

Efficacy of 2 Diet Plans Designed for People with Type 2 Diabetes on Weight and Health Measures

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Abstract

Background: While weight loss is remarkably effective at controlling type 2 diabetes, the amount of weight loss achieved on diets is typically less for overweight people with type 2 diabetes than for those without diabetes. We compared a portion-controlled, supplement-based diet to a traditional reduced-calorie diet of equal caloric prescription. **Methods:** 126 overweight (BMI 25-40) type 2 diabetics (age 38-69, mean 55) desiring weight loss were recruited by advertisement and screened. 112 were enrolled (49 males, 63 females) and randomized to either a 25% energy deficit diet similar in composition to standard ADA recommendations (SD), or an equicaloric portion-controlled diet using Medifast Plus for Diabetics food supplements (PCD). An initial weight loss period of 34wks was followed by 52wks maintenance with re-randomization of PCD pts to either 26wks of PCD followed by 26wks of SD (PCD1) or vice versa (PCD2) at a maintenance calorie level. **Results:** Of patients completing the initial weight loss phase, average weight loss was 6.84% (n=31, mean wt loss=16 lbs) for PCD and 3.70% (n=17, mean wt loss= 8.1 lbs) for SD (p=0.039). 61% of PCD pts lost >5% of initial body weight (BW) vs. 23% of SD pts (p<.01). A 10% minimum weight loss was obtained by 29.0% of PCD vs. 5.9% of SD (p=0.04). After the 86wk study, average weight loss for PCD pts was 5.4% (n=16, mean wt loss=13 lbs) vs. 2.5% (n=7, mean wt loss=5.3 lbs) for SD (p=.31). 44% of PCD pts had sustained 5% BW loss vs. 14% of SD pts (p=.15). Results were not significantly different between sub-groups of PCD maintenance. Final BW loss was 5.2% (mean=12.9lbs) for PCD1 pts vs. 5.6% (mean=13.1 lbs) for PCD2 pts (p=0.92). Dropout rates were less on the PCD (p=.03). **Conclusions:** Significantly greater results were achieved by participants in the PCD group in all primary outcome measures, and dropout rates were less on PCD. It is our recommendation that a PCD be considered for type 2 diabetics desiring weight loss, but that periodic use of SD during weight maintenance will not adversely affect weight loss efforts.

Background

Obesity rates in America continue to rise, with a current estimation of 65% of U.S. adults classified as overweight, and 31% classified as obese. 1 The rates of non insulin dependent diabetes mellitus (NIDDM) or type 2 diabetes are also on the rise. Currently affecting an estimated 18.2 million Americans², type 2 diabetes is a serious health problem only expected to continue increasing. There is an expected 165% increase in diabetes between 2000 and 2050.³ Obesity and type 2 diabetes are commonly linked, with an estimation of over 70% of type 2 diabetics also being overweight and another 33% who are obese.⁴ Obesity has been known to confound the complications that are typically associated with type 2 diabetes. Diabetics who lose even as little as 2% of their body weight, often see marked improvement in their metabolic disturbances including 24-hour blood glucose profiles, insulin sensitivity, and hemoglobin A1c.⁵ In addition, weight loss also contributes to decreased systolic and diastolic blood pressure, plasma triglyceride, and cholesterol levels.^{5,6,7,8} These improvements may, in part, be the cause for a decreased mortality that has been seen in diabetics that intentionally lose weight.⁹ Unfortunately, once diabetic, it often becomes more difficult for people to lose weight.^{10,11,12}

As with obesity, long-term management of type 2 diabetes mellitus may hinge on the role of compliance of the weight loss regimen that has been implemented. The longer that a patient adheres to a specific weight loss program, the greater potential for the regulation of specific

diabetic factors such as: glycemic control, insulin sensitivity, and lipid profile in addition to the metabolic effects of weight loss in general. Portion-controlled meals specifically created to serve the needs of the diabetic patient may provide the key to long term dietary compliance.

In 1999, Ditschuneit and associates found in a 27 month prospectively, randomized trial that those on a meal replacement diet lost significantly more weight (approx 48% more) than those who were on a self-selected conventional food diet with a comparable macronutrient makeup. A study in women by Hannum et al has shown that subjects who consumed portion-controlled meals had a statistically significant greater weight loss and "dietary adherence rate" than their standard food diet counterparts in the short term. Other studies have shown that these meal replacements are convenient to use, easy to comply with, and are simple to incorporate into the lifestyle of the patient.^{14,15,16}

The purpose of this study is to evaluate the efficacy of the standard ADA (American Diabetic Association) self-selected diet vs. a portion controlled diabetic food diet in obese patients with NIDDM. The study also aims to evaluate not only the metabolic effects in the long term, but also compliance and any consequent medication changes in patients of the two weight loss regimens. The meal replacements used in this study are soy-based products (bars, shakes, soups) that are considerably lower in sugar than their non-diabetic counterparts and other popular diet products on the market.

Table 1: Baseline Demographics

Measurement		PCD	SD	P-value
N		54 (48.2%)	58 (52.8%)	
Gender	Male	25 (46.5%)	24 (41.4%)	0.6
	Female	29 (53.7%)	34 (58.6%)	
Age		54.6±7.01	55.48±7.16	0.51
Race	Caucasian	43 (79.6%)	43 (74%)	0.45
	African-American	11 (20.4%)	14 (24.1%)	
	Asian	0 (0%)	1 (1.7%)	
Education	Some HS	3 (5.6%)	1 (1.7%)	0.66
	HS grad	15 (27.8%)	10 (17.2%)	
	Some College	15 (27.8%)	18 (31%)	
	BS/BA	15 (27.8%)	12 (20.7%)	
	MS/MA	9 (16.7%)	15 (25.9%)	
	Doctoral	3 (5.6%)	2 (3.4%)	
Income	<\$25k	12 (23.5%)	9 (15.5%)	0.45
	\$25k-\$50k	16 (31.4%)	18 (31%)	
	\$50k-\$75k	5 (9.8%)	12 (20.7%)	
	\$75k-\$100k	8 (15.7%)	4 (6.5%)	
	>\$100k	10 (19.6%)	5 (25.9%)	

Methods

126 overweight or obese type 2 diabetics desiring weight loss were recruited by advertisement and screened. 112 were enrolled (49 males, 63 females) and randomized to either a 25% energy deficit diet similar in composition to standard ADA recommendations (SD), or an equicaloric portion-controlled diet using Medifast Maintain food supplements (PCD). An initial weight loss period of 34wks was followed by 52wks maintenance with re-randomization of PCD pts to either 26wks of PCD followed by 26wks of SD (PCD1) or vice versa (PCD2) at a maintenance calorie level. Inclusion Criteria: age 18-70; BMI 25-40; diagnosed with type II diabetes mellitus for a minimum 3 months prior to enrollment and on a stable dose of medications; normal ECG or abnormalities deemed medically acceptable; not using appetite-affecting medications unless on established and stable dose; not using weight loss drugs; permission of primary care provider; using an acceptable method of birth control for women of childbearing potential. Exclusion Criteria: Chronic uncontrolled health problems (not including obesity and diabetes); type 1 diabetes mellitus; participants may not have bulimia, laxative abuse, substance abuse, alcohol intake > 10 drinks per week, or have an uncontrolled psychiatric disorder as determined at screening; breast-feeding or pregnant at screening by serum pregnancy test if female of childbearing capacity

In both group, diets consisted of a similar macronutrient breakdown of approximately 45-50% carbohydrate, 25-30% fat, and 15-25% protein. The caloric target for each individualized diet was calculated using the Harris Benedict Equation with a 25% deficit in calculated daily caloric needs. The PCD group received approximately 50-60% of their calories from Medifast Maintain supplements. Each participant received 3 individual consultations with the dietitian to review their meal plans during the study: one at the beginning, one mid-way through the diet phase, and one entering maintenance. All participants attended group educational sessions one time every other week during the 34w weight loss, and one time every four weeks during the 52w maintenance.

Table 2: Baseline Measurements

Measurement	PCD Mean	SD Mean	P-value between
Weight	223.2±34.1	226.1±36.6	0.67
BMI	35.28±3.46	35.68±3.76	0.6
Systolic BP	144.19±1.97	138±3.18	0.1
Diastolic BP	86.67±1.19	86±1.51	0.73
Body Fat	34.24±0.97	33.81±3.18	0.77
Total Cholesterol	206.95±5.64	200.17±4.88	0.37
HDL	47.88±1.67	46.35±1.57	0.51
LDL	116.85±4.09	114.58±3.74	0.68
Triglycerides	208.34±15.89	201.69±16.12	0.77
Insulin	19.39±2.23	15.02±1.31	0.1
Fasting Glucose	163.45±7.63	142.94±5.90	0.04
Hemoglobin A1C	7.73±0.22	7.13±0.21	0.05

Figure 1: Weight Loss in Pounds Over 34-Week Weight Loss and 52-Week Maintenance by Group

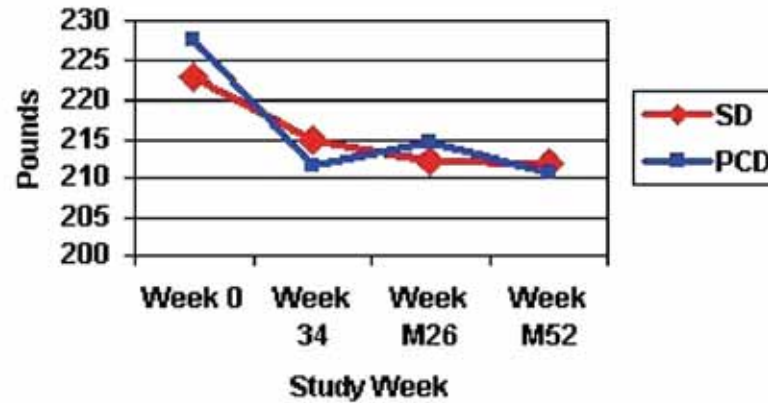


Figure 2: Percent Weight Loss Over 34-Week Weight Loss and 52-Week Maintenance by Group

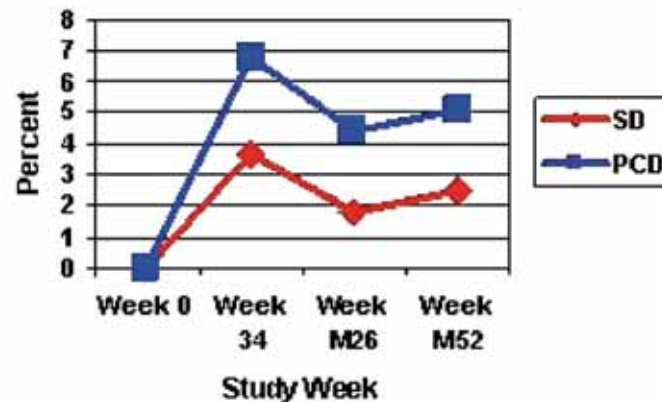


Table 3: Physical Measurements at 52 Weeks

Measurement		PCD 0-52 Mean	P-value	SD 0-52 Mean	P-value	P-value between
N		16		7		0.02
Weight	0	223.1±35.1	<0.0001	217.2±34.7	<0.0001	0.259
	52	210.8±31.2		211.9±34.5		
BMI	0	35.7±3.8	0.000	34.3±3.1	<0.0001	0.307
	52	33.9±3.5		33.5±3.5		
Waist	0	44.1±5.3	0.000	43.6±3.7	0.000	0.530
	52	42.4±5.4		42.8±4.9		
Hips	0	47.3±3.9	<0.0001	46.5±4.4	<0.0001	0.321
	52	45.8±2.9		45.8±4.8		
Systolic BP	0	135.1±18.98	0.003	149.1±21.2	0.571	0.248
	52	127.5±14.2		132.6±13.9		
Diastolic BP	0	81.6±7.2	0.899	87.4±9.6	0.030	0.160
	52	78.9±7.1		78.6±10.5		
%Body Fat	0	32.9±9.8	<0.0001	33.9±8.3	0.002	0.460
	52	34.2±6.7		33.6±9.0		
Total Cholesterol	0	192.7±20.3	0.567	199.7±15.98	0.776	0.578
	52	186.5±36.1		202.3±16.2		
HDL	0	47.1±14.4	<0.0001	44.3±12.2	0.093	0.135
	52	57.2±16.9		62.9±35.1		
LDL	0	108.6±19.4	0.544	120.0±22.1	0.819	0.836
	52	107.1±30.0		116.2±19.8		
Triglycerides	0	185.8±89.6	<0.0001	186.0±122.6	0.319	0.351
	52	175.7±108.9		162.3±93.3		
Insulin	0	13.1±5.9	0.676	12.5±7.9	0.898	0.486
	52	12.6±10.0		6.1±3.8		
Fasting Glucose	0	138.2±32.4	0.774	139.9±39.2	0.569	0.773
	52	129.5±38.6		147.5±52.3		
Hemoglobin A1C	0	6.6±0.98	0.185	7.9±1.6	0.522	0.252
	52	6.7±1.4		7.5±0.8		

Figure 3: Percent of People Having a Change in Type 2 Diabetes Mellitus Medications by Group and Sub-group

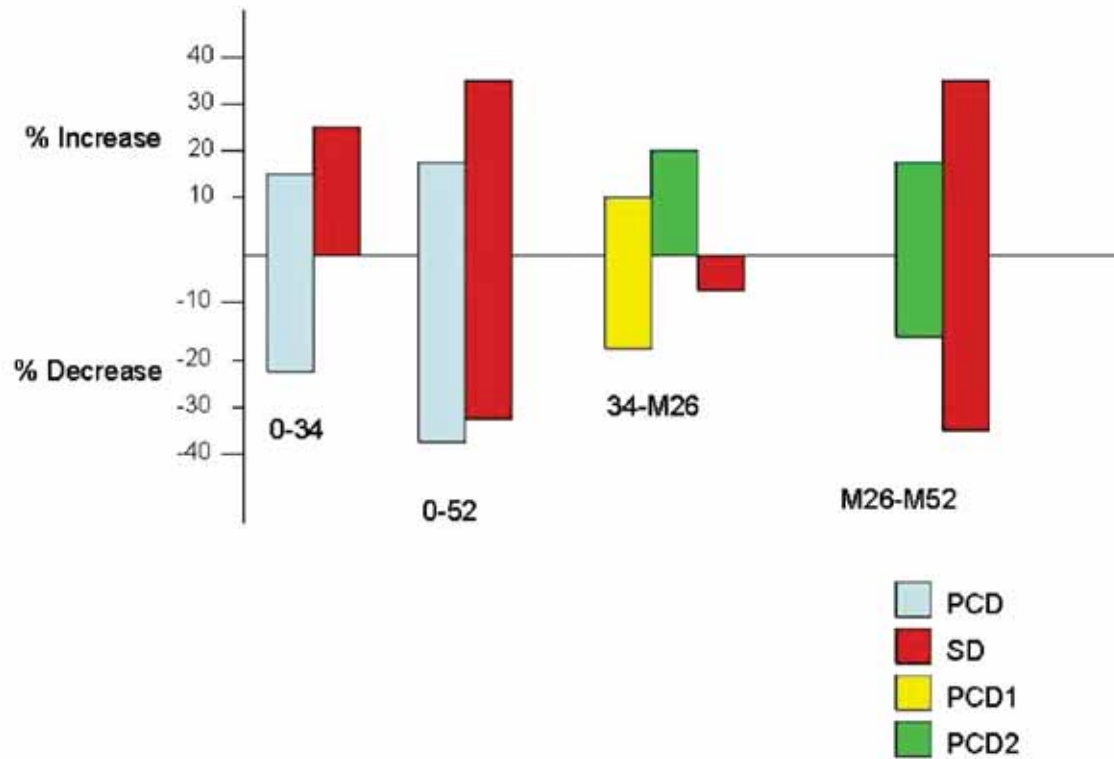
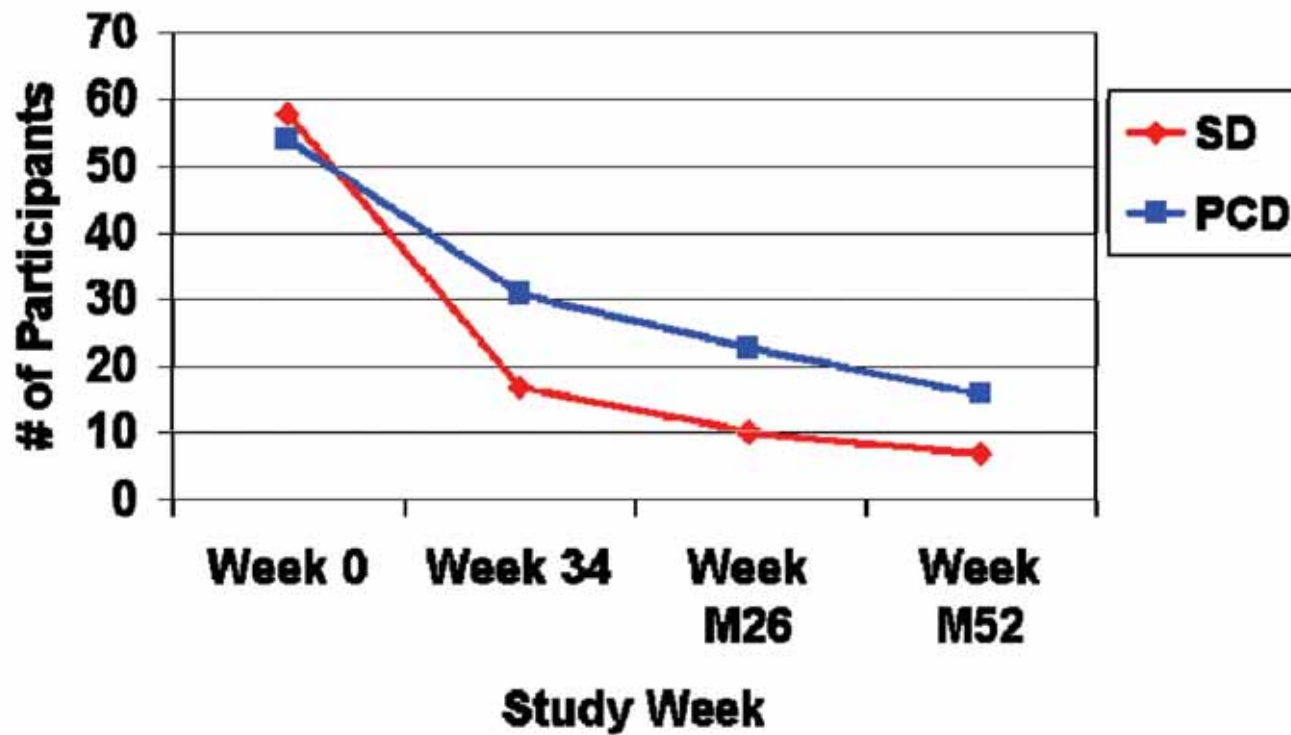


Figure 4: Retention Over 34-Week Weight Loss and 52-Week Maintenance by Group



Discussion

Significantly greater results were achieved after the initial 34-weeks of weight loss by participants in the PCD group in pounds and percent weight loss, insulin level and hemoglobin A1c. The PCD group also saw significant improvements within group in BMI, systolic BP, diastolic BP, waist/hip measurements, cholesterol, HDL, triglycerides, glucose and percent body fat. (Table 3) Dropout rates were less on PCD in both weight loss and weight maintenance ($p=0.02$). (Figure 4) During weight loss, participants in the PCD group significantly decreased their use of medications to treat Type 2 DM. (Figure 3) All of these improvements may lead to better quality of life for people living with Type 2 DM. Participants in the PCD group also self-reported higher ease of compliance with the diet compared to the SD group (64.2% v 56.0%). It is our recommendation that a PCD be considered for type 2 diabetics desiring weight loss, but that periodic use of SD during weight maintenance will not adversely affect weight loss efforts. Our research supports that using a portion-controlled diet will produce comparable if not better outcomes in type 2 diabetics attempting to control their weight.