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Six Month Outcomes of a Primary Care-Based Weight Loss Trial Using a Lay-Trained Counselor

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Abstract

Background: Obesity remains an important problem in primary health care settings. Intensive counseling from trained nutrition professionals has proven efficacy but is resource intensive. Trials have begun to assess the effectiveness of lower cost counselors.

Methods: This paper describes the 6-month outcomes of a high intensity counseling intervention on weight (primary outcome), as well as cardiovascular disease risk factors and health-related quality of life (secondary outcomes). We also sought to assess whether baseline characteristics were associated with 6-month weight change. Participants (n=106) had obesity and at least one co-morbid medical condition. The trial used a trained layperson counselor and provided study participants with subsidized access to an evidence-based regimen of portion-controlled foods. Weight change data were analyzed using intention-to-treat analysis. Participants who dropped out prior to 6 months were assumed to have regained weight.

Results: Average weight loss after 6 months was 7.0 kg, equal to 6.5% of initial weight. Significant improvements were noted in blood pressure, waist circumference, glycemic control, mood, and overall health-related quality of life. Most baseline characteristics were not associated with weight loss after 6 months.

Conclusions: An intensive lifestyle intervention, using a trained layperson and portion-controlled foods, produced clinically significant weight loss at 6 months. Improvements were also noted in cardiovascular disease risk factors and in quality of life.

Keywords: Obesity; Lifestyle modification; Portion-controlled foods; Primary care

Introduction

Obesity and its related medical co-morbidities continue to be among the most common problems encountered by primary care physicians. One study, using national data from the U.S., conservatively estimated that 30% of clinical items addressed in a visit are related to excess weight [1]. This same study reported that 8% of total primary care physician time can be attributed to overweight and obesity [1]. Recent trials have begun to address obesity more routinely in clinical settings [2-7] and to disseminate effective interventions to primary care and community settings [8,9].

Despite these efforts to integrate treatment of obesity with primary care, which direction the field will take remains unclear. One of the main questions relates to the cost of the interventions. Trials have taken quite different approaches to this question. For example, one recent study offered participants multiple interventions for treating obesity, with relative disregard for cost. Specifically, participants were offered a medically supervised low-calorie diet consisting of meal replacements, plus intensive group behavioral treatment, plus the option to use weight loss medication [10]. In contrast, three recent trials (funded under a cooperative UO1 mechanism from the U.S. National Institutes of Health) tested the use of lower cost counseling personnel that did not have professional degrees in nutrition or psychology. One trial employed telephone coaches who worked with patients remotely [2]. The second trial used medical assistants who worked in the primary care practices [6]. The third trial employed a website and an interactive voice response telephonic system [3].

Closely related to the issue of cost is the issue of which interventions should be reimbursed for primary care patients with obesity. In the U.S., health care payers (employers and insurance plans) generally do not reimburse for weight loss medications or for the use of meal replacements or other foods formulated for weight loss [11]. This is unfortunate, given that these are two of the most effective non-surgical interventions for treating obesity. However, the U.S. national epidemics of diabetes and pre-diabetes have led to increased attention on excess weight [12]. This attention, in turn, has led to efforts to disseminate the highly successful intervention developed by the Diabetes Prevention Program (DPP) [13]. Some health care payers and health care institutions are now offering the DPP at low or zero cost to individuals at high risk for diabetes.

This paper has three aims: 1) to describe the design and start-up of a clinical trial targeting primary care patients with obesity and a related co-morbidity; 2) to quantify outcomes between baseline and 6 months; and 3) to examine baseline predictors of weight loss. The primary outcome at 6 months was weight change. Secondary outcomes included changes in cardiovascular risk factors and health-related quality of life.

Methods

Study design

The overall study was designed to test the hypothesis that in-person visits, provided during a period of weight maintenance, would be associated with greater weight loss at the end of 18 months. This

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paper describes the outcomes of the first 6 months of treatment (i.e., the initial weight loss phase). All participants were offered a series of 12 in-person counseling visits during the first 6 months. As described below, all participants also were offered discounted access to portion-controlled weight loss foods throughout the trial.

Participants

We recruited individuals from two primary care internal medicine practices at the University of Colorado. Individuals aged 18-79, with a body mass index (BMI) 30-49.9 kg/m^2 and an ICD-9 (International Classification for Diseases) code for either type 2 diabetes, hypertension, hyperlipidemia, or obstructive sleep apnea, were sent letters inviting them to participate in a research trial for weight loss. Exclusion criteria included a weight change of ≥ 5% of starting weight within the previous six months, use of chronic glucocorticoids or second generation anti-psychotics, previous bariatric surgery, or if the individual was unable or unwilling to travel for in-person visits and to use portion-controlled foods for weight loss.

Potential participants were screened by telephone to ensure eligibility. Eligible individuals were then asked to attend two screening visits. At the first screening visit, they provided informed consent and completed baseline questionnaires. At the second screening visit, they met with the study's principal investigator for a clinical interview. The purpose of the clinical interview was to assess readiness for participation in an 18-month clinical trial. The flow chart (see Results section) describes the flow of study participants.

Intervention

During the first 6 months, all participants were offered 12 in-person weight loss counseling visits. The written materials used for these visits were modified from the Diabetes Prevention Program (DPP). The DPP showed that a weight loss of 7% of starting weight reduced the incidence of type 2 diabetes by 58% after 4 years of follow-up, despite partial weight regain [13]. Follow-up of DPP participants showed that the cumulative incidence of diabetes remained lower after 10 years [14]. We slightly modified the materials from the DPP and then reviewed these with study participants at each visit. The modifications to the materials reflected updates in the behavioral and dietary treatment of obesity. For example, we modified the list of snacks from the original DPP materials to focus more on whole grain carbohydrate foods with lower glycemic index. Visits in the current study lasted 20-30 minutes each time. Participants were assessed at baseline and at 6 months.

The primary counselor was a professional research assistant at the University of Colorado. She had no formal training in nutrition or weight management but holds a Master's degree in psychology. She had collaborated with the Principal Investigator on one previous weight loss trial [15].

Portion-controlled foods

The use of portion-controlled weight loss foods has been demonstrated in randomized trials to increase weight loss beyond the provision of a calorie prescription with the same target for energy intake [16,17]. Participants were offered the Nutrisystem® weight loss program at a deeply discounted rate of $95 per month (the typical retail cost of the program is $250-$300 per month). The Nutrisystem® program includes three portion-controlled entrees and two portion-controlled snack items per day. Participants are required to purchase their own fruits, vegetables, and dairy items while using the Nutrisystem® program. The Nutrisystem® meal plan (including provided items and recommended grocery additions) provides approximately 1200-1500 calories per day, with approximately 50%, 25%, and 25% of energy from carbohydrate, fat, and protein, respectively. The Nutrisystem® meal plan is consistent with the *Dietary Guidelines for Americans-2010* targets for fiber, saturated fat, and sodium.The program has been shown to be effective in randomized controlled trials [18-20].

Outcomes and assessments

The primary outcome of the study was weight change. We weighed participants in light clothing on a digital scale (model #740; Tanita Corporation; Tokyo; Japan). Secondary outcomes included changes in body mass index (BMI), waist circumference, glycemic control, blood pressure, lipids, mood, and health-related quality of life. Waist circumference was measured by trained staff at the Center for Translational and Clinical Research (CTRC) at the University of Colorado Hospital. Blood pressure was measured by CTRC staff, taking three measurements and resting 1 minute between each measurement. Blood for fasting lipids, highly sensitive C-reactive protein (hsCRP), and hemoglobin A1c were drawn after an overnight fast and analyzed on a Beckman-Olympus AU400e chemistry analyzer (lipids, glucose and hsCRP), a Siemens DCA Vantage analyzer (hemoglobin A1c), or a Perkin-Elmer Wizard 1470 Gamma Counter (insulin). Mood was measured with the Patient Health Questionniare (PHQ-9). Dietary outcomes were assessed with the Diet History Questionnaire (DHQ). Health-related quality of life was measured with the SF-12 (Medical Outcomes Study, Short Form 12) and with the feeling thermometer of the EuroQol-5D (EQ5D).

Data analysis

To analyze weight change between baseline and month 6, we used a conservative assumption that participants who dropped out prior to 6 months regained weight. Specifically, we assumed that individuals who dropped out gained 0.3 kg per month. We assumed that weight regain occurred either until they reached their baseline weight or until they reached 6 months (whichever event occurred first). This assumption of weight regain has been empirically validated [21]. Use of this method facilitated an intention-to-treat (ITT) analysis in which we were able to estimate weight change for all 106 individuals who entered the trial.

Weight loss predictors

Univariable regression analysis was conducted to explore the association of baseline characteristics with the outcome of weight loss at 6 months. Continuous variables (e.g., age, number of medications taken) were collapsed into categories for ease of interpretation from regression analyses, and t tests were used for dichotomous variables (e.g., gender). Variables with a p value of < 0.2 in univariable analysis were included in the multivariable model. Variables were added sequentially to the multivariable model, ultimately keeping those only with a p value < 0.05.

Sample size and power

We did not compute power for the outcome of weight loss at 6 months, as all participants received the same treatment during this time.

Funding and role of sponsors

The trial was funded through a scientist development grant from the American Heart Association to the principal investigator (award # 10SDG2610292). The funder did not have a role in the design of the trial or in data analysis or writing. Nutrisystem subsidized the use of its food products for study participants but did not pay funds to the study

Characteristic	Mean or N
Age, years	54.9 (10.5)
Gender	
Female	79 (74.5%)
Male	27 (26.5%)
Race	
White	85 (80.2%)
Black/African-American	14 (13.2%)
Mixed or other race	7 (6.6%)
Latino	
Yes	8 (7.5%)
No	98 (92.5%)
Education	
High school graduate	47 (44.3%)
College graduate	29 (27.4%)
Advanced degree	30 (28.3%)
Baseline conditions	
Diabetes	34 (32.1%)
Hypertension	58 (54.7%)
Hyperlipidemia	73 (68.9%)
Sleep apnea	35 (33.0%)
Number of medications	3.5 (2.7)
EQ5D thermometer (overall self-rated health; range 0-100)**	65.7 (17.9)
PHQ-9 (depression score; range 0-21)	6.7 (4.4)
IWQoL (range 30-155, higher scores better)	70.4 (20.9)
Weight loss goal (% initial weight)	25.7 (9.4)
TV time (hours per day)	3.1 (2.1)
Weight loss motivation (scale of 0-10)**	8.8 (1.6)
Alcohol intake (total drinks per week)	2.0 (3.1)
Stressors† (range 0-9)	1.5 (1.5)
Tobacco use	
Current smoker	3 (2.8%)
Past smoker	42 (39.6%)
Non-smoker	61 (57.4%)
Exercise limitation±	38 (38.4)

*Mean (sd) or categorical, listed as n (%)
**n = 104
†Sources of stress include work, financial, relationships, and others
± n = 99

Table 1: Baseline Characteristics of Study Participants*.

team. The study also received support from the CTRC at the University of Colorado for lab assays. The study was approved by the Colorado Multiple Institutional Review Board (protocol #10-0719).

Results

Participant flow

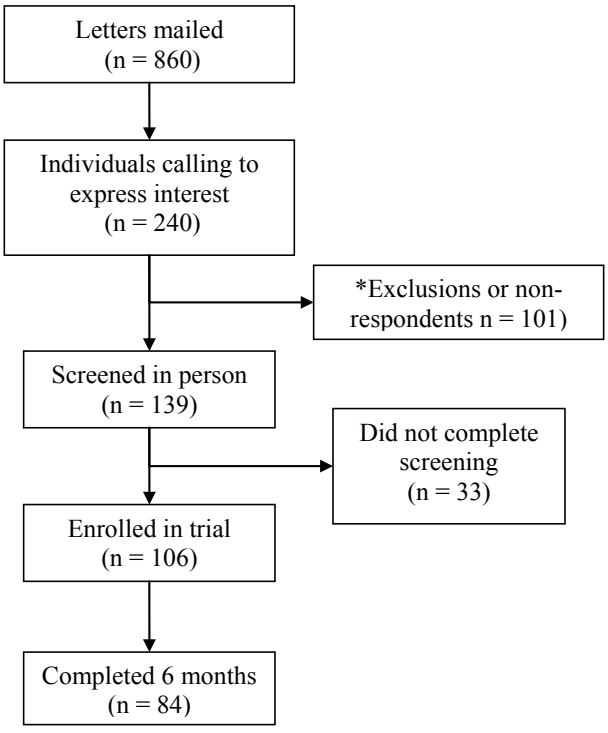
Table 1 shows the baseline characteristics of study participants. Participants had an average age of nearly 55, most were women, and more than half were college graduates. The Figure shows the flow of participants during the trial. A total of n=240 individuals were screened by telephone for participation. Of these, n=139 signed a consent form, of whom n=106 completed all enrollment procedures and entered the trial. A total of n=84 completed the first 6 months. Thus, attrition during the first 6 months was 22/106 (20.7%) (Figure 1).

Weight loss

Using intention-to-treat analysis with the assumption of weight regain, average weight loss from baseline to 6-month follow-up was 7.0 ± 7.0 kg, equal to 6.5 ± 6.1% of initial weight.Average weight loss among completers (n=84) was 8.6 ± 7.0 kg, equal to 8.0 ± 5.9% of initial weight.

Secondary outcomes

Changes in secondary outcomes are summarized in Table 4. Highly significant improvements were noted for most outcomes, including three out of four measures of health-related quality of life. These were the SF-12 Physical Component Summary, the Impact of Weight on Quality of Life (IWQoL), and the feeling thermometer of the EQ5D. No significant change was observed in the SF-12 Mental Component Summary Score. Significant improvements were noted in the PHQ-9 (depression) score and in the two nutrition parameters of most interest (total calorie intake and grams per day of fat). Significant improvements also were noted in cardiovascular disease risk factors. These risk factors included systolic and diastolic blood pressure, waist circumference, and glycemic control, as measured by hemoglobin A1c (the average participant went from a "pre-diabetes" value of 5.88% to a normal A1c value of 5.63%). Improvements were also noted in ratio of total to HDL cholesterol, in LDL cholesterol, and in triglycerides. Of



*Other exclusions: BMI out of range (n = 10); medical exclusions (n = 20); unable/unwilling to use portion-controlled foods (n = 10); no co-morbid condition present (n = 9); non-respondents after first call (n = 17); unable to attend in-person visits (n = 22); recent weight change of ≥ 5% (n = 11); other (n = 2)

Figure 1: The flow of participants during the trial.

	Baseline	Six Months	Change	P value
Waist circumference	114.9 ± 14.1	108.0 ± 12.7	-6.8 ± 6.0	< 0.001
Hemoglobin A1c	5.88 ± 0.71	5.63 ± 0.55	-0.25 ± 0.39	< 0.001
Highly sensitive C-reactive protein	5.46 ± 6.90	4.15 ± 4.85	-1.31 ± 5.59	0.03
Systolic Blood Pressure	127.4 ± 10.2	122.5 ± 12.9	-4.9 ± 9.6	< 0.001
DiastolicBlood Pressure	77.6 ± 8.0	74.9 ± 8.5	-2.7 ± 7.6	0.002
Ratio of total cholesterol to HDL cholesterol	3.91 ± 0.11	3.80 ± 0.11	-0.10 ± 0.06	0.09
LDL cholesterol	107.2 ± 3.5	103.0 ± 3.5	4.2 ± 2.3	0.08
Triglycerides	126.4 ± 5.8	114.0 ± 5.4	12.4 ± 4.5	0.007

*Values are mean ± sd

Table 2: Changes in Cardiovascular Risk Factors*.

	Baseline	Six Months	Change	P value
SF-12 PCS SF-12 MCS	47.9 ± 7.5 47.7 ± 10.0	51.2 ± 7.4 49.8 ± 9.1	3.3 ± 9.1 2.1 ± 11.7	0.018 0.23
IWQoL**	68.4 ± 21.3	52.1 ± 15.8	-16.3 ± 16.3	< 0.001
PHQ-9**	6.2 ± 4.1	3.3 ± 3.1	-2.9 ± 4.3	< 0.001
EQ5D	67.7 ± 18.1	75.7 ± 15.1	8.0 ± 17.5	< 0.001
DHQ Total calorie intake Fat grams/day	1934 ± 1179 76.8 ± 49.1	1441 ± 749 45.8 ± 29.3	-493 ± 912 -30.9 ± 39.3	< 0.001 < 0.001

*Values are mean ± sd
**A decrease in the IWQoL and in the PHQ-9 score indicates an improvement in the score.

Table 3: Changes in Health-Related Quality of Life, Mood, and Diet*.

the improvements in lipids, only the change in triglycerides reached statistical significance (Tables 2 and 3).

Univariable regression analysis

Several baseline characteristics had an association with weight change at 6 months. However, most associations did not reach statistical significance in univariable testing ($p<0.05$). Factors associated with greater weight loss at six months included: greater medication use; older age; male gender; lower PHQ-9 (depression) score, greater number of hours per week of television; and fewer stressors listed in the Weight and Lifestyle Inventory [22] (Table 4).

Multivariable regression analysis

In multivariable analysis, only older age and greater number of hour/week of television watched were associated with weight change (Table 5).

Discussion

In this summary of the results from the non-randomized phase of a clinical trial, clinically significant weight loss was achieved, even with conservative analysis assuming weight regain. Substantial improvements also were observed in cardiovascular disease risk factors, mood, and health-related quality of life. The weight loss of 8.6 kg among individuals completing 6 months of treatment was nearly identical to the mean weight loss of 8.5 kg reported in the Weight Loss Maintenance (WLM) trial among individuals completing the first 6 months of treatment [23]. The current trial is one of the first to use a trained layperson to treat individuals recruited from a primary care medical setting. The WLM Trial, for example, used trained behaviorists to lead their intervention.The current study used a layperson who received training from the principal investigator.

The six month weight losses in this study compare favorably with other trials of participants recruited from primary care settings. For example, Tsai et al. found a control-subtracted weight loss of 3.5 kg after 6 months among individuals recruited from two primary care clinics [24]. In a larger trial, Wadden et al. [21] reported a control-subtracted weight loss of 1.5 kg after 6 months among participants who received monthly counseling from medical assistants, based in primary care clinics [6]. These two trials offered moderate-intensity lifestyle interventions (approximately monthly visits). In two trials that used high-intensity intervention, Ma et al. reported a control-subtracted weight loss of 5.9 kg in their in-person coaching group [5], and Weinstock et al. reported a weight loss of 4.3 kg for their in-person intervention (4.5 kg for a conference call intervention that used the same curriculum) [7].

In this trial, very few baseline characteristics predicted weight loss. The only substantial predictor of weight loss was older age. This result is consistent with results of previous studies, including the multi-center Look AHEAD Trial, in which older age was a consistent predictor of greater weight loss [25]. Older individuals may have more predictable routines and fewer responsibilities (e.g., child care), giving

Variable	Weight Loss (% initial weight)	P value
Baseline conditions		F test: p = 0.08
1	**	
2	-2.71% (1.32)	0.26
3	-3.85% (1.70)	0.20
4	-0.25% (2.28)	0.59
Number of medications		F test: p = 0.08
0-1	**	
2-3	1.75 (1.55)	0.26
4-5	-2.21% (1.70)	0.20
≥6	-0.96% (1.76)	0.59
Age category		F test: p = 0.10
26-51	**	
52-60	-2.30% (1.43)	0.11
61-76	-2.87% (1.39)	0.04
Gender		
Women	-5.97% (0.69)	0.10
Men	-8.23% (1.07)	
Education		F test: p = 0.74
High school	**	
College graduate	-0.65% (1.44)	0.66
Advanced degree	-0.60% (1.43)	0.68
Race		F test: p = 0.26
White	**	
African-American/Black	1.23% (1.74)	0.48
Other race	3.68% (2.38)	0.12
Latino		
No	-6.81 (0.62)	0.12
Yes	-3.33 (1.41)	
IWQoL†	-0.01% (0.03)	0.84
PHQ-9†	0.23% (0.13)	0.09
EQ5D thermometer†	-0.02% (0.03)	0.55
Weight loss goal (% of initial weight)	0.02% (0.06)	0.78
Television time (hours per week)	-0.58% (0.28)	0.04
Weight loss motivation (0-10)	0.00% (0.39)	0.99
Alcohol (drinks per week)	-0.12% (0.19)	0.53
Stressors††	0.71% (0.42)	0.09
Current smoker		
Yes	-6.90% (3.00)	0.92
No	-6.53% (0.60)	
Past smoker		
Yes	-6.56% (0.98)	0.98
No	-6.53% (0.74)	
Exercise limitation		
Yes	-6.44% (0.98)	0.97
No	-6.39% (0.79)	

* Values are given as mean (SE).
** Comparator group
†IWQoL = Impact of Weight on Quality of Life; PHQ9 = depression score; EQ5D thermometer = "your overall health on a scale of 0-100"
†† From the Weight and Lifestyle Inventory; sources of stress include work, financial, relationships, and others

Table 4: Univariable Associations between Baseline Characteristics and 6-Month Weight Loss*.

The weight loss value lists the incremental change in weight (% of initial weight) between the comparator group and the subgroup listed in the table. The coefficient represents the incremental changes in weight (negative sign = weight loss) per unit change in the predictor variables. For example, a one unit increase in the PHQ-9 (depression) score at baseline was associated with weight gain of 0.23% of starting weight after 6 months. For categorical variables, the p value for the overall F test is also listed in the first row of the cell. For variables with two categories (e.g., gender), the mean weight loss for each group is listed, along with the p value for the t test.

	Weight Loss (% initial weight)	P value
Comparator Group	-2.84% (1.32)	0.04
Age category		
26-51	**	
52-60	-2.47% (1.41)	0.08
61-76	-3.05% (1.37)	0.03
Television time† (hours per week)	-0.61% (0.28)	0.03

* Values are mean (SE). A negative sign implies greater weight loss.
** Comparator group
†Percent weight change for each hour of television watched per week at Baseline.

Table 5: Multivariable Associations between Baseline Characteristics and 6-Month Weight Loss*

them more time to exercise and to plan meals that facilitate weight loss. Interestingly, in the current study, greater television watching at baseline also was associated with better weight loss. This result suggests that individuals who lost weight may have reduced their television watching time during the first 6 months. [We did not inquire at the 6-month time point about television time].

This study has at least three important limitations. First, this was a relatively high socioeconomic status population, and thus, participants likely had more time and resources to help control their weight, as compared to lower income populations. Second, although individuals were recruited from primary care settings for the trial, they were provided high-intensity treatment in a University-based weight loss center, with counseling visits lasting longer than they would in a typical primary care office setting. Third, participants were offered subsidized use of portion-controlled foods for weight loss, which is not typical of how health systems in the U.S. reimburse treatment for obesity.

In summary, this analysis shows excellent weight loss after the first 6 months of treatment, along with substantial improvements in secondary outcomes. Future publications will describe changes in medication utilization as well as weight losses at 18 months (12 months after randomization to a weight maintenance condition).

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