

# PREFER study: A randomized clinical trial testing treatment preference and two dietary options in behavioral weight management — rationale, design and baseline characteristics<sup>☆</sup>

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## Abstract

**Background:** Obesity, a disorder associated with a myriad of comorbidities, is increasing at an alarming rate around the world. Given that pharmacotherapy has limited available options and that bariatric surgery is reserved for those who are morbidly obese or who have significant comorbidities, the most common approach to the treatment of obesity is standard behavioral treatment. This approach includes behavior modification related to eating and activity habits. The purpose of this paper is to describe the rationale, design, methods and baseline sample characteristics of a randomized controlled trial of a behavioral intervention in weight loss management, referred to as the PREFER study.

**Methods:** The PREFER study, using a four-group design, includes: (1) a randomization scheme that permits participants to indicate a preferred dietary treatment approach, and (2) two dietary options, one of which is a lacto-ovo-vegetarian diet that has demonstrated potential for long-term adherence. The intervention (32 treatment sessions) is delivered over 12 months and is followed by a 6-month maintenance phase; final assessment occurs at 18 months.

**Results:** We screened 932 individuals and randomized 197 to the study: Treatment Preference-Yes ( $n=84$ ) and Treatment Preference-No ( $n=98$ ). To maintain a balance across the four treatment groups, 15 subjects who preferred the standard diet had to be discarded from the Treatment Preference-Yes group. Retention at 18 months for the first of three cohorts was 82%.

**Conclusions:** The PREFER study is a single center study and is the first randomized controlled trial examining a lacto-ovo-vegetarian diet as part of weight loss treatment. The ethnically diverse sample includes males and females with a body mass index of 27 to 43. The study has the potential to make a contribution to understanding the role of treatment preference and the potential of a lacto-ovo-vegetarian diet for long-term weight loss.

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**Keywords:** Obesity; Treatment preference; Lacto-ovo-vegetarian diet; Standard behavioral treatment of obesity; Randomized clinical trial; Research design; Two-factor analysis; Adherence

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## 1. Introduction and background

According to the 1999–2000 National Health and Nutrition Examination Survey (NHANES) estimates, obesity is increasing at an alarming rate [1]. In 1999, the prevalence of adult obesity was 18.9% and today it is 33%, while 31% of adults in the U.S. are overweight [<http://www.cdc.gov>, access Feb. 2, 2005]. Severe or morbid obesity affects 4.7% of U.S. adults [2]. Countries outside the U.S. are showing similar trends with developing countries reporting a faster increase in prevalence compared to developed countries, and increases occurring in the more affluent families. According to International Obesity Task Force estimates, 1 billion people are overweight and 300 million are obese [task force site <http://www.iotf.org>, access Feb. 2, 2005].

Obesity is associated with a myriad of medical conditions, including hypertension, dyslipidemia, gallstones, osteoarthritis, sleep apnea and certain cancers [1]. It is also associated with several of the risk factors for coronary heart disease (CHD), e.g., insulin resistance, metabolic syndrome, and inflammation [1,3–5]. However, weight loss is associated with reduced symptoms, improved function, and metabolic benefits are seen with a modest loss of 5% of initial weight [6].

Treatment for obesity includes pharmacotherapy, which is limited, and surgery, which is indicated only in those who are morbidly obese or have serious comorbidities [4]. The more common form of treatment is cognitive-behavioral therapy, which includes behavior modification, dietary intervention and physical activity and referred to as standard behavior treatment (SBT) [7]. Numerous dietary approaches have been studied but the standard approach is a low-fat diet (<25% of calories from fat) with a calorie deficit of 500 to 1000 kcal per day, which will result in an initial weight loss of 1 to 2 lb per week. Calorie prescription is usually based on the person's initial weight, e.g., a person weighing >200 lb would follow a 1500 kcal/day eating plan. In addition to restricting energy intake, physical activity goals, usually set at being physically active at least 30 min per day most days of the week, aim to increase energy expenditure. Various approaches to the behavioral treatment of obesity have been studied for over 20 years [8]. The most significant achievement in these two decades has been in substantial initial weight loss. However, maintaining weight loss in the long-term is problematic. Typically, individuals regain approximately 35% of their lost weight in the year following cessation of treatment, and return to their baseline weight within 3 to 5 years. Therefore, the greatest challenge in the treatment of this disorder is identifying strategies that can improve long-term maintenance of weight loss. With this challenge in mind, we designed the PREFER study.

The purpose of this paper is to describe the rationale, design, methods and baseline sample characteristics of the PREFER study, a randomized controlled trial of a behavioral intervention program in weight loss management. The PREFER study design includes: (1) a randomization scheme that permits participants to choose their preferred dietary treatment approach, and (2) a lacto-ovo-vegetarian (LOV) dietary option that has demonstrated, in the literature, potential for long-term adherence. The LOV diet is compared to a standard calorie and fat restricted diet.

The first factor in the PREFER study is effect of treatment preference or choice of outcome. An emerging body of empirically based literature focuses on patients' preference for treatment choice, involvement in decision-making, and satisfaction with medical care [9–14]. Three studies that used treatment choice in weight loss had methodological limitations, such as nonstandardized treatment groups, a small sample and high attrition rates, but showed promise for better adherence and weight loss and less regain among those who received their choice condition. However, Renjilian et al. [13] reported no significant effects for treatment preference or the interaction for treatment preference by type of therapy. More recently, the literature has gone beyond patients' preference for treatment and has addressed desire for involvement in decision-making and satisfaction with medical care.

Preference for decision-making is more common among younger, more educated persons [15]. Individuals born after World War II represent a cohort that has been part of a societal shift toward increased involvement in health-care decision-making [16]. Individuals who value control over their health care derive satisfaction from participating in health-related decision-making [17,18]. Not only is satisfaction an important attribute of quality care [19], but it is also associated with improved health status and therapeutic outcome [20]. These findings suggest that providing individuals their treatment preference and involving them in decision-making may result in improved outcomes. Thus, the PREFER study design, which has overcome the limitations of the previous studies that examined treatment preference, permits the investigators to explore the influence of dietary preference on weight loss and maintenance.

The second factor in the PREFER study is that some participants will be assigned to a lacto-ovo-vegetarian eating plan. As a group, vegetarians provide a striking contrast to the temporary adoption of lifestyle habits or "diets" common among the overweight and obese. Individuals who adopt a vegetarian meal plan report following it

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