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Targeting pregnancy-related weight gain to reduce disparities in obesity: Baseline results from the Healthy Babies trial

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ABSTRACT

Background: Obesity affects African American women more than any other group in the US. Pregnancy represents a critical life stage of heightened vulnerability for new or persistent obesity, yet few interventions have been effective in reducing excessive gestational weight gain among African American women. We describe the design and baseline findings of Healthy Babies, a two-arm randomized controlled trial testing a mobile health intervention to minimize excessive gestational weight gain versus usual care in this high risk group.

Methods: African American women in early pregnancy were recruited from two large obstetric practices as well as Philadelphia Women, Infants, and Children's clinics. Participants randomized to the intervention received behavior change goals, daily text messages with feedback, web-based weight gain graphs, health coaching, and a Facebook support group. Data collection included baseline (< 22 weeks' gestation), 36-38 weeks' gestation, and 6-month postpartum anthropometric measures and assessments of demographics, contextual factors and behavioral targets. The primary outcome was prevalence of excessive gestational weight gain.

Results: Among participants at baseline ($n = 262$), the majority met criteria for obesity (63%), were multiparous (62%), single (77%), and were on average 25.6 ± 5.4 years old with a gestational age of 13.9 ± 4.1 weeks. While 82% completed high school, 61% met criteria for inadequate health literacy. Nearly 20% were food insecure. Eighty-eight percent reported a gestational weight gain goal discordant with Institute of Medicine guidelines. There were no significant differences in baseline characteristics between study arms.

Conclusions: Participants represent a high-risk group for excessive gestational weight gain with demonstrated need for intervention.

1. Introduction

Obesity affects African American women more than any other racial/ethnic group in the United States [1]. As a result, African American women suffer disproportionately from obesity-related consequences, including diabetes [2,3], heart disease [4], and cancer [5]. Pregnancy represents a critical life stage of heightened vulnerability for new or persistent obesity [6–9], especially for African American women, who retain 2-3 times more weight after pregnancy than whites [8,10–13]. Gestational weight gain is the strongest identified risk factor for retaining a substantial amount of weight postpartum [7,14–21], yet few interventions have been effective in reducing excessive weight gain in

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pregnancy, particularly among low-income African American mothers. These women may be especially disadvantaged, as they are the most likely to enter pregnancy overweight [1,22], which is a strong risk factor for gaining in excess of Institute of Medicine (IOM) guidelines [23]. Moreover, higher weight gains are independently associated with a number of additional adverse outcomes during and after pregnancy, including maternal hyperglycemia and hypertension [24–28], infant macrosomia [29,30], cesarean delivery [19,31,32], and childhood overweight [33–36]. Without intervention, the implications are clear: most mothers will exceed IOM recommended weight gains and incur significant morbidity for themselves and their children.

In order to fill this treatment gap and guide intervention development, partnering with African American mothers of lower socioeconomic position is necessary to identify the attitudes, beliefs, values, and contextual constraints that shape dietary and physical activity behaviors. Through focus groups and interviews, African American mothers reveal motivation to engage in healthful weight-related behaviors is strongest in pregnancy (compared to any other period in the life course) so as to protect fetal well-being [37–42]. Despite best intentions, however, these same medically vulnerable mothers acknowledge multiple barriers (e.g., food access/availability, misperceptions about babies' energy needs, transportation, income, family pressure to eat and rest) that make it difficult to engage in traditional weight control programs with complex caloric prescriptions, costly meal replacements, and repeated in-person visits. Instead, mothers are more interested in remote delivery modalities (e.g., text messaging, calls, Facebook) that would allow for convenient access to program content focused on simplified diet and activity targets, tailored to their unique needs. Our pilot intervention testing this approach cut in half the proportion of African American mothers gaining in excess of IOM guidelines [43]. There have, however, been no adequately powered demonstrations of successful weight control interventions in pregnancy using remote technologies among African American women.

This report describes the design and baseline findings from Healthy Babies, a fully-powered, two-arm randomized controlled trial testing a mHealth-delivered behavioral intervention to minimize excessive gestational weight gain, versus usual obstetric care, in a large population of socioeconomically disadvantaged African American women. We intentionally designed Healthy Babies to be delivered outside of the clinical encounter, not formally integrated within it, as data suggest that healthcare providers lack time and/or resources to adequately address weight control versus other clinical needs [44]. Results have the potential to demonstrate efficacy-based weight control treatment in pregnancy that could be readily used as an adjunct to clinical care for African American mothers.

2. Materials and methods

2.1. Overview of study design

Healthy Babies was a randomized controlled trial conducted in coordination with obstetric practices affiliated with Temple University Health System (TUHS) and the Women, Infants and Children (WIC) Food and Nutrition Program of Philadelphia. The primary outcome was prevalence of excessive gestational weight gain, and secondary outcomes include cardiometabolic risk factors, mode of delivery, infant birth weight and 6-month postpartum weight retention. Weight and additional assessments (e.g., health literacy, food security, self-reported physical activity, diet, depression) were measured for all participants at baseline (< 22 weeks' gestation), 36-38 weeks' gestation (~6 months post baseline) and at 6 months postpartum (~12 months post baseline). The Institutional Review Board at Temple University approved the study protocol and the study is also registered with ClinicalTrials.gov (NCT02229708).

2.2. Eligibility criteria

Eligibility criteria focused on enrolling obstetric patients over age 18 years who were in the first or early second trimesters of pregnancy (< 22 weeks' gestation). While entering the study at 22 weeks' gestation may have resulted in a shorter window for intervention, we still had half of pregnancy left to make an impact. Participants were required to have a body mass index (BMI) at enrollment between 25.0 and 44.9 kg/m^2 and own a cell phone with unlimited texting capabilities. Women with BMI ≥45 kg/m^2 were not recruited given a lack of guidance from the IOM about appropriate weight gain ranges for women with severe obesity [23]. Participants were excluded if they were pregnant with multiples (e.g., twins, triplets), had previous bariatric surgery or a chronic condition that could influence weight (e.g., diabetes, thyroid disorder, HIV, severe depression), or reported significant tobacco use (> 5 cigarettes daily) or drug use.

2.3. Setting

Participants were primarily recruited from two large obstetrics clinics located within the auspices of TUHS. TUHS reports approximately 3000 deliveries annually, and Temple's obstetrics clinics provide prenatal care to > 125 new pregnant patients monthly. More than two-thirds of patients are African American, receive Medicaid, and seek care in the first trimester. Additionally, we recruited from two Philadelphia WIC clinics that serve the majority of TUHS patients.

2.4. Recruitment, enrollment, and randomization

Using an IRB-approved waiver preparatory to research, senior obstetric staff generated weekly lists of potential participants from the electronic health record at TUHS (pregnant, age ≥18 years, BMI ≥25 kg/m^2). Within one week, identified patients were either called or approached in-person at upcoming obstetric clinic visits by trained research staff who explained the purpose of the study, assessed interest, and evaluated eligibility. We additionally recruited in-person at WIC on new certification days.

For all participants with confirmed eligibility and interest, we scheduled an in-person baseline visit at our research office (located on Temple University's Health Sciences campus, within a 3-mile radius from the two obstetric practices and WIC sites). At the baseline visit, study staff collected written informed consent, led assessments, and randomized participants 1:1 using a computer-based algorithm generated by our study statistician to one of two treatment arms: 1) usual obstetric care; or 2) mHealth-delivered behavioral weight control intervention.

2.5. Sample size

We hypothesized that there would be a 20% difference in the proportion of women with excessive gestational weight gain between behavioral weight control intervention and usual obstetric care arms – based on data that includes a range of between-group differences, from 13% to 30% [43,45–49]. We used results from our own preliminary studies and published data from earlier trials in pregnant women with obesity to approximate our ability to detect differences in weight gain between treatment arms. Sample sizes of 105 per arm provide power of at least 0.8 with alpha = 0.05. Conservatively assuming loss of 20% for miscarriage or lack of follow-up, the required sample size was 131 subjects per arm or 262 total.

2.6. Treatment arms

2.6.1. Usual obstetric care

This arm was meant to represent standard clinical care provided to pregnant mothers at TUHS, which typically includes: 1) an initial visit in the first trimester, at which time obstetric providers complete a comprehensive patient history, physical exam, ultrasound, and blood work; 2) monthly follow-up visits from early pregnancy until week 24 and visits every 2 to 3 weeks until week 36, where providers assess patient weight, blood pressure, urine protein, fetal heart rate, diabetes risk, as well as offer intermittent counseling about substance abuse and nutrition; and 3) weekly patient visits from week 36 until delivery to evaluate for cervical changes and fetal health. Additionally, nearly all usual care participants received WIC food/beverage vouchers, designed to provide access to foods that are good sources of specific nutrients – protein, iron, calcium, and vitamins A and C, along with nutrition counseling from WIC providers two to three times during pregnancy. Brochures were provided at baseline that contained information by the American College of Obstetricians and Gynecologists and the IOM about a healthy diet and optimal weight gain during pregnancy.

2.6.2. Behavioral weight control intervention

In addition to the usual care described above, participants in the intervention arm received a multi-component, theory- and evidence-based pregnancy weight control intervention, integrating aspects of Social Cognitive Theory, which highlights self-efficacy as a driver of behavior change [50,51], and a Social Ecological Approach, that focuses on the influence of context [52,53]. Our intervention was designed to motivate and maintain behavior change, facilitated by four carefully selected components, leveraging mHealth technologies already well integrated in mothers' lives.

2.6.2.1. Behavior change goals. Our treatment utilized the interactive obesity treatment approach (iOTA) that focused on adhering to a set of simple behavior change goals chosen for their relevance to the target population, ease of self-monitoring, concreteness, and empirical support for weight control [40,54–57]. This approach, rather than setting a caloric target, is consistent with IOM guidelines [23]. Additionally, in contrast to caloric prescriptions, our behavior change goals have fewer literacy/numeracy barriers and are well suited for technology-based implementation. We expanded upon our pilot study to include eight goals (Table 1): 1) "Track your weight! Weigh yourself every day"; 2) "More fruits and vegetables, less junk and grease! Limit junk and high fat foods to no more than 1 per day"; 3) "More water, less juice! Limit sugary drinks like juice and soda to no more than 1 per day"; 4) "Make your meal size 'baby-friendly'! Stick to one plate of food at every meal"; 5) "Walk more, sit less! Walk 30 minutes or 5,000 steps every day"; 6) "Make your snack size 'baby-friendly'! Aim for snacks less than 200 calories"; 7) "More eating at home, less eating out! Limit fast food to no more than 2 meals per week"; 8) "Turn off the TV! Stick to no more than 2 hours of TV per day". Goals were communicated without nuance, one at a time, with a new goal introduced every 2-4 weeks to maintain novelty and minimize habituation. To assist with adherence, at baseline participants were provided with a digital "bathroom" scale for self-weighing, pedometer to track steps, water bottle, and smaller plates/cups.

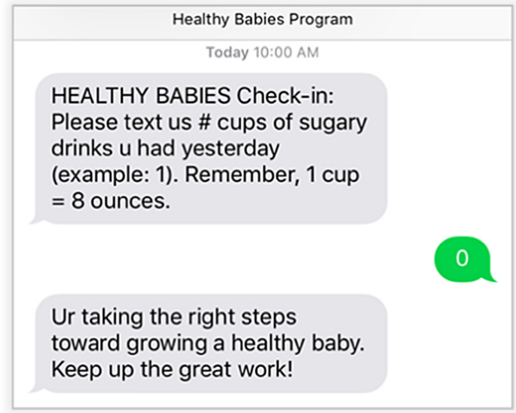

Fig. 1. Example of self-monitoring texts.

2.6.2.2. Interactive self-monitoring text messages. Regular self-monitoring is one of the most efficacious behavior change strategies [58], though adherence notoriously wanes over time [59]. Data from our pilot trial showed that we can achieve and maintain self-monitoring engagement among African American women in pregnancy through text messaging [43]. Texts are inexpensive to develop, simple to tailor, and scalable. Greater self-efficacy and satisfaction are observed when text messages are encouraging and motivational in obesity treatment trials, with the use of testimonials from peers for support and tailored recipes/tips for concrete ideas [60–62]. We developed a robust texting system that incorporated these strategies for this study. Fully automated self-monitoring texts matched to each participant's current behavior change goal were sent out daily. Once a participant entered her data, she received immediate, personalized self-monitoring feedback through text messaging to reinforce successes and/or offer motivational strategies (see example, Fig. 1). Raffles for $25 gift certificates, to incentivize participants to text their self-monitoring data, were held on a monthly basis. Each time a participant responded to a self-monitoring prompt, she received a raffle entry; an automated computer program randomly chose a monthly winner. Over the entire treatment, we additionally sent intervention participants text message prompts to self-weigh daily using study provided battery-operated digital scales [63]. Once participants texted their weights to our system, individual progress was viewable through links to web-based graphs that participants could access by texting the word "GRAPH" (Fig. 2).

2.6.2.3. Tailored skills training materials. Tailored materials can enhance the personal relevancy of interventions, provide cues to action, and increase engagement [64]. We offered intervention participants' skills training content that corresponded to their assigned behavior change goals via daily text messages and a reference binder full of handouts, with topics including (but not limited to): negotiating barriers; stress reduction; eating out; serving

Table 1
Behavioral goals and health coach counseling schedule.

Study week	Coach session	Behavioral goal discussed
Baseline	In-person	Track Your Weight! Weigh yourself every day.
Weeks 1,2 & 3	Telephone	More Fruits and vegetables, less junk and grease! Limit high fat foods to no >1 per day.
Weeks 4 & 6	Telephone	More Water, Less Juice! Limit sugary drinks like juice and soda to no >1 per day.
Weeks 8 & 10	Telephone	Make Your Meal Size "Baby Friendly"! Stick to one plate of food at each meal.
Week 12	Telephone	Walk More, Sit Less! Walk 30 min or 5000 steps every day
Week 16	Telephone	Make Your Snack Size "Baby Friendly"! Aim for snacks less than 200 cal.
Week 20	Telephone	More Meals at Home, Less Eating Out! Limit fast food to no >2 meals per week.
Week 24	Telephone	Turn Off the TV! Stick to no >2 h of TV per day.
Week 28 (End)	In-person	Staying Motivated!

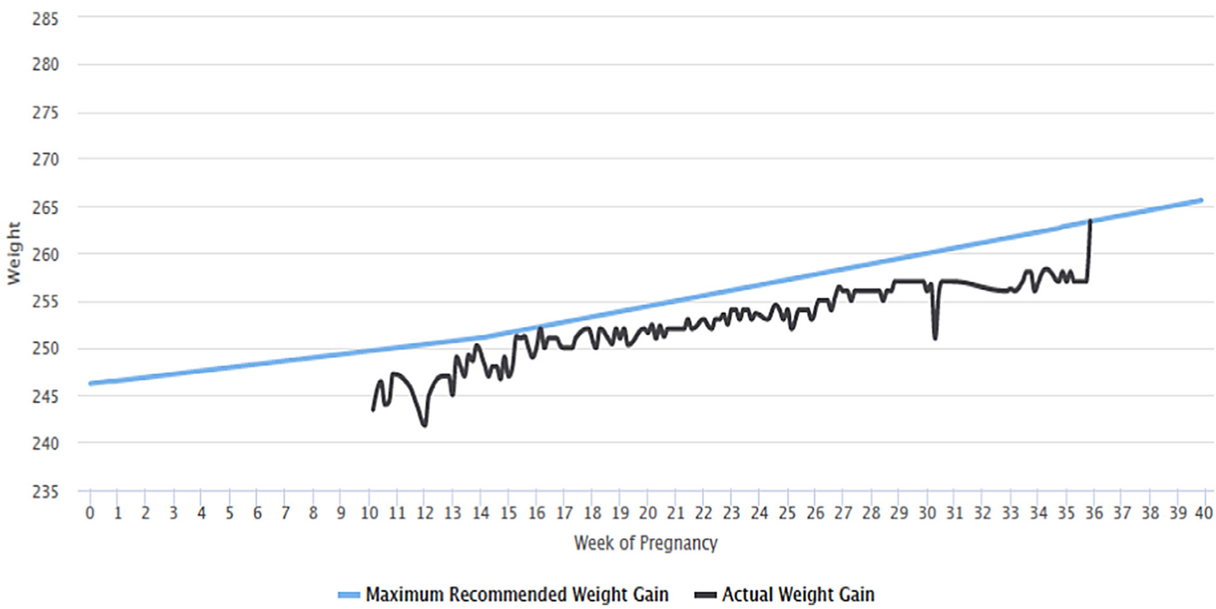

Fig. 2. Graphically presented weight change.

sizes; and engaging social support – all designed for mothers from resource constrained settings with low-literacy levels (example skills text: “Craving something sweet? Instead of grabbing junk, eat applesauce, yogurt, or a fruit cup. Ur baby will thank u ☺”). Some text messages included short quotes from previous study participants to increase receptivity (for example, “A mom says, ‘When I bake my pork chops, and everyone else is eating fried chops, it's like I know those taste good, but I resist it. I want to be healthy’”).

2.6.2.4. Interpersonal counseling support. Social support is a strong determinant of weight loss success [58]. In keeping with our pilot study, we provided interpersonal support via two mechanisms: coach counseling and Facebook.

2.6.2.4.1. Health coach counseling. Digital health interventions paired with interpersonal support from a human interventionist produce significantly greater weight losses than digital health interventions alone [65,66]. One of two health coaches that were trained in the behavioral treatment of obesity through required readings and role play, either a registered nurse or clinical psychologist, oriented/problem solved with participants in person (baseline) or by phone (follow-ups) when a goal change occurred or new goal was introduced. Each participant was assigned the same schedule (Table 1); however, coaches could override the goal order and/or timing, if a change was necessary because of participant progress or preference. To incentivize call adherence, participants were provided with $25 for completing at least four out of six possible calls within the first two study months, followed by an additional $25 for completing at least four out of the five remaining calls until intervention completion (~36-38 weeks' gestation). Our coaches engaged in problem solving with participants to overcome barriers and delivered behavioral skills training, using phone scripts adapted from our pilot study. A web application presented each session's call script, allowed for note taking, provided access to self-monitoring data, and automatically stored process data (e.g., date/time of call). Coach calls were audiotaped, and approximately 10% were reviewed at bimonthly meetings with Dr. Herring (with remediation/re-training if needed).

2.6.2.4.2. Facebook. We chose to incorporate Facebook because data suggest a strong link between social influence and healthy (or risky) behaviors, particularly among young adults [67], which we and others have leveraged through Facebook's unique communication features (e.g., frequent messaging/posts to increase exposure to weight-related skills; reciprocal interactions through instant messaging and/or Facebook's “pokes” for persuasion) [68,69]. At baseline, intervention participants with Facebook (69%) were enrolled in a private group and encouraged to communicate with one another via Facebook mail, live chat, and online postings. We posted bimonthly contests or questions with prizes (e.g., vote for your favorite healthy recipe, etc.) to foster consistent interaction (Fig. 3). Tailored skills training materials and links to video testimonials were posted daily to maintain novelty and minimize habituation. Participants were asked to log-in at least weekly to receive support and content. Health coaches monitored posts and dispelled misinformation. We considered using a range of social media platforms in the current study (e.g., Twitter, Instagram, Snapchat); however, conversations with pilot study participants revealed that Facebook was preferred.

2.7. Data collection

At the baseline visit (< 22 weeks' gestation), a trained research assistant measured weight and height in duplicate using standardized procedures on calibrated equipment, and administered a number of questionnaires assessing demographics, psychosocial factors, contextual factors, physical activity, dietary intake, and sleep quality in our private research space on Temple University's Health Sciences campus. Questionnaires were checked for accuracy and completeness before

Fig. 3. Example of Facebook contest.

Table 2
Survey measures and descriptions administered in the Healthy Babies study.

Construct	Survey description
Weight perception [87]	A modified version of the NHANES weight perception questions that ask if individuals consider themselves overweight, underweight, or about the right weight.
Depression [88]	Scores ≥13 indicate probable depressive symptoms via the 10-item Edinburgh Postnatal Depression Scale (EPDS).
Health literacy [89]	The Rapid Estimate of Adult Literacy in Medicine, Revised (REALM-R) tool categorizes participants at risk for poor health literacy if fewer than 6 out of 8 words are pronounced correctly.
Food security [90]	A 6-item short form from the U.S. Household Food Security Survey defines food insecurity with scores ≥2.
Weight gain goals [91]	Participants are asked if they have an idea in mind of how much weight to gain in pregnancy. Using IOM guidelines, women's responses are categorized as concordant, discordant, or no goal.
Dietary intake [92]	Diet quality questions adapted from the Diet History Questionnaire (DHQ) assess dietary patterns. The DHQ has demonstrated equal or superior validity in assessing most nutrients compared to other popular food frequency questionnaires [93], and its design and scoring software support modification of the measure.
Physical activity [94]	The Pregnancy Physical Activity Questionnaire (PPAQ), a standardized measure of physical activity that has demonstrated reliability in pregnancy, measures weekly levels of physical activity by intensity (light, moderate, or vigorous) and type (household/caregiving, sports/exercise, occupational). The self-reported time spent in each activity is multiplied by its intensity to arrive at a measure of average weekly energy expenditure (MET-h·wk-1) attributable to each activity.
Eating environment [95]	The Kitchen Survey is a pictorial survey of 24 household items related to cooking. The survey measures which items the respondent has in their home and if they use the item.
Sleep [96]	The 19-question Pittsburgh Sleep Quality Index (PSQI) responses are summed to obtain a total, global score ranging from 0 to 21. Scores ≥5 indicate poor sleep quality.
Social support [97]	The Social Support and Eating Habits/Exercise Survey has 3 subscales: Participation, Social Support, and Rewards/Punishment. Responses, using a five-point Likert-type scale, are summed to produce a final score for each subscale.
Self-efficacy [98]	The Physical Activity and Nutrition Self-Efficacy scale, an 11-item instrument, measures weight-loss self-efficacy among childbearing women of lower income. Respondents rate how confident they feel about doing the identified behavior on a scale of 1 (not at all) to 9 (completely). Responses are summed to obtain a total score.

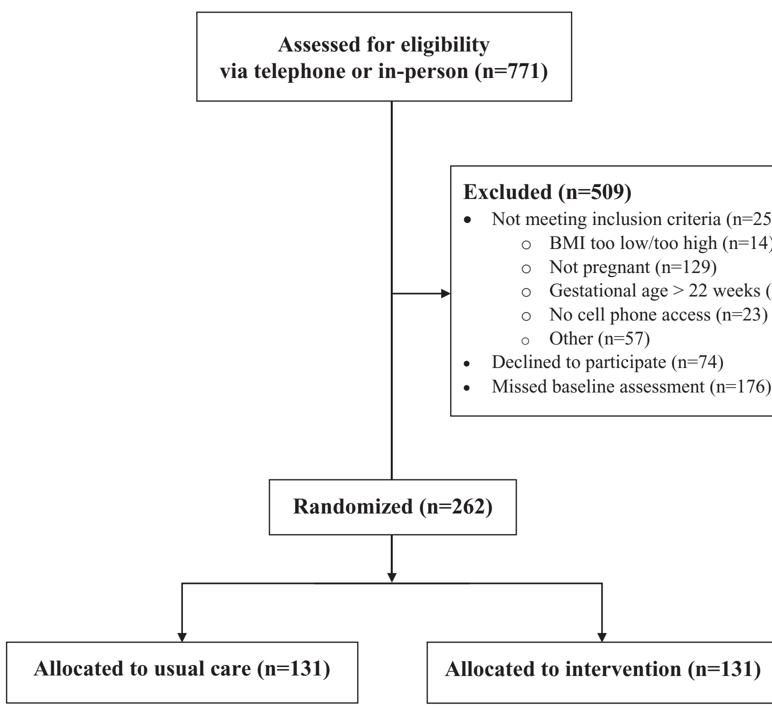

Fig. 4. CONSORT diagram for Healthy Babies study.

each participant left her visit. At follow-up visit 1 (36–38 weeks' gestation) and follow-up visit 2 (6 months' postpartum), mothers returned to Temple for measurement of weight and completed additional questionnaires. Measures were also collected at delivery via medical record abstraction, and include mode of delivery, prevalence of gestational hypertension or diabetes in pregnancy, and infant birth weight. Study data were managed using REDCap electronic data capture tools hosted at TUHS. If transportation was an issue, we scheduled home visits to collect follow-up measures using protocols from our previous work [43,70]. Staff collecting baseline assessments were blinded to group assignment; however, most follow-up assessments were conducted by un-blinded but trained staff due to budgetary limitations. Participants were reimbursed $50 each at baseline and follow-up visit 2, along with $25 at follow-up visit 1, for their time and travel.

2.8. Measures

Table 2 provides a description of the validated measures used to query participants at baseline and follow-up visits that assess a range of relevant constructs. Demographic variables collected at baseline included age, marital status, occupational status, and educational attainment. At baseline, follow-up 1 and follow-up 2, weight was measured in light clothing, without shoes, by trained research staff to the nearest 0.1 kg using high-quality calibrated SECA digital scales. Height

Table 3
Baseline characteristics of the Healthy Babies sample.

	All participants (*n* = 262)	Intervention (*n* = 131)	Usual care (n = 131)
BMI (kg/m2)	32.3 ± 4.8	32.3 ± 4.8	32.3 ± 4.9
BMI category			
Healthy weight (< 25.0 kg/m^2)	5 (2%)	3 (2%)	2 (2%)
Overweight (25.0-29.9 kg/m^2)	91 (35%)	42 (32%)	49 (37%)
Obese (≥30.0 kg/m^2)	166 (63%)	86 (66%)	80 (61%)
Age (years)	25.6 ± 5.4	26.0 ± 5.3	25.3 ± 5.4
Gestational age (weeks)	13.9 ± 4.1	13.7 ± 4.1	14.1 ± 4.1
Nulliparous	99 (38%)	48 (37%)	51 (39%)
Marital Status			
Single	201 (77%)	98 (75%)	103 (79%)
Married or living as married	55 (21%)	31 (24%)	24 (18%)
Divorced/separated/widowed	6 (2%)	2 (2%)	4 (3%)
Education			
Some high school or less	47 (18%)	23 (18%)	24 (19%)
High school graduate	123 (48%)	65 (50%)	58 (46%)
Post high school training and/or some college	70 (27%)	31 (24%)	39 (31%)
College graduate and/or postgraduate work	17 (7%)	11 (8%)	6 (5%)
Employment Status			
Employed full- or part-time	129 (49%)	69 (53%)	60 (46%)
Not currently employed	133 (51%)	62 (47%)	71 (54%)
Weight perception			
Too heavy	135 (53%)	68 (52%)	67 (53%)
About average	114 (44%)	55 (42%)	59 (46%)
Too light	8 (3%)	7 (5%)	1 (1%)
Weight satisfaction			
Dissatisfied with my weight	99 (38%)	56 (43%)	43 (34%)
Neither satisfied nor dissatisfied with my weight	46 (18%)	24 (18%)	22 (17%)
Satisfied with my weight	113 (44%)	51 (39%)	62 (49%)
Gestational weight gain goals concordant with IOM guidelines	31 (12%)	15 (11%)	16 (13%)
Doctor/Nurse weight gain advice			
Gain weight in pregnancy	47 (18%)	18 (14%)	29 (23%)
Lose weight in pregnancy	5 (2%)	3 (2%)	2 (2%)
Stay the same weight in pregnancy	17 (7%)	11 (8%)	6 (5%)
A doctor/nurse has not discussed weight	188 (73%)	98 (75%)	90 (71%)
Opinion is "important" about how much to eat in pregnancy			
Baby's father	141 (55%)	75 (57%)	66 (52%)
Participant's mother	134 (52%)	69 (53%)	65 (52%)
Obstetric provider	205 (80%)	101 (77%)	104 (83%)
Enrolled in WIC			
Yes	100 (39%)	44 (34%)	56 (44%)
No, but planning to enroll	149 (58%)	82 (63%)	67 (53%)
No, not eligible	8 (3%)	4 (3%)	4 (3%)
Food insecure (USDA short form score ≥ 2)	49 (19%)	24 (18%)	25 (20%)
Depressed (EPDS ≥13)	39 (15%)	16 (12%)	23 (18%)
Inadequate health literacy (REALM-*R* ≤ 6)	158 (61%)	80 (61%)	78 (61%)

Values in table are either expressed as means ± standard deviation or n (%). The sample sizes indicate that some participants did not have complete data on all the variables.

was measured to the nearest 0.1 cm using a calibrated stadiometer. The participant stood on a firm, level surface, with her head in a horizontal plane.

2.8.1. Primary outcome: proportion of women with excessive gestational weight gain

We define excessive gestational weight gain as the proportion of mothers exceeding weekly IOM weight gain targets in the second and third trimesters (> 0.32 kg/week for women with overweight BMI; > 0.27 kg/week for women with obesity) [23], to better account for the effect of gestational age at delivery on total weight gain (especially relevant for mothers with preterm births). Similar to the LIFE-Moms Consortium [71], we calculate gestational weight gain per week as the difference between study measured weight at 36-38 weeks' gestation (follow-up 1) and baseline weight divided by the number of weeks between the two dates. We additionally define excessive gestational weight gain as total weight gain in pregnancy > 11.5 kg for women with overweight body mass index (BMI) and > 9 kg for women with obesity [23]. We calculate total gestational weight gain as the difference between weight in kilograms measured at 36–38 weeks' gestation (follow-up 1) minus weight in the first trimester. For this calculation, we plan to use multiple imputation to estimate first trimester weight among mothers enrolled after 14 weeks' gestation, applying a regression model used previously by our group (linear in time with estimated error variance) to predict first trimester prenatal weight [40]. In the rare case that a mother delivers her infant before follow-up 1 occurs, we will abstract her last prenatal weight from her medical chart.

2.8.2. Secondary outcomes

2.8.2.1. Cardiometabolic risk factors. Participating women underwent routine glycemic screening to identify disorders of glucose tolerance (mild hyperglycemia, GDM) between 24 and 28 weeks' gestation (follow-up 1), as part of usual clinical care. Venous blood was sampled for glucose one hour after a 50-gram oral glucose load. If the glucose result was ≥130 mg/dL, the participant was referred for a 100-gram fasting 3-hour OGTT. Normal 3-hour OGTT glucose results include: < 95 mg/dL at baseline, < 180 mg/dL at 1 h, < 155 mg/dL at 2 h, and < 140 mg/dL at 3 h [72]. In this study, we define glucose intolerance in two ways: 1) 1-hour OGTT values ≥130 mg/dL (mild hyperglycemia), and 2) two or more abnormal values from the 3-hour OGTT (GDM). The small number of GDM cases in our sample precludes our ability to look at this outcome alone. Glucose values at a level of 130 mg/dL or higher are associated with adverse pregnancy outcomes [73,74], and have been used by us and others to define milder states of glucose intolerance [75,76]. Blood pressure was assessed by the OMRON HEM907XL device. Using methods identical to our prior studies [77,78], two measurements (separated by 1-minute intervals after 5 min of sitting) were obtained at baseline and follow-up 2. We define hypertension as a mean systolic pressure > 140 mm/Hg or a mean diastolic pressure > 90 mm/Hg.

2.8.2.2. Mode of delivery. After abstracting delivery data from participants' medical records, we categorize participants as either operative delivery (cesarean section) or non-operative delivery (vaginal delivery), stratified by birth history to account for the larger number of surgical deliveries among mothers with prior cesarean sections.

2.8.2.3. Infant birth weight. We define macrosomia as infant birth weight ≥4000 g (using delivery records). We plan to calculate sex-specific birth weight for gestational age percentile based on US national data [79]. To evaluate intervention safety, we will examine the proportion of small-for-gestational age (SGA) infants by treatment group (e.g., those with birth weights < 10th percentile for gestational age).

2.8.2.4. Six-month postpartum weight retention. We determine the proportion of women in each treatment group at (within 0.9 kg) or below their early pregnancy weights by 6 months postpartum. While observational data repeatedly suggest that excessive gestational weight gain is the strongest predictor of postpartum adiposity [80], few studies have evaluated this relationship in the context of a clinical trial. Similar to pregnancy weight assessments, we measure each participant's weight in duplicate via SECA scales while shoeless, wearing light clothing.

2.8.3. Process measures

We measure intervention engagement via: 1) number of responses to self-monitoring text prompts; 2) type and frequency of Facebook posts and/or likes; and 3) number of health coach visits and calls completed. Relying on an approach by Olson and colleagues, we will report the extent to which level of engagement is associated with gestational weight gain [81]. We will additionally examine compliance with prenatal visits by assessing number of visits attended in each treatment group.

2.9. Data analysis

Using multivariable logistic regression, we will test the effect of treatment assignment on the odds of excessive gestational weight gain while simultaneously adjusting for covariates known to be prognostic, confounding, or effect-modifying for weight gain or discovered to be unbalanced between the treatment groups at baseline. Data will be analyzed using an intent-to-treat (ITT) approach where subjects are analyzed according to their treatment assignment at randomization, regardless of level of engagement. Since an ITT analysis is planned, two methods are proposed for accounting for the missing data. First, multiple imputation methods will be used to estimate weight at 36–38 weeks' gestation (follow-up 1) based on intermediate outcomes, mediating variables, and data collected on subjects with complete follow-up [82]. A second approach will be to perform model-based analyses with direct maximum likelihood methods [83]. Analysis of covariance (ANCOVA) will be used to examine total gestational weight gain on a continuous scale in a completely analogous fashion. A priori subgroup analyses of the primary outcome are planned, including: stratification by trimester of study entry; baseline BMI category; and level of intervention engagement.

Secondary outcomes will also be examined using logistic regression models for binary outcomes (e.g., glucose intolerance, cesarean section, macrosomia) and ANCOVA for continuous outcomes (e.g., blood pressure, infant birth weight).

3. Results

Between October 2014 and December 2016, we randomized 262 pregnant women (34% of the 771 approached via phone or in-person) to either the weight control intervention (n = 131) or usual obstetric care (n = 131, Fig. 4).

3.1. Ineligible persons randomized

Eight participants were noted to be ineligible after randomization due to minor miscalculations in BMI at enrollment (e.g., using self-reported pre-pregnancy weight instead of measured baseline weight to calculate eligibility criteria); five participants for BMI < 25.0 kg/m^2 at baseline (range 23.9-24.9), and three participants for BMI ≥45.0 kg/m^2 (range 45.0-48.3). All eight persons remain in the study and will be analyzed following the ITT principle. Excessive gestational weight gain will be defined in accordance with IOM guidelines for women at a healthy BMI (e.g., the proportion of mothers exceeding 0.45 kg/week in the second and third trimesters) for the five mothers < 25.0 kg/m^2, and > 0.27 kg/week for those with BMIs at or above 45.0 kg/m^2.

3.2. Baseline characteristics of study participants (Table 3)

Overall, the average gestational age at enrollment was at the end of the first trimester (13.9 ± 4.1 weeks' gestation). Nearly two-thirds of participants had obesity (63%). Average age of the sample was 25.6 ± 5.4 years. Participants were mostly single (77%), multiparous (62%), and eligible for WIC (income proxy, 97%). While 82% completed high school, 61% met criteria for inadequate health literacy. Nearly 20% were food insecure. The majority (73%) reported that their obstetricians had not yet discussed weight gain in pregnancy, and 88% did not have a gestational weight gain goal concordant with IOM guidelines. Most participants (80%) reported their obstetric providers opinions were “important” in their decision about how much to eat in pregnancy. There were no statistically significant differences in baseline characteristics between study arms.

4. Discussion

There has been increasing interest in understanding how to best treat antenatal overweight and obesity; however, few studies have targeted the medically vulnerable – those who are low-income and often racial/ethnic minorities. Healthy Babies was designed to overcome this evidence gap by evaluating a multicomponent weight control intervention in pregnancy delivered through digital health technologies compared to usual obstetric care among a population of at-risk African American women. Indeed, the baseline characteristics of the Healthy Babies sample reflect a group at high risk for excessive gestational weight gain and morbidity in pregnancy. The sample is largely composed of urban African American women with obesity and a demonstrated need for goal setting around recommended gestational weight gain targets. This later finding is particularly intriguing given the strong link between weight gain goals and actual gestational weight gains [84,85], and is emphasized in our intervention (both weight gain goal setting and weight gain monitoring).

In this study, we focus exclusively on pregnancy, as weight gained during this period is the strongest predictor of women's weight status later in life and has implications for additional short- and long-term maternal/fetal morbidity. While we considered a longer follow-up period (e.g., one to two years postpartum) to examine sustained weight change, with few previously published gestational weight control studies involving low-income African Americans, a more limited, highly focused efficacy trial is warranted. If our intervention is deemed efficacious, we will be well-positioned at the close of this trial to examine longer-term outcomes in both mothers and offspring. We also considered the possibility of cluster effects by provider, as mothers in both arms may be patients of the same obstetrician or WIC provider. We have attempted to mitigate these cluster effects by: 1) having no provider delivered components; 2) blinding providers to treatment assignment; and 3) having no intervention activities or data collection at clinics in front of providers. It is important to note that evidence shows physician-delivered weight control counseling in routine obstetric visits is not common; most providers have inadequate weight counseling skills, limited clinical visit time and a lack of confidence [44,86]. However, most mothers find their obstetric providers' advice about eating and weight important, as evidenced by our baseline results; and thus, future work incorporating providers is needed to better leverage this significant resource. Finally, we recognize that our intervention has multiple components, (e.g., text messaging, Facebook, coach calls), and thus, may appear to be too intensive to be sustainable. We deliberately chose components that were already integrated into low-income African American mothers' lives, so to lower costs and promote ease of use. We developed the proposed study in collaboration with African American mothers, to ensure that this project will be meaningful and sustainable if proven effective. At the completion of the intervention, participants were asked to rate their satisfaction with each component, and thus, we will be able to explore which aspects of the intervention are most/least acceptable.

The proposed trial has several important strengths and represents an innovative intervention approach to slowing the trajectory of weight gain among African American women. We are focusing on specific, achievable, and measurable weight-control targets in pregnancy with messages framed around babies' health and mothers' social context so to promote adherence and motivation. Our use of technology to deliver intervention content aims to overcome barriers to traditional weight control programs for low-income African Americans. We believe this approach will provide a widely sustainable model of obesity prevention.

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Disclosures

Currently, Dr. Foster is a full-time employee and shareholder of WW (formerly Weight Watchers International). WW did not provide financial support for this study nor did they have any influence on the methods in this study. Dr. Bennett is an equity holder in the privately held corporation Coeus Health LLC and is a scientific advisor to Nutrisystem and Interactive Health, all of which are unrelated to this study. All other authors declare no conflicts of interest.

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