



Two year maintenance of weight loss after a VLCD and behavioural therapy for obesity: correlation to the scores of questionnaires measuring eating behaviour

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OBJECTIVE: To investigate changes in weight, Three Factor Eating Questionnaire and Binge eating scores during a two-year period from the start of a VLCD (Nutrilett®) and behavioural modification therapy for obesity.

DESIGN: Prospective study of a 17-weeks weight loss programme with one- and two-year follow-up visits.

SUBJECTS: 62 healthy, overweight subjects without previous eating disorders. The mean (\pm SD) age 41 ± 8 years and BMI 36.4 ± 2.6 kg/m².

MAIN OUTCOME MEASURES: Weight loss, Binge eatingscale, Bulimic Investigatory Test and Three Factor Eating Questionnaire before and after therapy and at 1 and 2 year control visits.

RESULTS: The mean weight loss (\pm SD) at the end of the treatment was 14.9 ± 4.6 kg ($n = 59$) and at the two-year control 5.8 ± 7.6 kg ($n = 57$). After two years 20 (32%) patients had a weight loss of more than 10% (good result), 24 patients a weight loss of 0-10% of their initial weight (partial result) and 13 patients weighed more than before therapy (poor result). The mean binge eating, disinhibition and hunger scores decreased in all patients by the end of the therapy. At the end of two years these improvements in the scores were maintained in patients with a good result but the scores returned to the pretreatment levels in the patients with partial or poor result. The mean restraint scores increased in all patients after treatment and were maintained in those with a good or partial result.

CONCLUSIONS: VLCD combined with behaviour modification is a useful mode of therapy for obesity with low drop-out rate and majority (71%) of patients below pretreatment weight at the two-year control. One third of the patients succeeded to maintain positive changes in the scores measuring eating behaviour which was associated with sustained weight loss.

Keywords: obesity, weight loss, very-low-calorie diet, binge eating, eating behaviour

Introduction

The high prevalence of obesity and obesity-related diseases in Finland^{1,2} demands effective methods for weight loss. With conventional low-calorie diets weight losses are modest, whereas programmes including very low calorie diets (VLCDs) provide larger and more rapid weight losses.³ They are safe and easy to use⁴ and have become popular in the treatment of moderately and severely obese patients. The maintenance of weight loss after treatment with VLCD alone is relatively poor.⁵ However, weight regain can be reduced by a combination of behaviour therapy and VLCD.⁶

Recently binge eating behaviour has been found to be common among obese patients in weight loss treatment programmes.⁷ A link between strict dieting and binge

eating in obese patients has been noted by many investigators, but the relationship is not as clear as in anorexia or bulimia nervosa.⁸ Restrained eating has initially been viewed in this connection as a trigger of binge eating.⁹ Later, restrained eating has also been used as an indicator of cognitive eating control during successful behavioural treatment of obesity.¹⁰ This was measured by a three factor eating questionnaire by Stunkard and Messick.¹¹

Special concern has been raised that weight loss programmes which include VLCD increase the risk of bingeing. Prolonged modified fasting may lead to loss of eating control resulting in binge eating. In recent studies both an increase¹² and decrease¹³ in bingeing after VLCD have been reported during short-term follow-up periods.

We investigated changes in eating behaviour in 62 moderately and severely obese patients during a two-year period from the start of seventeen weeks of therapy which consisted of VLCD and behaviour modification.

Methods

Subjects

The subjects were recruited by an advertisement in a magazine seeking obese persons to participate in an obesity treatment study using a medically supervised very low calorie diet programme. Six hundred subjects responded to the advertisement and they were initially screened for suitability by telephone. The criteria for entering the study were age 20–60 years, stable weight during the preceding 2 months, body mass index 32–40 kg/m², no diabetic or hypertensive medication and a subjective feeling of good health. A random sample of 73 suitable responders was screened: they were examined by a physician, weight and height were measured, blood pressure and medications were recorded and ECG, blood chemistry profile and analysis of urine were done. At screening eleven patients were excluded. Exclusion criteria were major diseases, lactose intolerance, previous eating disorder (anorexia or bulimia, definition by interview and previous medical history) and an alcohol problem.

Sixty-two patients (57 women and 5 men) entered the study. The mean age was 41 years (range 22–55). The mean weight before treatment was 99.0 kg (78.6–122.0) and the mean body mass index was 36.4 kg/m² (31.5–42.0). Six percent of the subjects had never earlier attempted to lose weight, 63% had been in a weight reduction programme and 31% had tried by themselves to lose weight. 78% were married, 11% single and 11% divorced.

Procedure

The weight reduction programme consisted of a group therapy which included twelve 1 h sessions during 17 weeks. There were four groups, two in Turku and two in Helsinki. The weight reduction programme was identical in every group. The groups were conducted by two dietitians (Turku) and by a trained nurse (Helsinki).

During the first visit general information was given, and the patients were instructed keep food diary during the first week. This was the basis for the future dietary changes. From the second visit patients began an eight-weeks' VLCD period. During this, the VLCD completely replaced normal food, and only a limited amount (about 100 kcal per day) of low calorie vegetables were allowed. The patients were recommended to drink a minimum of two liters of non-caloric beverages daily. The VLCD preparation used was Nutrilett® (Nycomed Pharma AS). The daily dose was five sachets and this contained 429 kcal/1759 kJ of energy, 60 g of protein, 7 g of fat, 30.5 g of carbohydrate of which 17.5 g was fiber. The VLCD preparation was in powder form and was mixed with water. In addition to the powder preparation, the VLCD included one daily tablet containing the recommended daily amounts of vitamins, minerals and trace elements and one capsule containing essential fatty acids. After the VLCD phase, normal food was reintroduced during the following eight weeks. The patients changed gradually to normal

diet by eating three sachets and one limited meal during first week and a 1200 kcal/day diet without VLCD during the second week after VLCD. After that, the patients were advised to reduce their caloric intake by 500–1000 kcal from their pretreatment levels mainly by decreasing the amounts of fat in food.

Each 1 h visit included weighing in light clothing without shoes and behaviour therapy conducted by the therapist. Issues included recording of eating behaviour (amounts, times, etc.), control of eating stimuli, slowing of eating rate, planning ahead, eating in only one place, using a complete place setting, having only low-calorie snacks, modifying thoughts and emotions concerning eating and weight loss, goal setting to help change eating habits, discussions of the caloric and nutrient content of foods and low-calorie shopping and cooking. Patients were encouraged to increase their exercise corresponding to a 30 min walk daily. The focus of treatment was behavioural, emphasizing the identification of eating-associated cognition and alteration of behaviour.

There were two follow-up visits: one year after (month 12) and approximately two years after the start of the treatment (month 24–27). During follow-up, no special maintenance programme was used. Patients were free to attain other obesity treatments or use VLCD by themselves. All 56 subjects at the one year control were weighed. At the two-year control, 48 (84%) of the 57 patients were weighed and the weight of nine (16%) subjects was obtained by telephone.

The VLCD preparation and the whole treatment programme was free of charge for the patients. The patients gave informed consent before the start of treatment, and they were free to withdraw from the study at any time during the treatment. The Ethics Committee of the Third Department of Medicine in Helsinki University Hospital approved the study protocol.

Questionnaires

Patients completed four questionnaires before the start of the treatment, at the end of the treatment (week 17), at the one-year and two-year visits. They were completed during the sessions, except at the 2-year control when 14 patients completed questionnaires at home. One patient had elective surgery during the one-year control. Her questionnaires and weight data from that time are not available and she was excluded from the repeated data analysis.

The *Symptom Check List* (SCL-90-R) by Derogatis¹⁴ was used to measure psychiatric symptoms. This was composed of 90 items reflecting psychiatric symptoms, and these are rated on a five-point scale of distress. There are nine subscales (somatization, obsessive compulsive, interpersonal sensitivity, depression, anxiety, hostility, phobic anxiety, paranoid ideation and psychotic behaviour) and an overall index of psychopathological status, General Symptom Index (GSI).

The *Bulimic Investigatory Test* Edinburgh (BITE) by Henderson and Freeman¹⁵ consists of a symptom subscale (30 items) and a severity subscale (six items) measuring binge eating pattern. Question no. 13 was excluded

because of a technical error throughout the study. The total score (symptom subscale + severity subscale) is used in this study.

Binge Eating Scale (BES) by Gormally¹⁶ consists of 16 items.

Three-Factor Eating Questionnaire (TFEQ) by Stunkard and Messick¹¹ measures three aspects of eating attitudes: restrained eating (21 items), disinhibition (16 items) and hunger (14 items).

Statistical analysis

The data were divided into three outcome groups which were compared by one-way analysis of variance followed by the Scheffe's multiple comparison method. Changes within groups were calculated by analysis of variance for repeated measurements. Correlations between the numerical variables were studied by using bivariate scatter plots and Pearson's correlation coefficient. This analysis was performed by using the BMDP software.¹⁷

The effects of potential prognostic factors on weight loss were studied by linear regression analysis. The analyses were performed by the SAS program. All tests were two tailed and the significance level was 0.05.

Results

Drop-outs

No one dropped out during the VLCD period. During refeeding, two patients dropped out without telling us any reason, and one patient discontinued (as suggested by her own doctor) because of worsening asthma. At the one year control one patient withdrew because of work on a ship and one patient could not be reached. One woman had elective surgery at that time, but she was reached for the two year control. The mean initial weight and initial scores of the questionnaires of the drop-outs did not differ significantly from those who completed the programme and follow-up (data not shown). The mean weight loss during VLCD of the five who later dropped-out was 10.2 kg (SD 4.5). At the end of the programme the mean weight loss of the two who dropped out during the follow-up was 15.4 kg (SD 2.7).

Weight data

The mean weight reduction during the eight-weeks VLCD ($n = 62$) was 12.9 kg (range 4.6–21.6), at the end of the programme ($n = 59$) 14.9 kg (5.5–25.1), at the one-year control ($n = 56$) 9.0 kg (–1.6–24.9) and at the two-year control ($n = 57$) 5.8 kg (–9.8–22.0). At the two-year control 20 (32%) patients had lost more than 10% and 24 (39%) patients had lost 0–10% of their initial weight. 13 patients (21%) were above pretreatment weight. At the two-year control the mean weight reduction of the nine patients who gave weight by phone was 6.1 kg (–6.2–14.5) and that of the 48 patients who were weighed 5.7 kg (–9.8–22.0).

Linear regression analysis showed no effect of sex, marital status, education, smoking, age of obesity onset

or previous weight loss attempts on weight loss at one or two years. Those who exercised before treatment at least once a week for 30 min had a better one-year weight loss result than those who did not exercise at all ($p < 0.05$), but the two-year weight losses between these groups did not differ significantly.

According to the outcome at the two-year control the patients were divided into three outcome classes: good result, weight loss more than 10%, partial result, weight loss 0–10% of the initial weight and poor result if the weight was above the pretreatment level. Weight changes of these three outcome groups over the two years are presented in Figure 1 and baseline data in Table 1. Statistically significant differences were not detected between these three outcome groups in initial weight or BMI, but those with a good result were significantly older than those with a poor result. Three of the nine patients who gave weight by phone at the two-year control had good result, four had partial and two had poor result in weight loss.

Eating questionnaires and psychiatric data

Within the three outcome groups the questionnaire scores over two years are presented in Figures 2 and 3. Between these outcome groups the baseline scores of the binge scales and TFEQ did not differ significantly. The scores between men and women did not differ significantly at any timepoint, so their results were combined.

The mean eating behaviour and psychological scores of the 56 patients (of whom data at all timepoints were available) showed a significant decrease at the end of treatment, and a return to the pretreatment level later (Table 2) in BES, disinhibition and hunger scores. Neither the baseline BES ($r = -0.14$; $p = 0.29$), BITE ($r = -0.15$ and $p = 0.27$), nor TFEQ scores (restraint $r = 0.04$, $p = 0.77$, disinhibition $r = -0.18$, $p = 0.17$ and hunger perception $r = -0.03$, $p = 0.82$) correlated with the two-year weight loss. In the SCL-90, baseline GSI did not correlate with the final weight loss result

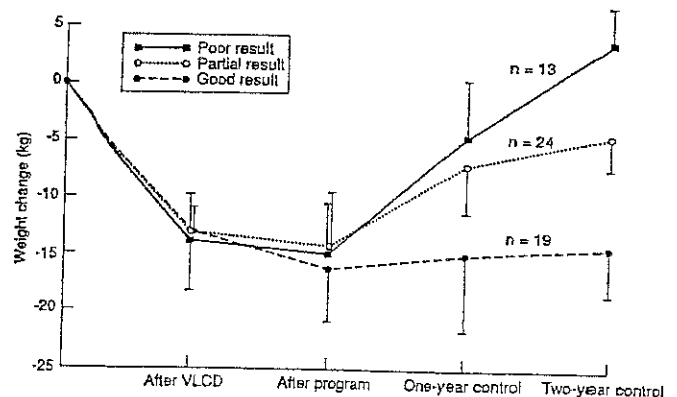


Figure 1 Changes (mean \pm SD) in weight during treatment and follow-up in the three outcome groups. Good result is more than 10% weight loss, partial 0–10% weight loss and poor result increased weight from pretreatment weight at the two-year follow-up.

Table 1 Demographic and weight data in the three outcome groups. The values are mean (SD)

	Good n = 20	Partial n = 24	Poor result n = 13
Sex (male : female)	2 : 18	1 : 23	1 : 12
BMI (kg/m ²)	35.7 (2.7)	36.5 (2.2)	36.7 (2.8)
Age (years)	44.2 (7.6)	39.6 (9.5)	38.1 (4.5)*
Weight (kg)	96.4 (10.5)	98.7 (8.6)	101 (13.7)

* $p < 0.05$ as compared with the good outcome group (analysis of variance).

($r = -0.08$, $p = 0.54$). The baseline GSI correlated significantly with the baseline BES ($r = 0.40$, $p = 0.001$) and BITE ($r = 0.42$, $p < 0.001$), but not with the baseline BMI ($r = 0.08$, $p = 0.53$). Age did not correlate with any of these baseline scores.

Changes in the binge eating scores: A decrease in scores over the two years (BES $r = 0.5$, $p < 0.001$ and BITE $r = 0.40$, $p = 0.003$) correlated significantly with the two-year weight loss. In the three outcome groups the

mean BITE and BES scores decreased after treatment, and this change lasted for over two years in the good result group (Figure 2).

Changes in the three factor eating questionnaire scores: An increase in the restraint score during the two years

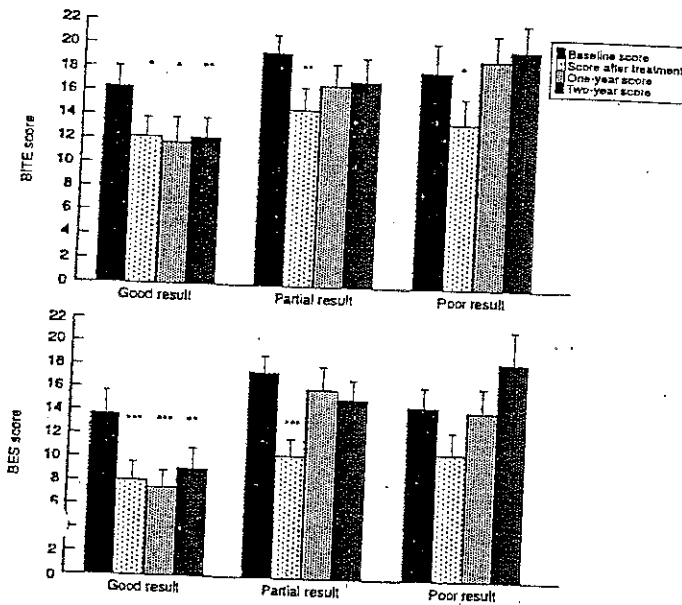


Figure 2 Mean scores (\pm SEM) of Bulimic Investigatory Test (BITE) and Binge Eating Scale (BES) in the three outcome groups. * $p < 0.05$, ** $p < 0.01$ and *** $p < 0.001$ as compared with the baseline score. Good result is more than 10% weight loss ($n = 19$), partial 0–10% weight loss ($n = 24$) and poor result increased weight from pretreatment weight ($n = 13$) at the two-year follow-up.

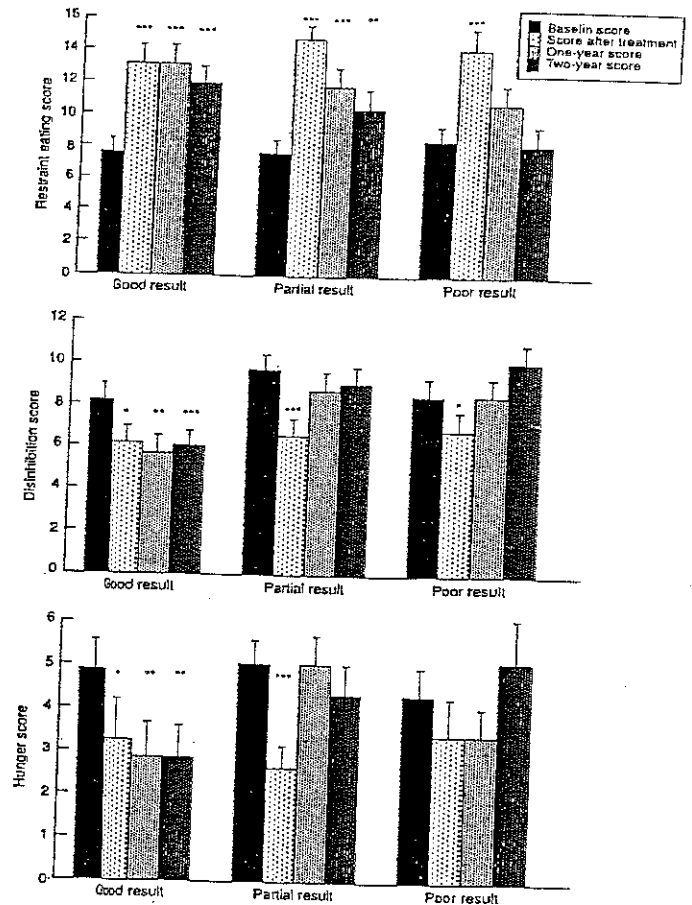


Figure 3 Mean scores (\pm SEM) of Three Factor Eating Questionnaire (TFEQ) in the three outcome groups. The abbreviations and groups are explained in the legend to Figure 2.

Table 2 Mean scores (SD) of the questionnaires in the 56 patients who completed the study

	Baseline	After treatment	One year control	Two-year control
BITE	18.1 (6.9)	13.7 (7.4)***	15.7 (8.4)*	16.1 (8.0)*
BES	15.7 (7.1)	9.7 (7.0)***	12.9 (8.8)**	14.2 (8.7)
Three-factor eating questionnaire:				
Restraint	7.8 (3.7)	14.1 (4.4)***	12.0 (4.8)***	10.4 (4.6)**
Disinhibition	8.9 (3.1)	6.5 (3.3)***	7.7 (3.5)**	8.4 (3.6)
Hunger	4.9 (2.7)	3.1 (3.2)***	4.0 (3.5)*	4.1 (3.5)
SCL-90	0.36 (0.31)	0.21 (0.27)***	0.25 (0.3)**	0.33 (0.36)

*** $p < 0.001$, ** $p < 0.01$, * $p < 0.05$ as compared with the baseline (ANOVA for repeated measures). BITE = Bulimic investigatory test, BES = Binge eating scale, SCL-90 = Symptom check list.

correlated significantly with weight loss ($r = 0.35$, $p = 0.01$). Decreases in disinhibition ($r = 0.56$, $p < 0.001$) and hunger perception ($r = 0.28$, $p = 0.04$) over the time period studied correlated significantly with weight loss. In each outcome group (Figure 3) the mean restraint eating score increased significantly from baseline to week 17, and remained significantly higher than baseline over the time period studied in the partial and good weight loss result group. In each outcome group the mean disinhibition and hunger scores decreased during treatment and this change was maintained only in the good result group.

Changes in the SCL-90 scores: A decrease in the SCL-90 GSI score over the time period studied ($r = 0.13$, $p = 0.34$) did not correlate with weight loss. At the end of the treatment the GSI decreased in each weight loss outcome group, but none of these changes lasted for two years. Transient decreases in all subscales scores were observed after treatment (data not shown).

Discussion

Our study is the first to measure long-term changes in binge eating and three factor eating questionnaire scores after a weight reduction programme using VLCD. At the end of the programme the scores measuring binge eating behaviour were significantly improved as compared with the pretreatment status. This is in accordance with the results of Wadden *et al.* which also demonstrated decreased binge eating behaviour after their weight loss programme.¹³ One third of our subjects succeeded in maintaining this improvement for two years, and this was associated with a sustained weight loss. In the subjects with poor long-term control the binge eating scores returned to the pretreatment level.

We measured changes by repeating questionnaires and this may theoretically affect the results. The effect of repeated use of these questionnaires has not been systematically investigated. However, a decrease in the BITE scores during and after therapy in patients with bulimia has been interpreted to reflect true changes in behaviour.¹⁵ The fact that changes in the scores of the questionnaires in our study were clearly associated with the weight loss outcome classes suggests that the changes observed were not caused by repetition, but indicate actual changes in binge behaviour and in the overall eating pattern.

During a one-year therapy (including 12 weeks VLCD) Telch and Agras found an increase in bingeing during refeeding after VLCD, but at the three-month follow-up visit most of the binge eating behaviour had returned to the pretreatment level.¹² We did not measure binge eating during the programme, and we cannot exclude worsening of eating behaviour in our subjects immediately after VLCD. In any case, at the end of the programme (eight weeks after VLCD) the scores of the BITE and BES showed significant improvement.

Yanovsky and Sebring¹⁸ reported a significant decrease in BES scores among bingers but not in non-bingers three months after successful weight loss treatment including VLCD. Differences in baseline scores may explain why a decrease in scores was seen in our patients. The mean pretreatment score of the non-bingers was 7.6 and of the bingers 32.9 in Yanovsky's and Sebring's study, whereas our patients' baseline mean score was 15.8. Some of our patients may have been subclinical binge eaters, whereas Yanovsky's and Sebring's non-bingers had scarcely any problem with bingeing.

Binge eating behaviour has been associated with increased psychopathology.⁷ Before treatment the SCL-90 scores of these subjects were within normal limits, and did not change permanently over the two-year follow-up. However, the baseline correlation between binge scores and psychiatric symptoms may indicate a close association also among our subclinical binge eaters.

Eating pattern, as measured by the three factor eating questionnaire, showed an improved profile (less hunger and disinhibition, more restraint) in all patients after treatment. Stunkard and Messick¹¹ reported an increase in the restraint score of about six points and Clark *et al.*¹⁹ a decrease in disinhibition of five and hunger of two points following behaviour treatment. Changes in scores were approximately of the same degree in our study after therapy, but during follow-up they lasted for over two years only in those who succeeded in maintaining weight loss. Björvell *et al.*¹⁰ reported a correlation between weight loss (and maintenance) and increase in restraint score in patients following behavioural treatment, but lack of a correlation between weight loss and disinhibition or hunger scores. In this prospective study also the decrease in disinhibition and hunger perception correlated with long term weight control.

This comprehensive VLCD program enabled moderately and severely obese patients to lose an average weight of 14.9 kg (15% of the initial weight) in 17 weeks. Two years later, 32% of the patients were still more than 10% below the pretreatment weight. This degree of relative weight loss achieves a considerable improvement in obesity related disorders.^{20,21}

In this study pretreatment scores of TFEQ and binge eating scores failed to predict the success of long term weight loss. Björvell *et al.*¹⁰ have previously suggested that the restraint score of the TFEQ is a useful monitor of progress in behaviour treatment. This study implied that during follow-up binge scales and TFEQ could be used to monitor the maintenance of behaviour treatment. For those who are not able to maintain the improved eating pattern (measured by binge scales and TFEQ) special treatment should be provided.

The subjects in our study represented healthy, well-motivated and mostly middle-aged women. The results may not be directly applicable to all patients in obesity clinics or to other groups of obese persons. Despite this limitation our results suggest that a behavioural

therapy-based weight reduction programme using VLCD is a useful therapy for obesity and does not lead to binge eating behaviour in previous non-bingers. One third of these subjects were able to maintain positive changes in the scores measuring eating behaviour for two years and this led to sustained weight loss.

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