

Two Shakes and a Sensible Dinner

Ashley JM, St Jeor ST, Schrage JP, et al. Weight control in the physician's office. *Arch Intern Med* 2001;161:1599-604.

Study Overview

Objective. To determine if a long-term lifestyle change using meal replacement can successfully be implemented in a primary care office, and to determine if a dietitian-administered lifestyle modification program incorporating meal replacement is as effective as the same program using a standard food-exchange strategy.

Design. Randomized study. Analysis was by intention to treat.

Setting and participants. Overweight or obese premenopausal women aged 25 to 50 years with a body mass index (BMI) between 25 and 35 were recruited for the study, which was conducted at the University of Nevada. Only subjects who obtained a medical release form signed by their physician were selected. Women were excluded who suffered from current chronic or psychological disease; had significant abnormal serum laboratory values; were receiving hormone replacement therapies; were pregnant, planning to become pregnant, or lactating; or were planning to move out of the area in the following year.

Intervention. Patients were randomly assigned to 1 of 3 intervention groups. Each intervention consisted of 26 sessions held over a 1-year period, with diet instruction including instructions to follow a low-calorie diet of about 1200 kcal/day based on the U.S. Department of Agriculture food guide pyramid. Patients in group 1 attended small classes led by a registered dietitian and followed a diet in which all meals and snacks were prepared from self-selected conventional foods. Patients in group 2 also attended small dietitian-led classes but substituted 2 of the 3 main meals with meal-replacement shakes or bars. Patients in group 3 received an intervention that incorporated meal replacement with individual visits to a primary care physician or nurse. Subjects in groups 2 and 3 who achieved their target weight (a loss of 10% of initial body weight) were instructed to replace just 1 (rather than 2) of their 3 meals with a shake or bar. If subjects regained weight, they were to resume their original diet (substituting 2 of 3 meals with meal replacements) until the regained weight was lost. Funding for the study was provided by the Slim-Fast Nutrition

Institute, and meal-replacement products were produced by Slim-Fast Foods Co.

Main outcome measures. Weight, skinfolds, waist circumference, blood pressure, resting energy expenditure, and height were measured at baseline and 1 year. Secondary measures included levels of insulin, lipids, and glucose.

Main results. Of 113 female subjects who met inclusion criteria and agreed to participate, 74 patients (65%) completed the study. Patient characteristics at baseline and dropout rates were similar across study groups. When results for subjects who completed the study were evaluated, subjects in group 2 had lost significantly more weight at 1 year than those in either group 1 or group 3 ($P = 0.03$). Mean weight loss was 7.7 ± 7.8 kg ($9.1\% \pm 8.9\%$ of initial body weight) in group 2, 3.5 ± 5.5 kg ($4.3\% \pm 6.5\%$ of initial body weight) in group 3, and 3.4 ± 5.4 kg ($4.1\% \pm 6.4\%$ of initial body weight) in group 1. In addition, a significant decrease in BMI occurred in group 2 compared with group 1 ($P = 0.02$).

Year-end weight changes were also determined in the intention-to-treat model, which included all patients enrolled in the study whether or not they completed the 1-year intervention ($n = 113$). In this analysis, similar findings were obtained. Group 2 patients lost the most weight in 1 year, losing an average of 3.7 kg more than group 1 patients ($P = 0.008$) and 3.0 kg more than group 3 patients ($P = 0.04$). Analysis across groups showed that weight loss of 5% to 10% was associated with a significant reduction in percentage of body fat, BMI, waist circumference, resting energy expenditure, insulin level, total cholesterol level, and low-density lipoprotein level ($P = 0.01$). Weight loss of 10% or more was associated with additional significant improvements in blood pressure and triglyceride level ($P = 0.05$).

Conclusion. Lifestyle interventions using meal replacements and performed in either a physician's office or in a dietitian-led group setting can achieve significant and sustained weight control.

Commentary

Obesity has become a serious problem in the United States.

Between 1988 and 1991, the percentage of obese individuals (ie, those with a BMI of more than 30 kg/m²) nearly doubled among men and rose by 50% among women [1]. The total number of obese people in the United States is around 97 million. Obesity increases risk for developing diabetes, coronary artery disease, hypertension, congestive heart failure, and cardiovascular accident [2]. Unfortunately, weight reduction is difficult to achieve and maintain. In 1998, the National Institutes of Health published guidelines [3] to address this issue and found that a few interventions are effective, including pharmacotherapy, behavioral intervention, and gastroplasty. However, health providers often do not adequately educate and counsel their patients on weight control. A recent study demonstrated that less than one half of obese adults reported that a health care professional had advised them to lose weight [4].

This interesting study by Ashley and colleagues is the first long-term study to examine the efficacy of meal replacement combined with behavioral modifications performed in a primary care office. The randomized design, intention-to-treat analysis, and acceptable dropout rate (35%) are among the study's strengths. In addition, the use of a primary care clinic makes results more realistic. One notable weakness was the self-referred patient population, whose overall motivation was likely higher than would be expected in "regular" patients seen in the office. If the study were repeated with patients who were not self-referred, results would probably be less impressive. Also, weight losses were relatively modest despite the intensity of the intervention (26 visits in 1 year). As is typical in similar programs, benefits may not persist beyond 1 year because of the difficulties involved in following such intense treatment. Finally, only women were enrolled in the study, and thus study results cannot be generalized to men. Despite these shortcomings, Ashley et al's work

confirms findings from previous studies showing that weight reduction can be achieved and that even modest weight reduction has significant health benefits.

Applications for Clinical Practice

The results from this study would be probably difficult to reproduce in a regular primary care clinic. Because meal replacements are safe and simple to use, they may be worth trying in addition to other modalities that have been shown to be effective. Doing so could improve obesity-related health problems, even if only a modest weight reduction is achieved [5].

References

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