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Suzanne Phelan, Ph.D.
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May 16, 2011

Dear Dr. Phelan:

I am pleased to inform you that the modifications to your proposal, "***Internet-Based Intervention to Reduce Postpartum Weight Retention in WIC Women***", have been approved through May 16, 2012. If the data collection phase of your study should continue beyond this date, please contact me about another extension of approval.

Please make the changes to your informed consent form we discussed this afternoon, and consult with Dean Opava regarding review of Spanish language materials.

In addition, please continue to contact either myself or Dean Opava as soon as reasonably possible if there is an outcome that adversely affects a human subject.

For informational purposes, the Federal Wide Assurance Number for our institution is: #00000342. We are Human Subjects Committee Registration Number: IRB 000001118.

Thank you for following the Cal Poly Human Subjects Committee review procedures. On behalf of the IRB, best wishes for continued success with this research.

Sincerely,



Steven C. Davis, Ph.D., RCEP
Chair, Cal Poly Human Subjects Committee

Xc: Opava, Research & Graduate Programs ✓
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IRB PROTOCOL CHANGES SUMMARY

Fit Moms

- Modification followed by IRB approval on 04_16_2013
 - Changed minimum amount needed to exceed pre-pregnancy weight from at least 6.8 kg (15 pounds) to at least 5 kg (10 pounds)
- Modification followed by IRB approval on 07_14_14
 - Skinfold measures added to infant (not presented in current paper)
- Modification followed by approval on 06_29_2015
 - Clarified that participants could exceed pre-pregnancy weight by 10 pounds and be normal weight or currently be overweight or obese (Previously, criteria unclearly just indicated: BMI \geq 22).
- Continuous approval without modification from 09_01_2016 to present.

**“FIT MOMS”:
STUDY OF AN INTERNET-BASED POSTPARTUM WEIGHT LOSS PROGRAM**

Suzanne Phelan, PhD; Kinesiology Department

Each year, approximately four million American women give birth. Of these women, an estimated 25% experience major weight gain after pregnancy, retaining more than 4.5 kg.^{1, 2} High postpartum weight retention has troubling long-term consequences for the health of the mother, including a continued trajectory of weight gain over time^{3, 4} and increased risk of lifetime obesity, cardiovascular disease, and type 2 diabetes. Moreover, women with high postpartum weight retention are heavier prior to their next pregnancy, which increases their risk of pregnancy-related complications, obesity, and obesity and serious health complications in the offspring.⁵⁻¹⁰

Paralleling obesity trends, high postpartum weight retention is particularly problematic for women of ethnic minority and low-socioeconomic status.¹¹⁻¹³ Low income Hispanic women, in particular, lose less weight during the initial postpartum period.¹⁴ Moreover, weight trends indicate that between 3 and 12 months postpartum, while Caucasian women continue to lose weight, Hispanic women experience weight gains.^{15, 16}

Preliminary efforts to promote postpartum weight loss in high weight retainers have met with some success and yielded short-term weight losses of 4.8 to 7.8 kg.^{17, 18} However, postpartum interventions have been limited by failing to reach to the populations most at risk, such as low income women, and high attrition ranging from 31 to 42%. During the postpartum period, women are busy with infant care and experiencing physical, social, and emotional adjustments to motherhood that may hamper adherence to standard interventions. Innovative methods are needed to leverage women’s naturally occurring motivation for postpartum weight control¹⁹ while captivating a greater proportion of the at risk postpartum population.

Over the past decade, Internet use has increased exponentially in the United States and most rapidly among young adult, low income and minority sub-groups.²⁰⁻²⁴ Surprisingly, 60-80% of postpartum low income mothers report having access to Internet, mostly from home.²⁵ Moreover, low income postpartum women have reported that the Internet is a preferred method of receiving nutrition information due to its flexibility and format.²⁶ Internet-based weight control interventions have been shown effective in promoting significant weight loss in obese populations^{27, 28} and significant changes in motivation for healthy behaviors in low-income postpartum women.²⁵ However, to date, no study has evaluated the effects an Internet-based program to prevent high postpartum weight retention in low-income women at risk for long-term weight gain, obesity, and related co-morbidities.

This project proposes to test the long-term efficacy of an Internet-based weight loss program tailored to low-income postpartum mothers. We will collaborate with the Women, Infants, and Children (WIC) program, which is a federally-funded community-based program providing nutritional support for low income multi-ethnic women during the pregnancy and postpartum periods. WIC dietitians and public health aides will reinforce use of the Internet-based weight loss program at regularly scheduled WIC visits. By collaborating with WIC, our goal is to test the effects of an intervention that fosters institutional support in order to maximize behavioral adherence at individual and interpersonal levels.

In this cluster randomized trial, 12 clinics will be randomized to receive a 12-month standard WIC program or Enhanced WIC + Internet-based postpartum weight loss. A total of 408 women (34 per clinic) with high postpartum weight retention will be assessed at study entry and at 6 and 12 months.

The primary hypothesis to be tested is:

- 3) Enhanced WIC plus Internet postpartum weight loss program will produce significantly greater weight losses than Standard WIC at 6 and 12 months. We expect the intervention will also increase the proportion of women who achieve pre-pregnancy weight at 6 and 12 months.

Secondary aims are:

- 4) To determine whether Enhanced WIC plus Internet postpartum weight loss program will result in greater improvements in eating and exercise behaviors (examined at 0, 6, and 12 months) and psychosocial parameters (i.e., depression, social support, self-efficacy, body image, stress) than standard care.
- 5) To identify baseline characteristics that may moderate the efficacy of the intervention (e.g., ethnicity, socioeconomic status, pre-pregnancy weight, parity, breastfeeding).
- 6) To examine the relationship between changes in behaviors, psychosocial factors, and weight changes during the 12-month period. These evaluations will help identify the mechanisms by which the intervention produces greater success compared to standard WIC.

Methods

Subjects: A total of 408 overweight/obese female WIC participants will be recruited from 12 clinics (n = 34/clinic) to participate in this study. Participant eligibility criteria will be assessed via phone screen.

Inclusion Criteria:

- Age 18-40 years.
- Delivery within 6-24 weeks
- Exceed pre-pregnancy weight by at least 6.8 kg (15 pounds)
- Current BMI \geq 22
- English or Spanish speaking
- Has internet access at home or a landline
- Literacy of at least 5th grade reading level
- Has a cell phone

Exclusion Criteria

- Pregnant or planning to become pregnant
- Relocating in the next year
- Serious psychological problems (untreated depression, schizophrenia, bipolar disorder) or medical problem (i.e. heart disease, cancer, renal disease and diabetes), for which physician supervision of diet and exercise prescription is needed.

Recruitment:

Recruitment will be through 12 WIC clinics, 6 in San Luis Obispo County and 6 in Santa Barbara County. All participants in this program will be enrolled in WIC and, thus, low income (185% of U.S. poverty level). WIC counselors will introduce the study to potential participants. Those expressing an interest will be called by Cal Poly staff to hear more about the study and be screened for eligibility. Those eligible will be scheduled for Visit 1.

Visit 1: Screening and Informed Consent: This visit (~90 minutes) will take place at the participant's WIC clinic and will begin with a review of the study and participant consent. The

consent will be reviewed in detail, including description of randomization and the components of both intervention and control groups. Participants will be given ample time to have all questions answered. Women who agree to participate in the study will be asked to complete the baseline assessments. Specifically, women will then be asked to complete the baseline packet of questionnaires, the interview-based assessments, and weight, waist circumference, and height will be measured. Participants will also be asked to provide names and addresses of people to contact if the participants are lost to follow-up. After participants complete the baseline assessment, they will be told of their clinic randomization status and receive a brief welcome orientation describing their group assignment. If randomized to the Intervention condition, participants will also be trained in using the Internet site, using our pre-established protocols.

Design

The proposed study is a clinic-randomized controlled trial comparing a comprehensive Internet-based behavioral weight control intervention to standard care.

Group 1: Standard WIC: Women who from clinics randomly assigned to the Standard Care Condition will attend a brief orientation visit at the time of Visit 1. This visit will serve the purpose of bonding participants to the study and will be used to welcome women to the study and congratulate them on their child's birth. Standard care participants will also receive basic training on using the Internet according to their computer proficiency. We will provide this training to ensure that computer proficiency is equivalent across the two groups (and reduce likelihood that ability to navigate the internet and access online health information in this manner could bias study results). We will also discuss how to obtain health information from credible resources online and will direct participants to their personal doctors as the "best" resource for health care advice. This group will also receive monthly educational newsletters about healthy eating, exercise, and stress management.

Group 2: "Enhanced WIC and Internet-Based Weight Control Program."

Patients from clinics randomized to this group will receive Standard WIC plus and Enhanced WIC and Internet-Based Weight Loss Program.

"Enhanced WIC": Institutional Level Intervention

WIC enhancement consists of WIC public health aides and dietitians spending 5-10 minutes during patients' regularly scheduled WIC visit to reinforce use of the Internet-based weight loss program. Practitioners will logon to our study administration website section set-up for WIC practitioners or review a printed copy provided to them. The tracking system or printout will show WIC practitioners the patient's login history and frequency of using and posting to the moderated-message board. A specific computerized protocol will suggest messages to follow-up with the participant – either briefly reinforcing their use of the web program or encouraging and enhancing motivation for using the site in the future.

Monthly group meetings will introduce new weight loss topics, further reinforce messages of the online program, provide opportunities to problem-solve barriers to weight loss, and provide additional support and education on selected topics, following structured protocols adapted from other studies.^{29, 30} Consistent with WIC practices, the groups will last 60 minutes, be "open" (i.e., newly enrolled participants may enter at any time), offered in Spanish and English, and allow adequate space for infants. WIC has reported high attendance (80%) and acceptability of ongoing breastfeeding support groups, which are tied to receipt of WIC vouchers.³¹ We expect ~20% of women will bring their infants with them to group (in our pilot, 2/12 women brought their children to the one face-to-face group meeting that was offered). Groups will be led by bicultural research intervention staff following structured protocols. We

considered having WIC dietitians lead these groups but decided that future research will test this program as fully disseminated into WIC.

Internet-Based Weight Control Program: Individual and Interpersonal Level

The program is based on prior empirically-proven treatment revised to fit the needs of low income postpartum WIC women. The web-based weight control intervention is based on social cognitive theory, specifically the concepts of self-efficacy, goal-setting, and self-regulation.^{32, 33} Moreover, consistent with this theory, the intervention builds skills to modify and restructure the environment (physical, social, cognitive) to gain antecedent and consequent control over weight control behaviors. Intrapersonal, interpersonal, and organizational supports are garnered to address particular barriers to change and practice changes within specific contexts.^{34, 35}

A relational database links participant logins with user-specific information that will serve as a unique participant identifier throughout the project period and facilitate program tracking/use. The research team has managed the details of web-based interventions in several other studies.^{32, 33, 36} The first onsite and online sessions will include personalized training on how to navigate the web-based program and related links and a brief orientation to the key features of the intervention (e.g., promoting changes in diet, activity, and monitoring). Throughout the study, participants will have access to online and phone-in technical support from members of the research team in North Carolina and California.

Overview: Developed and evaluated in a several interventions,^{32, 33, 36} this comprehensive, individually focused, SCT theory-driven, weight control program includes education, behavioral self-regulatory strategies, continuing contact, prompting, and access to social support. Co-Investigator Tate has examined this Internet behavioral weight control program in several studies and has published the results of 2 of these randomized trials in JAMA.^{28, 32} We expect to extend this work by adapting this program for postpartum mothers in WIC and testing the effects over 12 months.

Content: The content of the obesity intervention is based on the Diabetes Prevention Program (DPP) and Look Ahead lifestyle interventions.^{29, 30} Drs. Tate and Phelan have had more than 8 years of training with the content and approach used in the DPP and Look Ahead, having worked closely with our project consultant Dr. Rena Wing, the director of the Diabetes Prevention Program Lifestyle Intervention and Look Ahead study PI.

Website: The website is accessible to each participant anywhere they have an Internet connection. Participants can choose to logon at home, at work, or elsewhere. New content (lesson, tip, link & poll) is provided each week. The behavioral lesson can be viewed on screen or printed for reference. Participants are encouraged to login on Sundays or Mondays to get new guidance and then may check back periodically to see if new messages have been posted to the message board or to look for a specific link.

Web Diary: Participants are encouraged to use an Internet diary to look-up foods and record intake. The diary is very easy to use and is integrated with a comprehensive physical activity web diary developed for our other studies. Progress can be charted over time and participants can review such things as weight change over time, intake over time and calories burned via exercise. Since self-monitoring is the best predictor of weight loss, this strategy is encouraged. However, if patients are unable or unwilling to use this behavioral strategy, alternative evidence-based strategies associated with lowering calorie intake are suggested by the tailored program; for example, reducing portions, limiting sugar-sweetened beverages, increasing vegetable intake, following a simple, culturally relevant meal plan designed to be low cost and family-oriented.

Links: An organized directory of links to quality diet-related sites (e.g., general nutrition, menu planning, recipes, weight loss tips), exercise-related sites (e.g., lifestyle activities, overcoming barriers, walking information), and behavioral and other sites (e.g., managing emotional eating) that are monitored by program staff for quality and relevance/timeliness.

Weekly Structured Online Weight Management Lessons: Each lesson focuses on a topic related to weight regulation, eating, exercise, or behavior change strategies. Topics include: selecting appropriate calorie goals, modifying fat intake, increasing fiber, grocery shopping, label reading, restaurant eating, beginning exercise, aerobic fitness, self-monitoring, stimulus control, problem solving, social assertion, goal setting, body image, cognitive strategies for avoiding negative thinking and cognitive errors, overcoming barriers, relapse prevention training, strategies of successful weight losers in the National Weight Control Registry,³⁷ and numerous other diet or exercise topics based on the Diabetes Prevention Program Materials,³⁸ and other weight, nutrition and exercise projects.

Dietary Goals: Participants are instructed to follow a standard calorie restriction diet used in behavioral weight loss programs.^{29, 30, 38} Calorie goals are based on study entry weight, breastfeeding status, and designed to produce weekly weight loss of 1-2 lbs. In general, most calorie goals are 1200-1800 kcals/day based on a deficit of 500-1000 kcals per day, which has been shown in several studies to be safe in postpartum women and to have no impact on breastfeeding or infant growth parameters.¹⁴³⁻¹⁴⁵ Participants are also instructed to reduce calories from fat to 35% as calorie plus fat restriction has been shown to produce better weight loss than calorie restriction alone.³⁹

Exercise Goals: Participants are instructed to increase their physical activity to burn at least 1000 kcals per week in moderate intensity activities (a standard activity recommendation in behavioral weight loss programs expressed in terms of calories for energy balance).^{29, 30, 38} Walking is encouraged in this program but caloric expenditures associated with many different moderate intensity exercises are provided “Baby-friendly” activities will be suggested. Participants are encouraged to increase activity gradually and to use accumulation of activity from short bouts as a strategy for increasing overall energy expenditure.⁴⁰

Weight Loss Goals: Participants will be given a scale and told to aim for a weight loss of 1-2 lbs per week until reaching their pre-pregnancy weight. Patients desiring to lose more weight during either the weight loss or maintenance treatment phases will be encouraged to do so, provided they maintain reasonable eating and activity patterns and do not reduce below normal weight. As reviewed earlier, moderate weight loss does not appear to adversely effect lactation performance (i.e., change in milk volume, milk composition, energy output, and infant weight),^{17, 41, 42} we will nonetheless be monitoring such changes and tailor goals accordingly.

Computer-tailored Content and Feedback Each week upon participant login, the participant completes a check-in that inquires about weight loss progress, barriers to reaching goals, etc. Responses are compared with pre-programmed algorithms to determine if progress is 1) on track with expected weight loss, 2) slow progress, or 3) lack of progress. Tailored readings, feedback and recommendations are provided in a specific section of the website home page based on progress and individual barriers.

Online message boards. From the study website, participants will access a secure, study-specific message board. The message board is designed to provide patients with opportunities for group support, problem-solving, and feedback from study interventionists and peers. At any time, participants may post questions or comments. The board will be moderated by study interventionists on a daily basis who will answer questions, provide feedback, and provide weekly “topics” for discussion to amplify lessons (provided on the website) and/or address “fresh” topic areas (e.g., postpartum sleep).

Text Messaging. Participants will receive weekly text messages to further reinforce use of the online weight loss program. Approximately half of the text messages will require a reply, and those who do not respond will not receive text messages until the following regularly schedule text message.

Linguistic Adaptations The intervention will be adapted linguistically and be available in Spanish and English. Intervention materials (and research measures) will be translated into Spanish through an iterative process involving both translation and back-translation. We will

conduct 20 interviews with Latina women in WIC to improve the clarity of intervention (and assessment) text and to ensure that key messages are not lost in translation. Revisions to the linguistically adapted intervention will be made based on feedback. All methods in the proposed intervention will be reviewed for cultural sensitivity and low literacy, and all staff will be provided cultural competency training.

Dependent Measures

Demographics and Weight At baseline, participants will complete a demographic questionnaire assessing age, race, ethnicity, history of intentional weight loss, and weight history. Changes in smoking, prescription medications, unsafe dieting practices,⁴³ job status, and participation in other weight loss programs will be assessed at follow-ups. Food security and acculturation, parity, and interval between pregnancy will also be collected given prior relationships with postpartum weight retention.⁴⁴⁻⁵⁰ *Weight* will be measured to the nearest 0.1 kg using a calibrated standard digital scale. Two measures will be completed with participants measured in light clothing (without shoes). Scale calibration will be checked weekly with known weights. Standing *height* will be measured twice in patients without shoes in millimeters with a wall-mounted Harpenden stadiometers at WIC clinics. *Pre-pregnancy weight* will be based on self-report at time of last menstrual period. Our research and other studies have suggested that women are quite accurate in recalling their pre-pregnancy weight.^{51,52} However, to increase the validity, we will abstract pre-pregnancy measured weights from clinic charts whenever available. Adjustments will be made using the prediction equation used by Olson et al.⁵³ *Waist Circumferences* will be measured over bare skin or underwear using a tape measure, and following standard protocols; prior research has shown that obese women may retain more abdominal fat postpartum than non-obese.⁵⁴

Behaviors. *Physical Activity* will be measured using the Actigraph accelerometer (MTI, Inc) which provides minutes and time spent in light, moderate, and vigorous activity over a period of days or weeks.⁵⁵⁻⁵⁷ The assessment protocol and data cleaning procedure (Meterplus software) have already been established. *Dietary Intake* will be measured using 24-hour recalls on 3 random days over a week and completed using the Nutrition Data System Software (NDS).⁵⁸⁻⁶² The primary variables of interest will be: calories, protein, carbohydrates, and fat. Underreporting will be estimated by comparing reported energy intakes (based on 24-hour recalls) with estimated total energy expenditure (TEE) for each participant calculated based on estimated BMR (adjusted for age, gender, breastfeeding status)⁶³⁻⁶⁵ and level of physical activity.⁶⁶ If indicated, analyses will exclude extreme underreporters. *Weight Control Practices* will be assessed by frequency of self-weighing, self-monitoring, stimulus control, and problem solving.⁶⁷ We will assess *breastfeeding* intensity and duration² and information about introduction of formula. Similar to our prior research, *safety* will also be assessed using pre-established questionnaires, including injuries due to physical activity, instances of extreme hunger, fatigue, and changes in milk supply. These data will be monitored by the DSMP.

Treatment Fidelity and Process After regularly scheduled WIC visits, participants in both conditions will complete a confidential brief inquiry card asking whether WIC counselors discussed a wide range of different topics, including weight control, and use an Internet program. Research Assistants will also track the number of newsletters sent, and ask patients to report on the frequency they received and read newsletters. In the intervention group, we will also assess number of logins, number of online self-monitoring records completed and returned, attendance at monthly group meetings, frequency of self-weighing and other weight control practices (see Weight Control Practices above), frequency of posting to the message boards, text-messaging, email communications. All group treatment sessions will be audiotaped and coded for content by a trained RA (not involved in any assessment data collection). There is a minimal amount of cross-activity between clinics, but we will track clinic staff changes and moves to other clinics, and assess self-reported interactions with study participants outside of

clinic. We will also ask patients to indicate whether they had any interactions with WIC staff or participants outside their WIC clinic. Finally, to inform potential future dissemination, participants and WIC staff will rate *usefulness and satisfaction* with intervention content and its delivery, using the questionnaire developed in our pilot that includes ratings of various aspects of the program. Willingness to adopt the intervention will also be assessed in WIC clinic staff and county chiefs.

Psychosocial Measures The Beck Depression Inventory (BDI)⁶⁸⁻⁷⁰ will be used to examine levels of *depressive symptoms*, as new-onset postpartum depression is associated with substantial weight retention in the first postpartum year.⁷¹ *Body image* will be assessed using the Appearance Subscale of the Multidimensional Body-Self Relations Questionnaire,^{72, 73} as concerns about weight and shape have been found to increase during the postpartum period and may motivate postpartum weight loss.^{19, 74} Participants will complete the Sallis *Social Support Exercise and Eating Habits Surveys*,⁷⁵ and *self-efficacy* will be assessed by the Weight Efficacy Lifestyle Questionnaire.⁷⁶⁻⁷⁸ Both have been inversely related to weight, and increases in self-efficacy are related to greater weight loss success.⁷⁷ *Stress* will be assessed using the short-form of the Perceived Stress Scale,⁷⁹ which has been associated with prenatal weight gain^{80, 81} and postpartum relapse in smoking.⁸²

Cluster Level Assessment. Basic demographic information and lactation status is collected in all women in WIC. In addition, we will assess changes that may occur in and around the clinic environment, which may affect the clinic's nutrition and physical activity programs during the intervention period, and document external independent programmatic policy and environmental changes. Specifically, data will be collected annually related to levels of physical activity and nutrition that may affect women in WIC but that were not necessarily part of the study intervention, including: (1) aspects of the environment in the clinic and surrounding neighborhood (e.g., promotion of walking programs); (2) relevant grants and research program initiatives at clinics; (3) local, state or federal mandates; and (4) promotions and advertising.

Procedures to Retain Sample Participant retention strategies have been used effectively in our other studies of multiethnic childbearing women and include collecting *multiple* phone numbers and numbers of relatives and friends for contact. For each data collection visit, participants will be scheduled by phone, sent written reminders, and called the day before. Missed visits will be rescheduled and followed up. Costs for transportation and childcare coverage will be provided to participants with repeat missed assessments. If necessary, assessments will be completed at patients' homes. Compensation will be provided to further promote retention: \$25 for completing the baseline and 6-month assessments and \$50 for the 12 month assessment. As a retention tool, women also receive newsletters at 3-month intervals with basic information about weight control, exercise, nutrition, and wellness.

Statistical Analysis Overview The analysis strategy is based on a conceptual framework that explicitly recognizes that both differences between individuals within clinics and between clinics may contribute to variance in weight change. Randomly assigned group (standard care versus intervention) is the main independent variable for intent-to-treat (ITT) analyses. County is a stratification variable for randomization and is expected to be balanced across intervention and standard care groups by design. The primary outcome variables are 6 and 12 month weight losses. Our analysis approach uses linear mixed effect models to analyze differences between the intervention and standard care clinics allowing for within cluster covariance (participants within the same clinic) and within individual covariance (repeated measures).⁸³ The model will include factors for a fixed effect for treatment/group and random effects for clinic as well as a

group x time interaction term to test if the change over time in the dependent variable differs significantly for the 2 study groups. In addition, for primary and secondary outcomes, the model will include participant-level covariates to adjust for any baseline differences, or adjust for covariates that may relate to the outcome, including lactation, age, age at menarche, education, income, smoking status, language, SES, race/ethnicity, height, pre-pregnancy BMI, parity, gestational gain, interpregnancy interval, baseline BMI, history of weight cycling, and changes in marital status and employment^{2, 84-90} In addition, the model will include terms to account for whole-clinic (cluster-level) variates, including proportion Latina, lactation proportion, mean age, mean education, and mean SES.

PROTECTION OF HUMAN SUBJECTS

Risks to the Subjects

Human Subject Involvement and Characteristics: Participants in this study will be 408 healthy postpartum women, 18 to 35 years old, recruited from the 12 clinics in San Luis Obispo and Santa Barbara County WIC programs. Participants will have a body mass index (BMI) between 22 and 40 kg/m², be between 6 and 24 weeks postpartum, and, at that time, be exceeding prepregnancy weight by at least 6.8 kg (15 lb). All ethnic groups and both Spanish and English speakers are eligible for this study. Participants will also have a cell phone and home Internet access or a landline phone. The age range was selected because younger adults (<18 years) have different developmental needs during pregnancy. Similarly, older adults (>35 years) are at increased risk of maternal and fetal complications, which could require greater attention during the postpartum period. We are not including women with a BMI <22 in this study to reduce the likelihood of a woman becoming underweight if she lost \geq 15 lb (6.8 kg). We have selected only participants who are between 6 and 24 weeks postpartum to allow sufficient time for initial pregnancy-related weight loss to occur while still intervening early enough to prevent excessive weight retention at 12 months. We selected > 6.8 kg weight retention as this amount of weight retention would represent a significantly higher than average weight retention, increasing the risk of major weight gain in association with pregnancy, and has also successfully been used in other postpartum weight loss studies.¹⁸ Participants who do not have computer and/or Internet access from home will be provided with a laptop computer and/or Internet access if they have a landline phone, as we are able to provide home Internet access free of charge through UNC facilities. Cell phones are also required to receive the text messaging component of the intervention, but text messaging plans will be covered by the study. Both primiparous and multiparous, lactating and non-lactating participants will be eligible. Several studies have collectively shown that moderate weight loss, caloric restriction, and/or acute or regular physical activity do not appear to adversely effect lactation performance (i.e., change in milk volume, milk composition, energy output) and infant weight,^{17, 41, 42, 91} but we will be monitoring these outcomes (please see DSMP section below)

Participants will be excluded if they are pregnant, planning pregnancy, or relocating in the next year. They will also be excluded if they report serious current physical disease (e.g., heart disease, cancer, renal disease, and diabetes) for which physician supervision of diet and exercise prescription is needed, physical problems that limit the ability to exercise, history of eating disorders, current problems with drug abuse, or current treatment for a serious psychological disorder. Women with significant depressive symptoms (score > 20 on the BDI⁶⁸⁻⁷⁰) will require provider approval (e.g., social worker, physician) prior to enrollment or be referred for appropriate care. These exclusions are included for the safety of subjects. Note that the consultant (Aaron Kromhout, MD) will review medical issues related to participant eligibility.

Rationale for Exclusion of Children and Adolescents Although postpartum weight retention and obesity are significant concerns for younger adults, the proposed study excludes younger pregnant individuals because adolescents would likely require different treatments, different nutritional goals, and different levels of therapist and parental involvement than are proposed in

the current study.

Sources of Material: Participants will provide weight, waist circumference, height, physical activity, dietary, and questionnaire data specifically for research purposes. An electronic survey will be administered via participant email addresses or in a paper format if no response is obtained electronically. Data are also collected via phone (24-h recalls) and the actigraph. Prepregnancy weight will be abstracted from medical charts. The consent form will ask women for their permission to conduct these assessments.

Potential Risks: This study follows women for 12 months; the goals of the study are to promote significant weight loss and increase the proportion of women who achieve preconception weight after 12 months of treatment; and, to promote increases in healthy eating, exercise, and psychosocial parameters. Risks of participation in the postpartum intervention are considered minimal. Caloric restriction (with adjustments made for breastfeeding women) and moderate increases in physical activity are employed. Potential risks are a) subjects may not lose weight, b) may lose weight too rapidly, c) may engage in unsafe dietary practices, d) may experience some joint discomfort or minor injuries associated with initiating an exercise program. As discussed below, precautions will be taken to minimize these risks.

Using an electronic survey and an Internet program for treatment also poses some risks to loss of confidentiality, since there is the potential for data to be intercepted or accessed by unauthorized persons during transmission. These circumstances are quite rare; however, specific procedures to ensure confidentiality are also described below.

Adequacy of Protection Against Risks

Recruitment and Consent Procedures: Subjects will be recruited at 12 WIC clinics. Study staff will describe the project to women attending their WIC 6 or 12, or 24 week postpartum visit. Women who express interest in the study will be screened to determine eligibility. Eligible respondents will be given a consent form and invited to attend a Baseline Assessment and Randomization visit (Visit 1) within 2 weeks. The study will be explained in detail at this visit and informed consent will be obtained. The consent form will have been approved by the Institutional Review Board. All questions that subjects have will be addressed.

Protections Against Risk: We feel that the risks of this study are unlikely to occur. During the postpartum intervention, weight losses of 1-2 lb/week are targeted and women who are not losing weight at the expected rate will be given more tailored feedback to promote adherence. Several studies have found that moderate restriction of calories and fat and increases in physical activity have no adverse effects on lactation performance or maternal and child health,^{17, 41, 42, 92, 93} but we will nonetheless be carefully monitoring these outcomes (please see data safety monitoring plan). Although some studies have used 1000-1500 calorie/day goal, we have selected 1200-1500/day goal (with adjustments for breastfeeding women) in order to be less stringent. Participants will be advised to gradually increase exercise and to use walking as a primary form of activity. In the event that weight loss progresses too rapidly, the PI (a health psychologist) will discuss these issues with the patient and encourage alternative, healthier practices. If participants achieve below the BMI level defined by the IOM as normal weight (i.e., BMI < 19.8), the PI will advise them to stop losing weight and to work, instead, on weight maintenance.

In this low-income, postpartum sample, at any time during the study, women may report (either formally on our depression and eating disorders assessments or informally in conversation) symptoms of depression, suicidality, unsafe dieting practices, alcohol or drug abuse, physical abuse, child abuse, severe household food insecurity, or other problems (lack of electricity, homelessness). Although we expect instances of these to be quite rare, we have a protocol in place developed from several of our other studies for handling such reports. The protocol includes specific instances (e.g., score > 20⁶⁸⁻⁷⁰ on the depression inventory or reports of unsafe dieting practices on the EDE⁴³) that require triaging up to the Project Coordinator (Ms Brannen, a nutritionist), the PI (Dr Phelan, a health psychologist), the Co-I (Dr. Papathakis, a dietitian), or another health professional (nurse, physician) to assess the patient. Consistent with WIC practice, acute issues (abuse, suicidality with a plan, postpartum psychosis) will be handled immediately to protect the safety of patients and/or children (hospitalization, DHHS intervention, police intervention). Less acute issues will be handled through the process of referral. Fortunately, there are several community resources available for low income and uninsured women in both San Luis Obispo and Santa Barbara counties; these resources are funded by the First 5 Community, the USDA, and the Childhood Abuse Prevention Council. These include postpartum hotlines/warmlines, women's shelters, facilities services from the department of social services, drug and alcohol services, USDA food distribution centers, and a 24-h referral line (211) for other needs. Women will be provided a referral as indicated and a follow-up call, if needed based on clinical judgment.

The study intervention website will be password protected and on a secure server. All participants will self-select usernames and passwords for the program. These usernames will be used to login to the website and for transmission of self-monitoring data; therefore, actual names and identities will only be known to the researcher unless the participant voluntarily shares this information with others. Participants are permitted to select an alias for posting to the message boards. The message board is accessible only from our password protected site. Furthermore, our secure server also permits secure messaging on the site (similar to a private message board). If a participant chooses, e-mail messages can be posted to this private message board rather than delivered via e-mail. Similar protections are in place for all participants completing the electronic survey, which is also administered and stored on a password protected and secure server. Participants are advised about the nature of e-mails that will be sent from this study during the consent process and are permitted to select the e-mail address they prefer for study correspondence.

Potential Benefits of the Proposed Research to the Subjects and Others

The risks of participating in the intervention are considered minimal and the potential benefits markedly outweigh the risks. Preventing postpartum weight retention through healthful dietary change and increased exercise has the potential to substantially improve the health of participants. If, as expected, this study's findings demonstrate that the intervention prevents long-term weight retention, other individuals may gain significant health benefits through undergoing the intervention.

Importance of Knowledge to be Gained

The potential for minimal risks to human subjects is considered reasonable in relation to the importance of the knowledge that is expected to result from this study. We believe this project is significant because it deals with prevention of postpartum weight retention and weight gain, which is a major health problem. Findings from this study will have important implications for the prevention of weight gain in young adult multiethnic women.

Data Safety Monitoring Plan

Safety of Subjects

The data safety monitoring plan for this trial focuses on close monitoring by investigators in conjunction with oversight from two safety officers. Monthly meetings with the full investigative team will occur via conference calls to evaluate study progress, subject status, and any adverse events. The investigative team includes expertise in clinical and health psychology and behavior change (Suzanne Phelan, PhD; Deborah Tate, PhD; Rena Wing, PhD), nutrition and lactation in postpartum women (Peggy Papathakis, PhD, RD; Barbara Abrams, RD, PhD;), medicine (Aaron Kromhout, MD) and statistics (Andrew Schaffner, PhD). Naomi Stotland, MD, and Maureen Phipps, MD, MPH, will serve as the Data Safety Monitoring Officers on the project. Dr. Stotland is a practicing obstetrician and Assistant Professor at the University of California, San Francisco (Department of Obstetrics, Gynecology, and Reproductive Sciences) and San Francisco General Hospital. She has expertise and published studies on the prevalence and risk factors of excessive and inadequate weight gain and the relationship between weight gain and maternal/fetal outcomes. Dr. Phipps is also a practicing obgyn and researcher specializing in pregnancy outcomes, postpartum depression, and disparities in women's health. The safety officers will meet every three months by phone with study investigators to review referral rates (to social services, etc.), recruitment, attendance, and safety information, including participant reports of perceived milk supply, infant growth, and injuries associated with exercise on all participants. They will make recommendations to the PI and co-investigators and to the NIH Project Officer regarding the progress of the study and will be able to report to the Institutional Review Board or Office of Research Administration should she have concerns about the conduct of this research.

All participants will be instructed to call the PI and research coordinator directly if they experience any adverse side effects during participation in the program. Adverse events will be recorded to determine if they are unanticipated problems involving risk to subjects and others or not. Any serious adverse events will be recorded by the research coordinator, reported to the PI and investigative team, the Safety Officer, and the IRB. The NIH will be informed of serious adverse events and any actions taken.

Data

Participants will have their weight and height measured and complete questionnaires. Medical chart abstractions will also occur for mothers consenting to document pre-pregnancy weight. Only participant identification numbers will appear on data collection forms. The code that links the study ID and the name will be kept in a separate place than the data file until all of the measurements are complete. At that point, the personal information will be destroyed and all analyses will be conducted with the data that has no personal identifiers. All data will be stored on secured computers that are password-protected or locked in a file cabinet within 24 hours of its acquisition. Data will be removed for the purpose of coding, data entry, or auditing

only. The study's reach coordinator will work closely with the statistician and data manager to ensure the secure storage of all project databases and questionnaires.

Data Quality Control All staff involved in data collection will be trained by the PI and must demonstrate competence in administering all questionnaire measures. The Research Assistants will be blinded to randomization and review all assessment data for accuracy and completion. Participants will be re-contacted to provide missing data or to clarify responses. Electronic or paper data forms will be used for all questionnaire data. The electronic survey has built-in verification checks. Range checks will be applied to all entered data. Out of range values will be double checked with the original data form and/or referred back to the participants for correction, when appropriate. Edited data files will be examined for frequency distributions to check again for outliers. Once edits are completed, a SAS save file will be created. An additional data pass will be performed to create summary scores (e.g., overall score on BDI). This final master data file will then be saved in SQL server and used for analyses. Hard copies of data will be stored in a locked filing cabinet and electronic data file will be password protected and backed up. Nightly backups ensure recovery of data and database management system.

Educational Training: All investigators and staff will be required to obtain education regarding the protection of volunteers in research from their own institution. Key personnel who have undergone the mandatory Human Subjects Education Training include: Suzanne Phelan, Peggy Papatkakis, Deborah Tate, Karen Munoz-Christian, Andrew Schaffner, and Barbara Abrams.

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