Comparison of two behavioral models in obesity treatment

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Portland State University

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Title: Comparison of Two Behavioral Models in Obesity Treatment

One out of four American adults today is obese. As that ratio continues to increase so does the need for an effective treatment. Though the search for a truly effective treatment continues, obesity experts have agreed that regardless of the method of caloric restriction used to lose weight, a behavioral component is essential for
long term weight-loss maintenance.

This study compared the results of two methods of behavioral treatment in combination with a very-low-calorie-diet in the treatment of obesity. Subjects were 28 male and 106 female patients admitted to the medically supervised fasting program at Risk Factor Clinic in Portland, Oregon. Subjects were matched by gender, percent over ideal body weight, and age. Subject group I received a smorgasbord of behavioral techniques from various group leaders in a 60-minute weekly session. Presentation was didactic and theoretical and subjects were accountable to themselves for utilization of the techniques. Subject group II participated in 90-minute weekly sessions with a primary leader facilitating a problem solving and educational session in which patients were continually encouraged to participate. Subjects set goals and made weekly commitments to facilitate skill acquisition and behavior change. The leader collected data from patients each week on program compliance and physical activity.

There was no significant difference in weight loss (measured in total pounds or in percent of body weight lost) between groups. Group I averaged 59.7 pounds and 23.1 percent lost and group II averaged 59.1 pounds and 23.6 percent lost. The change in treatment method did
result in significant differences in attrition rate and number of patients joining the maintenance phase of the program. The 33 percent attrition rate of group I was significantly higher than the 18 percent for group II. The 78 percent of patients from group II joining the maintenance phase was a significant increase over the 52 percent joining from group I. Research findings support the premise that the longer a patient is in treatment the greater their chances for success. The results of this study support an increased chance of success for patients treated with the primary leader/group participation model implemented for group II.
COMPARISON OF TWO BEHAVIORAL MODELS
IN OBESITY TREATMENT

by

NINA LUCILLE DOMINY

A thesis submitted in partial fulfillment of requirements for the degree of

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in
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My thanks also to the staff of Risk Factor Clinic for their assistance and access to subjects and data for this study. Special thanks to clinic director, Margaret McMahon, for her trust in my ability to complete this project and for providing the resources to make it possible and to Linda Choat for her hours of labor in helping me gather data.

My deepest appreciation to my mentor, Nan Steenson, for her constant guidance, encouragement, and belief in me.

My gratitude also to my family and friends for their patience, tolerance, support and the unique expression of encouragement from each one. And finally my thanks to God for blessing me with the hunger for knowledge and the ability and resources to continue to learn and share that knowledge with others.
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CHAPTER I
INTRODUCTION

The search for an effective treatment for obesity has been a long and unsuccessful one to date. As the prevalence of obesity has increased to what some consider epidemic proportions, so has the frustration of bariatric physicians and weight management professionals. In 1985 the National Institutes of Health (NIH) estimated the number of obese adult Americans at over thirty-four million. Today approximately one out of four adults is obese as defined as 20 percent or more above desirable body weight (Bray, 1986; Burton, Foster, Hirsch, & VanItallie, 1985; Foreyt, 1987) and longitudinal data indicate that number is increasing (Foreyt, 1987; Kalodner & DeLucia, 1990).

The health risks of obesity have long been substantiated in medical literature. The NIH Consensus Development Conference Statement cites data showing the adverse effects of obesity include hypertension, hypercholesterolemia, type II diabetes, coronary artery heart disease and some forms of cancer. In terms of longevity, the mortality rate has been reported to be as much as 1200
percent among the extremely obese (NIH, 1985).

Other studies (Bray, 1986; Bray & Gray, 1988; Brownell, 1984b; Burton, et al., 1985; Dawber, 1980; Feinleib, 1985; Garrison & Castelli, 1985; Hubert, Feinleib, McNamara, & Castelli, 1983; Munro & Stolarek, 1989) established connections between obesity and development of cardiovascular disease, digestive diseases, ischemic heart disease, arthritis, gout, congestive heart failure, cerebrovascular disease, gallbladder disease, hypothyroidism and jaundice.

In addition, the NIH (1985) stated the greatest adverse effect of obesity may be the enormous psychological burden it creates. Studies support that obesity does indeed carry social stigma and may severely limit educational and employment opportunities (Allon, 1973; Allon, 1982; Bray, 1986; Cahnman, 1968; Canning & Mayer, 1966; Harris & Smith, 1983; Larkin & Pines, 1979; McLean & Moon, 1980; Richardson, Hastorf, Goodman, & Dornbusch, 1961).

This research indicates the tremendous social pressure to be thin results in the obese experiencing extreme prejudice and discrimination.

Treatment results have been discouraging at best. Though the average dieter is overweight by more than 40 pounds only 5% of dieters are successful at losing that amount. The average weight loss is 11-12 pounds. Of
those people who are able to lose weight, it is estimated as high as 90-95% will eventually regain all of the lost weight following treatment (Bray, 1986; Bray & Gray, 1988; Brownell & Kramer, 1989; Burton et al., 1985). Some researchers have gone as far as to hypothesize that a cure for obesity is an impossibility (Kalodner & DeLucia, 1990).

The benefits of weight loss have also been well documented. Reduction in weight has been shown to reverse most, and in some cases all, the disadvantages of obesity (Bray, 1986). In cases of extreme obesity weight loss may be considered lifesaving (NIH, 1985).

In 1959, Stunkard and McLaren-Hume reviewed the results of thirty years of obesity treatment and concluded that most obese people will not stay in treatment for obesity and of those who do stay most will not lose weight. They further concluded that of those few who are able to lose weight most will regain it (Stern and Lowney, 1986).

Early treatment was based on the theory that overweight individuals overate simply because they lacked willpower. All that was needed was for the obese person to eat less. Physicians and other weight management professionals handed obese patients a diet to follow and expected the patient to follow that diet. The majority of
patients were unsuccessful at following the diet for a substantial length of time.

Treatment was also complicated by the common belief that curing obesity was simply a matter of somehow enabling the obese person to lose the excess weight. Once their weight was reduced the formerly obese would be able to live normally as they had before and the weight would stay off (Wilson, 1980). Only recently has obesity been recognized as a chronic disease which requires long term treatment and follow-up (Blackburn, Lynch, & Wong, 1986; Bray & Gray, 1988; Brownell & Kramer, 1989; Schlundt, Sbrocco, & Bell, 1989).

Behavioral techniques were applied to the problem of weight reduction for the first time by Ferster, Nurnberger and Levitt in 1962. Effects were reported to have been minimal but no outcome data was available. The original goal of behavioral treatment was to alter the eating habits in order to decrease caloric consumption (Brownell & Kramer, 1989; Wilson, 1980). Later, interventions to alter activity habits were added with the aim of increasing caloric expenditure.

In 1967, Stuart published results of his application of behavioral techniques. These results were a dramatic improvement over any reported earlier in the literature. From these optimistic results and Stuart's description of
treatment procedures has sprung a vast body of research on the behavioral treatment of obesity.

The first results of behavioral programs were published in the early 1970s (Brownell & Kramer, 1989). In its early development, theory was more important than actual weight loss. Investigators were excited by studies reporting 5 to 8 pound weight losses.

Though weight loss was minimal, these initial studies did produce two very important results. They provided an opportunity to develop and perfect the procedures of the behavioral program. They also attracted researchers in the areas of psychology and psychiatry.

Over the years the scope of behavioral treatment has broadened to focus not only on eating and exercise behaviors, but also attitudes, social support, nutrition and any other factors related to eating (Brownell & Kramer, 1989). Treatment incorporates numerous specific techniques in each of these areas to assist the patient in controlling his/her behavior.

Brownell (1989) suggested a list of 89 possible interventions including eating in one place, shopping on a full stomach, exercising with a partner, and increasing fiber in the diet. The accepted procedure teaches the patient as many behavioral interventions as possible. The patient then incorporates these techniques to alter
his/her eating behaviors.

Though behavioral treatment was advancing, it was still lacking in two important areas. Questions arose as to the long-term efficacy of behavioral treatment. In addressing that question, Stalonas, Perri and Kerzner (1984) confirmed other disappointing long-term outcomes in a 5-year follow up. Their data supported gradual return to original, pretreatment weight. In reviewing present literature Brownell and Kramer (1989) were forced to draw the same conclusion. Abramson (1982) concluded there has been no demonstration of the long-term effectiveness of behavioral treatment.

The second shortfall is of particular significance to the more than seven million morbidly obese who are in excess of 50% or 100 pounds over ideal body weight. Though weight losses increased with the development of behavioral treatment, no program reported average weight losses of greater than 30 pounds (Brownell and Kramer, 1989). More extreme caloric restriction is necessary for extremely obese patients to lose a significant amount of weight in a reasonable amount of time. This was the basis for the development of very-low-calorie diets (VLCD) (Howard, 1989). Though it wasn't until 1966 that Bolinger and coworkers became the first researchers to formulate the concept of a "protein-sparing fast" the development of
the VLCD dates back to 1924 when the first scientific studies were conducted by Mason (Blackburn, Lynch, & Wong, 1986).

Early researchers implemented total fasting as a method to induce rapid weight loss. What they discovered was a significant loss of body protein. Because the body does not produce protein and was receiving none while on total fast it began to use up protein in the form of muscle. Their conclusion was that the state of malnutrition was self-defeating.

In 1954, the Simeons diet, consisting of meat/fish, green vegetables, crispbreads and fruit, was developed. It totalled 575 kcal and included 80g protein. Bollinger (Bollinger, Lukert, Brown, Guevara & Steinberg, 1966) and Appelbaum (Apfelbaum, Bagaitis, Giachetti & Serog, 1981) introduced the use of lean meats and egg albumin in 1966. These regimens were termed by Blackburn as protein sparing (PSMF) because they provided enough protein to sustain the body's lean muscle. The terminology was later changed to very-low-calorie diet (VLCD) which refers to complete diets containing nutrients other than protein (Howard, 1989).

In the early 1960's researchers discovered the importance of carbohydrate in a calorie restricted diet (Genuth, Castro, & Vertes, 1974; Genuth & Vertes, 1974;
Genuth, Vertes, & Hazelton, 1978). Inclusion of carbohydrate corrected defects such as excessive ketosis, loss of sodium, potassium and magnesium and high serum uric acid.

VLCD research encountered a major setback in 1977-78 when 17 deaths were associated with liquid protein diets. These deaths were attributed to use of protein of extremely poor biological quality. This lack of quality protein caused the body to utilize its own stored muscle protein. Most of the resulting deaths were attributed to heart complications due to muscle deterioration and excessive strain on the heart. The safety of VLCDs came under close scrutiny.

Commercial VLCDs became available in 1978. It is estimated that over the past ten years 12-15 million people world-wide have used VLCDs.

To address the safety controversy 'the COMA report' was published by the United Kingdom Department of Health and Social Security (Department of Health and Social Security, 1987). The report established the following guidelines and recommendations for use of VLCDs:

1. VLCDs should be considered only after the failure of conventional food diets.

2. People should consult their physician before using them.
3. VLCD use is contraindicated in infants, children, pregnant/lactating women, the elderly, and people with BMI below 25, porphyria or gout.

4. The minimum composition should be 400 kcal/40g/-day protein for women, 500 kcal/50g protein for men and tall women plus recommended daily allowances (RDA) of vitamins and minerals included as part of the product.

The Journal of the American Medical Association (JAMA) published a commentary by Wadden, VanItallie and Blackburn (1990) which presented further guidelines for the safe use of VLCDs. They recommend these diets be limited to persons who are a minimum of 30% overweight, have had a recent medical examination and electrocardiogram with satisfactory results and who are free of contraindications which include a recent myocardial infarction, cardiac conduction disorder, history of cerebrovascular, renal or hepatic disease, cancer, type I diabetes or significant psychiatric disturbance. These authors further recommend patients receive appropriate medical supervision throughout treatment including weekly examination by a physician and assessment of electrolyte levels every other week.

In spite of the difficulty in their development VLCD's have great value. It is the only dietary approach which consistently gives excellent weight loss results in
the severely obese (Marks & Howard, 1986). Compliance is aided by the encouragement of rapid weight loss. Some patients find VLCDs easier to follow than conventional diets because they are simple, restrictive, and clearly defined (Blackburn, et al., 1986; Munro & Stolarek, 1989). People also report they feel well, have few if any side effects, and are not hungry.

Many people achieved substantial weight loss with VLCDs and this approach became the treatment of choice for obesity (Blackburn, et al., 1986; Cox, Kreitzman, Coxon, Walls, & Rattan, 1989; Munro & Stolarek, 1989; Shapiro, Weinkove, Coxon, Kreitzman, & Rodgers, 1989; Stordy, 1989). The long term follow up results of the VLCD alone, however, mirrored that of conventional approaches. As the long term results of weight loss were collected in the early 1980s it became clear that losing weight was not the end of the problem, but that greater difficulty existed in maintaining the weight loss. The challenge now, according to Munro & Stolarek (1989), is to develop a program which will work effectively in conjunction with VLCD to enable maintenance of weight loss.

Numerous researchers have concluded that regardless of the method used to lose weight, a behavioral treatment component is necessary to achieve long-term maintenance (Bray & Gray, 1988; Brownell & Kramer, 1989; Hovell, et
Blackburn, Lynch and Wong (1986) stated more specifically the use of VLCDs in conjunction with behavior modification and careful physician-supervised follow-up care is the preferred approach to weight reduction.

Studies comparing weight loss of patients in treatment groups of VLCD alone, behavior treatment alone, and VLCD combined with behavior therapy showed patients in combined treatment having significantly higher weight losses (Hovell, et al., 1988; Kirschner, Schneider, Ertel & Gorman, 1988; Miura, Arai, Tsukahara, Ohno, & Ikeda, 1989; Wadden & Stunkard, 1986; Wadden, Stunkard, Brownell, & Day, 1984; Wadden, Sternberg, Letizia, Stunkard, & Foster, 1989).

Although research has compared weight loss programs with a behavioral component to those without, this investigator was unable to find any research conducted to evaluate the effectiveness of different behavioral methods in combination with the same form of caloric restriction.

In the many years of development of behavioral treatment of obesity some behavioral techniques and their combination have been found to be more effective than others (Brownell & Stunkard, 1980; Brownell, Stunkard, & Albaum, 1980; Foreyt & Kondo, 1984; Harris & Hallbauer, 1973). Finding the optimum behavioral method utilizing a
combination of the most effective techniques and application could maximize success of obesity treatment.

Self-monitoring, or record keeping, is a central component of behavior modification (Ferguson, 1975). When initially used it acts as a stimulus for controlled eating since people tend to eat less when they are recording intake. Ultimately it is an account of caloric intake and expenditure (Abrams, 1979). Record keeping has also been shown to increase motivation and awareness and serve as a data base for problem solving and behavior change (Brownell & Kramer, 1989). Cowles, Kaplan, Framer, & Lindewall (1984) found record keeping to be positively correlated with greater weight loss and likelihood of program completion. Wilson (1980) supported record keeping as a vital component in successful treatment.

Extensive research supports physical activity as the most consistent behavioral predictor of weight loss and maintenance of weight loss (Blackburn, et al., 1986; Blair, 1981; Colvin & Olson, 1983; Cowles, et al., 1984; Gormally, Rardin, & Black, 1980; Hill, Sparling, & Shields, 1987; Hoiberg, Berard, Watten, Caine, 1984; Marston & Criss, 1984; Oscai, 1973; Pavlou, Steffee, & Lerman, 1985; Warwick & Garrow, 1981). When comparing caloric restriction alone with caloric restriction combined with physical activity, those using combined
treatment lost a greater percentage of fat and less lean body mass (Bray & Gray, 1988).

Other recognized benefits of increased physical activity are increased rate of weight loss, increased resting metabolic rate, alleviation of mild depression, elevation of mood and improvement of self-concept. People who exercise regularly tend to weigh less, have a lower body fat percentage and are able to eat more than sedentary individuals (Blair, 1981; Oscai, 1973).

Evidence indicates exercise helps individuals maintain a reduced body weight not only through increased caloric expenditure but also because lifestyle changes necessary to increase activity help prevent gain (Blackburn, et al., 1986). Lemons, Kreitzman, Coxon, & Howard (1989) reported subjects on exercise regimes experienced a feeling of well-being and a conviction that the exercise was of considerable benefit. Their motivation to sustain the regime correlated with the success of their weight loss. Brownell (1984a) suggests an individual's success in obesity treatment may be predicted by his/her willingness and ability to be physically active.

Compliance is enhanced by presenting specific and well-defined assignments and encouraging patients to make a public commitment to completing them (Wilson, 1980). Thus behavioral compliance increases in a group setting.
and with the ease of implementation of the activity. Consistent findings in the literature show that as the complexity of treatment increases, compliance decreases.

In reviewing obesity treatment research findings Bray & Gray (1988) suggested other predictors of success to be initial one week weight loss, frequency and regularity of attendance at a weight loss program, and belief of the person that he/she can control his/her own weight. Maintenance results reported by Hovell, et al. (1988) supported programs concentrating on utilizing techniques that will increase completion rates.

Inclusion of a problem solving component encourages participants to become self-managers of their weight and provides them with a framework for dealing with difficult situations that arise following treatment (Ferguson, 1975). It identifies more effective alternatives to handling personal high risk situations by utilizing modeling, coaching, rehearsal, and feedback. (Schlundt, Sbrocco, & Bell, 1989).

The therapeutic relationship that exists in behavioral treatment of any complex problem is also important (Colletti & Brownell, 1982; Pistole, 1989; Wilson, 1980). Efficacy of behavioral methods and adherence to therapeutic assignments can be enhanced by a skilled therapist. Trust in the therapist can significantly
influence compliance and provide security and safety for the individual to experiment with behavioral changes. Findings of Halstead, Brooks, Goldberg, & Fish (1990) indicate practitioner and patient must work toward the strongest alliance possible for most satisfactory results.

Positive reinforcers such as praise and approval will increase the occurrence of the behavior it follows. The strength of the reinforcer is enhanced by the importance of the person providing the reinforcement. The more important the provider is, the greater the impact of the praise and approval. Studies have supported this in establishing weight loss behaviors (Brownell, Heckerman, Westlake, Hayes, & Monti, 1978; Weisz & Bucher, 1980). Reinforcement by significant others increases the likelihood of long term maintenance of those behaviors as well (Hall, 1980; Skelton & Levy, 1981). Punishment such as reprimand or threat of expulsion, however, leads to avoidance behaviors and lessens the likelihood that the desired behaviors will be developed and maintained. Punishment is often aversive enough to lead to discontinuation of the program.

A single leader group in which interaction is encouraged between the leader and the group members fosters the development of rapport and trust. This increases the power of reinforcers provided by that
leader. In a didactic group situation in which various leaders present information this connection is less likely to occur and the significance of the reinforcers is reduced.

Clearly, a behavioral program designed to utilize techniques and procedures correlated with the highest degree of weight loss and maintenance success should produce more optimum results than a program using fewer or less effective techniques. The following hypotheses will therefore be tested:

1. The primary leader/group participation model of behavioral treatment in which group II participated facilitates compliance with VLCD and results in greater weight loss than the didactic presentation of numerous behavioral techniques by various leaders in which group I participated.

2. Utilization of techniques shown to produce positive long term results in the primary leader/group participation model of group II will produce a higher percentage of patients completing treatment and entering the maintenance phase of the program than the didactic model of group I.

3. The effectiveness of techniques used in the primary leader/group participation model of group II will result in lower attrition than didactic model of group I.
CHAPTER II

METHOD

SUBJECTS

Subjects were 28 male and 106 female patients admitted to the medically supervised supplemented fasting program at Risk Factor Clinic in Portland, Oregon. All patients were referred to the program by their primary physician. Subjects participated in one of two behavioral treatment modes dependent upon date of admission. Patients from the designated time periods were matched by gender, percent over ideal weight and age. The matching process resulted in 67 pairs of subjects representing the two groups. Baseline characteristics for the groups are shown in Table I.

Each subject signed an Informed Consent Form releasing relevant information for use in conducting research. Confidentiality of patient data and identity was guaranteed. Patients had the option of discontinuing treatment at any time.
TABLE I

BASELINE CHARACTERISTICS OF SUBJECTS*

<table>
<thead>
<tr>
<th>Variable</th>
<th>Group I</th>
<th>Group II</th>
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<tr>
<td>Age, years ± s.d.</td>
<td>40.8 ± 7.6</td>
<td>40.9 ± 7.4</td>
</tr>
<tr>
<td>Percent Over Ideal Weight</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Percent ± s.d.</td>
<td>73.9 ± 36.5</td>
<td>73.8 ± 26.1</td>
</tr>
<tr>
<td>Weight, lbs ± s.d.</td>
<td>247.6 ± 61.2</td>
<td>246.4 ± 57.7</td>
</tr>
<tr>
<td>Height, ins ± s.d.</td>
<td>66.2 ± 3.6</td>
<td>66.1 ± 3.0</td>
</tr>
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</table>

*None of the differences between groups were statistically significant.

PROCEDURE

Each patient completed an application and medical history for determination of appropriateness of treatment. Patients were at least 20% above their ideal body weight and had none of the following contraindications present: history of active liver disease; myocardial infarction or cerebral vascular accident within the past six months; accelerated angina; history of alcohol or drug addiction; pregnancy or lactation; active ulcer disease; and recent treatment for psychiatric illness. All patients were then
evaluated thoroughly with a review of medical history, physical examination, electrocardiogram, multiphasic blood chemistry, lipid profiles, and thyroid function tests. Each patient completed a Beck Depression Inventory for detection of chronic depression.

The patients began the program in groups ranging in size from 12-22. They were instructed to stop all food except for non-caloric fluids and were started on a VLCD supplement of HMR 500 or HR 70 to be taken five times per day. This nutritionally complete dietary supplement developed by Health Management Resources is based on non-fat dry milk and egg white. The supplement has a superior amino acid profile and contains 150% of the RDA for most nutrients. The HMR 500 contains high enough levels of potassium (56 meqs.) to make supplementation unnecessary in most cases and those patients consuming lactose-free HR 70 take supplemental potassium. The HMR supplement also contains more carbohydrate than any leading supplement (79 grams) which maximizes protein sparing and reduces micronutrient loss.

Patients were instructed to attend clinic weekly at the designated time. Weekly visits consisted of weigh in and medical monitoring including blood pressure. Blood was drawn every other visit. Patients then attended an educational/behavioral group session.
The 67 patients in treatment mode one (group I) were admitted to the fasting program between June 1985 and June 1986. The behavioral component of the program consisted of 60 minute weekly group sessions. The group presentations were didactic and predominantly theoretical in nature. Lectures were presented by various clinic staff including a nutritionist, nurse practitioners, and two lifestyle counselors, one with a Ph.D. and the other with a M.S. in psychology. Although two staff members had lost weight in the past none had participated in a fasting program. The 22 week curriculum consisted of various weight related topics in random order. No fundamentals were presented to tie the various topics together. Patients were introduced to as many behavioral techniques relating to weight loss as were available. Patients were encouraged to select techniques and implement them on their own. No follow up was done to see if any techniques had actually been implemented or to evaluate effectiveness of those that were used. Two unexcused absences from clinic were grounds for dismissal from the program, but patients were not required to make up missed groups. Discussion of noncompliance with the fast (eating) was not acceptable in group. Patients were told noncompliance was grounds for termination from the fasting program.

The 67 patients in treatment mode two (group II) were
admitted to the fasting program between January 1989 and January 1990. Prior to beginning the program patients agreed to commit to weekly attendance, keeping records and joining the maintenance program. The behavioral component consisted of required 90 minute weekly group sessions. The first 30 minutes of group were spent on problem solving, discussion of fasting and maintenance issues, planning, goal setting, behavior shaping and follow up of plans and goals from the previous week. This process included openly reporting physical activity calories for the previous week and establishing a goal for the upcoming week. The subsequent 60 minutes were spent in an educational format in which patient participation was encouraged. The behavioral staff included a nutritionist and a behavioral health educator with master's training in psychology. Both leaders attended introductory and advanced trainings through Health Management Resources. The health educator had participated in the fasting program and was maintaining a significant weight loss. Each group was assigned to one primary group leader. This leader was responsible for tracking each member of the group throughout the program, facilitating the first half hour of group, collecting individual data on compliance, record keeping and physical activity, and conducting the majority of the educational sessions. The
second group leader presented a few special topics. The curriculum was designed to teach fundamental skills such as record keeping and physical activity first and then to build on those with more specific and individual information as the group progressed. Fundamentals were reviewed weekly and a connection was drawn with the new topic being introduced. Two unexcused absences were grounds for dismissal from the program and patients were required to make up the actual topics they missed when absent. Discussion of noncompliance was acceptable and problem solving was done to help patients resume fasting. Noncompliance was not grounds for dismissal from the fasting program. Table II shows a comparison of structure and content of the two groups.

**TABLE II**

**COMPARISON OF STRUCTURE AND CONTENT OF GROUPS**

<table>
<thead>
<tr>
<th></th>
<th>Group I</th>
<th>Group II</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Structure</strong></td>
<td>22 week curriculum</td>
<td>22 week curriculum</td>
</tr>
<tr>
<td></td>
<td>weekly meetings</td>
<td>weekly meetings</td>
</tr>
<tr>
<td></td>
<td>60 minute</td>
<td>90 minute</td>
</tr>
<tr>
<td></td>
<td>didactic</td>
<td>problem solving</td>
</tr>
<tr>
<td></td>
<td>theory based</td>
<td>skill acquisition</td>
</tr>
<tr>
<td></td>
<td>5 presenters</td>
<td>1 primary leader</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1 secondary leader</td>
</tr>
<tr>
<td></td>
<td></td>
<td>data collection</td>
</tr>
<tr>
<td></td>
<td>Group I</td>
<td>Group II</td>
</tr>
<tr>
<td>--------------------------</td>
<td>-------------------------------------------------------------------------</td>
<td>--------------------------------------------------------------------------</td>
</tr>
<tr>
<td><strong>Patient commitment</strong></td>
<td>attend clinic weekly for medical supervision</td>
<td>attend clinic weekly for medical supervision and group keep records join maintenance</td>
</tr>
<tr>
<td><strong>Content</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Record Keeping</strong></td>
<td>concept one of many techniques available no records required multiple form options presented</td>
<td>skill data supporting essential for weight-loss maintenance begin keeping records week 2 data collected on compliance weekly specific form provided</td>
</tr>
<tr>
<td><strong>Physical Activity</strong></td>
<td>concept helpful no follow up</td>
<td>skill essential taught in calories expended weekly goals set problem solving to reach goals</td>
</tr>
<tr>
<td><strong>Environmental Control</strong></td>
<td>concept behavior modification techniques presented</td>
<td>practical application problem solving of individual needs and situations</td>
</tr>
<tr>
<td><strong>Calories</strong></td>
<td>helpful to know</td>
<td>taught system for learning calories</td>
</tr>
</tbody>
</table>
Upon completion of the fasting phase of the program, patients from both subject groups entered a minimum four week refeed phase during which they were slowly reintroduced to food. Fasting phase completion was determined by attainment of goal weight or inability to continue fasting. Following refeed, patients entered the 18 month maintenance phase of the program. Group I patients who reached maintenance prior to completion of the 22 week curriculum transferred immediately to a maintenance group. Patients in group II remained with the fasting group through the entire 22 weeks even if they had completed the fasting and refeed phases. Patients who had not completed fasting at the end of 22 weeks continued with another fasting group.
CHAPTER III

RESULTS

Total weight loss for Group I was 59.7 ± 43.0 pounds and for Group II was 59.1 ± 32.8 pounds. Total percent of body weight lost during the fasting phase was 23.1 ± 13.1 and 23.6 ± 9.9 respectively. T-tests for dependent means showed no significant difference between groups for either measure (T=0.130 and T=-0.020). Table III shows beginning and ending measures for both groups.

Changes from baseline in weight (T=11.364 for group I and T=14.734 for group II), percent overweight (T=11.583 and T= 15.274) and cholesterol (T=7.131 and T=6.848) were statistically significant for both groups at p<.001. Change in triglyceride level was significantly different from baseline for both groups at p<.005 (T=3.210 and T=3.294).

Beginning cholesterol level was significantly different between groups at p<.05 (T=2.000) and ending cholesterol level was significantly different between groups at p<.01 (T=2.772). Beginning triglyceride level was significantly different between groups at p<.10 (T=-1.902) but no significant difference existed between
groups on ending triglycerides (T=0.688).

**TABLE III**
PRE AND POST WEIGHT AND LIPID MEASURES

<table>
<thead>
<tr>
<th>Variable</th>
<th>Group I</th>
<th>Group II</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Weight, lbs ± s.d.(a)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pre</td>
<td>247.6 ± 61.2</td>
<td>246.4 ± 57.7</td>
</tr>
<tr>
<td>Post</td>
<td>187.9 ± 49.6</td>
<td>187.4 ± 49.2</td>
</tr>
<tr>
<td><strong>Percent Overweight, % ± s.d.(a)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pre</td>
<td>73.9 ± 36.5</td>
<td>73.8 ± 26.1(e)</td>
</tr>
<tr>
<td>Post</td>
<td>32.1 ± 30.5</td>
<td>32.1 ± 31.8</td>
</tr>
<tr>
<td><strong>Cholesterol ± s.d.(a)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pre</td>
<td>218.6 ± 33.7(d)</td>
<td>203.6 ± 46.3(d)</td>
</tr>
<tr>
<td>Post</td>
<td>189.4 ± 35.6(c)</td>
<td>171.8 ± 35.7(c)</td>
</tr>
<tr>
<td><strong>Triglyceride ± s.d.(b)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pre</td>
<td>134.2 ± 71.9(e)</td>
<td>172.4 ± 189.9(e)</td>
</tr>
<tr>
<td>Post</td>
<td>110.1 ± 62.9</td>
<td>103.9 ± 46.6</td>
</tr>
</tbody>
</table>

(a) Significant change from baseline for both groups at p<.001.
(b) Significant change from baseline for both groups at p<.005.
(c) Difference between groups was significant at p<.01.
(d) Difference between groups was significant at p<.05.
(e) Difference between groups was significant at p<.10.
Subjects in group I fasted an average of 20.9 ± 12.4 weeks and group II 18.9 ± 9.8 weeks. No significant difference existed between groups on this variable (T=1.211).

A simple Chi-Square test showed the 78% of subjects from group II joining the maintenance program was a statistically significant increase over the 52% joining from group I ($\chi^2=9.47$, p<.005).

A Chi-Square test was also performed to detect difference in drop out rates of the two groups. The 33% attrition rate of group I was significantly higher ($\chi^2=3.94$, p<.05) than the 18% for group II.
CHAPTER IV

DISCUSSION

Very-low-calorie diets have consistently produced significant weight loss in obese patients. The weight losses with this method of treatment have been consistent regardless of any existing behavioral component. The lack of significant difference in total weight loss for the two groups did not support the hypothesis that a primary leader/group participation model would facilitate greater compliance and result in larger weight loss for group II. The success of very-low-calorie diets in the weight loss phase may be primarily dependent upon the patients' decision and ability to comply with the fasting regimen. With such a rigid and clearly defined method of calorie restriction the addition of a behavioral component would have no impact on weight loss. The simplicity and restrictiveness aids compliance and the rapid weight loss supplies needed encouragement. Patients also report experiencing feelings of euphoria resulting from compliance with fasting which then encourage continued compliance. There are no choices to be made by the patient which might be affected by behavioral techniques.
Once a patient is able to comply with the supplemented fast, weight loss cannot be impacted by introduction or implementation of behavioral techniques primarily designed to assist in the maintenance of the weight loss. On a set caloric intake patients are limited to the number of pounds they can lose each week. Because the patients were matched for gender, percent over ideal weight and age, patients fasting in either group would show comparable weight losses.

This lack of difference in weight loss between the two groups also supports that losing weight is no longer the unsolved problem. Patients report that once they are past the initial weeks the VLCD is easy and they experience little, if any, hunger. Simply weighing in weekly and receiving the medical monitoring required to continue the VLCD may supply the patients with the structure and accountability they need to comply with a program this rigid. The result of this compliance is weight loss.

The statistically significant changes from baseline in weight and percent overweight give additional support for the effectiveness of the VLCD in treatment of obesity. Other treatment options seldom result in losses of greater than 30 pounds with the average being 11-12 pounds. Both groups in this study averaged losses of over 59 pounds.
with losses as high as 197 pounds in group I and 160 pounds in group II.

The reversal of health complications of obesity through weight loss is seen in reduction from baseline of lipid levels in both groups. The difference between groups in pre and post cholesterol levels may be attributable to increased general societal attention on the choices and behaviors that affect cholesterol level and the dangers of high cholesterol. This increased awareness may have resulted in patients in group II making some changes that would lower cholesterol prior to joining the program.

Beginning triglyceride levels were significantly higher for group II than group I. This is consistent with the continued increase in percentage of fat in the American diet and the resulting increase in incidents of hypertriglyceridemia. Lack of significant difference in final triglyceride levels may be the result of reduction to normal range resulting from the fasting treatment and approaching the lower limit of normal range.

The change in behavioral treatment had a significant impact on attrition rate and percentage of patients entering the maintenance phase of the program. The statistically significant 15% reduction in attrition rate for group II supports the hypothesis that the primary
leader/group participation model would increase program compliance through patient commitment to attend and keep records and result in a lower percentage of drop outs. The 26% increase in patients entering maintenance in group II over group I was statistically significant and thus supports the hypothesis that utilization of self-management skills in the primary leader/group participation model would produce a higher percentage of patients completing treatment and continuing with the maintenance phase. Research has shown that the longer a patient remains in treatment the greater their chance for success. These significant findings support an increased chance of long term success for patients in group II.

Some variables would make a small percentage of drop outs inevitable for either group. Some patients find it necessary to drop for financial reasons or for other unforeseen personal life events such as pregnancy, relocation or illness. Some patients report experiencing a feeling of optimism and control as they begin to lose weight successfully that may encourage discontinuation from the program. The basis of this feeling is the belief that now that they have gotten started and are losing weight they could continue to lose weight on their own. This results in some patients leaving the program.

Patients in both groups remained in the program as
long as they were able to comply with the VLCD and they were losing weight. Patients in group I unable to comply with the fasting regimen reported dropping in anticipation of being dismissed from the program. Since noncompliance was not discussed among members of the group or with the group leaders the patients were overcome with feelings of failure and guilt that resulted in dropping from the program. Weight loss was the only empirical measure of success and deviation from fasting would decrease or halt weight loss and eliminate that element of encouragement. Since there were numerous leaders the patients were more often uncomfortable seeking help from any one of them when having difficulty.

The decrease in attrition rate for group II was attributable to several variables. The initial commitment on the part of the patient to follow through with the program was a point of focus during difficult times. It was also a reminder that this is a long term process and though there are difficult stages involved, continuing to the end increases chances of success. The increase in structure and problem solving assisted in making compliance easier for those having difficulty. Also the ability to discuss difficulties around staying on the program with their group leader and other fasting patients allowed more objectivity and lessened feelings of failure.
The identification with one primary group leader might made seeking help easier. Willingness of the staff to work with patients who were unable to comply with the supplemented fast kept patients in the program longer. Empirical measures of success other than fasting and weight loss such as records and physical activity level gave patients other behaviors to focus on developing. Role modelling of staff members who had lost weight on the fast and were successfully doing maintenance gave patients evidence that it would work if they followed through.

A maintenance phase was offered to groups in both behavioral approaches. It is reasonable that some patients would join with the understanding that if it was important enough to offer they might need to join. Some attention was placed in both treatment modes on the importance of long term treatment follow-up. It is likely, however, that there were patients in both groups who still believed that losing the weight was the entire battle. Patients holding this belief would be unlikely to enter the maintenance phase since they also believed they could keep the weight off on their own.

Several changes in the program contributed to the significantly higher percentage of patients entering maintenance from group II. Patients made a commitment to joining the maintenance phase even before they began
fasting. This commitment and the necessity of maintenance was addressed repeatedly throughout the weight loss phase. Unlike those in group I, patients in group II acquired skills of self-management that they practiced and had in place to carry them into maintenance. The fundamental skills of record keeping and physical activity gave patients some means of control over their weight maintenance. This gave them empirical representation of their behavior changes. Role modeling of staff successfully maintaining reinforced the importance and gave patients encouragement that they could keep the weight off if they were willing to do the work.

Other variables did exist that may have impacted the outcome of treatment. No method existed for measurement of group leader effectiveness. A change in staff took place with the implementation of the primary leader model. One leader did conduct groups under both models. Although all staff had comparable credentials there was no evaluation of teaching effectiveness as a group leader. One leader in group II had been a successful participant in the program. This afforded a sense of understanding and empathy group I did not experience and increased program credibility. The impact of increase in length of session from 60 to 90 minutes alone could not be measured and may have affected the results.
The use of VLCD progressed from an acceptable treatment for obesity to a recommended treatment during this time period. This increased confidence in committing to the program and trust the treatment was effective for patients in group II.

The true test of any behavioral component is in long term follow-up to evaluate duration of new behaviors and amount of weight kept off. This study does show, however, that specific elements of a behavioral treatment model can impact the outcome of treatment at least in terms of keeping patients in treatment longer and getting them into a maintenance program. A follow up study of these patients to collect data on long term results would provide valuable information on the difference between the two models. The next step beyond that would be to develop a way to identify which specific elements have the greatest positive impact and how to implement them in the most effective manner.
CHAPTER V

CONCLUSION

It is clear the very-low-calorie diet is an effective approach to weight loss for obese patients. The challenge remaining is the development of an effective behavioral component to enable patients to keep the weight off long term. Increased structure, accountability and patient commitment appear to be crucial elements of effective behavioral treatment. The medical community and weight loss professionals are now recognizing obesity as a chronic problem which necessitates long term treatment. Implicit in this long term treatment is retreatment for weight regained. This study suggests that developments can be made to decrease the need for retreatment by keeping patients in treatment longer and facilitating long term weight-loss maintenance.
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