

ORIGINAL RESEARCH

## Physiological Effects of a Doctor-supervised *Versus* an Unsupervised Over-the-Counter Weight-loss Program

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*A comparison of two different 10-week intervention programs, both focused upon weight loss, was made. One of these programs (DSP—Doctor Supervised Program) was supervised by a health professional, and the other was a popular unsupervised OTC program (OTC—Over-the-Counter). Observed intergroup comparative changes included serum cholesterol (DSP mean = -13 mg dl<sup>-1</sup>; OTC mean = -17 mg dl<sup>-1</sup>), HDL cholesterol (DSP mean = -9.7 mg dl<sup>-1</sup>; OTC mean = -9.6 mg dl<sup>-1</sup>), weight loss (DSP mean = -11 lb; OTC mean = -13 lb). These differences between the groups were not statistically significant. Two statistically significant differences between the groups were changes in thyroid stimulating hormone (TSH) and body composition (BC). No change in TSH was observed in the DSP group pre- and post-intervention, whereas a significant increase (150%, p = 0.04) was observed in the OTC group. In addition, participants in the DSP group lost significantly more fat (mean = 10 lb) than the OTC group (mean = 1 lb). The intergroup difference for this change in body composition was highly significant (p = 0.001). These data indicate that a supervised weight-loss program helped to preserve muscle and to promote selective loss of fat in comparison to an unsupervised OTC program. This difference may be due to endocrine-modulated effects associated with differential aspects of nutritional quality between the two programs.*

**Keywords:** weight loss, thyroid, lean body mass.

### INTRODUCTION

Recently, weight-loss programs and the weight-loss industry in the USA in general have come under severe scrutiny. Concern has focused on the safety and effectiveness of over-the-counter diet products related to low-calorie or very-low-calorie dietary regimes. It is now recognized that the typical weight-loss diet consumer is an individual preoccupied with a 'hurry up and get it done' attitude and is therefore very susceptible to exaggerated claims concerning the rate of weight loss achieved with certain weight-loss programs.

In light of these concerns surrounding weight loss, investigators have attempted to define the characteristics of a weight-loss program which is both effective and safe [1]. A conclusion of these investigations is that a safe weight-loss program maintains muscle and organ protein stores while selectively promoting loss of body fat, it maintains resting metabolic rate, it provides essential nutrients necessary for the conversion of stored fat to energy, it maintains proper fluid, electrolyte and pH

balances of the body, and results in long-term improvement in body composition through diet and behavioral modifications [2].

Weight-loss programs that are nutritionally imbalanced produce many adverse side effects including constipation, fatigue, orthostatic dizziness, dry skin, hair loss, cold intolerance, muscle cramps, menstrual irregularities, increased risk to gallstones and behavioral dysfunctions [3]. It is also recognized that a poorly controlled weight-loss program can result in repetitive weight loss and weight regain which depresses resting metabolic rate and lipolytic activity, making it even more difficult to lose weight in subsequent trials [4].

It is assumed by most individuals who engage in an unsupervised weight-loss program using one of the many over-the-counter low-calorie meal replacement products that are commercially available, that the success of the program is measured by the number of pounds lost. What has not been evaluated, however, is the relative safety and effectiveness of these regimes in providing weight loss that fulfills the criteria of safety as defined above. In order to evaluate the relative difference between the safety and effectiveness of a doctor-supervised weight-loss program and that of an unsupervised program utilizing an over-the-counter meal replacement formula, the following study was performed. The doctor-supervised weight-loss program utilized a 1000 kcal per day diet made up of 60% carbohydrate (20% simple carbohydrate as fructose), 10% fat (polyunsaturated) and 30% protein (balance of vegetable and animal origin). This dietary regimen was high in potassium and low in sodium, low in cholesterol and provided at least 100% of the USA RDA for all micronutrients. The over-the-counter weight-loss product and program were represented by the most frequently used commercial product available in the USA. Participants in this program were counseled to follow exactly the instructions included with the product. This program provided 800–1000 kcal per day partitioned as 50% carbohydrate (40% of which was simple sugar, sucrose), 20% fat and 30% protein (principally non-fat milk origin).

The doctor-supervised weight-loss program was delivered as a beverage two meals per day along with fresh fruits and vegetables and a low-fat mixed meal each evening. The unsupervised program was provided as the over-the-counter powdered meal replacement twice daily and a low-fat mixed meal in the evening as described in the product package insert.

Thirty-four individuals were recruited into the study, all of whom had body composition of greater than 20% body fat and were normally healthy by all other accounts. Twenty-two of the subjects were assigned to the doctor-supervised program, and 12 followed the unsupervised over-the-counter weight-loss program, with both groups complying with their respective programs for 10 weeks.

Physiological and anthropometric measurements were made on all subjects before initiating the program, at 2 weeks, at 6 weeks and at the completion of the 10-week period in order to evaluate the relative difference in both effectiveness and safety of these two weight-loss programs.

## MATERIALS AND METHODS

### Subject Selection

Subjects were solicited through the placement of local newspaper advertisements and screened in personal interviews. Criteria for admittance to the study included a minimum of 20% body fat, a perceived level of commitment to the program and prior experience with other weight-loss programs or products.

A total of 34 subjects were selected. Twenty-two were placed in the doctor-supervised (DSP) group, and 12 were placed in the unsupervised (OTC) group.

Selected subjects were notified by phone of their acceptance into the program and

were sent a food diary form to track their food intake for the week prior to initiation of the study.

DSP subjects were instructed to consume a meal replacement formula (UltraMaintain, HealthComm Inc., WA 98335, USA) three times per day with a mid-morning and mid-afternoon snack of fresh fruits and vegetables for the first 5 days of the program. For the remainder of the 10-week program, DSP subjects consumed the meal replacement formula two times daily, consumed the mid-morning and mid-afternoon snacks and ate a low-fat mixed food dinner from a prescribed recipe plan. These subjects visited the office for evaluation and consultation every other week throughout the 10-week program.

The OTC group consumed an over-the-counter formulation (Ultra SlimFast, Thompson Medical Inc., NY 10150, USA) as per the label instructions twice daily along with a low-fat mixed food meal as prescribed in the package insert material. These participants had physiological testing done every other week, but no extensive consultation or discussion was conducted with a health professional throughout the 10-week program concerning behavior modification or exercise.

Data collected for each subject at baseline, 2 weeks, 6 weeks and 10 weeks included the following:

*Blood chemistries.* Complete blood count with differential, cardiac risk profile including total, HDL and LDL cholesterol and triglycerides, liver enzymes, free thyroxin and thyroid stimulating hormone, and serum ferritin. (Subjects were required to fast for a minimum of 12 h before their scheduled blood draw.)

*Urinalysis.* Twenty-four hour urinalysis was used to gather information on urinary creatinine and nitrogen as possible indicators of muscle catabolism. All subjects were given an explanation of how properly to collect a urine sample and were instructed to mail an aliquot sample of their 24-h collection in self-mailers to the laboratory.

*Body composition.* Body composition was measured with the use of a bioelectrical impedance analyzer (RJL Systems, Body Comp Analyzer, BIA-101, Detroit, Michigan, USA).

*Anthropometric measurements.* Weight, height, bust, hips, waist and circumference of biceps, thighs and calves were measured on each subject throughout the 10 weeks.

*Fitness evaluation.* The YMCA 3-min step test and heart rate recovery were administered using a Uniqcic Pro-Trainer (Computer Instruments Corporation, Hempstead, NY 11550, USA).

During the first visit, DSP subjects were oriented to the overall design of the study and its individual components and were instructed how properly to prepare meals and initiate an exercise program for their current level of fitness.

DSP subjects were instructed to phone in every day for the first 5 days of the program to a pre-recorded telephone message which gave a motivational message and indicated typical physical symptoms a person could expect to experience during the first phases of the program. DSP subjects received a recipe and menu planner and nutrition education from a trained professional, an exercise guide, motivational materials and additional food diary forms.

Instructions to the OTC group were kept at a minimum in an attempt to simulate normal conditions of purchase and application of an over-the-counter weight-loss product. The OTC product information suggested regular daily exercise, but no attempt to measure compliance to this recommendation in the OTC group was made.

Each time the DSP subjects came in for data collection, the results of the previous

collection were shared with them and discussed with a registered dietitian. They had a brief interview with the program coordinator to check the status of their progress and their continued commitment to the program. Participants in the OTC group were also interviewed by the dietitian and surveyed as to their progress with their program.

## RESULTS

Sixty-four per cent of the DSP subjects completed the full 10-week program, whereas only 42% of the OTC group completed the 10 weeks. In those who completed the program, differences between baseline and endpoint data were computed. There were no significant differences in the following parameters in each group: free thyroxin, systolic blood pressure, diastolic blood pressure and serum triglycerides. Total urinary creatinine and urea data were incomplete and therefore not of statistical significance.

Differences between baseline and endpoint analysis were found for total serum cholesterol, which decreased in both groups. This cholesterol reduction was seen as a reduction in both HDL and LDL cholesterol. Thyroid stimulating hormone increased significantly in the OTC group, but not in the DSP group. Body weight was reduced in both groups, but only the DSP group showed significant loss of weight as body fat. The OTC group was found to have lost the majority of weight as muscle protein, not as body fat.

Statistical analysis was accomplished using GB-Stat. Baseline values and 10-week endpoint values were analyzed using a *t*-test for paired values. In the event that values were not normally distributed, results were checked using a non-parametric analysis, Wilcoxon-paired test. Differences between groups were analyzed by *t*-test and checked using a non-parametric analysis, Mann-Whitney U Test. Results of the study are indicated in Table 1.

## DISCUSSION

Two notable differences between the DSP and the OTC groups were observed. The first was the significant increase in thyroid stimulating hormone levels found in the OTC group, whereas no such change in thyroid stimulating hormone was seen in the DSP group. This undoubtedly relates to the fact that there was a compensatory neuroendocrine modification in the OTC group in response to this program, as contrasted to no discernible neuroendocrine alteration in the DSP group. It is recognized that the inclusion of protein of high biological quality in weight loss regimes minimizes the risk of neuroendocrine disturbances [5]. The effect on thyroid hormone metabolism during a weight-loss diet is modified by the quantity of dietary protein and its biological quality. Kaptein *et al.* [6] have reported that  $T_3$  levels are modified as a consequence of protein quantity and quality. The OTC group consumed an OTC meal replacement product whose major protein source was non-fat milk powder, whereas the DSP group consumed as its major protein source soy protein isolate and predigested whey protein concentrate. It is now recognized that soy protein isolate has a very high net protein utilizability [7], and the data imply that protein quality could have contributed to the differences seen in thyroid stimulating hormone and thyroid hormone metabolism between the OTC and DSP groups.

Foster, Wadden and Stunkard have recently reported that thyroid hormone metabolism is altered and free  $T_3$  is depressed when calorie intake drops below 1000 kcal per day or the weight-loss dietary program is nutrient imbalanced. They note these physiological changes are consistent with a reduced energy expenditure and increases in muscle catabolism [8].

The reduction in resting energy expenditure and its association with altered thyroid hormone metabolism during low-calorie diets have been observed by a number of

TABLE 1. Summary of results mean values ( $\pm$ SD): *p* values are derived from the two-tail test

Parameter	Units	DSP group (14M & 8F)				OTC group (5M & 6F)				
		Baseline	Week 10	% Change	Within group statistical significance	Baseline	Week 10	% Change	Within group statistical significance	Between group statistical significance
Age	(yr)	44.1 (3.5)				42.7 (3.9)				
Free T4	(ng/dl)	1.3 (0.3)	1.3 (0.2)		n.s.	1.3 (0.3)	1.2 (0.15)		n.s.	n.s.
TSH	(uIU/ml)	0.55 (0.10)	0.54 (0.10)		n.s.	0.8 (0.3)	1.2 (0.6)		<i>p</i> =0.043	<i>p</i> =0.01
Cholesterol	(mg/dl)	200 (37)	187 (25)	-6.5 (10.3)	n.s.	208 (31.5)	191 (33)	-8.7 (5.7)	<i>p</i> =0.043	n.s.
HDL	(mg/dl)	51.9 (13)	48.0 (16)	-11.7 (12.3)	<i>p</i> =0.005	53.2 (16.3)	47.4 (12.3)	-9.6 (5.9)	<i>p</i> =0.053	n.s.
Systolic BP	(mmHg)	131 (26)	120 (23)		n.s.	110 (12)	115 (23)		n.s.	n.s.
Diastolic BP	(mmHg)	72 (9.5)	68 (13)		n.s.	67 (11)	63 (49)		n.s.	n.s.
Total weight	(lb)	205 (49)	194 (54)	-8.3 (2.6)	n.s.	213 (54)	200 (46)	-6.1 (2.0)	n.s.	n.s.
Lean body mass	(lb)	133 (32)	137 (27)		n.s.	136 (35)	125 (29)		<i>p</i> =0.047	n.s.
Change in lean body mass	(lb)		-4.4 (8.1)		n.s.		-11.4 (11.1)		n.s.	<i>p</i> =0.05
Change in fat weight	(lb)		-11.0 (9.2)	-22.9 (12.7)	n.s.		-0.91 (4.0)	-0.7 (4.6)	n.s.	lb <i>p</i> =0.032 % <i>p</i> =0.001

TABLE 2. Doctor-supervised program (DSP)

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Energy:	150 kcal
Protein:	15 g
Carbohydrate:	20 g
Fat:	1 g
Sodium:	160 mg
Potassium:	690 mg
Dietary fiber:	4 g
Vitamin A (vitamin A palmitate):	1750 IUs
Vitamin C (ascorbic acid):	21 mg
Thiamine (thiamine mononitrate):	0.525 mg
Riboflavin (riboflavin):	0.595 mg
Niacin (niacinamide):	7 mg
Calcium (calcium carbonate):	250 mg
Iron (ferrous fumarate):	6.3 mg
Vitamin D (cholecalciferol):	140 IUs
Vitamin E (D-alpha-tocopherol acetate):	10.5 IUs
Vitamin B <sub>6</sub> (pyridoxine hydrochloride):	0.7 mg
Folic acid:	0.14 mg
Vitamin B <sub>12</sub> (cyanocobalamin):	2.1 mcg
Phosphorous (potassium phosphate):	250 mg
Iodine (potassium iodide):	52.5 mcg
Magnesium (magnesium oxide):	100 mg
Zinc (zinc oxide):	5.25 mg
Copper (copper sulfate):	0.7 mg
Biotin:	0.105 mg
Pantothenic acid (calcium pantothenate):	3.5 mg
Manganese (manganese sulfate):	1 mg
Chromium (ChromeMate GTF™):	67 mcg
Molybdenum (sodium molybdate):	50 mcg
Selenium (sodium selenite):	30 mcg
Vitamin K:	20 mcg

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Ingredients: soy protein blend (soy protein isolate, soy protein concentrate), maltodextrin, partially hydrolyzed whey protein concentrate, non-fat dry milk, fructose, soy fiber, corn bran, stabilized canola oil, corn syrup solids, guar gum, potassium chloride, purified cellulose, potassium phosphate, calcium carbonate, natural and artificial flavors, rice syrup solids, potato starch, pea starch, DL-methionine, magnesium oxide, aspartame, ascorbic acid, vitamin E acetate, mono- and diglycerides, ferrous fumarate, niacinamide, zinc oxide, calcium pantothenate, vitamin A palmitate, copper sulfate, pyridoxine hydrochloride, riboflavin, thiamine mononitrate, ChromeMate GTF™, vitamin D, folic acid, biotin, sodium selenite, potassium iodide, vitamin K, cyanocobalamin.

Preparation: mix 1 scoop (45 g) in 8 oz of water.

investigators. Den Besten *et al.* [9] have found that diet-induced thermogenesis was altered during poorly controlled weight loss in obese humans.

It was also observed that the percentage of fat-free mass of the DSP group increased over the course of the 10 weeks, whereas in the OTC group the percentage of fat-free mass decreased. This indicates that the supervised weight-loss program resulted in preferential mobilization of fat due presumably to enhanced lipolytic activity, whereas in the unsupervised group, significant mobilization of body protein stores occurred which resulted in retention of body fat and a resultant decrease in percentage fat-free mass at the end of 10 weeks. The observed thyroid stimulating hormone differences between the two groups may in part reflect the increased lean body composition of the

TABLE 3. Over-the-counter product

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Energy:	100 kcal
Protein:	5 g
Carbohydrate:	19 g
Fat:	1 g
Sodium:	110 mg
Potassium:	240 mg
Dietary fiber:	5 g
Vitamin A (vitamin palmitate):	1250 IUs
Vitamin C (ascorbic acid):	18 mg
Thiamine (thiamine mononitrate):	0.45 mg
Riboflavin (riboflavin):	0.17 mg
Niacin (niacinamide):	7 mg
Calcium (calcium phosphate):	150 mg
Iron (ferric orthophosphate):	6.3 mg
Vitamin D (vitamin D <sub>3</sub> ):	40 IUs
Vitamin E (vitamin E acetate):	10.5 IUs
Vitamin B <sub>6</sub> (pyridoxine hydrochloride):	0.6 mg
Folic acid:	0.1 mg
Vitamin B <sub>12</sub> (cyanocobalamin):	1.2 mcg
Phosphorous (calcium phosphate):	150 mg
Iodine (potassium iodide):	15 mcg
Magnesium (magnesium oxide):	100 mg
Zinc (zinc oxide):	4.5 mg
Copper (cupric sulfate):	0.7 mg
Biotin:	0.105 mg
Pantothenic acid (calcium pantothenate):	2.5 mg
Manganese (manganese sulfate):	1 mg

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Ingredients: sucrose, protein (sources are one or more of the following: calcium caseinate, non-fat dry milk, soy, whey), Dutch processed cocoa, purified cellulose, bran fiber, fructose, carrageenan, lecithin, guar gum, natural and artificial flavors, aspartame, DL-methionine, calcium phosphate, magnesium oxide, potassium chloride, ferric orthophosphate, vitamin E acetate, ascorbic acid, niacinamide, zinc oxide, vitamin A palmitate, manganese sulfate, calcium pantothenate, cupric sulfate, pyridoxine hydrochloride, thiamine mononitrate, vitamin D<sub>3</sub>, riboflavin, biotin, folic acid, potassium iodide, vitamin B<sub>12</sub>.

Preparation: 1.16 oz of powder (1 packet) into 8 oz of 1% low-fat milk.

DSP group. It is recognized that resting energy expenditure, thyroid hormone metabolism and thermogenic response to diet are related to body composition [10]. Because the DSP participants were generally more lean at the end of the 10 weeks, this may have resulted in higher resting energy expenditure and improved thermic response to food and been correlated with the absence of impact of the program on thyroid stimulating hormone activity and thyroid hormone metabolism.

It is also not clear whether the differences between DSP and OTC results were a consequence of nutrition quality alone, or could also be a consequence of improved compliance to the total DSP program, as contrasted to the OTC program. Recently, Davis and his colleagues have pointed out that there is a considerable gap between patient reading comprehension and the readability of patient education materials [11]. It may be that the description provided with the OTC program was not effective in communicating critical aspects of the program to the participant, which resulted in either suboptimal nutritional intake or lack of exercise. This does not appear to be the complete explanation, however, in that both the DSP and OTC groups did receive

consultation with the dietitian throughout the 10 weeks to make sure they did understand the nature of their programs. Given this support, it is highly unlikely that the difference in results between the two groups was principally a consequence of differences of participant understanding of the program or compliance. Both groups lost virtually the same amount of weight over the 10-week period with the difference being the type of weight lost. Because the OTC group lost the majority of weight as muscle and not fat, it would suggest that differences in nutritional quality and compliance were the major factors accounting for the difference in thyroid stimulating hormone levels and changes in body composition over the 10 weeks.

It should also be pointed out that the higher drop-out rate of the OTC *versus* the DSP group (58% *versus* 36%) indicates that the unsupervised program was more difficult to comply with. Data demonstrating the differences between the two programs would have been even more dramatic if information from those who dropped out during the program were included.

The results of this study clearly indicate there is a marked difference in the physiological outcome between a doctor-supervised and an unsupervised weight-management program. Because the doctor-supervised program resulted in a much higher fat-free mass, which is associated with long-term weight management [12], and had less impact upon thyroid stimulating hormone and presumably thyroid hormone metabolism, it would be considered a much safer and more efficacious approach toward weight control. Foreyt has demonstrated that for individuals who are moderately obese, the aggressive use of a nutritionally balanced calorie-restricted diet, along with an effective exercise and behavior modification program delivered by competent health professionals results in much better long-term weight maintenance and reduced probability of relapse [13]. This study indicates that there is strong support for both the safety and effectiveness of a properly controlled, professionally supervised weight-loss program as contrasted to an unsupervised over-the-counter program. These results have potentially significant implications for the vast numbers of individuals who are self-selecting into unsupervised weight-loss programs utilizing OTC diet products.

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