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Goals for Reaching Optimal Wellness (GROWell): A clinical trial protocol of a digital dietary intervention for pregnant and postpartum people with prenatal overweight or obesity

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Abstract

Background: Excess gestational weight gain (EGWG) is associated with multiple pregnancy complications and health risks for birthing people and their infants. Likewise, postpartum weight retention (PPWR), or not losing all pregnancy weight, has long-term health consequences. EGWG among people who enter pregnancy with overweight or obesity have worse obstetric outcomes and increased PPWR compared to women who gain within Institute of Medicine guidelines.

Methods: This study protocol describes the details of a blinded, randomized clinical trial of *GROWell*: Goals for Reaching Optimal Wellness, a mHealth tool designed to improve diet quality among people who enter pregnancy with overweight or obese BMIs to help them achieve appropriate GWG and safe postpartum pregnancy weight loss. Individuals with overweight and obesity will be randomly assigned to an attention control or intervention arm. The intervention group will receive personalized, goal-oriented text messages regarding dietary choices, while the attention control group will receive text messages about healthy pregnancy, labor, delivery, and

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Authors' contributions

LAS designed the study and drafted the protocol. JEP edited and revised the manuscript and contributed to the protocol development. PMS drafted the recruitment section of the protocol. CO, DN, and EB contributed to study design. SL contributed to the statistical analysis plan. CO, PMS and CW contributed to recruitment processes. CW was responsible for determining the clinical safety of the study design. All authors have read and approved the final manuscript.

Ethics approval and consent to participate

The University of California, Davis, IRB has approved this protocol and informed consent will be required by all participants prior to participation. A data safety monitoring committee is in place for this study.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

early infancy. Both groups will complete online surveys at baseline, follow up, 3 and 6 months postpartum.

Results and discussion: Currently, 162 subjects have been enrolled. Outcomes associated with GWG and pregnancy are expected in late 2023, while outcomes on postpartum weight retention *GROWell* adherence are expected in late 2024. The results of this trial will support the use of an evidence-based mHealth tool to be integrated into clinical practice to reduce EGWG and PPWR among pregnant people with overweight and obese BMIs, a resource that is currently lacking.

Trial registration: ClinicalTrials.gov identifier: NCT04449432. Registered on June 26, 2020.

Keywords

Gestational weight gain; Postpartum weight retention; Mobile health intervention; Overweight; Obesity; Pregnancy

1. Introduction

Overweight and obesity are significant risk factors for cardiometabolic diseases, including type 2 diabetes, hypertension, heart disease, and stroke [1]. People who enter pregnancy with overweight and obesity increase those risks when they experience excess gestational weight gain (EGWG), defined as gaining more weight during pregnancy than Institute of Medicine (IOM) guidelines for prepregnancy body mass index (BMI) [2–5]. Importantly, national data show that EGWG complicates more than half of all pregnancies when the individual enters pregnancy with BMI ≥ 25 [6]. EGWG is associated with increased risk for: (a) poor obstetric, neonatal, and maternal outcomes (e.g., gestational diabetes, preeclampsia, fetal growth abnormalities) [7–18]; (b) postpartum weight retention (PPWR) at 6 months post-birth, a time point now recognized as critical for predicting whether individuals will ever return to their prepregnancy weight [19–21]; (c) moving to the next BMI class, thereby increasing the risk status of subsequent pregnancies [17,22–25]; and (d) offspring overweight, obesity, cardiometabolic disease, poor cognition, and mood disorders across the lifespan [13,15,26–30]. Moreover, a recent study found that postpartum weight gain occurred in 57% of people and resulted from increased energy intake, not decreased energy expenditure, thus highlighting the importance of nutritional interventions to prevent PPWR [31].

Attempts to prevent EGWG have had limited impact on the problem, particularly in populations with overweight and obesity [32]. Most interventions to reduce GWG have not employed technology and varied widely in approaches and success rates, including few large randomized trials and inconsistency in: (a) provider type [33,34] (e.g., dieticians, health coaches, health educators; (b) approach (e.g., individual, group, in-person, telephonic) [35–39] (c) intensity [35–38] (e.g., 30–60 min sessions, 5-min session after prenatal visits, 16 90 min sessions). Results from these trials have shown that higher intensity interventions with at least some individualized support were associated with lower GWG compared to control conditions.

Interventions that leverage technology, social media, and other web-based platforms are growing in popularity. In one such study, called, “MomTech,” participants who received two daily text messages and four lifestyle appointments with a midwife had lower GWG than control participants, but the study was not powered for statistical significance [40]. e-Moms Roc included an informational website with mobile phone applications, weight gain trackers, and goal-setting tools for diet and physical activity. Only participants with access to the personalized weight, diet, and physical activity tools had lower GWG [41]; however, results of this intervention in a randomized control trial (RCT) were inconclusive, perhaps due to lack of participant use of the provided behavior change tools [42]. The VideoDoctor trial found no improvement in GWG from an actor-portrayed doctor delivering two brief video messages about diet, exercise, and weight gain [43]. The Health in Pregnancy and Postpartum (HIPP) trial, which tested counseling, podcasts, and social media, found that the intervention group had similar total GWG at delivery as the standard care participants, albeit fewer adverse pregnancy outcomes (e.g. low birth weight infants, gestational hypertension). There also were differences in GWG outcomes among African Americans with overweight versus obese BMIs [44,45]. These findings reflect the conclusions of several recent reviews that technology-based interventions can improve physical and mental health and monitor health markers remotely (e.g. blood glucose, blood pressure, weight), however, an insufficient number of RCTs have been conducted to establish clinical and economic benefits, safety, and mechanisms of potential benefits [46–49]. Interventions that tailor text messages to each participant have been found to be more effective than those that send generic messages [50]. Additionally, a lack of alignment between messaging and outcomes is a common methodological shortcoming in text messaging studies for maternal and infant health [51].

Behavior change interventions that focus on the postpartum period are severely lacking, and this may be critical for limiting PPWR. Postpartum interventions are difficult for new parents for many reasons including caregiving duties, lack of time, and fatigue [52,53]. However, the postpartum period is also an ideal window to help birthing people to mitigate new risks that may have been discovered by diagnosed pregnancy complications [54]. Birthing people also may be particularly motivated during this window due to their new responsibilities as a parent [52]. Additionally, research has shown that interventions during pregnancy to limit GWG are not sufficient to prevent PPWR [31], which is a risk factor for future chronic illness [55,56]. The proposed study addresses this gap by extending 6 months into the postpartum period and encouraging healthy dietary intake that will not affect milk supply for those who are breastfeeding [57]. Some participants may lose more weight than they gained, but we do not encourage this as a specific goal.

1.1. Design

We propose to conduct one of the first, fully powered RCTs to test the efficacy of *GROWell*, a personalized digital dietary intervention for people who entered pregnancy with an overweight or obese BMI. *GROWell* was adapted from the Interactive Obesity Treatment Approach (IOTA) [58–61] for the specific needs of pregnant and postpartum birthing people, given that dietary requirements change from pregnancy through postpartum and with breastfeeding. *GROWell* is based on previous work of the study team and

their collaborators. In one study, pregnant, urban-dwelling Black people with overweight or obesity receiving WIC ($N = 66$) were enrolled in a multi-faceted intervention that included IOTA. Compared to the control group, participants in the intervention group were within IOM recommendations for prepregnancy BMI (66% vs. 37%, $p = 0.033$) with no loss to follow up [62]. A second pilot was conducted to examine the feasibility of goal-setting and action planning specifically for postpartum birthing people who had gained excess gestational weight, because this has been an understudied population. Intervention participants were recruited in the hospital post-birth. Overall, the intervention group lost a mean of 12.2 pounds compared to a mean weight gain of 16.6 pounds for the control group [63]. These studies supported the feasibility and acceptability of our approach to leverage digital tools to achieve personalized behavior change goals during pregnancy and postpartum to positively impact weight outcomes.

The premise of our study is that a theoretically driven, standalone mHealth tool with a high intensity intervention, timed during pregnancy through six months postpartum, will help individuals with overweight and obesity to gain appropriate gestational weight and prevent PPWR. *GROWell* employs algorithms and text messaging to personalize food preferences, goal-setting, diet tracking, skills training, and adherence feedback to improve diet quality and increase the proportion of days on which participants consume diets that are consistent with nutrient needs for pregnancy and healthy postpartum weight loss. *GROWell* is based on Self-regulation Theory [64–67], which posits that individuals must consciously plan their actions and monitor their behaviors to achieve desired goals (Fig. 1). Previous studies based on Self-regulation Theory [68] show that goal attainment is enhanced when individuals receive support, including problem-solving skills, that can be applied to their actions. Self-regulation happens in this study through response to text messages regarding goals and measurement of weight on a study-provided Bluetooth scale.

We are currently conducting a blinded RCT of *GROWell* to determine whether the intervention is efficacious at achieving GWG within IOM-recommended ranges and reducing six-month PPWR compared to an attention control. Fig. 2 provides an overview of the study design. Due to the emergence of the COVID-19 pandemic, we modified our study to allow for the protocol to be implemented fully remotely rather than solely in the clinic with study staff.

1.1.1. Justification and rationale for study design—The weight of a pregnant person is one of the key clinical indicators of the health of a pregnancy. This trial was designed to determine whether pregnant participants can make dietary changes to impact pregnancy and postpartum weights. While multiple behavioral change interventions can prove helpful [69], it is also difficult to isolate the effects of specific behaviors on outcomes. We chose to focus on diet, as research shows that diet is more important than exercise in terms of weight loss [70]. Goals are incremental and manageable, with the “dose” being consistent with previous studies using IOTA [58–61]. While gaining inadequate weight during pregnancy introduces the risks of low birthweight and difficulties breastfeeding, we focused only on EGWG due to the extra cardiometabolic risk both during pregnancy and throughout the lifetime of the birthing person who gains too much weight during pregnancy [71]. *GROWell* was designed to be an app-based text messaging intervention because:

(1) nearly 90% of the population participates in text messaging, particularly racial and ethnic minorities [72,73]; (2) regular (especially daily) self-monitoring is very important for weight loss success [74,75]; (3) self-monitoring of food intake is positively correlated with weight change [76], and while it can be done on paper, technology is less burdensome and thus more likely to be used for successful weight management [77]; and (4) text messaging has been shown to be very effective at promoting weight control [60]. *GROWell* is unique compared to other intervention studies targeting weight gain in pregnancy because it: (1) is fully remote; (2) provides personalized messaging to participants based on their progress toward dietary goals; and (3) follows participants from early pregnancy to 6 months postpartum. Given the limited studies on postpartum weight management and diet, we measured diet quality at 3 and 6 months to determine whether dietary changes made during pregnancy persist postpartum and/or whether differences in progress on goals during pregnancy impact diet quality at 3 and 6 months postpartum.

1.1.2. Study sample—We are recruiting individuals aged 18–44 who are 10–16 weeks gestation of a confirmed pregnancy (i.e., ultrasound/heartbeat detected) and nulliparous or > 12 months since previous birth. Women with BMI ≥25 and <42 who are willing to receive and respond to texts using their own cell phone or a study-provided phone can be included. Exclusion criteria include: (a) known pregnancy or fetal complications/high-risk status (e.g., fetal chromosomal abnormality, chronic hypertension), (b) multiple gestation, and (c) unable to read/write English. We also exclude individuals ≥45 years and at the extreme high end of the BMI range (≥42) due to increased risk for pregnancy complications, and thus higher likelihood of dropping out [78,79]. Smokers and those who quit smoking <6 months prior to recruitment are excluded given data that show smoking is associated with increased risk for pregnancy complications [80,81] and smoking cessation affects eating patterns and weight [82–84]. Individuals with untreated depression (i.e., not on a stable class/dose of antidepressant for ≥6 months or with Edinburgh Scores >12 based on first trimester clinic screening) are excluded due to documented relationships between depression, appetite changes, and eating behaviors [85,86]. Our enrollment target for race/ethnicity is 50% non-Hispanic white and 50% historically minoritized groups. We are monitoring our enrollment targets monthly and adjusting our advertisements and approach as necessary. For instance, we have recently started geotargeting zip codes where there are high racial/ethnic minorities and are deploying a Spanish language version of the app in early 2022.

1.1.3. Recruitment strategies—We are employing two primary recruitment strategies: (a) social media and (b) clinic-based recruitment. Our California-targeted social media campaign includes a variety of vibrant, animated ads on Facebook and Instagram. We partner with an organization called StudyPages, by Yuzu Labs PBC, to run our social media ad campaign. StudyPages provides reports based on number of ads clicked, screening surveys completed, and enrollments generated; the number of social media ads displayed each month is adjusted accordingly to meet our enrollment goals. While a pregnancy must reach 10 weeks gestational age for a participant to enroll, we are allowing people from 8 to 10 weeks gestational age to pass the screening and we follow up once they have reached 10 weeks gestation. Meantime, we provide these early pregnant people with information about the study and allow them time to consider the study and ask questions.

This helps online and clinic recruitment because many people going to appointments at the clinic are around 8 weeks pregnant. This early, active engagement very often converts potential enrollments into official enrollments. Clinic-based recruitment includes using clinical research coordinators (CRCs) reviewing the automated appointment system in the electronic health record to generate weekly lists of patients receiving prenatal care and delivering at our academic medical center who meet preliminary eligibility criteria (i.e., age, gestational week, singleton pregnancy, parity, BMI). CRCs either: (1) approach potential participants at their usual obstetric visit after introduction from a member of their provider team to describe the study and receive verbal consent to administer formal prescreening; or (2) email opt-out letters from the clinic director and follow up via phone with potential participants who do not opt out to determine interest in study participation and conduct screening. All participants consent using an IRB-approved form, which can be administered virtually or in person on a mobile device.

1.1.4. Randomization and treatment assignment—Treatment assignment occurs after completion of the baseline computer assisted interview. Computerized stratified randomization with permuted blocks of size 3 are used to assign eligible participants to GROWell (n = 240) or the attention control (n = 240). Prepregnancy BMI categories (overweight = BMI 25- < 30; class 1 obese = BMI 30- < 35; class 2 obese = BMI 35 < 42), race, and recruitment method (clinic or via social media) will be the stratification variables. The technology platform performing the randomization is managed by a third-party vendor; staff at this vendor are unblinded to which groups study participants are assigned. Researchers and participants are both blinded to their group assignment.

1.1.5. GROWell intervention design and platform overview—Upon enrollment, participants take a brief survey on their specific dietary behaviors, their readiness and self-efficacy to change these behaviors, and dietary preferences/restrictions. The results are tallied, and our prescription algorithm assigns two, personally tailored dietary change goals. The algorithm prioritizes goals in highest need of change and for which the participant has high self-efficacy and readiness, based on the results of their intake survey. Daily texts help the participant with the action planning aspect of self-regulation theory; these messages help participants plan their actions to meet the prescribed goals, and include meal suggestions, healthy cooking strategies, and educational messages on the benefits of making the prescribed dietary change. Fig. 3 demonstrates an example of how the mobile app looks for participants. Participants engage with *GROWell* Monday through Friday. Once weekly, participants report via text or the mobile application how many days in the previous week they adhered to their goal. The remaining four days, participants receive supportive, goal-focused text messages with problem-solving skills and dietary tips tailored to the previous week's progress on their goal. When participants do not respond, we use a complex text-back protocol that reminds participants to report adherence if they do not respond to the initial prompt. The protocol is based on timing of initial and subsequent prompts and participant requested times to receive study texts. This protocol has produced weekly self-monitoring adherence rates between 72% and 84% at 12 months [87,88]. Since we know pregnant people are often using their cell phones and participating in text messaging[73]

[,90], a digital intervention like *GROWell* has the potential to increase adherence to dietary guidelines for pregnancy and the postpartum period, which are notoriously low [91–93].

During the prenatal period, the library of dietary behavioral goals is consistent with controlling energy intake and meeting nutrition recommendations for pregnancy. These recommendations include increasing micronutrient needs such as iron, calcium, and folic acid, consuming a balanced diet of whole grains, healthy fats, dietary fiber, fruits, vegetables, and lean protein. Table 1 lists all of the *GROWell* goals. These goals emphasize diet quality, including reducing high energy dense foods and increasing low energy dense foods, which has been shown to be associated with weight loss and weight loss maintenance [94].

As women successfully meet their goals with >70% adherence (i.e., at least 5 out of 7 days) for 2 consecutive weeks, they are assigned the next goal for which they have the highest need combined with the highest readiness to change.

Approximately 10–14 days postdelivery, participants retake the *GROWell* dietary assessment online. We also collect information on breastfeeding status, including whether they left the hospital breastfeeding, and if so, whether or not they were supplementing with formula. The prescription algorithm assigns two new, personally tailored dietary change goals based on breastfeeding status to meet micronutrient needs (e.g., calcium, iron, protein, etc.) and promote safe postpartum weight loss (½−2 pounds per week). Among breastfeeding mothers, continued breastfeeding is reassessed with weekly self-monitoring texts (e.g., Are you still breastfeeding? If yes: Full or partial? If no, when did you stop?). When breastfeeding status changes (i.e., full or partial to partial or none), the participant will receive a link to retake the *GROWell* assessment online so that new dietary goals can be prescribed that reflect non-breastfeeding status. See Table 2 for sample texts.

1.1.6. Attention control—Research on behavioral trials has suggested that significant differences between intervention and usual care or non-attention controls may contribute to inflated results or lack of clarity regarding whether effects are the result of actual intervention components or mere attention [95–97]. In our preliminary work, we developed an attention control delivered using text messaging to reduce the potential placebo effect that interacting with our mHealth system may have on pregnancy weight gain and postpartum weight loss. By providing information to control participants that is specific to pregnancy, labor, delivery, and early infancy, but not to diet, we will isolate the effects of diet-focused goal-setting, self-monitoring, and feedback in *GROWell* as compared to receipt of a general pregnancy education intervention. Based on information we collect about partner and employment status, parity, breastfeeding intentions, etc., participants assigned to the attention control receive: (a) pregnancy, fetal development, labor and delivery, and early infancy educational messages provided via text once weekly between enrollment and 37 weeks gestation; and (b) education on infant development via weekly texts from birth to 6 months postpartum (see Table 2

2. Data collection

2.1. Baseline

Prior to treatment assignment, each participant completes an online baseline survey. All participants are paid $45 for completion of this survey, which takes ~45 min. The survey includes basic demographics, parity, diet quality, depression/anxiety, and physical activity. Each participant receives a Bluetooth scale, which is mailed for those remotely recruited. They also receive written and video instructions on how to sync their scales to their phones and to provide weights at the same time points as the online assessments. See more information on weight calculations below.

2.2. Online follow-ups

Each online follow-up reminds participants to weigh themselves with their Bluetooth scale. For the postpartum period, breastfeeding status is assessed weekly until cessation. At each time point, the following information is assessed:

1. 26–28 weeks gestation: diet quality, new diagnoses of pregnancy complications (e.g., gestational diabetes, hypertension, etc.). Time required: ~30 min, compensation: $15
2. 36–38 weeks gestation: diet quality, depression/anxiety, physical activity, demographics update, new diagnoses of pregnancy complications (e.g., gestational diabetes, hypertension, etc.). Time required: ~45 min, compensation: $60
3. 3 months postpartum: diet quality. Time required: ~30 min, compensation: $15
4. 6 months postpartum: diet quality, depression/anxiety, physical activity, demographics update, and intervention satisfaction. Time required, ~45 min, compensation: $90

2.3. Primary outcomes: excess GWG and PPWR

GWG will be calculated as: $[weight_{(delivery)} - weight_{(preconception)}]$. Participants will be categorized as gaining excess gestational weight if they started pregnancy with overweight and gained more than 25 pounds or started pregnancy with obesity and gained more than 20 pounds. Otherwise, participants will be categorized as not gaining excess gestational weight. If a participant gained inadequate gestational weight, they will be categorized with the group that did not gain excess gestational weight. PPWR will be calculated as: $[weight_{(6\ months\ postpartum)} - weight_{(preconception)}]$. Participants will be categorized as experiencing PPWR if postpartum weight at 6 months is greater than 1.05*preconception weight. Otherwise, participants will be categorized as returning to their prepregnancy weight. Preconception weight will be obtained from participant medical records or defined as the first measurement on the Bluetooth scale if no preconception weight is available in the medical record. Delivery weight will be obtained from participant medical records or the last measurement on the Bluetooth scale if weight was not recorded at delivery. Studies suggest that early prenatal weights (4–12 weeks gestation) are accurate proxies for 90% of pregnant people in all BMI classes [98]. Still, because variation does exist, we will

address discrepancies in measuring both preconception weight and delivery weight by using propensity score matching [99,100]. Using the imputed weights will ensure that variance in preconception and delivery weight estimates as a function of later entry into prenatal care, inaccurate recall, variance in gestational age at delivery, variance in clinic or Bluetooth scales and other sources of error is minimized. We have selected the 6-month time point given research that shows if someone is not within 5% of their prepregnancy weight by 6 months postpartum, they are significantly less likely to return to prepregnancy weight [17,19,20]. We will compare the proportion of participants in each group who gain excess gestational weight and retain postpartum weight versus examining statistical differences in weights between because: (1) previous intervention studies aimed at reducing GWG have demonstrated that, while reductions in weight gain are achieved, birthing people are still gaining more than IOM recommendations for prepregnancy BMI [34]; (2) in clinical obstetric practice, the current guidelines still use the classifications for GWG ("inadequate," "appropriate," and "excessive") as a guide for weight/diet counseling in postpartum and interpregnancy care [101]; and (3) raw weight gains do not have ecological validity when comparing across different starting weights (e. g., a 150 lb. person and a 200 lb. person may both gain 20 lbs. but it is a different percent of starting weight and may or may not reflect a clinically meaningful difference in appropriate weight gain).

2.4. Exploratory maternal, obstetric, and neonatal outcomes

Although we are not powered to detect significant effect size differences in maternal, obstetric, and neonatal outcomes, robust evidence suggests excess GWG negatively affects these outcomes [7,10,11,23,102,103]. We may obtain important preliminary data for future pragmatic trials of *GROWell* where we are powered to examine differences in one or more of these factors. Blinded research staff will abstract the following data from the EHR: (a) delivery type (cesarean or vaginal), and (b) fetal growth abnormalities (small-for-gestational age, large-for-gestational-age, macrosomia) or none. Pregnancy complications (e.g., gestational diabetes, hypertension, preeclampsia, eclampsia, placental abruption, fetal death, antepartum admission, preterm birth with and without NICU admission) will be documented categorically using a combination of participant self-report, the 26–28 week and 36–38 week prenatal online assessments, and the EHR. Rates of each of these outcomes will be calculated as a percent (the total number of events/total number of participants) for each arm.

2.5. Control variables

We will use validated instruments and questions to describe the sample characteristics and assess key behavioral factors that may influence our primary outcomes.

2.5.1. Demographics—Race/ethnicity and clinic type are included as stratification variables. We will record age as a continuous variable. Categorical variables include: educational level (<12 years, 12+ years), partner status (yes, no), health insurance type (private, public), employment status (full-time, part-time, not employed), and parity (primagravida yes/no).

2.5.2. Diet quality—Online assessments at 36–38 weeks and 6 months postpartum will capture diet using the web-based Automated Self-Administered 24-Hour Dietary Assessment Tool (ASA24®)(C) [104]. Developed by the NCI, the ASA24® enables automatically coded, self-administered 24-h diet recalls. Participants report on foods they consumed in the previous day calculated from midnight-to-midnight, including form, how it was prepared, portion sizes, and when and where it was consumed. We will use Diet*Calc software to calculate an Alternate Healthy Eating Index-2015 (AHEI-2015) value for use in all analyses [105–107]. At each online assessment (baseline, 24–26 weeks, 36–38 weeks, 3 months and 6 months postpartum) we will also ask participants to fill out the Rapid Eating Assessment for Participants (REAP) questionnaire. The REAP survey is faster to complete than the ASA24, thus we ensure that even if participants do not complete the ASA24, we are obtaining diet quality information across the timeline each participant is enrolled in the study.

2.5.3. Physical activity—We will assess physical activity using the Kaiser Physical Activity Survey (KPAS) [108], which has been validated for use in pregnant [109] and nonpregnant women [108], making it a good instrument to assess physical activity across the prenatal and postpartum periods. Test-retest reliability is good at $r = 0.84$ and $r = 0.79–0.91$ for pregnant and nonpregnant women respectively. The KPAS shows concordant validity ($r = 0.71–0.84$) with the Pregnancy Physical Activity Questionnaire, a widely used instrument to assess prenatal physical activity.

2.5.4. Breastfeeding—We will measure breastfeeding categorically as exclusive, partial (some formula use and/or solid introduction), or none.

2.5.5. Depression/anxiety—We will measure symptoms of depression and anxiety using the Edinburgh Postnatal Depression Scale (EPDS) [110–112], which has been validated for pregnant and postpartum women. Total scores have been validated as a measure of clinically significant depressive symptoms, while the anxiety subscale (items 3–5) has been validated as a measure of clinically significant anxiety symptoms [113].

2.6. GROWell adherence

We will measure adherence to text-based self-monitoring cumulatively by week as the number of times a participant responds to weekly prompts to report on her progress to the number of times she was prompted, calculated to a percent. Based on previous trials, we will consider good cumulative adherence to be ≥70%. Rates will be calculated separately for the prenatal and postpartum periods. We will measure adherence to prescribed goals cumulatively by week as the proportion of goals for which a participant has “good adherence” during the previous week. Because goals change over time with improved adherence, participants are working on two goals at once, and some behaviors are easier to change than others, we consider average weekly adherence to be good at ≥50%. Rates will be calculated separately for the prenatal and postpartum periods. We will monitor adherence based only on how well participants do with their goals and how often they complete their check-ins. For the intervention group this involves weekly goal reporting and the 4 online follow-ups (26–28 weeks, 36–38 weeks, 3 months postpartum, 6 months postpartum).

For the control group, check-ins occur at the 4 online follow-ups. We also have check-ins regarding breastfeeding for participants who leave the hospital breastfeeding.

3. Data analysis

We will conduct descriptive analyses, including examining means, proportions, and variability for each variable overall and by intervention arm. Then we will fit models to test the aims' hypotheses. Tests of statistical significance will be two-sided and a priori statistical significance will be set at $P < 0.05$.

3.1. Aim 1

To determine whether *GROWell* was efficacious at reducing the proportion of participants who have EGWG we will create an indicator variable for excess weight gain during pregnancy using IOM guidelines. If a participant's prepregnancy BMI is in the overweight category (25- < 30) and the difference between the weight at delivery and prepregnancy weight is greater than 25 pounds, then the indicator will be 1. If a participant's prepregnancy BMI is in the obese class I (30- < 35) or obese class II (35- < 40) categories and the difference between the weight at delivery and prepregnancy weight is greater than 20 pounds, then the indicator will be 1. A series of logistic regression models will be fitted to estimate the association between excess weight gain during pregnancy and the arms (*GROWell* and attention control). The first model will control only for BMI groups, race/ethnicity, and recruitment source (e. g., clinic or community). The second model will include baseline demographic variables (age, parity, diet quality, physical activity). The last model will add the group arm (e.g., *GROWell* or attention control).

3.1.1. Aim 2—Compare the efficacy of *GROWell* to the attention control in reducing postpartum weight retention at 6 months postpartum as measured by the proportion of participants who are within 5% of their pre-pregnancy weight while controlling for demographics, parity, physical activity, diet quality, breastfeeding status, and depression/anxiety. Hypothesis: The proportion of participants who retain pregnancy weight will be significantly lower for those in the GROWell arm than those in the attention control arm. An indicator variable for postpartum weight retention will take the value of 1 if a participant's 6-month postpartum weight is greater than 1.05 of the participant's prepregnancy weight, and 0 otherwise. A similar series of logistic regression models estimated in aim 1 will be fitted to estimate the association between postpartum weight retention and the intervention. Results from each model will be presented.

3.1.2. Exploratory outcomes—Relative frequencies and crude adjusted odds ratios will be computed for the maternal, obstetric, and neonatal outcomes by intervention arm. Adjusted odds ratios will be computed for the outcomes by intervention arm to obtain information about the strength of the association of intervention on the outcome. Control variables will include demographics, diet quality, physical activity, and depression/anxiety.

3.1.3. Sub-group analyses for GROWell adherence—To determine whether adherence to *GROWell* affected our primary outcomes, we will use latent growth curve models with data from *GROWell* participants only to examine whether there are systematic

trends in prenatal self-monitoring adherence rates and prenatal goal adherence rates. If systematic trends are found, we will examine whether latent factors representing changes in adherence over time (e. g., intercept, slope) predict GWG and PPWR in the structural equation modeling (SEM) framework. If no systematic trend is found, we will compute individual-specific summary statistics (e.g., mean and variance) of the adherence measures and test them as predictors of GWG and PPWR. The first model will control only for BMI groups. The second model will include baseline demographic and health behavior variables (race/ethnicity, age, parity, diet quality, physical activity, breastfeeding [postpartum model], and GWG [postpartum model]). The final model will add the recruitment source.

3.1.4. Power analysis—Our team's preliminary work showed the proportion of participants who gained excess gestational weight was 37% in the group using mHealth vs. 66% receiving usual care, a 29-unit difference [82]. Using a text messaging plus in-person education intervention among obese pregnant women, Soltani et al. [58] found that 28% in the intervention group gained excess gestational weight vs. 50% in the control group, a 22-unit difference. Based on power calculations for fitting a standard logistic regression including all covariates, the proposed analyses for aims 1 and 2 have 80% power to detect a minimal adjusted difference of 15 percentage units (OR: 0.55) between the intervention arms for excess gestational weight gain and postpartum weight retention with a total sample size of 354 for a 2-sided significance level of 0.05. This effect size is consistent with previous studies and is nearly representative of a Cohen's small effect, 10 percentage units (OR: 0.67). Power calculations were performed using PROC POWER in SAS version 9.4.

4. Results

Currently, this project has 165 enrolled and randomized subjects; 67% are White, non-Hispanic; 33% are from historically minoritized populations. The average age of participants is 34, average gestational age is 13 weeks, 45% have overweight, 26% have obesity Class 1, and 29% have obesity Class 2. Outcomes associated with GWG and pregnancy are expected in late 2023, while outcomes on postpartum weight retention *GROWell* adherence are expected in late 2024.

5. Discussion

Excess GWG and PPWR have significant negative long-term impacts on maternal and offspring health, including increased risk for poor pregnancy and birth outcomes and cardiometabolic disease across the lifespan. Thus, pregnancy and early postpartum/infancy are critical time periods for dietary interventions that may improve population health. We are implementing a large, RCT of a digital dietary intervention that addresses several key deficits in previous approaches to reducing GWG and associated postpartum weight retention. First, most studies that found no reductions in GWG provided generalized dietary education rather than content specific to pregnancy or the participant's needs and goals [34]. Indeed, previous reviews of dietary interventions in pregnancy have noted that future interventions should include specific, person-centered dietary goals to improve success rates [34,114], which *GROWell* offers. Second, among the studies that did find positive intervention effects on GWG, the majority were high intensity and involved either in-person

or telephonic educational and counseling sessions, some lasting 1.5 to 2 h over multiple visits [33,34]. While the literature supports the need for high-dose interventions to achieve positive behavioral change [115], such approaches frequently require significant human resources to deliver these interventions, which limits generalizability in real world settings. *GROWell* offers high-intensity support using digital health, thereby providing the level of contact necessary for change without the need for significant human resources. Third, few technology-based interventions have been investigated in large-scale RCTs [46]. This is a significant missed opportunity given that among pregnant people ages 18–44 across all race/ethnicities, incomes, educational levels, and geographic locations, at least 90% own cell phones and at least 72% own smart phones [73]. Young adult women specifically have high penetration of eHealth use, or using mobile and smart phones, Internet, and social media for general health information seeking and sharing [72], and pregnancy-specific information, including gestational weight gain [90]. In fact, national data show that being young and female is a consistent predictor of eHealth use more than any other demographic [116]. Thus, we are using an approach that is likely to resonate with birthing people across all socioeconomic statuses, geographic locations, and race/ethnicities. Lastly, and importantly, few previous interventions have extended into the postpartum period, but rather, ended in the late third trimester despite calls for inter-pregnancy weight control strategies [117–120] and strong evidence that PPWR six months post-birth is highly prevalent and increases risk for poor midlife health, including morbid obesity, related cardiometabolic disease, and cancer [22]. Continuing *GROWell* through six months postpartum may provide participants with longer-term support that has the capacity to improve dietary intake well beyond pregnancy, including supporting intrapartum health for individuals who have future children.

During the current COVID-19 pandemic, conducting non-essential clinical trials has become ever more challenging. However, there is also a unique opportunity to use technology to allow access to clinical trials to previously underrepresented participants [121]. Before the pandemic, we included in-person study visits that would have been difficult for us to accomplish for our more rural participants or for those with transportation, time, or other barriers. Now we are able to reach people across the state of California. Additionally, individuals who may have not wanted to participate due to the in-person requirement can now participate entirely remotely. Making a clinical trial completely virtual is not feasible for all studies, but it worked well for *GROWell* after a few modifications, including creating options for: (1) the ability to provide a signed consent via DocuSign; (2) mailing a Bluetooth scale for weight data that interfaces with our application; and (3) online surveys rather than in-person data collection.

Novel approaches to maintaining GWG within IOM-recommended ranges and supporting postpartum weight loss are critical to advancing health across the lifespan. Additionally, given the rise in children's rates of overweight and obesity and associated cardiometabolic conditions (e.g., hypertension, hypercholesterolemia) that have been linked to intrauterine exposures (e.g., maternal diet, over-weight/obesity, and adiposity) and dietary consumption in early infancy, prenatal and early postpartum interventions are likely to have the greatest impact on lifelong health. Establishing *GROWell* as effective at reducing GWG and PPWR may provide a foundation for using digital health to promote healthy behaviors during pregnancy for optimal population health in the 21st century.

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Abbreviations:

GROWell	Goals for Reaching Optimal Wellness
GWG	gestational weight gain
IOM	Institute of Medicine
BMI	body mass index
PPWR	postpartum weight retention
RCT	randomized controlled trial
CRC	clinical research coordinator
IRB	institutional review board
EHR	electronic health record
NICU	neonatal intensive care unit
DHQ-II	Diet History Questionnaire-II
KPAS	Kaiser Physical Activity Survey
ASA24®	Automated Self-Administered 24-Hour Dietary Assessment Tool
AHEI-2015	Alternate Healthy Eating Index-2015
EPDS	Edinburgh Postnatal Depression Scale
SAR	self-monitoring adherence rates
GAR	goal adherence rates

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Fig. 1.
Conceptual model for GROWell.

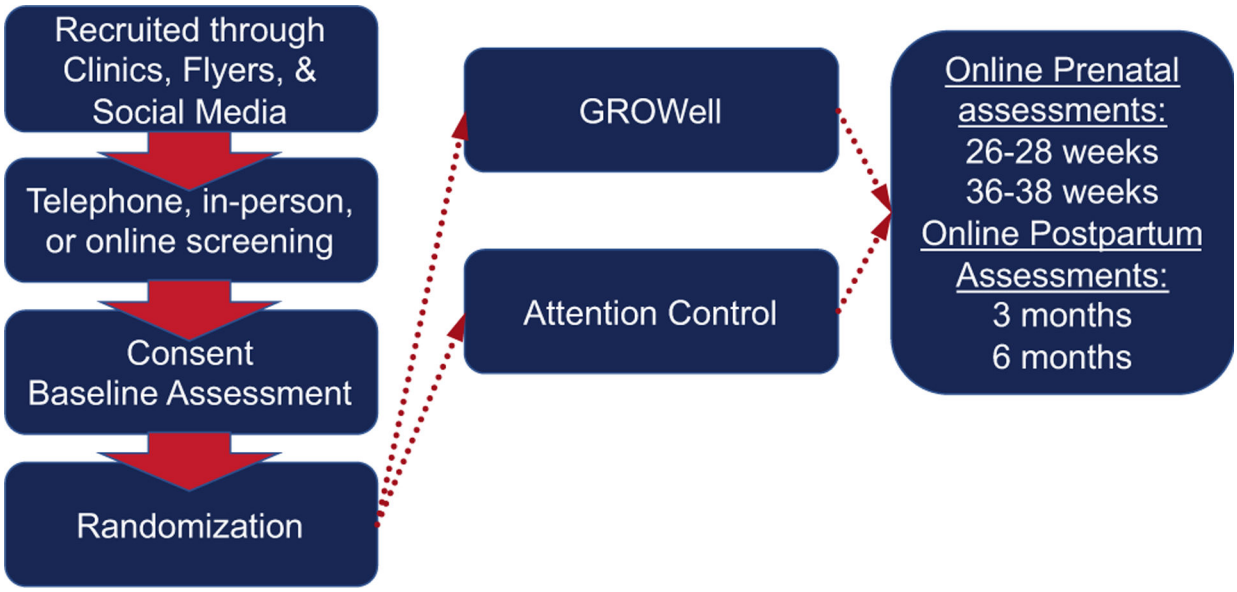

Fig. 2.
Overview of study design.

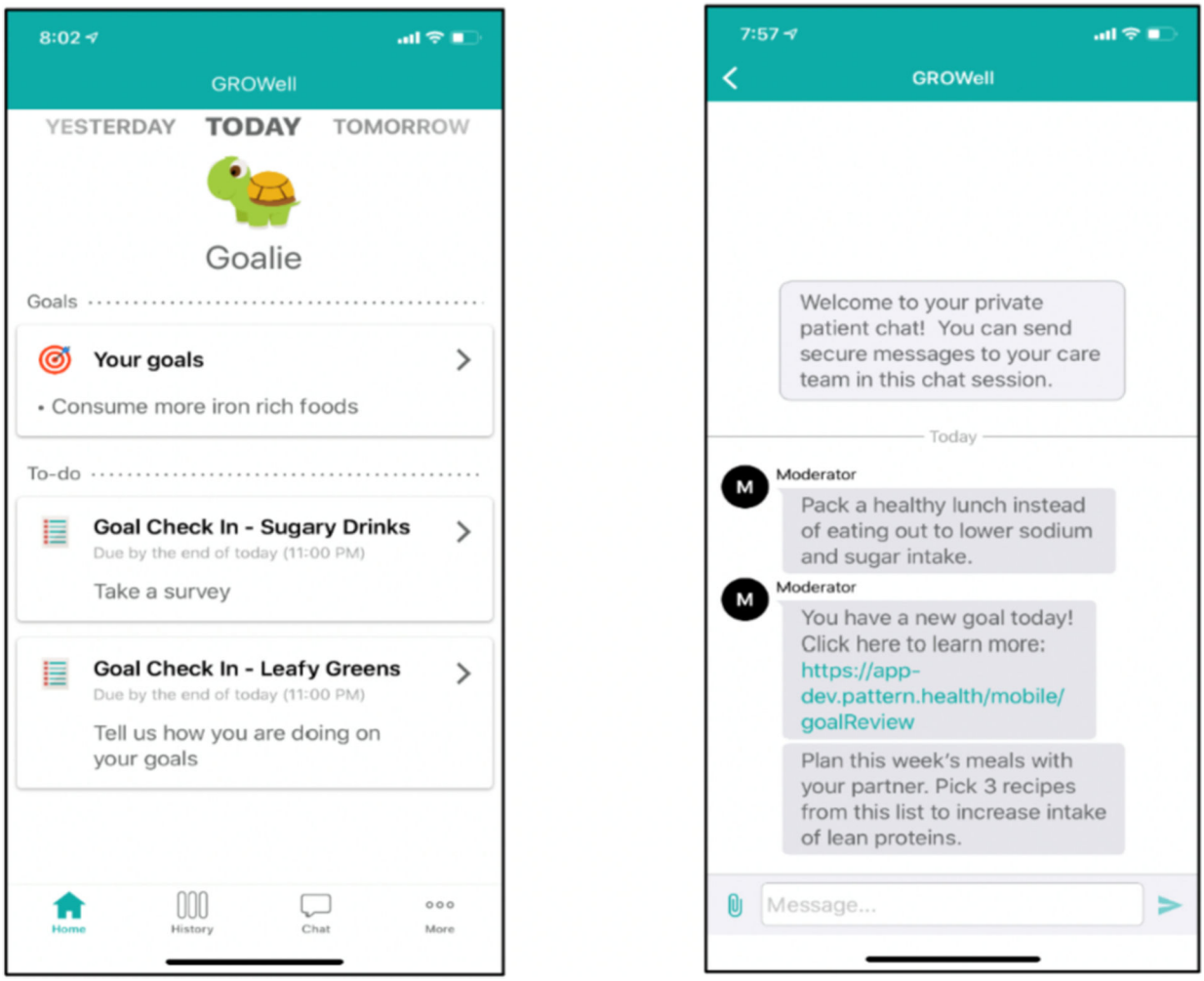

Fig. 3.
Example view of the mHealth platform and text messages.

Table 1

GROWell dietary goals.

Foods to reduce	Foods to increase
Fried foods	2-3 fruits daily
Sugary drinks	Whole grains every day
Salty snacks	Healthy fats every day
High sugar sweets	Lean protein daily
High fat/high salt seasoning	Healthy breakfast daily
Fast food	Iron rich foods
Salt	Dark leafy greens daily
Red meat	3 veggies daily
	Healthy calcium daily
	Folate-rich foods
Processed meats	Fiber-rich foods

Table 2

Sample text messages.

Participant characteristics	Intervention	Control
Prenatal		
All	Eating iron-rich foods, such as [examples specific to dietary preferences] supports your baby's development.	Trouble sleeping? Follow these tips for better ZZZZs. https://cle.clinic/2wCSRzM
Working outside the home	Pack a healthy lunch instead of eating out to lower sodium and sugar intake.	Time to find out what kind of leave you have at your work. Talk to human resources and make a plan.
Has partner	Plan this week's meals with your partner. Pick 3 recipes from this list to increase intake of lean proteins.	Adding a new baby to the family can affect your relationship. Take at least 1 h each week to spend alone time together.
Postpartum		
Breastfeeding	Getting enough calcium is important while breastfeeding. 1 oz. of almonds is a great snack that provides healthy fats, calcium, and fiber.	Eye contact with baby is important for communication. Look into your baby's eyes while feeding [him/her] rather than watching TV or working on your cell phone.
Returning to work outside the home	Prepare mason jar salads on Sunday to make sure you keep eating dark, leafy greens when you go back to work. http://bit.ly/3bXbSwX	Returning to work is hard enough, but it's really hard when baby cries when you leave [him/her] with a caregiver. Know that baby is learning to trust other adults and that mom comes back when she leaves. Both are important for baby to develop secure attachment.