

Retrospective Study of The Center For Medical Weight Loss Diet

Summary of major findings

A retrospective study was conducted to determine the typical weight loss achieved by patients of The Center for Medical Weight Loss diet (CMWL).

The participants studied were new patients who initially were assigned to the CMWL diet and had stayed on it at least 4 weeks. If they subsequently added appetite suppressants, food or made any other diet changes the data for the subsequent time periods was excluded.

This study documents that it is possible to achieve significant, progressive and durable weight loss for any duration up to a year with the CMWL diet. This is without drug intervention and with moderate medical monitoring.

Based on a stratified sample of about 349 patients on this diet we found the following:

Very significant and progressive weight loss over a six month period starting out at 3% weight loss from initial body weight the first week, to 6% the first month, 12% at 3mos and about 19% for the half year.

For dieters of one month duration up to and including one year essentially 100% of the sample achieved and maintained their maximum diet weight loss or very close to it by the time of their last weigh in or before dietary switches.

The diet is medically safe.

Since achieving significant weight loss is difficult and maintaining weight loss is even more so, these findings, which demonstrate real world performance, are remarkable for a no-drug and relatively simple diet plan with moderate monitoring.

The findings are so dramatic and consistent that the diet merits additional study to understand the reasons for its effectiveness, its detailed impact on markers of cholesterol, insulin resistance etc and its usefulness in different clinical settings.

Study Objective

The obesity epidemic both in the US and abroad demands interventions that work. It is well documented in the literature that weight loss diets including diets with weight loss pills don't work very well. Weight loss frequently is too small to have an impact on health and the weight loss is not maintained.

Because excessive weight has a negative impact on health from high blood pressure, to metabolic syndrome, diabetes, stroke and heart disease there is an urgent need to develop more effective clinical alternatives.

The objective of this study is to document the representative weight loss over a medium time frame of The Center for Medical Weight Loss diet. CMWL is an example of a dietary intervention that works: significant progressive weight loss in a real world setting. It merits further study.

Methodology/Data Issues

Methods: Eligibility and Study Design

The overall sample of 349 (238 female, 111 male) patients was created by combining two stratified samples from two The Center For Medical Weight Loss offices.

The patient data of office A consists of at least 6 years worth of data with about five participating doctors over that time period. For office B about 3 years of data with about 4 doctors was included. Office B had suffered a hard drive crash and patients that had started as patients before August 2004 were not included. Within each office the samples were representative of patients that met the stratification criteria described below. There were more patients from office A than office B because the office had been open longer and was a bigger office and the data from office B was further limited because of the hard drive crash.

Patients that were included were stratified by

- A) The Center for Medical Weight Loss diet was their initial diet as patients of the Center for Medical Weight Loss
- B) They had stayed on the diet at least 28 days. Staying on the diet for at least 28 days was considered a condition for inclusion because diet duration was an implicit measure of motivation and a recognition that it takes time to lose weight.

- C) Almost everyone has had at least two visits to the doctors office within those first 31 days.
- D) They were weighed again within 29 days of the last office visit or their weight could be reasonably extrapolated for the next 29 days or less or their diet data after that point was not included in the study.
- E) No modifications in the diet were allowed such as adding food or appetite suppressant for the time period that we were examining. Because this is a real world study it is possible that some patients cheated i.e. sometimes added regular food which makes the results even more remarkable.

We are therefore studying a pure Center For Medical Weight Loss diet with no prescribed modifications of any type in a real world setting: doctors' offices.

Patients with congestive heart failure, type 1 diabetes and or active acute illnesses are not put on this diet. See the diet safety section below.

The patient weights used in the study were acquired off computer data that was recorded from the Tanita automated scale. The accuracy of the scale was .5 lbs. If individuals were weighed twice in the same day the higher weight was used to be more conservative. The difference in almost all cases was half a pound. Patients were weighted with their seasonal clothes. It is likely that winter clothes weighed slightly more than summer clothes but adjustments were not made for that but given the absolute amounts of weight loss documented the effect would be minimal.

Time periods examined in this study for actual weight loss were 7, 14, 21, 28, 42, 56, 84 and 183 days. For diet duration less than 84days, 183 days, less 365 days and greater than 365 days was also examined.

Not everyone in this study was weighed on the exact day of the respective time periods. This was a real world study and not every participant came in to the doctor's office every week nor were they weighed every week. The number of patient weights per time period differs. The objective was to include actual weights that were close to the weigh in time period and to avoid extrapolations as much as possible. Weigh-ins did not have to be done exactly on the above specified dates if they were close time wise they were included. This is especially true if no significant weight changes were occurring. The results for the average percent weight loss which I consider the most representative suggests that this effort was successful because the mean, mode and median are the same or close.

Judgments were made as to whether include the weight or not for a specific time period. In the case of the half year time period most weights were not included. Many of the dieters did not stay on the diet for 183 days or were weighed past the 29 day weigh in time limit. The data up to and including the 84 days is most representative of CMWL weight loss because significantly more weights were included with sample sizes above

100 even when looking at men and women. With respect to the 183 half year mark weights were included or extrapolated for time periods that were less than or equal to 29 days into the future.

This study includes individuals still on the diet and individuals that have ended the diet. The patients with or without the consultation of the doctors determined how long they stayed on the diet since they were paying for the food and the professional services. It is possible that they were more motivated than the average dieter since they were paying for the services.

Study Low Calorie Diet (CMWLD) description:

The Center for Medical Weight Loss (CMWL) diet consists of pre-packaged food and counseling.

1) Pre-packaged food

The CMWL diet consists of 800-1280 calories of pre-packaged shakes, bars and soups. The pre-packaged nature of the diet helps to eliminate choices and dietary indiscretion that often occurs when people are required to calculate the caloric value of portions. It makes it easy for the patients to receive complete nutrition in the lowest caloric form possible without having to weigh and measure their daily portions.

The shakes bars and soups are considered to be a high protein, moderate carbohydrate and low fat. All of the patients on the diet received a minimum of 640 of their daily calories from shakes. The shakes are all 160 calories each (powdered and Ready to drink varieties). Each shake contains 25% of the RDA for vitamins and minerals. The powdered variety consists of 16gms of protein, 19.8gms carbohydrates and 2gms of unsaturated fat. The ready to drink liquid variety of shakes contain 15 gms of protein, 19 gms carbohydrates, and 3gms of fat with 2gms of that representing unsaturated fat and 1gm representing saturated fat. Neither the powder nor the RTD varieties contain any trans fats. All protein bars are 160 calories. All varieties have 10-15 gms of protein, 15-19gms of carbohydrates, 4-5gms of fat (none contain trans fats). All soups are 160 calories each. They contain 25% of the RDA for vitamins and minerals. The soups have 15gms of protein, 19gms of carbohydrates and 2gms of unsaturated fat

2) Counseling

Counseling and behavior modification is provided to all individuals on the CMWL diet. All patients are seen for a follow up in one week after initiation of the diet. Low risk medical patients (patients without any co-morbid conditions or medications that require adjustments for patient safety while on the CMWL diet) are seen every two weeks for counseling and a visit with the physician. High risk medical patients are seen on a weekly basis for counseling and medication monitoring. The counseling consists of proprietary interactive modules that ask the patients questions to bring back the following week for the visit with the physician. The physician counsels the patient for 15 minutes at each

visit on various topics that include lifestyle, fitness, nutrition and general health depending on the patient's responses to the questions that were asked.

The amount of calories used on the diet is determined by an individual patient's Basal Metabolic rate according to the following chart:

<u>BMR</u>	<u>Calories Given Daily (24 hour period)</u>
<2000	800
2000-2500	960
2501-3000	1120
>3000	1200

Diet Safety/Medical Management

Overall, the low calorie diet is a safe diet to prescribe. It must be physician prescribed because there are some inherent dangers that come along with rapid weight loss in patients that are on hypertensive and or diabetes medications. The risk of hypotension and hypoglycemia is high if proper reductions in the patients' prescription medications are not made.

With well controlled hypertension at diet onset the patients' medication dose was decreased by half if they were only on one medication. Doctors try to discontinue diuretics whenever possible because of the increased risk of electrolyte abnormalities with water weight loss. Patients were managed be well hydrated while losing weight to minimize the risk of hypotension. In some patients the diuretic was discontinued and an ACE-inhibitor was added in its place for blood pressure management.

Patients with congestive heart failure were eliminated from the diet secondary to the inherent risks of an exacerbation of the condition if the diuretics were discontinued. Patients with type I diabetes were eliminated from the diet given the increased risk of diabetic keto-acidosis with rapid weight loss. Patients with active acute medical illnesses were also eliminated from doing the full low calorie diet. . These patients are treated with a modified diet that allows the patient to eat one small 550 calorie food meal daily along with three 160 calorie shakes daily.

Patients with a well controlled hemoglobin A1c <7.0 at diet initiation had their diabetes medication reduced. Doctors would try to decrease the medications with the following pecking order first Insulin, second sulfonylureas, and third thiazolidinediones. These medications are felt to promote weight gain. Metformin was added or increased when needed for poorly controlled blood sugars when the above adjustments were made. The goal was to try to decrease the medications that are associated with weight gain as much as possible to help promote the maintenance of any weight that was lost. Exanatidine and Sitagliptin Phosphate were also added to some patients' medication regimens if needed for blood sugar control.

Detailed Weight Loss Results

The objective of the study is to document real world representative weight loss for the CMWL diet at different time periods up to six months and to document what percent of patients achieved weight loss for the respective time periods. The findings are representative of The Center For Medical Weight Loss (CMWL) patients at these two offices.

Both absolute and percent weight loss will be provided.

Patients and most weight loss studies focus on absolute pounds lost from initial weigh in and these figures are described first since they provide a comparison with other studies. We will then look at percent weight loss from initial weight.

Absolute weight loss averages however fluctuate based on the proportion of men and women in the sample and the proportion of heavy patients versus thin ones. Men generally tend to be heavier than women and men generally tend to loss more absolute weight. These figures would tend to fluctuate for different offices given the mix of patients. Even given this qualification absolute weight loss results are excellent.

RESULTS

Absolute average weight loss results

All: Proportional

	7 days	14 days	21 days	28 days	42 days	56 days	84 days	183 days
Mean	-6.65	-9.53	-12.86	-14.95	-19.57	-22.87	-31.46	-59.03
Median	-6.50	-8.50	-11.50	-13.50	-18.00	-21.00	-28.00	-49.75
Mode	-6.50	-6.50	-10.00	-11.00	-17.50	-15.00	-21.00	-25.50
Included weights sample	299	322	298	297	266	227	172	36

Proportional means that no adjustments were made to the proportion of women to men which is about 2:1. It is my considered judgment that combining women and men's absolute weight data is not particularly that meaningful but is included for comparison purposes.

Absolute average weight loss by male or female

Separating men and female weight loss results is a more meaningful way at looking at absolute weight loss since men and women differ in overall weight and BMI.

The averages fairly reflect typical weight loss by sex over the half year. This is reinforced by the fact that the median closely mirrors the averages. As to be expected men lose more weight on average than women. The half year data given the small sample sizes should be taken with a grain of salt. Weight loss at that time period can fluctuate significantly among individuals. Again different proportions of skinny and obese men and women would obviously change the results. The results refer to the typical mix of The Center For Medical Weight Loss patients in those two offices. This represents significant and medically safe weight loss.

Women

	7 days	14 days	21 days	28 days	42 days	56 days	84 days	183 days
Mean	-5.72	-7.76	-10.28	-12.34	-16.30	-18.38	-24.42	-40.35
Median	-5.50	-7.50	-10.00	-11.50	-16.50	-18.00	-23.25	-35.25
Mode	-5.50	-7.00	-10.00	-11.00	-17.50	-15.00	-21.00	-25.50
Included weights sample	199	223	197	203	185	159	114	20

Men

	7 days	14 days	21 days	28 days	42 days	56 days	84 days	183 days
Mean	-8.49	-13.51	-17.90	-20.58	-27.02	-33.36	-45.29	-82.38
Median	-8.50	-13.00	-17.50	-19.00	-26.00	-32.00	-41.25	-71.00
Mode	-6.50	-14.50	-13.00	-24.00	-27.00	-32.00	-73.50	#N/A
Included weights sample	100	99	101	94	81	68	58	16

Average Percent Weight Loss

Percent weight loss is a more accurate and invariant way of calculating weight loss and this is reflected in the figures. Men slightly lose more weight as a percent than women

but by sex or overall the percent weight results are remarkable since this is both medically safe and durable.

Women

	7 days	14 days	21 days	28 days	42 days	56 days	84 days	183 days
Mean								
Median	-0.03	-0.04	-0.05	-0.06	-0.07	-0.08	-0.11	-0.17
Mode	-0.03	-0.04	-0.05	-0.06	-0.08	-0.09	-0.11	-0.16
Included weights sample	0.00	-0.04	-0.05	-0.09	-0.09	-0.13	-0.11	-0.12
	199	223	197	203	185	159	114	20

Men

	7 days	14 days	21 days	28 days	42 days	56 days	84 days	183 days
Mean								
Median	-0.03	-0.04	-0.06	-0.07	-0.09	-0.10	-0.14	-0.22
Mode	-0.03	-0.04	-0.06	-0.07	-0.09	-0.10	-0.14	-0.22
Included weights sample	-0.03	-0.04	-0.06	-0.07	#N/A	#N/A	#N/A	#N/A
	100	99	101	94	81	68	58	16

ALL

	7 days	14 days	21 days	28 days	42 days	56 days	84 days	183 days
Mean								
Median	-0.03	-0.04	-0.05	-0.06	-0.08	-0.09	-0.12	-0.19
Mode	-0.03	-0.04	-0.05	-0.06	-0.08	-0.09	-0.12	-0.19
Included weights sample	0.00	-0.04	-0.04	-0.07	-0.09	-0.13	-0.11	-0.12
	299	322	298	297	268	227	172	36

Diet duration and effectiveness

	All	Women	Men
Mean	89.5 days	85.1 days	98.8 days
Median	75 days	72.5 days	77 days
Mode	42 days	42 days	42 days
sample	349 patients	238 patients	111 patients

Most patients, 94 % of the CMWL clients stay on the diet less than half a year and less than 1% stay on it for more than a year. Based on these results the vast majority of individuals use this diet to achieve short and medium term results defined as less than six months.

Of those patients that stay from one month up to a year essentially all achieve weight loss. If you can do the diet you will achieve weight loss.

The weight loss is almost 100% for whatever time period we have looked at from the third week thru six months. For this time period there are 1296 weigh-ins. Of those weigh-ins only 2 (.15%) did not show a weight loss.

In addition when one compares the last weigh in on the diet to the maximum achieved diet weight loss in the vast majority of patients (74%) the last weigh is also the maximum achieved weight loss. For 82% the last weigh-in is within 10% of the maximum weight loss. These figures would be higher if we just limited the analysis to the first six months. I am not aware of any other diet that can make these claims. They have to be qualified however by the fact that the study does not have a control group and not everyone stayed the same amount of time on the diet.

Discussion

The purpose of this study was to document significant progressive weight loss in a real world setting across a large number of patients with different doctors and two offices. That has been achieved.

The weight loss is significant, predictable, progressive and within the range that is considered medically safe. Typical weight loss compares favorably with any published diet weight loss program for the time durations studied.

With respect to the predictability of weight loss I am not aware of any diet that has essentially 100% weight loss for almost all participants which is what this diet achieves.

Because this study documents weight loss results in a real world setting and the results are predictable, significant and progressive. The Center For Medical Weight Loss diet represents an effective option for dieters that require rapid, predictable and safe weight loss over the short to medium term. Everyone who can follow the diet loses weight.

The diet plan has many of the features that are considered to be part of a good diet plan: simplification of food preparation since the food is standardized, calories restricted and counseling. The results in their totality are superior to most diets for the durations studied.

There is a significant need for diets that work. There is a significant need for weight loss diets for medical interventions to achieve weight loss to reduce co-morbidities, diabetes, heart disease, high blood pressure and insulin resistance. Given the excellent results more study is warranted.

Study limitations are that the diet duration is determined by the patients' willingness to continue be on the liquid diet and to pay to be on the diet or the doctors judgment to modify the diet by adding appetite suppressants or food etc. As such the diet duration is not the same for all patients. The diet is a limitation in social settings because individuals can't eat normal food.

Further study needs to be done to see who most benefits from this diet and study its use for longer time periods with large numbers of individuals.

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