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Low glycemic index vegan or low-calorie weight loss diets for women with polycystic ovary syndrome: a randomized controlled feasibility study

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ABSTRACT

The aim of this randomized pilot was to assess the feasibility of a dietary intervention among women with polycystic ovary syndrome (PCOS) comparing a vegan to a low-calorie (low-cal) diet. Overweight (body mass index, 39.9 ± 6.1 kg/m^2) women with PCOS (n = 18; age, 27.8 ± 4.5 years; 39% black) who were experiencing infertility were recruited to participate in a 6-month randomized weight loss study delivered through nutrition counseling, e-mail, and Facebook. Body weight and dietary intake were assessed at 0, 3, and 6 months. We hypothesized that weight loss would be greater in the vegan group. Attrition was high at 3 (39%) and 6 months (67%). All analyses were conducted as intention-to-treat and presented as median (interquartile range). Vegan participants lost significantly more weight at 3 months (–1.8% [–5.0%, –0.9%] vegan, 0.0 [–1.2%, 0.3%] low-cal; $P = .04$), but there was no difference between groups at 6 months ($P = .39$). Use of Facebook groups was significantly related to percent weight loss at 3 ($P < .001$) and 6 months ($P = .05$). Vegan participants had a greater decrease in energy (–265 [–439, 0] kcal/d) and fat intake (–7.4% [–9.2%, 0] energy) at 6 months compared with low-cal participants (0 [0, 112] kcal/d, $P = .02$; 0 [0, 3.0%] energy, $P = .02$). These preliminary results suggest that engagement with social media and adoption of a vegan diet may be effective for promoting short-term weight loss among women with PCOS; however, a larger trial that addresses potential high attrition rates is needed to confirm these results.

1. Introduction

Polycystic ovary syndrome (PCOS), which is associated with obesity, irregular menstrual cycles or complete anovulation, elevated testosterone levels, and infertility [1], is one of the most commonly seen endocrinopathy among women of reproductive age [2]. Dietary changes are considered the first line of treatment for those with PCOS [1]. Women with PCOS are at higher risk for developing several chronic diseases including diabetes, hypertension, and some forms of cancer [3]. Previously conducted

Abbreviations: GI, glycemic index; HER Health, Healthy Eating for Reproductive Health Study; LH, luteinizing hormone; Low-cal, low-calorie diet; PCOS, polycystic ovary syndrome; PCOSQ, PCOS Health-Related Quality of Life Questionnaire.

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lifestyle interventions for women with PCOS have typically excluded women who are trying to conceive, excluded women taking insulin-sensitizing medications (eg, metformin), or not included pregnancy as an outcome [1].

Well-planned vegan and vegetarian diets have been shown to be healthful and can be useful in the prevention and treatment of certain diseases [4]. People transitioning from an omnivorous to a low-fat vegan diet may have greater decreases in weight [5–7] and greater improvements in dietary quality [8] and fruit and vegetable intake [9,10] than people switching to an omnivorous, low-fat diet. In clinical studies, a low-fat vegan diet has been shown to be as acceptable to participants as other therapeutic approaches [9,11]. Because PCOS has a similar metabolic profile to type 2 diabetes [12], exploring dietary patterns as they relate to diabetes is important. Those following a vegan or vegetarian diet also have lower prevalence rates of type 2 diabetes as compared with other dietary approaches [13]. There has been limited research in the area of behavioral dietary interventions for PCOS, particularly focusing on fertility, satisfaction with treatment, and quality of life outcomes [1]. The epidemiologic literature points to a beneficial effect of a plant-based vegan diet on weight and type 2 diabetes outcomes [13,14]. It is unknown whether this type of dietary approach may be more useful for the treatment and management of PCOS as compared with a traditional low-calorie (low-cal) dietary approach. To date, no studies have examined the impact of a vegan diet on weight loss, quality of life, and fertility outcomes among women with PCOS.

The purpose of the Healthy Eating for Reproductive Health (HER Health) study was to examine the effectiveness of 2 dietary approaches for weight loss among women with PCOS who were trying to conceive: a low-fat, low–glycemic index (GI) vegan diet with no caloric restriction (vegan) and a standard, low-cal diet. We hypothesized that the vegan group would lose significantly more weight, have greater improvements in macronutrient profile, and report greater improvements in PCOS-related quality of life domains at 6 months than the low-cal group. A secondary outcome was to examine differences in ovulation detection, menstrual cycle frequency, and pregnancy achievement between groups.

2. Methods and materials

Overweight and obese (body mass index, 25-49.9 kg/m^2) women with PCOS were recruited in 2012 to participate in a 6-month randomized dietary weight loss intervention through local medical clinics and newspaper advertisements (clinical trials registry: NCT01509066). Women were eligible for the study if they were between the ages of 18 and 35 years, had a physician-confirmed diagnosis of PCOS (using the Rotterdam criteria) [15], had been trying to conceive for at least 6 months, were willing to accept randomization to either diet, had access to the Internet to complete questionnaires and receive the intervention, and were not currently taking fertility-enhancing medications (except metformin). Participants must have been on a stable dose of metformin for the previous 3 months in order to enroll. This study was approved by a university institutional review board, and all participants provided written, informed consent to participate in the study.

Participants were enrolled on a rolling basis. Once a participant was accepted into the study, she attended an orientation session to complete a consent form and learn more about the study. Participants completed online questionnaires assessing demographics, dietary intake (1 weekday and 1 weekend day of unannounced 24-hour dietary recall using the Automated Self-Administered 24-Hour Recall [16]), physical activity (Paffenbarger Physical Activity Questionnaire, a survey instrument that assesses leisure time activity in adults over the previous week [17]), and quality of life (PCOS Health-Related Quality of Life Questionnaire [PCOSQ] [18]) at baseline, 3 months, and 6 months. The PCOSQ was used to assess 5 domains related to quality of life among women with PCOS: emotional health, body hair, infertility, weight, and menstrual problems [18]. All PCOSQ domain scores range from 1 to 7, with 1 representing a lower quality of life and 7 relating to higher quality of life. Both the Paffenbarger questionnaire [19] and the PCOSQ [18] are validated measures.

Once all baseline questionnaires were completed, participants returned to the research site to meet with a study registered dietitian and have her height (calibrated stadiometer; SECA 217, Medical Measuring Systems and Scales, Hamburg, Germany) and weight (calibrated digital scale accurate to 0.1 kg; SECA 869) measured. Participants were then randomly assigned to the vegan or low-cal diet by the study dietitian using a computerized random number generator. Both groups received individual diet instruction and 3 months' worth of pregnancy and urinary luteinizing hormone (LH) test strips.

2.1. *Intervention diets*

Participants were randomized to follow 1 of 2 diets: vegan or low-cal. Participants in the vegan group were provided with a vegan recipe book and a list of high-GI foods to limit and the ones to include [20]. In addition, vegan participants were instructed to exclude all animal products (meat, fish, poultry, eggs, or dairy) from their diet and emphasize plant-based foods such as fruits, vegetables, whole grains, and legumes/beans. Low-cal participants received a daily caloric goal based on their current weight, which included daily energy intake targets of 1200 kcal/d for participants weighing 90 kg or less and 1500 kcal/d for participants weighing more than 90 kg. Low-cal participants also received a book containing calorie and fat grams of common foods. Both groups received individual face-to-face counseling on their assigned diets at baseline and received a booster session at 3 months.

2.2. *Intervention delivery*

With the exception of the 2 counseling sessions with a registered dietitian, participants received the entire intervention by remote means. Each Sunday, participants completed a questionnaire (24 total) that assessed dietary adherence, current weight, menstrual cycle, and results of LH and pregnancy tests. Duration of participation in the study was assessed as the number of weeks participants completed a weekly questionnaire. Each Thursday, participants received a weekly lesson about their diet and an e-mail message tailored to their weight loss and reported adherence to their assigned diet over the previous week. Participants also were provided