



# Using the ORBIT Model to Design an Intervention Promoting Healthy Weight Gain During Pregnancy: the Value of an Iterative and Incremental Approach to Intervention Development

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“Take a method and try it. If it fails, admit it frankly, and try another. But by all means, try something.”—Franklin D. Roosevelt

## Introduction

As behavioral scientists attempting to design behavior change interventions that can prevent or mitigate chronic diseases, we often confront problems that seem to defy our capacity for altering human behavior. Tobacco use, poor diets, sedentary lifestyles, low adherence to life-saving medications—all are behaviors that contribute substantially to the burden of chronic diseases in the USA and worldwide, and all represent continuing challenges that have met with varying degrees of success as we attempt to design effective interventions, especially in medically underserved and high-risk population subgroups. It is tempting to yearn for a “behavioral statin,” a strategy or intervention that can produce dramatic change in these and other behavioral risk factors across a wide variety of contexts and sociodemographic groups. Yet, the key to effectively tackling these complex behavioral problems may lie in our ability to stay the course, to understand the problems deeply and in all their complexity, and to use that knowledge to devise and conduct long-term, incremental, and progressive approaches to behavior change that approach failure as an opportunity to learn and improve and that require equal measures of creativity and patience to succeed.

Obesity is an example of a highly ubiquitous and challenging public health problem that is known to increase risk for cancers, cardiovascular diseases (CVD), diabetes, and many other chronic health conditions [1, 2]. Over the past several decades, increases in rates of obesity have occurred across the lifespan, in both men and women, and in all sociodemographic groups [3, 4], but are significantly higher in African-American and Latino populations and for those with lower incomes [5].

Excessive weight gain also poses special risks to women during pregnancy, with increased risks of obstetrical and neonatal complications as well as type 2 diabetes and CVD later in life [6–8].

As with obesity in general, these risks are exacerbated for low-income women of color [9], who often face a myriad of stressors in their daily lives, including lack of access to or difficulty affording medical care, poverty, discrimination, violence, lack of available healthy food and affordable housing, and many others. Research has shown that stress is associated in animal and human studies with non-homeostatic eating of high-calorie, unhealthy “comfort” foods, which results in excessive weight gain and can lead to obesity [10, 11]. Few interventions focused on preventing excessive weight gain in pregnancy have targeted low-income and minority women, and of those that have, the results are mixed [12–15]. In addition, interventions conducted in this vulnerable, highly stressed group of women have not typically included a stress reduction component. Thus, efforts to encourage healthy weight gain in low-income women of color by reducing stress and potentially altering non-homeostatic eating represent a novel approach to one of most important public health challenges confronting us today.

Epel and colleagues [16] are therefore to be lauded for their efforts to develop and optimize a behavioral intervention aimed at promoting healthy weight gain and reducing excessive weight in low-income pregnant women who are among the most vulnerable in our society and thus the most in need of

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new, more effective approaches and strategies to address this difficult problem. Their project was part of the Obesity-Related Behavioral Intervention Trials (ORBIT) consortium, a trans-NIH cooperative agreement program that consisted of seven research sites and a Resource and Coordination Unit (RCU) to facilitate cross-site activities. The goal of ORBIT was to accelerate the translation of discoveries from basic biological, behavioral, and social science research into innovative strategies aimed at preventing or treating obesity by conducting formative and experimental research, proof-of-concept studies, and feasibility pilots focused on obesity and obesity-related behaviors. The interventions being developed included a wide range of strategies aimed at promoting weight loss and/or preventing weight gain, focusing on diverse populations, including Latino and African-American adults, African-American adolescents, low-income populations, pregnant women, and women beginning the menopausal transition.

In their ORBIT project, Epel and colleagues sought to translate findings from basic biobehavioral studies that identified a link between stress and non-homeostatic eating (eating reflexively in response to factors other than caloric need or hunger) to develop an intervention to reduce unhealthy weight gain in low-income pregnant women. In a series of studies utilizing the Obesity-Related Behavioral Intervention Trials (ORBIT) model of intervention development [17], these researchers followed a systematic, careful, and iterative process of intervention design and preliminary testing that, while failing to meet the primary objective of reducing excessive weight gain in pregnancy, favorably altered several psychosocial and clinical drivers of gestational weight gain and maternal health risks, and thus shows great promise as a potentially viable approach to the problem of excessive gestational weight gain.

The ORBIT framework encompasses two overarching phases of intervention development [17], entitled “phase I” (intervention design) and “phase II” (preliminary testing). In phase I, treatment targets and components are initially defined, including the degree of change in the treatment target needed to demonstrate a clinically meaningful effect on an ultimate health outcome, and these components are tested and refined to achieve a well-defined treatment “package.” Phase II involves “proof-of-concept” testing, which aims to determine if the treatment package can achieve a clinically significant degree of change in the pre-specified treatment target, as well as feasibility and preliminary efficacy testing. The ORBIT model is bi-directional (allowing for movement across and between phases) and iterative (allowing movement back to previous phases for further definition and refinement of the intervention) with the goal being an intervention that can achieve clinically meaningful changes in behavioral treatment targets and culminating in evaluation of the intervention in a randomized trial powered to detect clinically important outcomes.

Guided by the ORBIT model, Epel and colleagues conducted a series of studies that defined, revised, and optimized an intervention involving training in mindfulness in progressive, yet iterative, fashion [18]. They began with phase I qualitative work (focus groups) in women during the second and third trimesters of pregnancy to assess acceptability of the mindfulness intervention techniques to be used [19]. The intervention was refined based on the feedback received from focus group participants, and several additional phase I studies were conducted to define and refine the components of the mindfulness intervention to maximize its effects on mindful attention, mood, and stress levels [19–22]. Moving into phase II of the ORBIT model, a proof-of-concept study was conducted to test whether the refined mindfulness intervention could produce clinically significant changes in the proposed drivers of unhealthy pregnancy weight gain—that is, whether changes in mindful attention and mindful eating could reduce stress and improve eating behavior. The intervention was found to produce clinically significant reductions in stress, depressive symptoms, and improved eating behaviors [23]. A subsequent study confirmed that the mindfulness intervention increased mindfulness, decreased distress (stress and depression), reduced dysregulated eating behavior, and was feasible and acceptable to participants [18].

Based on these findings, the investigators conducted the current study, which was designed as a phase II efficacy trial to determine the intervention’s effects on weight gain as a primary outcome, and on glucose tolerance, physical activity, and depression as secondary outcomes.

In this study, Epel et al. used a quasi-experimental design, assigning 115 pregnant, low-income, and predominantly minority women to receive the mindfulness intervention over an 8-week period, and 105 sociodemographically and weight-matched pregnant women to receive treatment-as-usual (TAU). Although participants receiving the intervention showed significant reductions in stress and depression and were less likely to have impaired glucose tolerance relative to the comparison group, approximately 2/3 of women in both the mindfulness intervention and comparison groups gained excessive weight according to IOM guidelines.

While this phase II preliminary efficacy study of a mindfulness intervention did not achieve its primary goal—to promote healthy pregnancy weight gain—it did achieve significant effects on several important secondary outcomes, including reductions in stress and depression and improvements in glucose control and physical activity. Furthermore, the reductions in depression were maintained over a 9-month period [24] and infants born to the mothers in the intervention group had a significant reduction in medical visits over the following year relative to those in the comparison group [25]. These outcomes represent promising signals that should be followed by further refinement and optimization of the intervention and eventually, to efficacy testing in a randomized clinical trial.

One of the advantages of utilizing a framework for intervention development, like the ORBIT model, is the ability to treat “failure” to achieve the primary aims in any given study not as a reason to abandon the project but as an opportunity to move back to earlier stages to refine and optimize an intervention, especially when promising results are found on secondary outcome measures. Epel et al. mention several areas that are worth exploring in subsequent studies aimed at bolstering the intervention’s effects:

- Begin the intervention earlier in pregnancy, or even prior to pregnancy—the authors note that, because the intervention was initiated as late as 20 weeks into pregnancy, a number of the women had already gained the recommended weight or close to it, or exceeded the recommended weight. Furthermore, it may be especially difficult to initiate behavior changes such as altered diets in women mid-pregnancy, when stress is rising due not only to the pregnancy and the physical changes accompanying it but also to psychosocial adjustments and accommodations needed in one’s daily life given the impending birth. Ideally, beginning the intervention prior to pregnancy, perhaps targeting young women pre-conception, may be the best option for achieving healthy weight gains during pregnancy, the post-partum period, and beyond [26].
- Embed the intervention in existing pregnancy programs—Epel et al. mention that recruitment and retention of this population was challenging and limited the investigators’ abilities to obtain repeated objective measures of important variables such as physical activity and insulin sensitivity. As they note, a future strategy to enhance recruitment, adherence, and retention is to include mindfulness-based interventions within existing, evidence-based programs such as Centering Pregnancy, a group approach to prenatal care that has shown success in engaging diverse groups of women at high risk for poor pregnancy and birth outcomes [27].
- Develop multilevel interventions that address both individual and environmental stressors—the target population was a diverse sample of low-income, sedentary, pregnant women with high levels of stress and food insecurity, a group facing a complex array of stressors that may limit the effectiveness of an individually oriented behavioral intervention such as mindfulness. An approach that combines individual behavioral interventions with contextual efforts to reduce stress for women whose environments lack safety, housing, food, and other basic needs—e.g., through provision of social services and access to resources that facilitate healthy eating and physical activity behaviors—may be required to reduce unhealthy weight gain during pregnancy.
- Make the intervention easier to engage in—future work may benefit from extending the intervention’s reach and

power through the use of mobile phones and the increasing ability to monitor and provide frequent, individually tailored interventions. Advances in technology allow the encouragement of physical activity and healthy eating throughout the day, including at times of greatest stress, and can reduce the number of in-person visits needed while enabling the mobilization of peer-support groups to bolster the intervention’s effects.

The ORBIT model is valuable for providing a roadmap for proceeding from basic behavioral science concepts, through intervention design and refinement, so that strategies are carefully characterized and tested for behavioral health problems, like excessive weight gain in pregnancy. It recognizes that advancements in both science and clinical care require a balance between creativity and incremental science, starting with idea generation and the exploration of new and innovative ideas, through phase I developmental studies that allow for “tweaking” of interventions, and ultimately to the protocol-driven, well-controlled phase II and III trials that can have substantial impacts on clinical care and important health outcomes. While we all wish for a “silver bullet” approach to problems like obesity, we know that progress often requires the dedication and long-term commitment of a team of experts from a range of disciplines who combine creativity with rigor to develop interventions that can achieve the kind of clinically significant outcomes that ultimately improve the public health.

This article exemplifies this journey and represents not an ending or a final word on this topic but rather a “waystation” signaling that we may be on the right path, but that continued attention is needed to further refine and enhance interventions targeting low-income and minority women prior to or during pregnancy. Given the difficulty in achieving behavioral changes resulting in clinically significant effects on weight gain during pregnancy for low-income and minority women who experience high levels of stress and challenging circumstances that limit their ability to engage in more traditional interventions, the authors deserve credit for tackling an important problem that is in need of more effective approaches than currently exist.

The ORBIT model and its emphasis on long-term, progressive characterization, refinement, and preliminary testing of an intervention prior to testing in a larger randomized controlled trial is well-suited for continuation of this line of research, and one can hope that the authors, with their dedication to devising more effective strategies for promoting healthy weight gain in low-income and vulnerable pregnant women, will continue along this challenging path with the ultimate goal of achieving healthy weight gains as well as positive metabolic and other health outcomes for the women, and their babies, in most need of these interventions.

**Compliance with Ethical Standards** This commentary does not involve research using human participants and/or animals.

**Conflict of Interest** The author served as lead Program Director for the trans-NIH Obesity-Related Behavioral Intervention Trials (ORBIT) Consortium, and was Project Officer for the grant on which this article is based (E. Epel, B. Laraia, N. Adler, PI's).

**Disclaimer** The views expressed in this manuscript are those of the author and do not necessarily represent the views of the National Institutes of Health or the US Department of Health and Human Services.

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