Web Tool Helps New Moms Shed Pounds

BY SUSAN LONDON

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SEATTLE – A Web-based intervention that promotes physical activity and a better diet helps new mothers lose excess weight in the postpartum period, according to a randomized controlled trial.

In the trial, new mothers assigned to the intervention had about a 1.25-kg/m^2 reduction in body mass index (BMI) after 16 weeks, whereas those assigned to a wait list control had roughly a 0.75-kg/m^2 reduction. In addition, 27% of those in the intervention group lost enough weight that they now fell into the normal weight category, compared with only 6% of their control counterparts.

"We saw a small differential effect on body mass index, not a dramatic effect, but in a fairly low-intensity intervention, we might not expect that," lead investigator Karen J. Calfas, Ph.D., said at the meeting.

Weight gain over a person's lifespan is accelerated during certain periods, including pregnancy and the postpartum period for women, noted Dr. Calfas, who is an assistant clinical professor of family and preventive medicine at the University of California, San Diego.

"Women often don't return to their prepregnancy weight, and then maybe a second pregnancy comes and there is kind of a compounding effect of pregnancy weight over time for some women," she said. Added to that, some women gain weight during the postpartum period because they are more sedentary and have readier access to food.

"Postpartum care is often focused really on the medical issues," she further noted, "and the weight issues for the moms don't always get addressed."

The investigators recruited women for the trial mainly by posting notices in community newspapers and obstetrician gynecologists' offices. To be eligible, women had to be 8 weeks to 12 months post partum and have a BMI placing them in the overweight to moderately obese category (25-35 kg/m^2). The 161 women enrolled were average age 31 years, and 59% were white. Dr. Calfas estimated that about three-fourths were first-time mothers, and roughly half were breastfeeding to some extent.

They were randomly assigned in nearly equal numbers to the 16-week Web-based intervention, called iMom, which encouraged increased physical activity and improved dietary intake with the goal of weight loss, or to a wait list control group.

The intervention entailed weekly Web-based educational content and behavior strategies, and monthly support phone calls. The mothers were encouraged to set goals, and they reported on their progress and received feedback online regarding weight, physical activity, and intakes of fat, fiber, and fruit and vegetables. The Web site also had a message board for connecting to other mothers.

The women 'especially appreciated the fact that they could do [the Web-based intervention] whenever it was convenient for them.'

"It's somewhat controversial to be recommending weight loss for women who might be breastfeeding," Dr. Calfas acknowledged. However, the energy deficit recommended in the intervention was carefully tailored according to whether women were breastfeeding and how much. "The research shows that if calories are reduced slightly and weight is lost slowly over time, that it does not affect either the quantity or the quality of breast milk that is produced," she noted.

Study results showed that mothers assigned to the intervention lost about 1.5 kg (3.3 lb) on average, whereas those assigned to the wait list lost about 0.5 kg (1.1 lb). The difference corresponded to a 1.21-kg (2.67-lb) greater loss for the former group. Similarly, BMI fell by about 1.25 kg/m^2 in the intervention group on average, compared with roughly 0.75 kg/m^2 in the control group. The difference corresponded to a 0.46-kg/m^2 greater reduction for the former group. Some 27% of women in the intervention group attained a body weight that now placed them in the normal weight category, compared with just 6% of their counterparts in the control group.

"The women, anecdotally, reported high satisfaction with [the intervention], and they especially appreciated the fact that they could do it whenever it was convenient for them," commented Dr. Calfas.

Ongoing analyses will be looking for any dose-response relationship, evaluating how much the new mothers actually used the Web site, she said, noting that overall use was not as high as hoped.

Dr. Calfas is cofounder of and stockholder in Santech Inc., a company that uses mobile and Web technologies to promote behavior change. ■

DRUGS, PREGNANCY, AND LACTATION

Nausea and Vomiting

Approximately 75% of all pregnancies are estimated to be complicated by maternal nausea and vomiting, or nausea alone. Although nausea and vomiting are associated with a decreased risk of miscarriage, persistent or more severe symptoms can negatively impact the pregnant woman's ability to work, as well as her quality of life. In a small subset of women (0.3%-1.0%), nausea and vomiting will progress to hyperemesis gravidarum, potentially leading to maternal dehydration, weight loss, hospitalization and adverse infant outcomes (N. Engl. J. Med. 2010;363:1544-50).

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Although dietary modifications can be effective, pharmacologic therapy for nausea and vomiting of pregnancy may be needed. For more than 25 years, Bendectin was available in the United States, and was widely used as an effective treatment for nausea and vomiting of pregnancy. However, in 1983 the drug was voluntarily removed from the market by the manufacturer on the basis of the extensive business costs and negative publicity associated with allegations of teratogenicity. In the ensuing 27 years, the drug has never been reintroduced into the U.S. market, despite the fact that the safety of Bendectin exposure in pregnancy has been extensively studied, and the overwhelming evidence does not support any teratogenic effect.

In recognition of the strong safety profile and effectiveness of the ingredients in Bendectin, present-day American College of Obstetricians and Gynecologists practice guidelines recommend first-line treatment for nausea and vomiting with a combination of vitamin B_6 and doxylamine (the formulation of Bendectin when it was removed from the market). This combination of ingredients, although not labeled for the indication of nausea and vomiting in pregnancy, is available in the United States as an over-the-counter product under the brand name Unisom SleepTabs. At the same time, a sustained-release formulation of the ingredients in Bendectin (Diclectin) has been approved in Canada specifically for the indication of nausea and vomiting in pregnancy, and has been widely used in that country for many years.

This month, a further chapter was added to the long history of Bendectin. In a double-blind, randomized clinical trial conducted at three centers in the United States, the Canadian sustained-release formulation of Diclectin was compared with placebo for the treatment of nausea and vomiting (Am. J. Obstet. Gynecol. 2010 [doi:10.1016/j.ajog.2010.07.030]).

In this trial, the final sample included 256 pregnant women who met baseline criteria for severity and frequency of nausea and vomiting of pregnancy. The women enrolled in the trial at a mean gestational age of approximately 9 weeks, and were treated with Diclectin or placebo for 15 days.

Using intent-to-treat analysis, a significant reduction in the study measure of frequency and intensity of nausea and vomiting was reported in the treated group, compared with the placebo arm. There was a similarly significant improvement in the treated group's global assessment of well-being over the course of treatment. Furthermore, there was no significant excess of serious or nonserious adverse events reported in the treated group vs. the placebo group during the period of the intervention.

Because of the study design, women tended to enroll at the peak time in gestation for symptoms of nausea and vomiting to occur. Thus, although the mean reduction in symptom score from baseline was 23% greater in the treated group than in the placebo group, there were substantial (close to 50%) mean reductions in symptom score from baseline in both groups by the end of the 2-week trial. This undoubtedly was due in part to the natural decline in symptoms with or without treatment as women in both arms approached the end of the first trimester. Had women been able to be randomized closer to the onset of symptoms (approximately 5-6 weeks' gestation), the treatment effect might have been stronger.

In addition, had earlier enrollment been possible, thereby allowing for a greater number of days of follow-up during the critical window of peak symptoms, the investigators might have been able to more effectively evaluate the economic impact of treatment on number of lost days of work due to nausea.

The study was not designed to test the hypothesis that early, effective treatment can reduce the rate of progression from nausea and vomiting to hyperemesis gravidarum in the small subset of women who are susceptible to this condition. However, ecological data suggest that this might be possible, given the approximate doubling of the incidence of hospitalizations due to hyperemesis following withdrawal of Bendectin from the market.

Adding to the large volume of safety data for Bendectin, this study provides evidence of the safety and effectiveness of the sustained-release product for the labeled indication, an extremely common condition of pregnancy.

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