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Treatment of Obesity in Primary Care Practice: The Practice Based Opportunities for Weight Reduction (POWER) Trial at Johns Hopkins

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Introduction

Obesity has emerged as one of the most important and common public health problems in the United States and throughout most of the world. In the United States, approximately one third of adults are obese with a BMI ≥ 30 kg/m^2, and another third are overweight (BMI of 25 to 29.9 kg/m^2).[1] Obesity is associated with a substantially increased risk of morbidity and mortality, especially from cardiovascular disease (CVD).[2] The adverse effects of obesity on CVD are likely mediated through the effects of weight on traditional CVD risk factors (*e.g.,* hypertension, dyslipidemia, and diabetes), and possibly through mechanisms that are independent of these risk factors. In this setting, obesity and its CVD consequences are extraordinarily common problems that physicians routinely encounter in medical practice.

Options to treat obese patients include behavior therapy (with or without meal replacements), drug therapy, and bariatric surgery. Bariatric surgery is highly effective but is not appropriate for the vast majority of Americans who are overweight or obese.[3] Clinical trials have demonstrated that pharmacotherapy is effective, however, it is only recommended as an adjunct to diet and physical activity programs.[3,4] Treatments that include diet, physical activity, and behavior therapy are often referred to as lifestyle modification. The goal of lifestyle treatments is to induce weight loss by reducing calorie intake and increasing physical activity. In efficacy trials, in-person lifestyle interventions commonly induce a 10% average weight loss from baseline.[5] However, primary care providers (PCPs) typically had no direct involvement in these interventions, which were implemented independently of the medical care that participants were receiving.

Lifestyle Modifications for Weight Loss

Numerous trials, including several conducted by the Johns Hopkins Investigative team, have demonstrated the efficacy of lifestyle interventions in producing initial weight loss and improving CVD risk factors in overweight and obese adults. A more limited body of

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evidence has focused on strategies to maintain weight loss. Early trials tested in-person interventions conducted by trained weight loss interventionists, often registered dietitians. These trials demonstrated that weight loss can lower blood pressure, prevent hypertension, and substitute for antihypertensive medications.[6–8] Subsequently, the PREMIER trial documented the benefits of a comprehensive lifestyle intervention that combined weight loss with other lifestyle recommendations that lower blood pressure (*i.e.*, sodium reduction, increased physical activity, and the Dietary Approaches to Stop Hypertension [DASH] diet).[9–11] The PREMIER intervention, which meets each of the major recommendations advocated by the 2005 U.S. Dietary Guidelines, lowered blood pressure, controlled hypertension, and reduced estimated coronary heart disease risk in a diverse population of overweight and obese individuals. Both of the active interventions tested in the Practice Based Opportunities for Weight Reduction (POWER) Trial at Johns Hopkins are based on the PREMIER intervention.

A variety of distinct theories have informed the design of behavioral weight-loss interventions. Still, most programs have common elements, including behavioral self-management, motivational enhancement, and personalized feedback. Another core component of contemporary interventions is self-monitoring of weight and key behaviors (calorie intake and physical activity). Most programs have an early weight-loss phase, characterized by frequent (often weekly) contacts, followed by a maintenance phase with less frequent (typically monthly) contacts. The reduction in contact frequency from the weight loss to the weight maintenance phase is driven by practical issues, mostly cost, rather than scientific considerations. Indeed, the best available evidence supports continued intervention with frequent contacts.[12] The desire to sustain intervention at reduced cost has also spawned interest in use of the telephone and Internet to deliver weight-loss programs.

Weight Loss in the Primary Care Setting

Obesity and its complications are extraordinarily common medical problems, and the medical setting presents a tremendous opportunity to advocate behavioral change. Still, in the setting of routine medical care, the best approach to supporting lifestyle-based weight loss is not clear. Through advice and by example, physicians can have a powerful influence on their patients' willingness to make dietary lifestyle or behavioral changes. Nonetheless, there are substantial challenges. Constraints include limited space, particularly for group counseling sessions; insufficient training on behavioral therapies (*e.g.,* motivational interviewing); and limited capacity to deliver an onsite, in-person intervention with frequent contacts.

> The behavioral interventions tested in the POWER trial at Johns Hopkins are based on a series of successful efficacy trials that achieved and sustained weight loss.

The expense, time, and logistical complexities associated with in-person interventions, as well as the need to reach a growing number of obese individuals, have fostered interest in alternative channels for delivering weight loss interventions. To date, a limited but promising body of evidence supports the use of telephone- and Internet-based interventions.

Perhaps the most relevant study is a recent, comparative effectiveness trial, the Weight Loss Maintenance trial, which tested two lifestyle interventions: an intervention with monthly personal contacts (mostly by phone) and an Internet-based intervention.[13] Both interventions led to sustained weight loss over 18 months, but only the telephone-based personal contact intervention was effective at 30 months.

Recent reviews have also concluded that telephone-based and Internet-based interventions are less effective than in-person–based interventions.[5,14] Nonetheless, in view of the need for frequent, inexpensive contacts in weight-loss programs, there remains substantial interest in use of telephone and Internet-based interventions. This is an especially critical issue for delivery of interventions that target medical outpatients, because the typical medical office has no space for large meetings and limited office space for one-on-one health counseling. In this setting, telephone interventions that use an existing healthcare delivery infrastructure, such as that found in disease management companies, have considerable appeal.

The POWER Trial at Johns Hopkins

The POWER trial at Johns Hopkins is one of three independent trials in the POWER Trials consortium, each supported by a U01 grant from the National Heart, Lung, and Blood Institute (NHLBI). The POWER trial at Johns Hopkins is a three-arm comparative effectiveness trial that tests the effectiveness of two practical behavioral weight-loss programs. The two active treatment groups—In Person Directed (IPD) and Call Center Directed (CCD)—are compared to a Self-Directed (SD) comparison group. Each of the active interventions is delivered by a weight-loss coach. In contrast to prior efficacy studies, the primary care physician (PCP) has an active supportive role in promoting weight loss. The IPD arm includes both group and one-on-one, in-person sessions, but the site of delivery is a clinical center that is separate from the participating medical practices. The CCD arm is implemented telephonically by coaches at Healthways, Inc., a disease management company. There are no in-person visits in CCD. An interactive website with portals for both patient and coach is a key component of the two active treatment arms.

Participants

Participants were recruited from six primary care practices in the Baltimore metropolitan and surrounding areas during a 1-year period. Recruitment occurred through physician referral, brochures, and targeted mailings. Patients at the participating clinics were eligible for the study if they were obese (BMI ≥ 30 kg/m^2), demonstrated basic Internet skills, had routine Internet access, and had at least one of the following cardiovascular risk factors: hypertension, hypercholesterolemia, or diabetes mellitus. Eligibility was determined over a series of contacts, including Web- and telephone-based contacts, as well as in-person visits. In order to increase the generalizability of these findings, the eligibility criteria were less stringent than previous weight-loss trials conducted by our research group.

Randomized Groups

Key features of the three randomized arms are displayed in Table 1. The contact pattern for each arm is provided in Table 2. Once randomized, all participants are given the same NHLBI brochure, *Aim for a Healthy Weight,* which provides guidance on how to eat healthy, reduce calories, and increase activity levels to lose weight.[15] All participants were also given a National Institute of Diabetes and Digestive and Kidney Disease (NIDDK) brochure, *What I need to know about Physical Activity and Diabetes*, which provides guidance for diabetics to safely increase their physical activity levels.[16] Participants in all three arms are encouraged to maintain their usual visit schedule with their PCPs. Special visits with the PCP for weight management are neither recommended nor discouraged.

The active treatment arms (IPD and CCD) have several common features, even though they differ in their mode of delivery and contact pattern. The goal of both arms is to induce a loss of 5%, or more, of initial weight by 6 months and to maintain this weight loss at 24 months. The active treatment arms share the same dietary and physical activity goals shown in Table 1. Both arms also receive access to the study website that includes the interactive educational modules and self-monitoring tools. The web-based modules include nine introductory weight-loss modules to be completed in the first 3 months (see Table 3) followed by an additional module every month across the remainder of the trial. The introductory modules focus on self-monitoring, stimulus control, social support, problem solving, and cognitive restructuring. Participants must complete a self-assessment quiz for each introductory module before gaining access to the next module. Because of the online access to self-learning modules and self-monitoring, participants can “restart” their program at any time by reviewing past materials.

Both of the active treatment arms receive weight loss coaching weekly for the first 3 months, followed by decreasing contact rates during less intensive phases (Table 2). Participants in the active treatment arms are encouraged to enter a weight every week. Ongoing self-monitoring of weight, diet, and physical activity on the website is encouraged throughout the study. Participants who have not entered a weight in the last 7 days cannot gain access to the rest of the study website until entering a recent weight. The next sections provide additional information about the three arms.

Self-directed arm

The SD arm serves as a comparison group, which reflects usual medical care (*i.e.,* provision of information). Participants assigned to SD meet with a weight-loss coach at the time of randomization for a brief orientation and again at the end of study. These participants also receive access to a webpage with links to recommended weight-loss websites.

In-person directed intervention

Participants assigned to IPD receive a lifestyle intervention consisting of: group and one-on-one meetings led by the weight-loss coach (Table 2); the Web-based lifestyle counseling curriculum; and online tools for behavioral self-monitoring. IPD participants have access to group weight-loss classes and receive one-on-one counseling from the coach either in person

or over the telephone. The coaches encourage participants to complete the educational modules and reinforce key behaviors with an emphasis on online self-monitoring of weight, food intake, and activity. In addition, a series of automated e-mails are sent to participants who have not logged into the website in the past 7 days. The coaches follow-up with reminder calls if website inactivity persists. Finally, automated monthly e-mails are sent to all participants in this arm to summarize weight loss progress.

Call-center directed intervention

Participants assigned to CCD receive a lifestyle intervention consisting of: contacts with a coach by phone; the Web-based lifestyle counseling curriculum; and online tools for behavioral self-monitoring. CCD participants receive telephone calls from the Healthways, Inc., coach throughout the study (Table 2). These calls cover the same topics addressed in the IPD sessions. The Healthways coaches encourage participants to complete the educational modules and reinforce key behaviors with an emphasis on online self-monitoring of weight, food intake, and physical activity. Participants in the CCD group receive the same automated e-mail reminders and follow-up reminder calls to login, along with the same automated monthly email feedback as those assigned to IPD.

Treatments that include diet, physical activity, and behavior therapy are often referred to as lifestyle modification.

Role of the Primary Care Provider

A novel and important aspect of the IPD and CCD interventions is PCP involvement. This component of the intervention was developed with substantial input from the medical directors of participating clinics. Rather than implementing the interventions, the PCPs have a supportive role in advising their patients to actively participate in the IPD and CCD interventions and in reviewing progress at routinely scheduled medical visits.

For counseling at upcoming office visits, the PCP receives an up-to-date report, intended to guide a brief supportive message on weight loss. A prominent feature of the report is a weight graph with the patients' baseline weights, their target weights, and self-reported weights from the website. The report also reminds the PCP to: (1) acknowledge that losing weight is challenging; (2) encourage the patient to keep scheduled appointments with their coach; (3) remind the patient that the program is based on proven principles; and (4) point out the individual health benefits of weight loss (*e.g.,* control of hypertension, hypercholesterolemia, and diabetes). These reminders focus on the weight management process and are independent of patient success with weight loss. When patients are not actively participating in their prescribed intervention, or not attending routine study data collection visits, letters are sent from the PCP encouraging continued involvement in the study.

Outcomes

The primary outcome variable is change in weight from baseline to 24 months post randomization. Secondary outcomes are other dimensions of weight (% weight change, % of participants without weight gain); blood pressure and hypertension control; lipid levels (total cholesterol, low-density lipoprotein cholesterol [LDL-C], high-density lipoprotein cholesterol [HDL-C], and triglycerides) and control; glucose, insulin, and insulin resistance, as assessed by the homeostasis model assessment of insulin resistance (HOMA-IR) index; and Framingham Risk Score. A cost-effectiveness analysis will be performed.

Discussion

Although obesity is an extraordinarily common problem in primary care practice, there is a dearth of evidence on how to induce and sustain weight loss in obese medical patients. Fortunately, there is a substantial body of evidence from efficacy trials, conducted in other settings, which can inform the design and implementation of interventions that target medical patients. The behavioral interventions tested in the POWER trial at Johns Hopkins are based on a series of successful efficacy trials that achieved and sustained weight loss.[6,7,9,13] The IPD and CCD interventions are adapted from these lifestyle intervention trials. A salient feature of the POWER interventions is the involvement of PCPs in supporting weight loss.

We anticipate that both the IPD and CCD interventions will reduce weight. Critical questions are the extent of weight loss from each program and cost of implementation. The IPD approach might reduce weight to a greater extent than CCD. Still, CCD should be less costly and more flexible to implement. The CCD approach also has the advantage of being readily “scalable,” that is, if successful, it could be rapidly implemented by healthcare organizations, including disease management companies, that implement telephone-based interventions. The IPD intervention has a more traditional approach to weight loss but could still be implemented in a variety of settings (*e.g.,* wellness programs, large clinics, HMOs, hospitals) and might be more applicable to higher risk patients.

Obesity and its complications are extraordinarily common medical problems.

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Table 1.

Features of Randomized Groups

	RANDOMIZED GROUPS		
	SELF-DIRECTED (SD)	**CALL CENTER DIRECTED (CCD)**	**IN-PERSON DIRECTED (IPD)**
Weight-loss goal	Advised to follow general diet and physical activity guidelines for weight loss: *Aim for a Healthy Weight*	5% weight loss from randomization	
Total calorie recommendation		1200 kcal/d if ≤ 170 lb 1500 kcal/d if > 170 lb and ≤220 lb 1800 kcal/d if > 220 lb and ≤ 270 lb 2200 kcal/d if > 270 lb	
Dietary recommendation		DASH diet	
Physical activity goal		180 minutes moderate intensity exercise per week	
Recommended frequency of tracking food intake and physical activity		Daily	
Recommended frequency of self-weighing		At least weekly	
Online feedback based on self-monitoring		After each weight log in	
Automated e-mail feedback based on self-monitoring		Monthly feedback, re-engagement reminders	

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Table 2.

Overview of Contact Types and Frequency by Randomized Group

	SELF-DIRECTED (SD)	CALL CENTER DIRECTED (CCD)	IN-PERSON DIRECTED (IPD)
Contacts (months 1–3)			
Group sessions	0	0	3 per Month
Individual face-to-face sessions	At randomization	0	Monthly
Telephone sessions	0	Weekly	0
E-mail	0	As needed for scheduling and re-engagement	
Contacts (months 4–6)			
Group sessions	0	0	Monthly
Individual face-to-face sessions	0	0	Monthly
Telephone sessions	0	Monthly	Monthly
E-mail	0	As needed for scheduling and re-engagement	
Contacts (months 7–24)			
Group sessions	0	0	Monthly
Individual face-to-face sessions	End of study	0	1 per 4 Months
Telephone sessions	0	Monthly	3 per 4 Months
E-mail	0	As needed for scheduling and re-engagement	
Restart options	None	Any time via online learning and self-monitoring feedback	

Table 3.

Summary of Module Topics for the First Six Months of Treatment

MONTH	MODULE	SESSION TITLE	DESCRIPTION
1	1	The Basics of Self-Monitoring	Use of self-monitoring features on website for weight loss
	2	Safe Effective Exercise for Weight Management	Introduce safe and appropriate exercise goals for weight loss
	3	Energy Balance—The Truth about Weight Loss	Calorie balance, reading labels, serving versus portion size
2	4	Nutrition for Health	Introduction to the DASH diet.
	5	Making Changes	Setting lifestyle goals: planning meals, shopping, healthier cooking
	6	Creating the Exercise Habit	Committing to the process of regular exercise and building social support
3	7	Common Challenges to Weight Management	Review common barriers and techniques to address these challenges
	8	Problem Solving	Learning individual problem solving skills
	9	Weight Management for Life	Preparing for a transition to independence and decreased contacts with coaches
4	10	Stress Management	Addressing common stressors that impact lifestyle goals of healthy eating and regular physical activity
5	11	Time Management	Making weight loss a priority in your daily schedule
6	12	Relapse Prevention	Identifying common causes of lapses and how to avoid them