Fast and Furious: Rapid Weight Loss Via a Very Low Calorie Diet May Lead to Better Long-Term Outcomes Than a Gradual Weight Loss Program


Study Overview

Objective. To determine if the rate at which a person loses weight impacts long-term weight management.

Design. Two-phase, non-masked, randomized controlled trial.

Setting and participants. Study participants were recruited through radio and newspaper advertisements and word of mouth in Melbourne, Australia. Eligible participants were randomized into 2 different weight loss programs—a 12-week rapid program or a 36-week gradual program—using a computer-generated randomization sequence with a block design to account for the potential confounding factors of age, sex, and body mass index (BMI). Investigators and laboratory staff were blind to the group assignments. Inclusion criteria were healthy men and women aged between 18–70 years who were weight stable for 3 months and had a BMI between 30.0–45.0kg/m². Exclusion criteria included use of a very low energy diet or weight loss drugs in the previous 3 months, contraceptive use, pregnancy or lactation, smoking, current use of drugs known to affect body weight, previous weight loss surgery, and the presence of clinically significant disease (including diabetes).

Intervention. Participants were randomized to the rapid or gradual weight loss program, both with the stated goal of 15% weight loss. For phase 1, participants in the rapid weight loss group replaced 3 meals a day with a commercially available meal replacement (Optifast, Nestlé Nutrition) over a period of 12 weeks (450–800 kcal/day). Participants in the gradual group replaced 1 to 2 meals daily with the same supplements and followed a diet program based on recommendations from the Australian Guide to Healthy Eating for the other meals over a period of 36 weeks (400–500 kcal deficit per day). Both groups were given comparable dietary education materials and had appointments every 2 weeks with the same dietician. Participants who achieved 12.5% or greater weight loss were eligible for phase 2. In phase 2, participants met with their same dietician at weeks 4 and 12, and then every 12 weeks until week 144. During appointments, the dietician assessed adherence based on participants’ self-reported food intake, and participants were encouraged to partake in 30 minutes of physical activity per day.
activity of mild to moderate intensity. Participants who gained weight were given a 400–500 kcal deficit diet.

Main outcome measures. The main outcome was mean weight loss maintained at week 144 of phase 2. Secondary outcomes were mean difference in fasting ghrelin and leptin concentrations measured at baseline, end of phase 1 (week 12 for rapid and week 36 for gradual), and at weeks 48 and 144 of phase 2. The authors examined the following changes from baseline: weight, BMI, waist and hip circumferences, fat mass, fat free mass, ghrelin, leptin, and physical activity (steps per day). A standardized protocol was followed for all measurements.

Results. Researchers evaluated 525 participants, of which 321 were excluded for ineligibility, being unwilling to participate, or having type 2 diabetes. Of the 204, 4 dropped out after randomization leaving 97 in the rapid weight loss group and 103 in the gradual group during phase 1. The mean age of participants was 49.8 (SD = 10.9) years with 25.5% men. There were no significant demographic or weight differences between the 2 groups. The completion rate for phase 1 was 94% in the rapid program and 82% of the gradual program. The mean phase 1 weight changes in the rapid and gradual program groups were –13 kg and –8.9 kg, respectively. A higher proportion of participants in the rapid weight loss group lost 12.5% or more of their weight than in the gradual group (76/97 vs. 53/103). 127 participants entered phase 2 of the study (2 in the gradual group who lost 12.5% body weight before 12 weeks were excluded). 1 participant in the rapid group developed cholecystitis requiring cholecystectomy.

In Phase 2, seven participants in the rapid group withdrew due to logistical issues, psychological stress, and other health-related issues; 4 participants in the gradual group withdrew for the same reasons, as well as pregnancy. 2 participants from the rapid group developed cancer. All but 6 participants regained weight (5 in rapid group, 1 in gradual group) and were put on a 400-500 kcal deficit diet. There was no significant difference in mean weight regain of the rapid and gradual participants. By week 144 of phase 2, average weight regain in the gradual group was 10.4 kg (95% confidence interval [CI] 8.4–12.4; 71.2% of lost weight regained, CI 58.1–84.3) and 10.3 kg in rapid weight loss participants (95% CI 8.5–12.1; 70.5% of lost weight regained, CI 57.8–83.2). This result did not change significantly in the intention to treat analysis where dropouts were assumed to return to baseline.

During phase 2, leptin concentrations increased in both groups, and there was no difference in leptin concentrations between the 2 groups at weeks 48 and 144, nor were they significantly different from baseline at week 48. Ghrelin concentrations increased in both groups from baseline, but there was no significant difference between the groups at the end of 144 weeks.

Conclusion. In highly selected Australian participants, rapid weight loss (12 weeks) using a very low calorie meal replacement program led to greater weight loss than a gradual weight loss program (36 weeks) using a combination of meal replacements and diet recommendations. In participants who lost 12.5% or greater body weight, the speed at which participants regained weight was similar in both groups.

Commentary

Obesity rates have increased globally over the past 20 years. In the United States, Yang and Colditz found that approximately 35% of men and 37% of women are obese and approximately 40% of men and 30% of women are overweight, marking the first time that obese Americans outnumber overweight Americans [1]. Approximately 45 million Americans diet each year, and Americans spend $33 billion on weight-loss products annually. Thus, we need to determine the most effective and cost-effective weight management practices. The Purcell et al study suggests that a 12-week intervention may lead to greater weight loss and better adherence than a 36-week program, and that weight regain in participants achieving 12.5% or greater weight loss may be the same in both interventions. While they did not formally evaluate cost effectiveness, these findings suggest that a rapid weight loss program through a very low calorie diet (VLCD) may be more cost-effective since they achieved better results in a shorter period of time. However, caution must be taken before universally recommending VLCDs to promote rapid weight loss.

Many organizations advise patients to lose weight slowly to increase their chances of reaching weight loss goals and long-term success. The American Heart Association, American College of Cardiology, and The Obesity Society (AHA/ACC/TOS) guidelines for the management of overweight and obesity in adults recommend 3 types of diets for weight loss: a 1200–
1800 calorie diet, depending on weight and gender; a 500 kcal/day or 750 kcal/day energy deficit, or an evidence-based diet that restricts specific food types (such as high-carbohydrate foods) [2]. These guidelines also state that individuals likely need to follow lifestyle changes for more than 6 months to increase their chances of achieving weight loss goals [2]. They acknowledge maximum weight loss is typically achieved at 6 months, and is commonly followed by plateau and gradual regain [2]. The US Preventive Services Task Force (USPSTF) also advises gradual weight loss [3].

The results of the Purcell et al study and others provide evidence that contradicts these recommendations. For example, Nackers et al found that people who lost weight quickly achieved and maintained greater weight loss than participants who lost weight gradually [4]. Further, those who lost weight rapidly were no more susceptible to regaining weight than people who lost weight gradually [4]. Toburo and Astrup also found the rate of initial weight loss had no impact on the long-term outcomes of weight maintenance [5]. Astrup and Rössner found initial weight loss was positively associated with long-term weight maintenance, and rapid weight loss resulted in improved sustained weight maintenance [6]. Finally, Wing and Phelan found the best predictor of weight regain was the length of time weight loss was maintained, not how the weight was lost [7].

VLCDs replace regular meals with prepared formulas to promote rapid weight loss, and are not recommended for the mildly obese or overweight. VLCDs have been shown to greatly reduce cardiovascular risk factors and relieve obesity-related symptoms; however, they result in more side effects compared to a low calorie diet [8]. Individuals who follow VLCDs must be monitored regularly to ensure they do not experience serious side effects, such as gallstones, electrolyte imbalance that can cause muscle and nerve malfunction, and an irregular heartbeat [9]. Indeed, 1 patient in the rapid group required a cholecystectomy. The providers in this study were obesity specialists, which may account for the strong outcomes and relatively few adverse events.

This study has many strengths. First, researchers achieved low rates of attrition (22% compared to about 40% in other studies) [9,10]. This study also followed participants for 2 years post-intervention and achieved high rates of weight loss in both groups. In addition to low dropout rates and long-term follow-up, the population was highly adherent to each intervention. Limitations of the study include that the authors were highly selective in choosing participants—none of the participants had obesity-related comorbidities such as diabetes or significant medical conditions. Individuals with these conditions may not be able to follow the dietary recommendations used in this study, restricting generalizability from a population that is largely overweight and obese. Further, all participants were from Melbourne, Australia. Since the authors did not provide data on race/ethnicity, we can assume a relatively homogeneous population, further limiting generalizability.

### Applications for Clinical Practice

This study suggests that rapid weight loss through VLCDs may achieve better weight loss outcomes and adherence when compared to more gradual programs without resulting in higher weight regain over time in highly selected patients treated by obesity specialists. Caution must be advised since primary care practitioners may not have sufficient training to deliver these diets. VLCDs have higher risk of gallstones and other adverse outcomes such as gout or cardiac events [11,12]. A more gradual weight loss program, similar to the 36-week program in the Purcell et al study, used meal replacements and achieved outcomes that were relatively high, with 72% achieving at least 5% weight loss, and 19% achieving 15% weight loss or greater ($P < 0.001$) [13]. Indeed, meal replacements of 1 to 2 meals per day have been shown to be safe and effective in primary care [14]. Current AHA/ACC/TOS guidelines on VLCDs are inconclusive, stating there is insufficient evidence to comment on the value of VLCDs, or on strategies to provide more supervision of adherence to these diets [2]. Thus, practitioners without training in the use of VLCDs should still follow USPSTF and other recommendations to promote gradual weight loss [2]. However, if patients want to lose weight faster with a VLCD, then providers can refer them to an obesity specialist since this may promote greater adherence and long-term weight maintenance in select patients.

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### References


Expanding High Blood Pressure Screening to the Nonprimary Care Setting to Improve Early Recognition


**Study Overview**

**Objective.** To identify the prevalence and characteristics of patients identified with high blood pressure (BP) in nonprimary care compared with primary care visits.

**Design.** Longitudinal population-based study.

**Setting and participants.** This study was conducted at Kaiser Permanente Southern California (KPSC) after implementation of a system-wide change to improve hypertension care, which included comprehensive decision support tools embedded in the EHR system, including BP measurement flag alerts. Patient eligible for the study were normotensive members (BP < 140/90 mm Hg), older than 18 years, and enrolled in a KPSC health plan for at least 12 months on January of 2009. A gap of < 3 months in health care coverage in the year prior was allowed. Excluded were patients with a history of elevated BP during an outpatient visit, an inpatient or outpatient diagnosis code for hypertension, prescription for any antihypertensive medication within 24 months prior to 1 January 2009, missing BP information or whose only BP measurements were from a visit indicating fever or in preparation for a surgery or pain management. Pregnant patients, patients with missing sex information, and missing visit specialty information were also excluded. The study period was from January 2009 to March 2011.

**Measurement.** BP was measured routinely at the beginning of almost every primary and nonprimary outpatient visit. Nurses and medical assistants were trained according to a standard KPSC protocol using automated sphygmomanometer digital devices. According to the study protocol, in cases in which BP was elevated (≥ 140/90 mm Hg), a second measurement was obtained. At KPSC, all staff members including those in
primary and nonprimary care are certified in BP measurement during their initial staff orientation and recertified annually.

**Main outcome measure.** An initial BP $\geq 140/90$ mm Hg during a primary or nonprimary care outpatient visit.

**Results.** The mean ages of patients at baseline and at end of follow-up for the primary outcome were 39.7 (SD, 13.9) and 41.5 (SD, 14.0) years, respectively. The total cohort ($n = 1,075,522$) was nearly equally representative of both men (48.6%) and women (51.4%). The majority of the patients (91.7%) were younger than 60 years. A large proportion of the cohort belonged to racial/ethnic minorities with 33.1% Hispanic, 6.5% black, and 8.4% Asian/Pacific Islander.

The total cohort had 4,903,200 office visits, of which 3,996,190 were primary care visits, 901,275 nonprimary care visits, and 5735 visits of unknown specialty. During a mean follow-up of 1.6 years (SD, 0.8) 111,996 patients had a BP measurement $\geq 140/90$ mm Hg. Of these, 92,577 (82.7%) were measured during primary care visits and 19,419 (17.3%) during nonprimary care visits. Of 15,356 patients with confirmed high BP, 12,587 (82%) were measured during primary care visits and 2769 (18.0%) patients during nonprimary care visits. Patients with a BP $\geq 140/90$ mm Hg measured during nonprimary care visits were older, more likely to be male and non-Hispanic white, less likely to be obese, but more likely to smoke or have a Framingham risk score $\geq 20%$. Ophthalmology/optometry, neurology, and dermatology were the main specialties to identify a first BP $\geq 140/90$ mm Hg.

The follow-up after a first elevated BP was marginally higher in patients identified in nonprimary care than in primary care. Among patients with a first BP $\geq 140/90$ mm Hg measured during a primary care visit, 60.6% had a follow-up BP within 3 months of the first high BP, 22.9% after 3 months or more, and 16.5% did not have a follow-up BP. Among individuals with a first BP $\geq 140/90$ mm Hg measured during a nonprimary care visit, 64.7% had a follow-up BP within 3 months of the first high BP, 22.6% after 3 months or more, and 12.7% did not have a follow-up BP measurement.

The proportion of false-positives, defined as individuals with an initial BP $\geq 140/90$ mm Hg who had a follow-up visit with a normal BP within 3 months, was the same for patients identified in primary and nonprimary care. False-positives were most frequent in individuals identified during visits in other specialty care, rheumatology, and neurology fields.

**Conclusion.** Expanding screening for hypertension to nonprimary care settings may improve the detection of hypertension and may contribute to better hypertension control. However, an effective system to ensure appropriate follow-up if high BP is detected is needed. Elderly, non-Hispanic, white male patients and those with very high BP are more likely to benefit from this screening.

**Commentary**

Hypertension is a common and costly health problem [1]. BP screening can identify adults with hypertension, who are at increased risk of cardiovascular and other diseases. Effective treatments are available to control high BP and reduce associated morbidity and mortality [2], but the first step is to identify patients with this largely asymptomatic disorder.

BP measurement is standard practice in primary care. However, many people do not regularly see a primary care clinician. In this study, researchers aimed to identify the prevalence and characteristics of patients identified with high BP in nonprimary care compared with primary care visits in a large integrated health care system that had implemented a system-level, multifaceted quality improvement program to improve hypertension care. Of the patients who were found to have high BP, 83% were diagnosed in a primary care setting and 17% in a specialty care setting, and the number of false-positive results were comparable.

In general, the study was well conducted and a strength of the study was the large sample size. Limitations included the fact that the study was conducted as part of a quality improvement project in an integrated health system, and there were no control clinics.

The authors noted that a high BP reading requires adequate follow-up, and nonprimary care detected elevated BP patients had lower follow-up rates. Also, some specialties had higher false-positive rates. Quality of measurement can be maximized with regular staff training.

**Applications for Clinical Practice**

Expanding routine screening for hypertension to nonprimary care can potentially improve rates of detection,
capturing patients who might otherwise have been missed. An effective system to ensure appropriate follow-up attention if high BP is detected is essential, and it is important that staff be well trained in using standard technique to minimize false-positives, which could lead to unnecessary resource use.

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References