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eMoms: Electronically-Mediated Weight Interventions for Pregnant and Postpartum Women. Study Design and Baseline Characteristics

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Abstract

Background—The influence of childbearing in the development of obesity is situated within two different but related contexts: pregnancy-related weight gain and weight gain prevention and control in young adult women. Pregnancy related weight gain contributes to long-term weight retention in childbearing women.

Objective—To present the study design, data collection procedures, recruitment challenges, and the baseline characteristics for the eMoms of Rochester study, a randomized clinical trial testing the effect of electronically-mediated behavioral interventions to prevent excessive gestational weight gain (GWG) and postpartum weight retention among women aged 18–35 years of diverse income and racial/ethnic backgrounds in an urban setting.

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Design—Randomized double blind clinical trial. A total of 1,722 women at or below 20 weeks gestation were recruited primarily from obstetrics practices and randomized to 3 treatment groups: control arm; intervention arm with access to intervention during pregnancy and control at postpartum (e-intervention 1); and intervention arm with access to intervention during pregnancy and postpartum (e-intervention 2). Enrollment and consent were completed via study staff or online. Data were collected via online surveys, medical charts, and measurement of postpartum weights. The primary endpoints are gaining more weight than recommended by the Institution of Medicine guidelines and weight retained at 12 months postpartum.

Conclusion—This study will provide evidence on the efficacy of behavioral interventions in the prevention of excessive GWG and postpartum weight retention with potential dissemination to obstetrics practices and/or health insurances.

Keywords

gestational weight gain; maternal weight; pregnancy weight; postpartum weight retention; internet; randomized clinical trial

INTRODUCTION

The influence of pregnancy in the development of obesity is at the intersection of two research areas: pregnancy-related weight gain and weight gain prevention and control in young adult women. Approximately 53% of pregnant women gain more weight during pregnancy[1] than recommended by the Institute of Medicine (IOM) (Table I).[2] Excessive gestational weight gain (GWG) is associated with maternal and offspring morbidity, including postpartum weight retention and childhood obesity.[3–10] Longitudinal data indicate that women gain a considerable amount of weight during their twenties and thirties[11] and that parity is associated with weight and waist circumference increases.[12]

Several trials have tested the effect of lifestyle interventions during pregnancy on weight accumulation. Randomized and non-randomized trials suggest that educational interventions comprised of physical activity (PA) and dietary counseling during pregnancy, commonly combined with weight monitoring, may lower the risk of excessive GWG[13–15]. Similarly, postpartum trials of both diet and PA or diet alone were effective in minimizing weight retention after childbirth[16]. To our knowledge, few studies have examined the effect of a combined pregnancy and postpartum intervention on GWG and postpartum weight retention[17] adapting the interventions to the lifestyle changes involved in transitioning from pregnancy to postpartum life [18]. eMoms of Rochester trial (eMoms) was designed to fill this gap.

The objective of the eMoms' study was to slow the accumulation of weight in childbearing women during pregnancy and the postpartum period by decreasing the prevalence of excessive GWG and minimizing postpartum weight retention in a socio-economically and racially/ethnically diverse sample of women. eMoms is part of the National Heart, Lung, and Blood Institute Early Adult Reduction of weight through LifestYle interventions (EARLY) consortium of weight control studies that tested innovative intervention approaches that incorporated digital technologies among young adults aged 18–35 to facilitate recruitment

and retention. [19] In addition to using digital technologies for most of the study procedures (e.g., enrollment, intervention delivery, adverse event reporting), eMoms has other unique features such as a three arm design, a large sample size to examine differential effects by subgroup, and a long follow-up period. The purpose of this report is to present the eMoms study design, data collection procedures, recruitment challenges, and the baseline characteristics of the study sample.

MATERAIL AND METHODS

Study Design

The goals of the eMoms interventions were to decrease the prevalence of excessive pregnancy weight gain and to decrease the amount of postpartum weight retention. The efficacy of the interventions was evaluated in a double blind, randomized, controlled effectiveness trial with a parallel group design in which the individual is the unit of randomization and analysis. The study was conducted in a metropolitan county in upstate NY, and started in 2009 with a projected duration of 5 years and consisting of two phases. In phase I (February, 2010 to May, 2011), two electronic behavioral change interventions for weight management and control in pregnancy and postpartum were developed based on formative research that investigated access and use of electronic communication media, women's preferences for intervention features (e.g.; weight gain tracker), barriers, strategies, and topics of interest and their potential differences between income groups.[20–22] In phase II, 1722 pregnant women aged 18–35 in the first 20 weeks of pregnancy were randomized to 3 arms: e-intervention group 1 receiving the electronic intervention during pregnancy only; e-intervention group 2 receiving the electronic intervention during pregnancy and postpartum; and a control group who was exposed to electronic material unrelated to weight management. Recruitment for Phase II started in May 2011 and lasted 14 months.

The primary hypotheses are: 1) the proportion of women who experience excessive GWG will be 10 percentage points lower in the intervention compared to the control conditions; 2) the control group will have an average weight retention of at least 4 pounds greater at 12 months postpartum compared to e-intervention group 1 and e-intervention group 2. By having two intervention groups, we will test whether interventions during pregnancy have continued effects on postpartum weight retention or whether interventions adapted to women's new life demands after pregnancy are needed to minimize weight retention after delivery. Secondary research questions include other weight outcomes (e.g. rate of gain by trimester, returning to early pregnancy weight, and retaining 5 pounds or more) and behavioral mediators of intervention effects. The protocol was approved by the University of Rochester Research Subject Review Board and the Cornell University Institutional Review Board.

Source Population

The county has a population of 75,468 females aged 20–34 (Census 2010). [23] Based on the number of total births in the county in 2007, there were a prorated 10,851 births during 15 months (the study accrual time) of which 5,765 were term singleton births to women

aged 18 to 35 with BMI 18.5 to <35.0 kg/m^2 without weight-affecting medical conditions according to data from a local population-based perinatal registry.[24]

Eligibility criteria

Inclusion and exclusion criteria are listed in Table 2 and were self-reported by participants at enrollment. Since eMoms is part of an NHLBI EARLY Trials cooperative agreement, some of the exclusion criteria were common to all trials.[19]

Recruitment and Enrollment

The study had two sources of subject recruitment, obstetric and family private practices and clinics (hereafter, practices) and the community.

Practices—Twenty out of 29 area practices agreed to participate in the study. Additionally, obstetric ultrasound offices were included to capture potential participants who obtained prenatal care in non-participating practices or in small practices where study staff was not regularly assigned. Memoranda of agreement were signed by all participating practices

Community-Based Recruitment—We created 'brand recognition' and curiosity among pregnant and non-pregnant women of childbearing age in the area with a community outreach strategy. Newspaper articles, brochures and posters in community settings, participation in community events (e.g. church meetings, fairs), television, radio and transit bus advertising, online ads on area websites, mass mailings coordinated with advertising campaigns, and emails to colleges' and universities' alumni networks in the area were utilized.

Participant enrollment—A majority of participants were recruited face-to-face at practices by study or practice staff. The procedures for participants screening and enrollment were adapted to each practice's needs. In brief, study staff screened for eligibility and consented participants on-site, or practice staff referred potential participants to the study after prescreening for age range, gestational age, and BMI category. Additionally, pregnant women recruited via our community outreach activities had two options for screening and enrollment: contact study staff via telephone, or visit the study website to screen and self-enroll. Participants provided written consent either online or in-person. Medical record release forms were signed by participants in person to ensure access to medical records for chart audits.

Recruitment, recruitment tracking, screening, randomization, and most data entry were accomplished using online tools specifically developed for this study. To decrease the risk of inadvertent entry of inaccurate data by staff or participants the tools included multiple data checks for data quality control purposes. For example, during data collection, the online surveys and online abstraction forms had range checks embedded that flagged out-of-range values for participants to check for accuracy.

Randomization—Once consented, participants were randomized via a computer-generated algorithm. A temporary password and unique, but otherwise non-informative,

study ID were immediately created. The email address and temporary password gave the subject access only to web pages corresponding to their assigned treatment. This process ensured blinding of study staff and participants to study arm allocation. Four strata were defined by early pregnancy BMI and income (two BMI groups: BMI 18.5–<25.0 and BMI 25.0–<35.0; and two income groups: above and below Medicaid eligibility). Block randomization (block size 6) within four strata to three study arms was done to obtain balanced treatment allocation within important known predictors of gestational weight gain and postpartum weight retention. Previous work by Olson [25,26] indicated BMI category and Medicaid eligibility were among the strongest predictors.

Intervention

The intervention was designed based on evidence-based behavior change strategies such as goal-setting and self-monitoring which were adapted and informed by formative research that explored media use and potential content and intervention elements. Details of the intervention development, content, and intervention implementation have been published elsewhere.[22] Briefly, the theoretical models for the intervention were Fishbein and Yzer's Integrative Model of Behavioral Prediction [27]combined with Fogg's Behavior Model for Persuasive.[28] During pregnancy, the online intervention features had 5 behavioral targets for the prevention of excessive gestational weight gain: entering weight in the project website 'weight gain tracker'; physical activity and diet goal setting; increasing caloric intake by the recommended amount in the second and third trimester; improving or maintaining the nutritional quality of their diets by consuming 5 servings of fruits and vegetables per day; avoiding excess sugar and fat intake and emotional eating; and engaging in 30 minutes of moderate to vigorous physical activity on at least 5 days per week. These behavioral targets were adapted to the postpartum period. For example, the intervention included a 'weight loss tracker' to encourage safe weight loss according to participant's weight and breast feeding goals. Website content for the control arm of the study included information on having a healthy pregnancy without providing behavior change strategies, self-monitoring tools, or logistical tips, which were similar to what is available on government websites. The information available to control participant was also available to intervention participants. Most of the intervention was delivered via a website with some reminders and informational content pushed out via either text or email messages (e.g.; pregnancy-related tips).

Data collection

Data were obtained from online surveys, medical chart reviews (prenatal, labor and delivery, and 6 week postpartum), and in-person measurements by study staff (postpartum weight and height) (table 3). Once a participant entered a data collection time point for the study the website alerted them as to which surveys, dietary recalls, and/or weights they were being asked to complete.

Online surveys—Surveys covered the following topics: media use, socio-demographic data, attitudes and beliefs about weight, physical activity, and diet, smoking, alcohol intake, sleep, depression, eating patterns, physical activity and sedentary behaviors, supportive relationships, employment status, and neighborhood food and physical activity environment.

Participants also entered medication use in an online tracking tool and completed two online 24-hour dietary recalls (one weekday and one weekend) at each data collection time point. [29] Participants were offer the option to complete surveys by telephone when an online survey hadn't been completed by the end of each data collection period.

Adverse Events—Medical adverse events were self-reported via an online questionnaire at all data collection points except at baseline. Adverse events covered pregnancy, labor and delivery, and infant complications, and non-pregnancy related medical events. Each adverse event, the study time point, and the date it was reported were available by participant ID within the eMoms staff website for review by the blinded study coordinator. Since adverse events were self-reported online, questions were devised to define the event severity in order to minimize study staff contact for determination of a serious adverse event (SAE) (e.g. whether a health care provider was seen, and what, if any, treatment was administered). Further information for the determination of an SAE, if needed, was sought from the participant directly or via the medical record. Potential SAEs were triaged within the online system to the Medical Officer for review.

Safety Alerts—The study generated safety alerts to participants for corrective actions in relation to:

-Inadequate weight gain during pregnancy: Women in the intervention arms were encouraged to enter their weights, measured by the health care providers at prenatal care visits, into an online weight gain grid. We defined two different safety alert levels for inadequate pregnancy weight gain for each of the three BMI groups using the 2009 IOM guidelines [2] to prevent maternal and fetal adverse outcomes. Based on the participants weight entries a first level of alert was sent when a participant's weight gain fell below the recommended range. The non-blinded interventionists emailed a personalized message with reference to relevant website content and encouraged the participant to discuss the under-gain with their prenatal care provider at the regularly scheduled visit. A second level of alert was sent when participants had serious under-gain that reached the small-for-gestational-age-risk threshold. In this case, the interventionist followed-up with a phone call and a referral letter to the participant indicating the need to discuss inadequate weight gain with her prenatal care provider.

-Rapid weight loss in postpartum: Considerable and rapid weight loss may interfere with exclusive breastfeeding, especially in the first 6 months postpartum. Thus, for women in the intervention arm whose weight loss exceeded 6% of their previous weight reported in the online tracking tool within one month, the interventionist contacted the research participant to investigate potential reasons for weight loss.

-Depression: When participants scored the depression scale in the online survey over a threshold indicating severe depression or if they indicated suicidal ideation, an automatically generated email prompted the study coordinator to send a letter to the respondent within 2 weeks (severe depression) or 1 week (suicidal ideation) encouraging them to consult their provider and including related community and online resources. At a second consecutive

score over the threshold, in addition to the letter, the project Safety Officer followed with a phone call to answer any questions and assist her in finding treatment.

Chart abstraction—To minimize practice site burden, we abstracted the bulk of prenatal data from electronic hospital records and collected the data only available in practice records directly from practice sites. Medical records existed in a variety of formats: paper, electronic (scanned and live), inpatient/outpatient, remote access or on site access.

Postpartum weight and height measurement—Using weight collection and pediatric appointment features on the study website, weight measurements were scheduled around the time of well-baby check appointments. To maximize retention, in addition to pediatric practices, locations such as workplaces, the medical center, and participant's homes were included for weight collection visits. Weight and height were measured with participants in street clothing and no shoes in a private place. Weights were measured to the nearest 0.1 kg at 6, 12, and 18 months postpartum by study staff using autocalibrated 'EatSmart' digital scales (EatSmart, NJ). Weights were measured twice and the average of the two weights differing by <0.2 kg rounded to the nearest 0.1 kg was used; otherwise, a third weight was taken. If only one pair of weights differed by <0.2 kg, the average of those two measures was used; if both pairs of measures differed by <0.2 kg, the average of all three measures was used. Height was measured using the pediatric office stadiometer or a Shorr Infant/Child/Adult Height/Length measuring board stadiometer (Weigh and Measure, LLC, Olney, MD) to the nearest 0.1 cm. The average of two measurements differing by <0.5 cm was used; otherwise, a third measurement was taken following the same process as described for weight measurements.

Process measures—Given that the intervention was delivered online, a rich database of process measures was collected to quantify exposure to the intervention both in magnitude (e.g. frequency of website intervention feature use such as time of weight entry) and in quality (e.g. types of website intervention features utilized such as dietary and physical activity assessment results from the goal setting tool;) as well as the timing of utilization (e.g. pregnancy by trimester or postpartum such as weight entry at prenatal visits). Examples of how the data on process measures can be used to provide insight into website utilization can be found in Demment et al.[30]

Incentives—Participants were offered incentives up to $140.00 in cash, check or electronic gift cards to one of five vendors for completion of data collection activities. Incentives ranged from $5.00 (first time login) to $10.00 (online surveys). Participants who completed all questionnaires and weight collections were eligible to earn an additional $150. A cash incentive was used for postpartum weight collection visits to promote retention. The incentive process for non-cash incentives was managed through the "Earnings" section of the website. The total amount earned was shown and a participant could select an e-gift card or check at any point in the study.

Outcomes Measures

Pregnancy Outcome—Gestational weight gain (GWG) is defined as the difference between weight in kilograms at the last prenatal visit and weight at the first prenatal visit (hereafter, anchor weight). Weights were abstracted from the prenatal charts. The estimation of GWG can be influenced by late entry into prenatal care (e.g.; in the second trimester in which women start gaining substantial amounts of weight) or by having their last prenatal visit before term (e.g.; preterm delivery). Consequently, if participants' anchor weights were recorded after 14 weeks gestation and/or if the last prenatal visit was before 37 weeks gestation, their anchor and last prenatal weights were estimated using multiple imputation. To answer the primary pregnancy hypothesis, GWG is modeled as a categorical variable: "excessive" defined as gaining weight above the upper limit, and "not excessive" defined as gaining within and below the lower limit of the IOM guidelines for GWG (Table 1).[2]

Postpartum outcome—Postpartum weight retention is the difference between the measured weights at each postpartum data collection point minus the anchor weight. Weight postpartum was obtained at 6 weeks from medical records, and measured by study staff at 6, 12 and 18 months, with the 12-month measure as the primary endpoint. Based on previous observational data[31,32], any postpartum weight collected within 3 weeks (± 1.5 weeks) of the 6 weeks postpartum data point and within 3 months (± 1.5 months) of the 6, 12, and 18 months postpartum data points were considered valid measures of the weight at each time point. Weights obtained outside these windows will be used to impute the weight to the appropriate time point. For the primary postpartum hypothesis, postpartum weight retention will be modeled as a continuous variable.

Statistical Considerations

Originally, eMoms of Rochester was designed to evaluate the primary hypotheses within four income and BMI strata separately with a total accrual goal of 3,453 subjects randomized. This sample size was determined by the power to detect a 5 pound difference in weight retention at 18 months postpartum. However, the rate of accrual we initially predicted was an over-estimate given the initial challenges of working with multiple practices and a fixed timeline of 15 months for the study accrual. After 9 months of accrual and 954 subjects randomized, the study was redesigned to allow for an overall intervention assessment with a target sample size of 1641. We intentionally over-accrued and randomized 1722 subjects in response to fraudulent subjects and a few subjects with invalid consents whose data could not legally be included in any analyses. After the accrual was completed, the study was again re-designed due to financial constraints. The primary postpartum endpoint was moved from the 18 to the 12 month postpartum time point The power calculation that follows justifies this primary outcome at 12 months following delivery.

Final Sample Size Justification—The significance level will be 1.67% (2-sided), conservatively using a Bonferroni procedure to reflect the 3 primary comparisons in this study. The mean clinically important difference in weight retention at 12 months postpartum between either of the intervention arms and the control arm was estimated to be 4 pounds with an estimated standard deviation of 14 pounds [16]. The total sample size required to achieve an estimated statistical power of 90% is 999 (333/ arm). We assumed a 15% attrition

rate due to miscarriage and withdrawal between randomization and delivery and an additional attrition of 30% and 40% between delivery and 12 and 18 months postpartum, respectively, due to second pregnancies and withdrawals.

Analysis Plan Summary—Treatment groups are defined according to randomization (intent-to-treat, ITT). For the pregnancy outcome, a multiple logistic regression model will be used to assess the effect of the pregnancy intervention on the odds of excessive GWG. The covariates included in the primary analysis besides randomized treatment assignment and the stratification factors (early pregnancy BMI and income strata) will be early pregnancy BMI (continuous), ultrasound adjusted gestational age of the baby to account for differing pregnancy durations, and the weeks between first and last pregnancy weight, and between the last pregnancy weight and delivery to adjust for pregnancy duration and measurement time. Although the randomization was done at the individual level, it is possible that the standard of care and other unmeasured factors may influence the effect of the intervention on the outcome. We expect that these 'clinic factors' will be balanced across arms. However, we will test for the presence of potential clinic effects, using a linear mixed model with clinic as random effects. Clinic effects will be dropped if not significant. For the postpartum outcome, in addition to randomized treatment, the model will include the factors time, income strata at randomization and early pregnancy BMI. Since weight retention was measured at 6 weeks, and 6 and 12 months and will be likely correlated across time in the same participant, we will handle the correlation structure using a generalized estimating equation approach unless significant clinic effects indicate the mixed model approach. The test for the primary postpartum hypotheses will be a treatment construct of weight retention at 12 months. For all outcomes, sensitivity analysis will be conducted after the ITT analysis is completed by testing the intervention effect on the outcomes once removing the participants that were ineligible randomized (protocol violations). Missing data will be addressed using multiple imputation within randomization strata (BMI and income). Since we do not expect to observe a monotone or nearly monotone missing data pattern, we will use a Markov Chain Monte Carlo procedure that handles arbitrary missing data patterns. The pregnancy and postpartum analysis data sets will have separate imputation procedures.

Descriptive Statistics—In this report, we are presenting selected baseline characteristics of participants for the entire sample by the best estimate of early pregnancy BMI. We define the best estimate of BMI as obtained by the most accurate height and weight based on the various sources of data we have for those measurements. For height, the sources in order of accuracy are: height measured by study staff at a postpartum weight collection visit; height recorded in the prenatal chart; height self-reported at screening. For weight, the sources in order of accuracy are: measured by health care provider before 14 weeks gestation obtained from prenatal chart; pre-pregnancy weight reported in the pre-natal chart; pre-pregnancy/ early pregnancy weight self-reported at screening. So for example, if we have height recorded from all sources, we used height measured by study staff in the BMI calculation. Otherwise, we used the second best source. Baseline characteristics reported are:

- Demographics, gestational age at enrollment, earliest pregnancy BMI and the gestational age at measurement.

- Smoking: Non-smoker, ex-smoker, and current smoker based on answers to the following questions: "have you smoked at least 100 cigarettes in your entire life?; do you now smoke cigarettes?; how long has it been since you last smoked cigarettes regularly?"[33]
- Alcohol intake: Percentage of participants who never drink.[]
- Depression: Center for Epidemiologic Studies Short Depression Scale (CES-D), a previously validated 10-item screening questionnaire for depression with a score that ranges from 0–30.[34,35]]
- Physical Activity (PA): Pregnancy Physical Activity Questionnaire (PPAQ)[36] to estimate the percentage of participants meeting the American College of Obstetrician and Gynecologist (ACOG) PA recommendations (accumulation of 30 minutes or more a day of moderate intensity most days of the week).[37] The PPAQ includes an open-ended section to add activities not listed that were scored.by two investigators (IDF, SG) matching the reported activities with those of the Compendium of Physical Activities.[38] The duration of time spent in each activity was multiplied by its intensity to obtain the average weekly energy expenditure (MET-h·week^{-1}) attributable to each activity. A participant met the ACOG recommendation if the scores was >7.5 MET hrs/week of any activity of moderate intensity or greater (this is the equivalent of 30 minutes/day of activity at >3 METS multiplied by 5 days).
- Perceived Availability of Healthy Foods Scale: Availability of healthy food in a neighborhood (quality and variety of fruits and vegetables and availability of low fat products) on a five-point Likert scale.[39] We dichotomized the responses into the proportion that strongly agree and agree versus all other responses.
- Proportion of participants who live in a high crime neighborhood from the Physical Activity Neighborhood Environment Survey [40]: This item is considered to hinder physical activity.

RESULTS

We recruited 1722 pregnant women in 14 months (28% of the 6215 approached) who were randomized into 3 equally sized arms (Figure 1). Approximately 70% of participants agreed to provide a saliva sample and 65% accepted to be contacted for further research. Reasons for ineligibility are listed in Table 4. If multiple reasons were applicable to a subject, one reason was selected for reporting. Attrition was approximately as originally estimated: 15% during pregnancy and 30% of the delivery sample at 12 months postpartum. The study had a total of 135 protocol violations due to ineligible persons randomized (n=104), lack of consent form on file (n=3), randomization problems (n=5), and fraudulent participants (n=23).

Protocol Violations

Ineligible persons randomized—Eligibility was determined via self-report at recruitment. However, in the course of reviewing the medical records reasons for

ineligibility, not reported at screening, were discovered. Ninety-six participants were found ineligible via chart review (e.g.; autoimmune diseases such as lupus, past weight loss surgery) and one participant contacted the study staff a day after randomization to inform she was not pregnant. Among the 97 ineligible participants randomized, 18 underweight women over-reported and 45 obese type II women under-reported their weight (3.7% of the ITT sample). All 97 participants remained in the study and were analyzed following the ITT principle. Seven participants were, in fact, minors at enrollment and were excluded from the study and analysis because participation as minors is illegal without parental consent.

Lack of consent on file—Three participants were excluded from analysis because they did not have a consent form on file.

Randomization problems—Two participants were randomized in the wrong stratum because one's weight and another's height were incorrectly entered, and thus, they were classified into the wrong BMI category. Additionally, three participants received the intervention different from the arm to which they were randomized due to a programming glitch at randomization.

Fraudulent participants—We had a total of 21 observations based on fictitious data and 2 participants who enrolled twice using their actual data. Nineteen of the fraudulent observations were through online enrollment, 18 of which occurred within a 48 hour period (August 19–21, 2011). Project coordinators observed unusual enrollment activity (e.g. same IP address, same estimated delivery date). Further investigation confirmed that information from one participant who had self-enrolled online was used to subsequently enroll 18 additional times. To prevent more fraudulent activity a protocol was developed to monitor online self-screening and consent. Once a subject was deemed eligible based on online self-screening, consent was blocked until after the study coordinator reviewed the following variables within 24 hours: e-mail address, telephone number, mailing address, practice providing prenatal care, IP address, date of birth, estimated delivery date, height, weight, insurance provider, and time and date of completion of online screening. If validity of the potential subject's responses was in doubt (i.e.; similarity to other subjects enrolled), the subject was contacted via phone to verify her identity and the information provided. Entry into the study was denied if: a) discrepancies existed between information provided in the call and the online screening tool; or b) phone number provided was not valid or a call was not returned within 7 days. After the procedures were established a total of 298 participants were contacted and 1 person was declined. Two additional participants enrolled via study staff providing data that were later discovered to be fraudulent. Another two participants enrolled twice in the study although providing truthful data. All fraudulent observations were excluded from the study.

Baseline Characteristics of Study Participants (Table 5)

Overall, the average gestational age at enrollment was at the end of the first trimester (11.2 ±4.2 weeks), but participants had a first recorded weight in the prenatal chart earlier in pregnancy (8.4 ±2.1 weeks) that did not differ across weight categories. Approximately 52% of our sample started pregnancy in a healthy weight category. The early pregnancy mean

BMI based on measured weight and height from the prenatal charts for the entire sample is slightly over the lower end of the overweight category (BMI of 25.4 ±4.3). The sample has a high proportion of African American (24.7%) and Hispanic/Latina (12.6%) women. Our participants are highly educated (almost 80% had some college degree or more), the majority are married (88.6%), employed (71.5%), non-smokers (67.6%) and non-drinkers during pregnancy (89.3%), and slightly over half of them have had a prior delivery (54%). These characteristics differ significantly across BMI category except for the alcohol intake measures. Although the mean depression score is in the lower half of the range (mean score 8.2 ±4.9, range 0–30), the mean score increases with increasing weight category. Across BMI categories, the most notable pattern is observed in the physical activity measure with 47.9%, 42.8%, and 33.9% of the healthy weight, overweight, and obese participants, respectively, meeting recommendations. The obese category has the lowest percentage of women strongly agreeing with the high quality of the food environment and the higher proportion of those who live in high crime areas are in the obese category.

DISCUSSION

This report describes the study design, methods, and sample baseline characteristics of the eMoms study, a double blind randomized clinical trial with a parallel group design that tested electronically-mediated behavioral interventions to prevent excessive gestational weight gain and minimize postpartum weight retention in women 18–35 years of age of diverse racial/ethnic and income backgrounds. Our sample has a larger representation of racial/ethnic minorities compared to the county percentages based on 2010 census data (African American 25% vs 16.7%, Hispanic 12.3% vs. 7.3%, study sample and county, respectively)[23] possibly due to a high participation of clinics primarily serving minorities. Our participants are also more educated, almost 50% of our sample has a college degree or more versus 35% in the county, a typical phenomenon of clinical trials volunteers. Interestingly, the proportion of women in the higher income range ($50,000) is lower than observed in the county (study sample 23% vs. county 57%)[23] despite a large representation of women with higher education. Although we have no data to explain the discrepancy between income and education, several reasons might explain it. For example, participants may still be graduate students, may have left the workforce to raise a family, and/or the lower income of educated women may reflect the current economic situation or gender salary inequalities. This discrepancy, however, should be interpreted with caution since a large proportion of education and income data were missing (21% and 29%, respectively).

A major strength of eMoms is that women receive an intervention and are followed from early pregnancy until late postpartum contributing to the literature on both pregnancy-related weight gain and weight management in young adult women. Our data will provide evidence as to whether an intervention delivered only during pregnancy has a long lasting effect on postpartum weight retention once the intervention stops at delivery (e-intervention group 1) or whether there is an additive effect of a postpartum component to a pregnancy intervention by adapting the strategies to their new life stage. Previous studies have examined pregnancy intervention effects on weight measures at 2 months[41,42], 6[43], and 12 months[44] postpartum, and two others with a 12 month follow-up are underway,[45,46] but very few

have tested interventions for both the pregnancy and postpartum periods. Huang TT, et al. [17] tested a lifestyle intervention using a three-arm design until 6 months postpartum with positive results, and Rauh et al.[47] have an ongoing cluster randomized pregnancy and postpartum intervention implemented until 6–8 weeks. Thus, eMoms will contribute a longer length intervention and follow-up of postpartum women and the ability to compare three conditions.

Other strengths of our study include: online trial processes and intervention delivery, the recruitment of a racially/ethnically and socioeconomically diverse sample; online randomization minimizing the possibility of bias in intervention allocation; the online intervention delivery that guarantees fidelity and prevents contamination, and the programmed data checks included in the online surveys, chart audit, and weight collection, thus reducing the probability of data entry errors. Finally, a key characteristic of our methods is the use of multiple and flexible modes for recruitment, enrollment, and retention.

The study encountered challenges related to the use of self-reported data. In addition to uncovering ineligible participants randomized during chart abstraction of prenatal medical records, participants also reported inaccurate information of the type and timing of adverse events. In this study, the prenatal record was considered the gold standard compared to self-reported data as it has been done previously in the perinatal literature.[48–50]

Technology support for lifestyle interventions and the use of online methodologies to conduct all aspects of randomized clinical trials have many advantages such as the stigma reduction due to responders' anonymity, timeliness, fidelity of intervention delivery, lower costs, and larger reach since geographical, time and mobility barriers are minimized.[51–55]. At the same time, online methodologies open the doors for other concerns such as the opportunity for participants to re-enroll in the study using different identities facilitated by the anonymity provided by the internet.[56 In our study, 21 online enrollments, approximately 5% of those who enrolled online, were repeat enrollments, which may have come from either a single participant and/or a participant who shared eligibility information with others. Other studies have reported from 1% to 11% of repeated online enrollment. [56,57] As the use of electronic media in research becomes widespread, investigators should be creative in controlling potential pitfalls that were not as common with previous methods. We developed a monitoring system for every online enrollment to prevent fraudulent participants. Other procedural/design, technical/software, and data analysis strategies have been suggested [58] eMoms was not designed to test whether electronically-mediated interventions are more effective in influencing weight outcomes than supervised or tele-health interventions. As a consequence, when analyzing the result of t, the effect of the intervention in and of itself and the effect of the method of intervention delivery (electronic media) will not be disentangled.

Finally, eMoms was originally designed to enroll 3,353 participants with a follow-up until 18 months postpartum. The challenges faced by working with clinical practices whose main concern is the delivery of health care and whose investment in research is secondary, the need to adhere to the proposed recruitment period, and budget constraints given unplanned extra costs led to changes in the target sample size and to a change in the primary outcome

to 12 instead of 18 months. Future trials planning a large RCT should consider these challenges for budgeting and study planning

Conclusions

Our study will provide evidence on the efficacy of behavioral interventions in the prevention of excessive GWG and postpartum weight retention, which potentially lead to obesity and associated cardiovascular risk factors. If the intervention strategies are successful in preventing the outcomes of interest and in engaging young adults, dissemination to practices and/or health insurances should be investigated.

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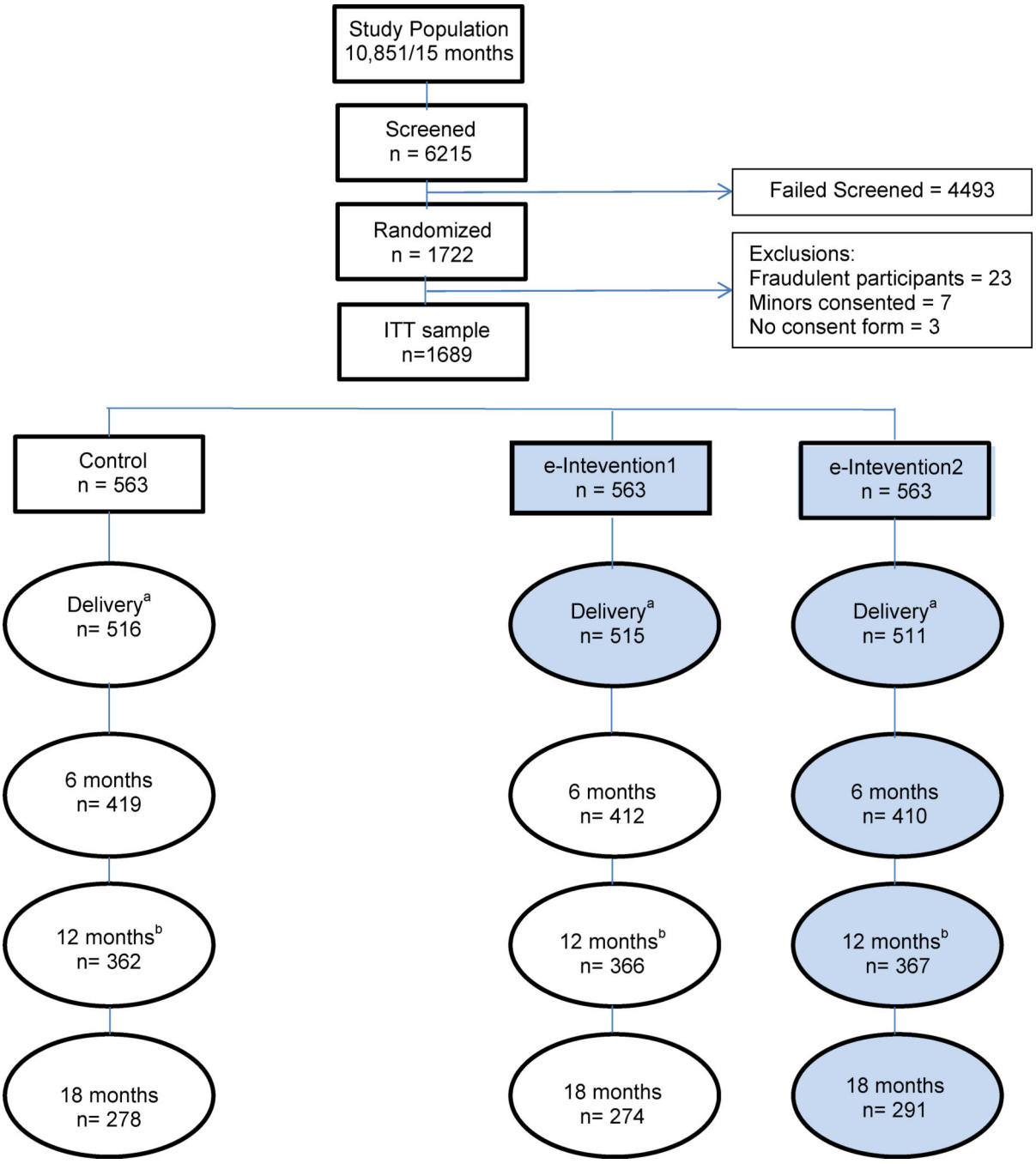

Figure 1.

eMoms of Rochester. Flowchart

[a]Main pregnancy outcome: gestational weight gain.

[b]Main postpartum outcome: 12 months postpartum weight retention.

Table 1

Recommended Gestational Weight Gain (IOM[a])

Pre-pregnancy BMI	Total Weight Gain Range in kg (pounds)
Underweight (< 18.5 kg/m^2)	12.5 – 18 (28–40)
Healthy weight (18.5 – 24.9 kg/m^2)	11.5 – 16 (25–35)
Overweight (25.0 – 29.9 kg/m^2)	7 – 11.5 (15–25)
Obese (≥30.0 kg/m^2)	5 – 9 (11–20)

Weight Gain During Pregnancy: Reexamining the Guidelines.

[a]Institute of Medicine

Table 2

eMoms of Rochester Study Eligibility Criteria

Inclusion Criteria	
	Age 18 – 35 at the time of enrollment
	Consented at or before 20 weeks gestation
	Intending to be available for a 24-month intervention
	Plan to deliver in one of the 4 hospitals in Rochester, NY
	Plan to carry the pregnancy to term
	Plan to keep the baby
	Read and understand English
Exclusion criteria	
Study Specific	
	BMI < 18.5 kg/m^2 or ≥ 35.0 kg/m^2.
	Multiple gestation. If multiple gestation was diagnosed after enrollment, participant was terminated from the study
	Medical conditions prior to pregnancy which could influence weight loss or gain: cystic fibrosis, hyperthyroidism, renal insufficiency, proteinuria, cerebral palsy, lupus erythematosus; rheumatoid arthritis, Crohn's disease (severity and other autoimmune diseases evaluated case by case), ulcerative colitis, maternal congenital heart disease (patients are often underweight); hypertension treated with medication
	Psychiatric medication associated with major weight gain or loss (e.g. Lithium & Divalproex) Having had three or more consecutive miscarriages (spontaneous abortions), because of the higher probability of another miscarriage.
Common Exclusion Criteria to EARLY trials	
	Household member on study staff
	Past or planned (within the next 24 months) weight loss surgery (e.g. gastric bypass, lap band, or liposuction); current participation in a commercial weight loss program (e.g. Weight Watcher's, Jenny Craig); currently enrolled or planned to enroll in a weight loss or another weight gain prevention study
	Regular use of systemic steroids, prescription weight loss drugs, and/or diabetes medications (oral or injected- insulin, metformin, byetta, TZDs, other). "Regular use" is defined as "taking this medication most days of the week for the previous month"
	Current treatment for eating disorder Positive screening for bulimia
	Cardiovascular event (heart attack, stroke, episode of heart failure, or revascularization procedure) within the last 6 months. Revascularization is defined as bypass surgery or stents
	Mental or psychiatric condition that precludes giving informed consent and completing questionnaires
	Current treatment for malignancy (other than non-melanoma skin cancer and CIN cervix) or in remission for less than 5 years

Table 3

eMoms of Rochester. Variables, Data Sources and Data Collection Points

	Early Pregnancy (randomization to 28 weeks gestation)	Late Pregnancy (32 weeks gestation to delivery)	Postpartum			
			6 weeks	6 months	12 months	18 months
Sociodemographic data	*online survey*	*online survey*	*online survey and chart audit*	*online survey*	*online survey*	*online survey*
Maternal/Infant Health						
Infant birthweight and gestational age			*chart audit*			
Parity			*chart audit*			
Prenatal tests (e.g.; glucose screen, urinary tests)			*chart audit*			
Prenatal diagnoses			*chart audit*			
Infant health			*online survey and chart audit*	*online survey*	*online survey*	*online survey*
Behavioral variables						
Smoking	*online survey*	*online survey*	*chart audit*	*online survey*	*online survey*	*online survey*
Alcohol	*online survey*	*online survey*	*chart audit*	*online survey*	*online survey*	*online survey*
Sleep	*online survey*	*online survey*	*online survey*	*online survey*	*online survey*	*online survey*
Breastfeeding			*online survey and chart audit*			
Physical Activity	*online survey*	*online survey*		*online survey*	*online survey*	*online survey*
Sedentary Behavior	*online survey*	*online survey*		*online survey*	*online survey*	*online survey*
Dietary and Energy Intake	*online survey*	*online survey*		*online survey*	*online survey*	*online survey*
Eating Patterns	*online survey*	*online survey*		*online survey*	*online survey*	*online survey*
Weight management	*online survey*	*online survey*				
Neighborhood Environment	*online survey*	*online survey*		*online survey*	*online survey*	*online survey*
Psychosocial Variables						
Depression	*online survey*	*online survey*		*online survey*	*online survey*	*online survey*
Social Support	*online survey*	*online survey*		*online survey*	*online survey*	*online survey*
Perceived Stress	*online survey*	*online survey*		*online survey*	*online survey*	*online survey*
Behavioral intentions, self-efficacy, barriers, beliefs, attitudes	*online survey*	*online survey*		*online survey*	*online survey*	*online survey*

	Early Pregnancy (randomization to 28 weeks gestation)	Late Pregnancy (32 weeks gestation to delivery)	Postpartum			
			6 weeks	6 months	12 months	18 months
Anthropometry						
Early Pregnancy Weight	*self-reported at enrollment*		*chart audit*			
Gestational weights			*chart audit*			
Postpartum Weight			*chart audit*	*measured by study staff*	*measured by study staff*[a]	*measured by study staff*
Height				*measured by study staff*		
Other						
Adverse Events		*online survey*	*online survey*	*online survey*	*online survey*	*online survey*
Prescription Medications	*online survey*	*online survey*	*online survey*	*online survey*	*online survey*	*online survey*
Genomic DNA	*by study staff at any face-to-face encounter*					
Process Variables	*website log activity and custom reports*					

[a]Postpartum outcome measure tested at 12 months.

Table 4

eMoms of Rochester. Reasons for Ineligibility (6,215 screened participants)

Criteria	N (% of ineligible)	% of screened
Not interested in participating in study	831 (19)	**13**
Tacit refusal of consent form online[a]	16 (<1)	**<1**
Refused to sign consent form	98 (2)	**2**
Age		
<18 years old	156 (3)	3
>35 years old	544 (12)	9
Out of range, age unspecified	10 (<1)	<1
Not expected to be available for 24 month intervention	29 (<1)	<1
Body mass index (BMI)		
BMI<18.5 kg/m^2	68 (2)	1
BMI ≥ 35 kg/m^2 and BMI <40 kg/m kg/m^2	687 (15)	11
BMI out of range, unspecified amount	44 (1)	<1
Pregnancy related		
Gestational age at screening > 20 weeks	664 (15)	11
Multiple gestation	117 (3)	2
>=3 consecutive fetal losses prior to this pregnancy	25 (<1)	<1
Delivering baby outside the study area	108 (2)	2
Plans to interrupt pregnancy / fetal loss during screening	8 (<1)	<1
Does not plan to keep the baby	4 (<1)	<1
Household member on study staff	0	0
Weight loss surgery, program, or intervention study (Past or planned)		
Past or planned (within 24 months) weight loss surgery	10 (<1)	<1
Currently/Plan to be enrolled in another diet/PA/weight loss intervention study	14 (<1)	<1
Medications		
Regular[b] use of systemic steroids	3 (<1)	<1
Regular[b] use of prescription weight loss drugs	0	0
Regular[b] use of diabetes medications (oral or injected)	31 (<1)	<1
Cardiovascular event[c] within 6 months	2 (<1)	<1
Currently being treated for cancer (other than non-melanoma skin cancer)	5 (<1)	<1
Currently being treated for an eating disorder/ has eating disorder	6 (<1)	<1
Investigator discretion	3 (<1)	<1
Does not read or understand English	170 (4)	3
Has been previously screened for eMoms project	716 (16)	12
Currently has no valid email account and not willing to obtain an email account	42 (<1)	<1
Medical conditions prior to pregnancy which could influence weight loss or gain including kidney disorders	37 (<1)	<1

Criteria	N (% of ineligible)	% of screened
Hypertension treated with medication (e-Moms blood pressure criterion)	18 (<1)	<1
Psychotropic medication (2nd generation anti-psychotics, mood stabilizers)	4 (<1)	<1
Mental or psychiatric conditions (Schizophrenia, Psychotic disorder NOS, Schizoaffective disorders)	2 (<1)	<1
Mentally incompetent[d]	8 (<1)	<1
Bulimia	13 (<1)	<1
Total	4493 (100)	72

[a]Participants did not return a mailed consent form.

[b]Regular use is defined as “taking this medication most days of the week for the previous month”.

[c]Heart attack, stroke, episode of heart failure or revascularization procedure.

[d]Recruiters’ discretion to evaluate the competence of a potential participant to effectively take part in the study.

Table 5

eMoms of Rochester. Selected baseline characteristics of study ITT sample (n= 1689)

		Early Pregnancy Weight Category			
	Total Sample N = 1689	**Healthy Weight[a] n = 871**	**Overweight n = 509**	**Obese Type I[b] n = 309**	**P-value[c]**
Age at enrollment (years), mean ±sd (n)	27.5± 4.7(1689)	27.4±4.7(871)	27.5± 4.7(509)	27.7± 4.5(309)	0.77
Gestational age at enrollment(weeks), mean ±sd (n)	11.2 ± 4.3(1689)	11.3± 4.3, 871	11.0 ± 4.2(509)	11.3 ± 4.2(309)	0.45
Early pregnancy weight (kg), mean ±sd (n)	68.3±12.9(1599)	59.0 ± 6.3, 826	72.8 ± 7.2(481)	86.9± 9.7(292)	<.0001
Gestational age at earliest pregnancy weight (weeks), mean ±sd (n)	8.4 ± 2.1(1599)	8.5,± 2.1, 826	8.4 ± 2.1(481)	8.4 ± 2.2(292)	0.30
Early pregnancy BMI, mean, sd,(n)	25.4 ± 4.3(1252)	22.1,± 1.7(670)	27.2± 1.5,(368)	32.7± 2.1(214)	<.0001
Race (n non-missing)	1573	825	464	284	<.0001
Black or African American, n (%)	388 (24.7)	170 (20.6)	114 (24.6)	104 (36.6)	
American Indian/Native Hawaiian Pacific Islander, n (%)	10 (0.6)	4 (0.5)	4 (0.9)	2 (0.7)	
Asian, n (%)	38 (2.4)	28 (3.4)	4 (0.9)	6 (2.1)	
White or Caucasian, n (%)	1069 (68.0)	594 (72.0)	316 (68.1)	159 (56.0)	
Multiple, n (%)	68 (4.3)	29 (3.5)	26 (5.6)	13 (4.6)	
Ethnicity (n non-missing)	1687	869	509	309	0.015
Hispanic/Latina, n (%)	213 (12.6)	90 (10.4)	78 (15.3)	45 (14.6)	
Education (n non-missing)	1340	720	403	217	<.0001
High School or GED and below, n (%)	291 (21.7)	143 (19.9)	96 (23.8)	52 (24.0)	
Some College or Associate Degree or Vocational School, n (%)	391 (29.2)	176 (24.4)	127 (31.5)	88 (40.6)	
College Graduate, n (%)	326 (24.3)	188 (26.1)	96 (23.8)	42 (19.4)	
Master or Doctoral Degree, n (%)	332 (24.8)	213 (29.6)	84 (20.8)	35 (16.1)	
Personal Income in the past 12 month (n non-missing)	1195	637	360	198	0.04
≤ $11,999, n (%)	365 (30.6)	193 (30.3)	116 (32.2)	56 (28.3)	
$12,000-24,999, n (%)	145 (12.1)	62 (9.7)	49 (13.6)	34 (17.2)	
$25,000–$34,999, n (%)	143 (12.0)	80 (12.6)	38 (10.6)	25 (12.6)	

	Early Pregnancy Weight Category				
	Total Sample N = 1689	**Healthy Weight[a] n = 871**	**Overweight n = 509**	**Obese Type I[b] n = 309**	**P-value[c]**
$35,000- $49,999, n (%)	213 (17.8)	116 (18.2)	56 (15.6)	41 (20.7)	
≥$50,000, n (%)	250 (20.9)	144 (22.6)	78 (21.7)	28 (14.1)	
Don't, n (%)	79 (6.6)	42 (6.6)	23 (6.4)	14 (7.1)	
Relationship status (n non-missing)	1336	717	404	215	0.0004
Single, n (%)	140 (10.5)	59 (8.2)	42 (10.4)	39 (18.1)	
Married / Co-habitating, n (%)	1183 (88.6)	654 (91.2)	356 (88.1)	173 (80.5)	
Separated / Divorced, n (%)	13 (1.0)	4 (0.6)	6 (1.5)	3 (1.4)	
Parity (n non-missing)	1686	869	508	309	<.0001
Nulliparous, n (%)	775 (46.0)	439 (50.5)	215 (42.3)	212 (39.2)	
Primaparous, n (%)	550(32.6)	281 (32.3)	166 (32.7)	103 (33.3)	
Multiparous [n (%)]	361 (21.4)	149 (17.2)	127 (25.0)	85 (27.5)	
Smoking (n non-missing)	1393	738	425	230	0.01
Non-smoker, n (%)	941 (67.6)	522 (70.7)	280 (65.9)	139 (60.4)	
Exsmoker, n (%)	364 (26.1)	177 (24.0)	120 (28.2)	67 (29.1)	
Current smoker, n (%)	88 (6.3)	39 (5.3)	25 (5.9)	24 (10.4)	
Alcohol (in the past 30 days) (n non-missing)	1395	740	425	230	
None, n (%)	1245 (89.3)	658 (88.9)	382 (89.9)	205 (89.1)	0.88
CES-D score, mean ±sd (n)	8.2±4.9(1414)	7.8±4.8(749)	8.6±4.9(430)	8.8±5.0(235)	0.003
ACOG criteria using PPAQ (n non-missing)	1359	729	409	221	.001
Met recommendation, n (%)	599 (44.1)	349 (47.9)	175 (42.8)	75 (33.9)	
Employment for Pay (n non-missing)	1342	719	404	219	0.42
Yes, n (%)	959 (71.5)	522 (72.6)	288 (71.3)	149 (68.0)	
Perceived Availability of Healthy Foods Scale (n non-missing)	1338	718	401	219	
Strongly agree, n (%)	469 (35.0)	275 (38.3)	143 (35.7)	51 (32.3)	0.0002

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	Total Sample N = 1689	Early Pregnancy Weight Category			
		Healthy Weight[a] n = 871	Overweight n = 509	Obese Type I[b] n = 309	P-value[c]
PA neighborhood environment (n non-missing)	1256	677	377	202	
High Crime, n (%)	249 (19.8)	118 (17.4)	83 (22.0)	48 (23.8)	0.06

[a] Includes 18 underweight women who over-reported their weight at screening

[b] Includes 45 obese class II women who under-reported their weight at screening

[c] Differences across BMI categories assessed by 1-way ANOVA (F-test; 2df) for continuous variables and by Chi-Square test for categorical variables. Differences in non-normal continuous factors across BMI categories was assessed using the Kruskal-Wallis test.