26.6	7.4	38.7	7.2
Acceptability	Baseline	46.0	4.3	53.6	4.5
	Wk 1	36.6	4.3	23.9	5.9
	Wk 2	45.1	6.8	27.2	6.2
	Wk 3	48.4	5.6	28.8	8.3
	Wk 4	49.9	5.1	33.8	8.4
Disruptive	Baseline	20.6	6.1	17.6	4.9
	Wk 1	24.6	9.0	32.9	7.4
	Wk 2	16.9	5.4	28.8	8.1
	Wk 3	15.6	5.6	31.9	8.2
	Wk 4	18.9	6.4	28.2	9.0

* Standard error of the mean.

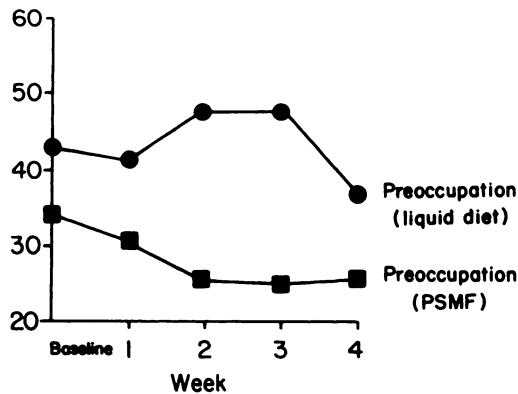


FIG 2. Comparison of reports of preoccupation with eating in subjects assigned to PSMF and liquid diet. High scores indicate greater preoccupation (ie, 0 = none at all, 80 = very great amount).

balanced diet. Liquid diet subjects, on the other hand, did not like their very-low-calorie diet nearly as much as the preceding 1000 kcal diet. Differences between groups reached statistical significance at the second, $F(1,13) = 7.24$, $p < .02$ and third weeks, $F(1,13) = 6.53$, $p < .03$ and approached significance at the first and fourth weeks (both values, $p < .08$). The within-subjects analyses revealed that ratings given by liquid diet subjects differed significantly from baseline at all 4 weeks (all values, $p < .01$); ratings given

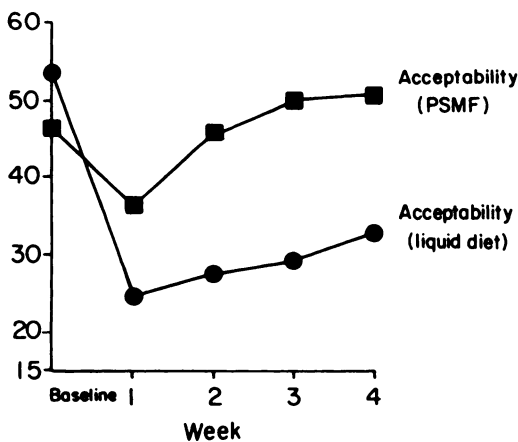


FIG 3. Comparison of reports of liking (acceptability) of diet in subjects assigned to PSMF and liquid diet. High scores indicate greater liking (ie, 0 = dislike very great amount, 80 = like very great amount).

by PSMF subjects did not change significantly from baseline at any time.

Disruptiveness of diets. Both the PSMF and liquid diet subjects reported that the very-low-calorie diet disrupted their normal social eating during the first week. Thereafter, ratings for PSMF subjects returned to baseline, whereas those for liquid diet subjects remained elevated (see Fig 4). The differences did not, however, reach statistical significance at any time. The within-subjects analyses revealed that only ratings given by liquid diet subjects the first week differed significantly from baseline ($p < .02$).

Psychological functioning

State and trait anxiety. Analysis of variance indicated that there were no significant differences between PSMF and liquid diet subjects at baseline in state or trait anxiety (see Table 2). Analysis of covariance (using baseline score as the covariate) indicated that there were no significant differences between subjects on either measure at any time during the very-low-calorie diet. Accordingly, scores were collapsed across conditions and examined for changes from pre- to posttreatment using paired t tests. Significant reductions were observed by the fourth week on very-low-calorie diet in state anxiety, $t(15) = 2.68$, $p < .02$, and trait anxiety, $t(15) = 4.37$, $p < .001$.

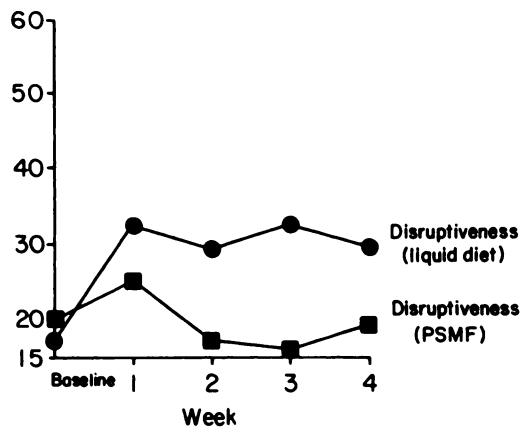


FIG 4. Comparison of reports of the social disruptiveness of very-low-calorie diet (ie, disrupted eating with family, friends, etc) in subjects assigned to PSMF and liquid diet. High scores indicate greater disruptiveness (0 = not at all, 80 = very great amount).

TABLE 2
Weekly self-ratings on psychological measures during baseline and very-low-calorie diet

Measure	Time of assessment	PSMF		Liquid diet	
		Mean	SEM*	Mean	SEM
Depression	Baseline	7.6	2.6	9.1	2.2
	Wk 1	8.5	2.0	8.3	2.1
	Wk 2	6.7	2.0	8.6	2.1
	Wk 3	5.8	1.4	6.8	2.0
State Anxiety	Baseline	46.6	3.8	45.9	3.4
	Wk 1	43.6	3.8	43.1	3.8
	Wk 2	45.7	4.2	47.2	4.0
	Wk 3	43.7	3.4	50.2	5.7
Trait Anxiety	Baseline	48.1	3.7	47.0	3.2
	Wk 1	46.9	3.5	45.0	2.9
	Wk 2	46.9	3.1	46.6	3.1
	Wk 3	46.3	3.5	47.0	5.2
	Wk 4	45.1	3.1	41.9	2.2

* Standard error of the mean.

Depression. Subjects in the two conditions did not differ significantly in depression at baseline (as determined by analysis of variance) or at any time during the very-low-calorie diet (as determined by analysis of covariance). Scores were again collapsed across conditions, and paired *t* tests showed decreases in depression that approached significance at weeks 3 and 4 ($p < .10$ and $p < .15$, respectively) on very-low-calorie diet. Thus, subjects tended to become less rather than more depressed while consuming both diets.

Physical complaints

Figure 5 shows that subjects reported relatively little physical discomfort on the very-low-calorie diets. The most intensely experi-

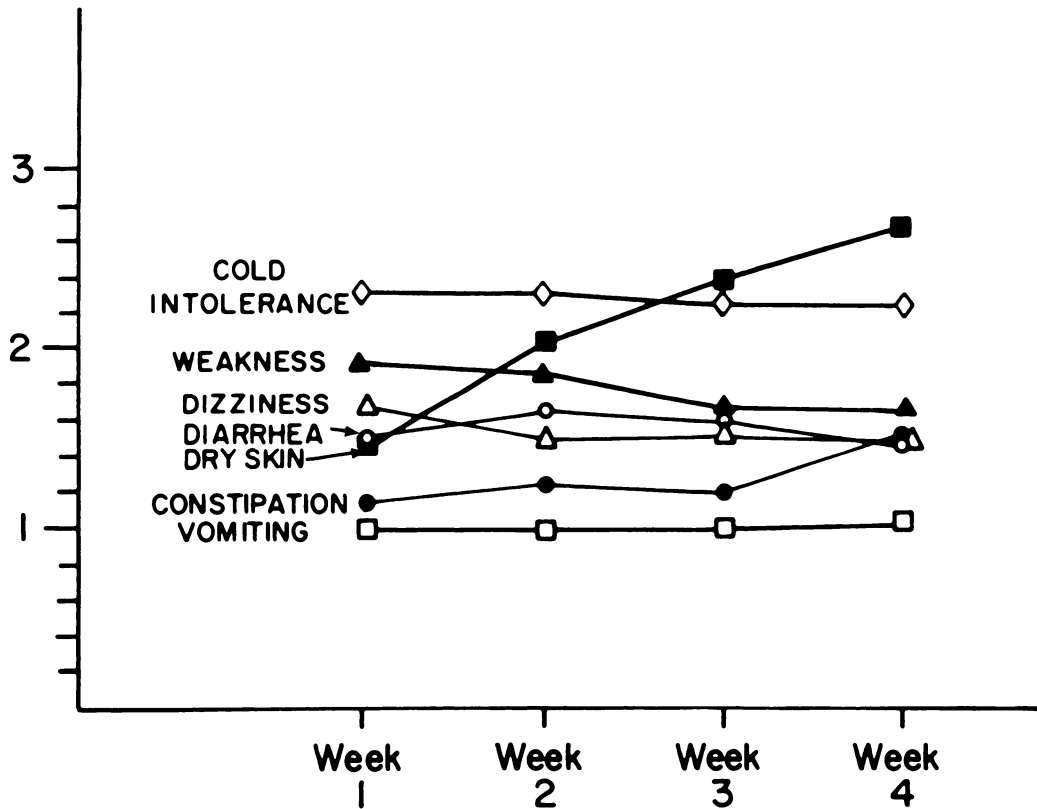


FIG 5. Report of physical symptoms associated with very-low-calorie diet. Intensity of symptoms was rated on 4-point scale, in which 1 = not at all and 4 = very great amount. Scores have been collapsed across conditions due to lack of significant differences.

enced symptoms were cold intolerance, dry skin, and weakness/fatigue, which were rated as only mild to moderate at their maximum. There were no significant differences between the two diet conditions on any of these measures at any time (and, thus, ratings were collapsed across conditions as seen in Fig 5). Complaints associated with dry skin were the only ones to increase during the 4-week period, $t(15) = 4.05$, $p < .01$.

Discussion

The results of this study confirm clinical impressions that comparable weight losses are achieved with PSMF and protein-formula-liquid diets. However, PSMF may have several advantages over liquid diet. In comparison with baseline ratings obtained on a 1000–1200 kcal balanced-calorie diet, PSMF subjects reported significantly less hunger and preoccupation with food during 2 of the 4 weeks on very-low-calorie diet, while liquid diet subjects reported slightly (though not significantly) more hunger and preoccupation during the same 2 weeks. Similarly, PSMF subjects tended to like their very-low-calorie diet as much as the preceding 1200 kcal diet, whereas liquid diet subjects liked theirs significantly less. Subjects found both diets to be somewhat disruptive of normal social eating, the liquid diet slightly more so than PSMF.

It is not clear why PSMF subjects reported less hunger than those consuming liquid diet. A possible explanation concerns differences in the taste, texture, and temperature of the diets. Liquid diet subjects complained of the lack of hot chewable food, the monotony of the diet (perhaps exacerbated by having only three flavors to choose from), and the difficulty in eating out easily. Each of these complaints was less intense among PSMF subjects who chose their meals from 15 different servings of animal protein, consumed them either hot or cold, retained the pleasure of chewing food, and found the diet more adaptable to eating outside of the home. Although these factors may not have affected physical hunger, they may have affected psychological dimensions involved in judgments of hunger.


The reduced hunger reported by PSMF subjects may have been due to ketosis (12). We cannot address this issue, however, because we did not measure ketone levels. Previous controlled studies have not shown that ketosis is associated with a therapeutic anorexia (13, 14). Rosen and his colleagues (13), for example, found no significant differences in reports of hunger between subjects randomly assigned to an 827 kcal carbohydrate-restricted diet or an equicaloric, non-ketotic diet. Nor did Silverstone and his colleagues (14) find that ketosis was associated with reduced reports of hunger in fasted subjects.

Subjects reported significant reductions in state and trait anxiety during the time that they consumed the very-low-calorie diet, with no increase in depression. These findings, which are similar to those of Rosen et al (13) with an 827 kcal diet, stand in striking contrast to earlier reports. In each of five studies reviewed by Stunkard and Rush (15), for example, untoward responses to dieting were observed in half of the participants, and more recently, Halmi, Stunkard, and Mason (16) reported symptoms in 75% of severely obese patients during extended dieting.

At least three factors may have been responsible for the absence of negative emotional responses in the present study. First, subjects reported that meeting as a group, rather than individually, provided valuable social support. In addition to providing an arena to share common concerns, the group facilitated an informal buddy system among many of the patients. Second, subjects generally experienced little physical discomfort on the diets. Aside from initial problems with fatigue and later complaints of cold intolerance and dry skin, most subjects reported feeling as well on the very-low-calorie diet as on the preceding 1000–1200 kcal diet. Finally, even those subjects who did experience occasional irritability or physical discomfort indicated that their satisfaction from losing weight outweighed the impact of these negative experiences.

The present study leaves unsettled the question of whether the PSMF would retain its advantage over the protein-formula-liquid diet for more than a few weeks. Figure 1



shows a trend for ratings of the diets to approach each other during the fourth week of very-low-calorie diet. Further research is needed to determine the long-term acceptability of these two diets. Studies are also needed to determine the effects of contextual factors on dietary adherence and ratings of hunger and palatability. Rosen et al's (13) study, for example, was conducted in a hospital setting, whereas the present investigation was conducted in a naturalistic setting—the patient's home. Future studies might observe patients in both settings to determine if ratings systematically vary from one environment to the next. 

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