A Mobile Health Intervention to Achieve Appropriate Gestational Weight Gain in Overweight/Obese Women

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CLINICAL TRIAL PROTOCOL

Abbreviations:

BMI: body mass index
GWG: Gestational weight gain
IOM: Institute of Medicine
IRB: Institutional Review Board
KPNC: Kaiser Permanente Northern California
mHealth: mobileHealth
PA: physical activity
RCT: randomized controlled trial

OBJECTIVE:

We conducted a cluster RCT of an mHealth intervention promoting appropriate GWG in pregnant patients with overweight or obesity in KPNC, an integrated healthcare system. Randomization was at the clinician level. The primary aim of this clinical trial is to evaluate whether an mHealth intervention designed to help pregnant patients with overweight or obesity and their clinicians manage GWG will improve GWG (Primary Outcome) in comparison to usual care.

BACKGROUND:

Sixty percent of pregnant patients in the United States are overweight or obese. Over half of pregnant patients with overweight or obesity exceed the IOM guidelines for GWG. which further increases their elevated risk of gestational diabetes, cesarean delivery, postpartum weight retention, severe obesity later in life, having a large-for-gestational-age infant and a child at risk of being overweight or obese. Thus, improving GWG among patients with overweight or obesity is a public health priority. Pregnancy is a unique window when women are in frequent contact with the health system and are motivated to make healthful changes out of concern for their baby, which presents an unparalleled opportunity to intervene on weight management. High-intensity behavior change interventions have significantly improved the percent of women meeting the IOM GWG guidelines. However, these interventions are too time-consuming for some patients. In addition, while patients view their clinicians as a persuasive, trusted source of behavior change advice, many clinicians lack experience and the tools to provide behavior change advice necessary to manage GWG. Interventions to manage GWG that support both patients' and clinicians' barriers, and can be implemented in the health system, could maximize their effectiveness and reach.

MHealth interventions offer a promising scalable solution to overcome patients' and clinicians' barriers to GWG management but have yielded mixed results. We propose that mHealth interventions must include key elements to impact weight. These include interactive technologies

such as “smart” wireless scales and wearable activity trackers that facilitate self-monitoring and real-time feedback. These elements have proven efficacious in weight management outside of pregnancy but were not previously included in mHealth GWG interventions. We also propose that tools and training for clinicians are essential.

STUDY SETTING:
Research activities took place at the (3) locations listed below:

1. Kaiser Permanente Northern California (KPNC), Division of Research, Oakland, California
2. University of Hawaii at Manoa School of Nursing and Dental Hygiene, Honolulu, Hawaii
3. School of Medicine, University of California, Davis, Sacramento, California

STUDY DESIGN:
This study conducted a cluster randomized trial to evaluate an mHealth intervention promoting appropriate GWG in an integrated healthcare system, with randomization at the clinician level. Consented patients received usual care or usual care plus mHealth intervention per their clinician’s randomization. The patient adaptive intervention provided personalized, automated feedback on GWG and physical activity using 1) a smartphone application, 2) a Wi-Fi scale and activity tracker; 3) weekly educational topics; and 4) step-wise support (added when GWG is >75th percentile of the GWG guidelines). Intervention clinicians received newsletters with motivational interviewing tips to facilitate discussing GWG.

STUDY POPULATION:
a. NUMBER OF SUBJECTS
58 total clinicians
1,335 total patients

b. INCLUSION AND EXCLUSION CRITERIA
Inclusion Criteria:

- Age 21 years or older
- Pregnant
- Women receiving prenatal care at Kaiser Permanente San Francisco and Oakland and whose obstetric care clinicians consent to participate
- Pregravid BMI 25 to <40 (as determined from a measured pregravid weight in electronic medical record)
- Has access to a smartphone and Wi-Fi
- Provides informed consent to participate

Exclusion Criteria:

- Multiple births
- Planning to move out of the area during the study period
- Inability to speak, read, or understand English
- Placed on bed rest at time of enrollment
- > 15 weeks' gestation at enrollment.

WAIVER OF INFORMED CONSENT and HIPPA PRIVACY RULE AUTHORIZATION:
A waiver of informed consent and HIPPA Privacy Rule Authorization was granted from KPNC IRB (IRB of record for this study) for clinicians and patients in the intervention arm and in the usual care arm. The only known risk is disclosure of confidential information. Safeguards were be put in place to prevent the loss of privacy and to prevent breaches of confidentiality. This study represented no more than minimal risk participants.

STUDY PROCEDURES:
Eligible clinicians were randomized into (2) arms: 1) an intervention arm and 2) a usual care arm. Obstetric clinicians randomized to the intervention arm received quarterly newsletters containing study updates on recruitment and retention efforts plus quarterly intervention newsletters containing tips on how to use motivational interviewing techniques to discuss GWG with their pregnant patients. Obstetric clinicians randomized to the usual care arm received quarterly newsletters containing study updates on recruitment and retention efforts.

Pregnant patients receiving prenatal care from consented clinicians were eligible to participate in the trial. Eligible patients of consented clinicians in both arm were invited to complete a trial survey. Patients in both arms were informed they might be invited to an mHealth program. Within one week of completing the survey, patients receiving care from clinicians in the intervention condition were subsequently invited to join the adaptive mHealth intervention and invited to consent to sharing app, activity, and weight data with the study team.

DATA ANALYSIS:
All data analyses were intent-to-treat, including all randomized clinicians and patients. Analysis of treatment arm differences was by original treatment group assignment, regardless of adherence. Log binomial regression was used to estimate the population average mHealth intervention effect on meeting the IOM GWG guide lines with estimation via generalized estimating equations (GEE; marginal model), accounting for the within-clinician correlation among patients to obtain valid estimates of treatment effects and associated standard errors. The probability of appropriate total GWG was modeled as a function of treatment arm and covariates used in the randomization procedure: clinician age, patient race/ethnicity, and patient BMI. In addition, this a priori specified set of model covariates included patient age and parity in the regression models given their strong association with GWG.

Linear regression was used to provide point and interval estimates of the between-arm difference in mean rate of GWG. The approach to estimation of model parameters (GEE) and inclusion of model covariates was as specified above for the analysis of our primary binary outcome. Linear regression with GEE was chosen rather than linear mixed effects regression for estimation of population average intervention effects given freedom from

distribution assumptions on cluster random effects, and to parallel the analyses of our binary outcome.

The approach to the analyses of trimester-specific GWG (kg/week) paralleled that described above for the total rate of GWG. Linear mixed effects models were used in analyses of the intervention in relation to GWG trajectory, accounting for the within-person correlation among repeated measurements (not necessarily equal numbers per subject) and within-clinician correlation between patients, to obtain valid estimates of treatment effects and associated standard errors. We used latent trajectory class modeling to identify and categorize patients with respect to patterns of GWG during pregnancy. Group-based trajectory analysis, an application of finite mixture modeling, is designed to identify clusters of individuals with similar patterns of change over time. Examination of the intervention in relation to pattern of change category utilized multinomial logistic regression with estimation via GEE to account for nesting within clinician. The approach to the analyses of postpartum weight retention at 6 weeks, change in moderate to vigorous physical activity (12 weeks to 33 weeks; MET hrs/week), overall diet quality at 12 weeks (Healthy Eating Index-2015), and birthweight (all continuous), and proportion of infants with appropriate size for gestational age (binary) paralleled that described for the primary outcomes or rate of GWG and meeting the IOM GWG guidelines. The approach to the analyses of the intervention in relation to 12-month infant growth (BMI Z-score) trajectory paralleled that described for analyses of GWG trajectory.