Lifestyle Intervention Trials During Pregnancy

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Recent data from the US Centers for Disease Control indicate that the prevalence of excessive gestational weight gain (Table) approaches 40% among women with a normal prepregnancy body mass index (BMI), and is even higher among women who are overweight.[1] Excessive maternal gestational weight gain is an established risk factor for increased risk of cesarean delivery, fetal macrosomia, and maternal weight retention in the immediate postpartum period and is possibly related to a wider array of other adverse pregnancy outcomes.[1]

Table. Cutoff Values for Excessive Gestational Weight Gain Based on 2009 Institute of Medicine Recommendations[1]

Pregravid BMI Category	Total Weight Gain (lb)	Rate/Week (lb)*
Underweight (<18.5 kg/m^2)	>40	>1.3
Normal weight (18.5–24.9 kg/m^2)	>35	>1.0
Overweight (25.0–29.9 kg/m^2)	>25	>0.7
Obese (≥30.0 kg/m^2)	>20	>0.6

*2nd and 3rd trimester
Source: Adapted from the National Academy of Sciences, 2009.

Growing evidence also exists to show that high maternal gestational weight gain increases the risk of child and adolescent obesity.[2,3] To address the health risks associated with excessive gestational weight, the 2009 Institute of Medicine Report, *Weight Gain During Pregnancy: Reexamining the Guidelines,* recommended that "those who provide prenatal care to women should offer counseling, such as guidance on dietary intake and physical activity, that is tailored to their life circumstances."[1]

In theory, this is an excellent idea. Unlike preexisting obesity, gestational weight gain is potentially modifiable during the course of pregnancy, with the potential to reduce negative in utero influences on the fetus that could persist over the child's life.[4] Pregnant women are concerned about having healthy babies and are perhaps more motivated to change their behavior during pregnancy than at other points of time.[5] It is possible that intervention during pregnancy could correct or improve

habits related to weight management that could translate into better health for women and their families over the long term.

The consistent contact with the medical care system through prenatal care could provide an ideal vehicle for delivery of behavioral interventions to women. However, current prenatal care systems are not set up to provide these services. In order to change the medical care system, research-based evidence is required to determine effective intervention strategies to promote healthy gestational weight gain in the clinical setting.

Interventions to Improve Maternal Diet and Physical Activity

In the past year, six different groups have published critical literature reviews comprised of approximately 12 trials investigating how behavioral interventions to improve maternal dietary intake and/or physical activity reduce excess gestational weight gain. One review focuses only on women who began pregnancy overweight or obese,[6] while five reviews include a wider range of prepregnancy BMI.[7-11] Three groups conducted meta-analysis.[7,8,12] and three did systematic reviews. Only controlled studies were included, and most were randomized controlled trials. Conducted in Australia, Belgium, Denmark, Norway, Sweden, and the United States, the sample size of these trials ranged from 41–560.

Researchers used a variety of intervention strategies, including counseling and education about weight gain, healthy eating, and physical activity and/or monitoring of weight gain, with or without feedback. The intensity and frequency of interventions and the number and combination of different components are variable. Even though all reviews used high-quality methodology to assess the evidence and all looked at the same accumulation of data, the conclusions vary. Three of the reviews conclude that interventions can effectively reduce gestational weight gain, although results are inconsistent,[8,10,11] two conclude that interventions are ineffective,[6,7] and one concludes that the quality of the studies is too weak to consider their findings for evidence-based guidelines.[9] Overall, these reviews demonstrate a clear need for more definitive research on which to base clinical practice.

The Fit for Delivery Study, conducted by Dr Suzanne Phelan and a multidisciplinary team and published in April 2011, adds to the knowledge summarized by these

reviews.[13] Informed by Social Learning Theory, this randomized, assessor-blinded, controlled trial tested an intervention that included the following:

- Nutritional counseling provided by a dietitian at enrollment, with a diet prescription of 20 kcal/kg
- A book to aid women in reducing fat and calorie intake
- Three telephone calls with the dietitian during the course of the study to assess progress
- Encouragement to moderately exercise, supported by a supplied pedometer with the ultimate goal of walking 10,000 steps/day, and the request that women keep a record of their progress
- Provision of a gestational weight-gain goal for each woman, based on the 1990 Institute of Medicine Recommendations,[14] as well as a scale and directions to monitor and record weight gain
- Feedback on weight-gain progress by postcard after each prenatal visit
- A "stepped-up care" approach for women who gain too much weight, with more frequent contacts and structured meal plans and behavioral goals
- Regularly mailed educational materials and "challenge" cards to strengthen motivation to healthfully control weight

Controls received one 15-minute meeting with the study dietitian to discuss general principles of diet and physical activity during pregnancy, as well as newsletters throughout the study that covered aspects of pregnancy unrelated to weight management. Both groups received standard prenatal care and pamphlets from the American College of Obstetricians and Gynecologists and the March of Dimes. The study randomized 401 women—200 to standard care and 201 to the intervention. Half of each group had a normal and half an overweight/obese BMI. Fig 1 shows that the intervention significantly reduced excessive gestational weight gain among those with normal BMI, but not those who began the study overweight or obese.

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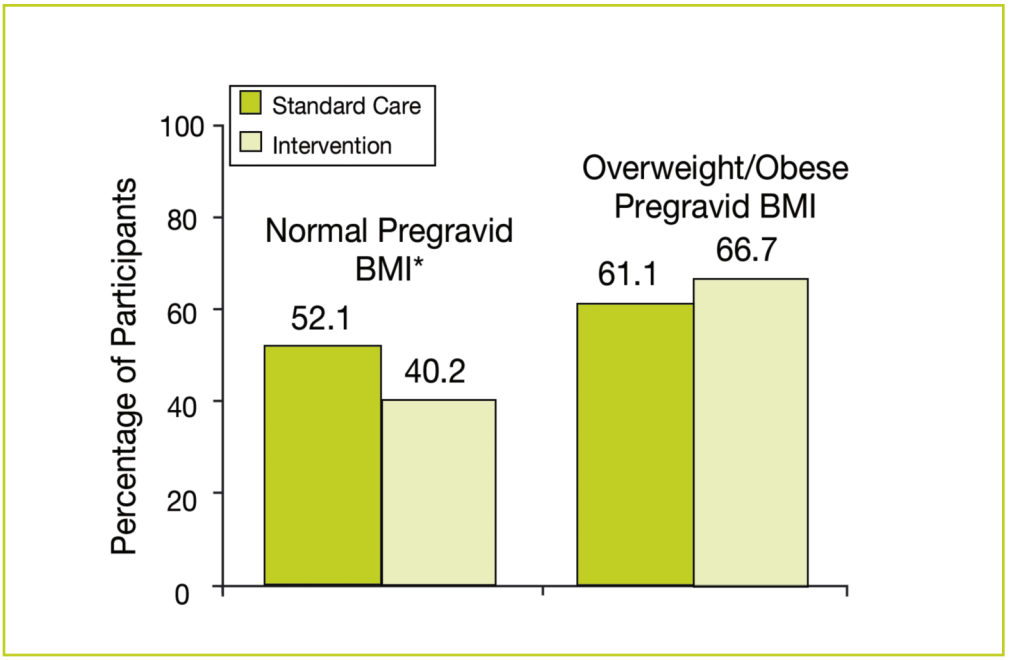

Fig 1. Excessive weight gain† in the Fit for Delivery Study women.[13] Results were based on an intention-to-treat analysis.

**P*<0.05
†Total pregnancy weight gain >35 lb for normal weight women and >25 lb for overweight/obese women

Source: Phelan S et al. Randomized trial of a behavioral intervention to prevent excessive gestational weight gain: the Fit for Delivery Study. *Am J Clin Nutr*. 2011;93:772-779. Reprinted with permission of the American Society for Nutrition.

However, at 6 months after delivery, the prenatal intervention increased the proportion of women who returned to their prepregnancy weight (defined as retaining <1 kg) in both groups (Fig 2), despite the fact that no additional intervention was provided after delivery.

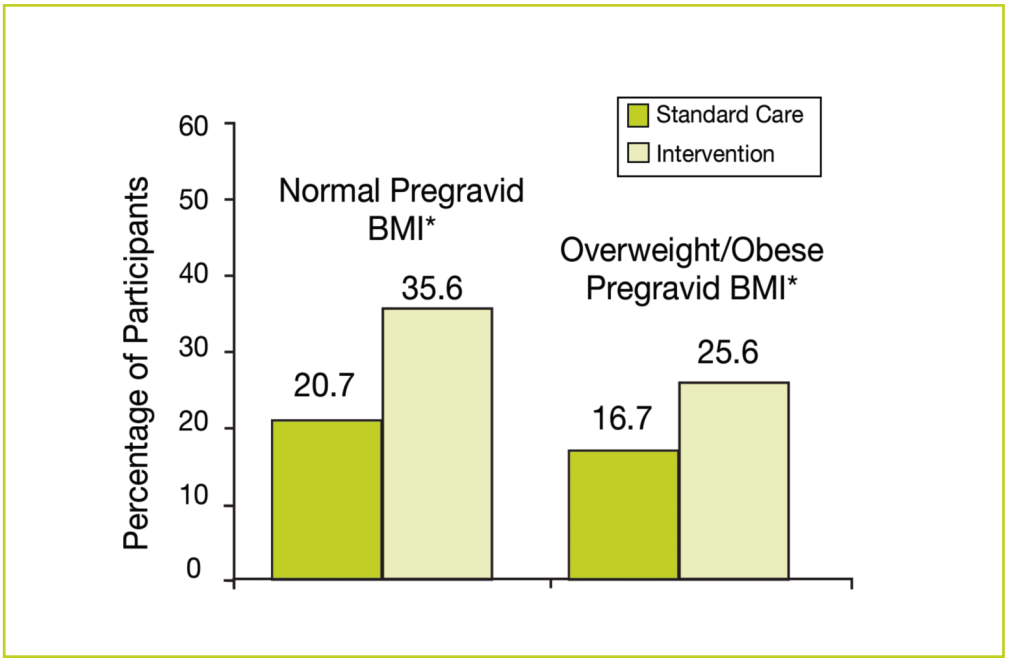

Fig 2. Postpartum weight status† 6 months after birth in Fit for Delivery Study women.[13]
Results based on an intention to treat analysis.

*$P<0.05$
†±0.9 kg or below prepregnancy weight

Source: Phelan S et al. Randomized trial of a behavioral intervention to prevent excessive gestational weight gain: the Fit for Delivery Study. *Am J Clin Nutr.* 2011;93:772-779. Reprinted with permission of the American Society for Nutrition.

These results, in addition to those from other trials, suggest that it is possible to moderate gestational weight gain through methods that are implemented in the clinical setting. Echoing previous results, Fit for Delivery intervention did not reduce excessive gestational weight gain in overweight/obese women, the group at highest risk for poor pregnancy outcomes. However, our finding of some effect on weight in this group postpartum is encouraging, suggesting that the prenatal intervention may have had longer term impact. Although a step in the right direction, the finding that 40% of normal-weight women in the intervention group still gained weight excessively indicates that even in normal-weight women, more effective strategies are needed.

Future Research and Improved Behavioral Interventions

Reviewers suggest a number of important ways to improve the study of behavioral interventions for pregnant women.[7-10] In addition to strengthening and standardizing study methodologies and reports to allow comparability, a fresh look at the interventions themselves is needed. Virtually all studies to date focus solely on changing each individual woman's diet and physical activity, but pregnant women do not live in a vacuum. It is likely that excessive gestational weight gain is a function of the same neighborhood and environmental factors that cause obesity in children and other adults, thus multilevel interventions are needed.[15] Still, we need to better understand the physical, psychological, social, cultural, and financial barriers that women face in addressing weight control during pregnancy and design interventions responsive to women's experiences and concerns. Evidence also shows that women receive contradictory messages from family, friends, the media, and clinicians about weight management during pregnancy. Use of a mixed-method research design, which combines qualitative and quantitative approaches, could help inform new strategies based on established behavioral theories.

Finally, studies in nonpregnant populations suggest that successful weight control is possible through more intensive lifestyle treatments than those that are typically used in pregnancy, such as a calorie prescription supported by structured meal plans and meal replacements, high levels of physical activity (60–90 minutes/day), daily monitoring of weight and food intake, behavior therapy, and continued patient-provider contact.[16] The safety, acceptability, and efficacy of these approaches in pregnancy, as well as application of these methods before and after pregnancy, deserve serious study.

As researchers augment current knowledge with new perspectives, there is every reason to believe that future research will yield the keys to utilizing the "teachable moments" of pregnancy to promote health in mothers and their children.

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Q & A

Q: Perhaps I missed it, but how did you determine if an obese person gained excessive weight given that the 1990 Institute of Medicine (IOM) recommendations gave no upper limits for women who were classified as obese?

Dr Abrams: We used the 1990 IOM upper limit for overweight women, which is 25 lb. When the 1990 committee wrote its report, there was concern that because gestational weight gain was severely restricted in the previous generation, a recommended upper limit for obese women would encourage clinicians to become overzealous in limiting maternal diet for obese women.

Because the committee did not have data to support the upper limit, it recommended that obese women should gain at least 15 lb, which is the estimated weight of the products of conception (fetus, placenta, amniotic fluid, increased maternal body water, blood volume, and fat). The 2009 IOM committee did put an upper limit for obese women, and called for research to fine-tune the amount that is consistent with the best maternal and child health outcomes.

Q: I have just a quick comment in relation to these interventions. Two very important things to consider are whether the ladies actually change their behavior and whether the intervention adopted is effective. These are two different things. Do you have any idea whether either your normal weight or overweight groups actually did change their behaviors?

Dr Abrams: I can speak very preliminarily. We actually are working on a paper right now, but I have not seen all the data. My understanding is that the normal weight group significantly reduced their fat intake, which was one of our targets. The overweight group reported increased physical activity.

Q: In that regard, did you look at the relationship between those women who gained less weight and birth weight?

Dr Abrams: No significant differences existed between the intervention and control groups for mean birth weight, low birth weight, or macrosomia. We did not compare birth weights by maternal weight gain, regardless of the intervention.